



The International Pharmacopoeia

Third Edition

Volume 3

Quality specifications

1988

World Health Organization 1988

| | | | |
|------|--|----|----|
| . | | : | • |
| | : | | |
| .372 | / 2 1 | / | .1 |
| | AMENDMENTS AND CORRIGENDA TO VOLUMES 1 AND 2 | | |
| .310 | /3 2 1 | / | .2 |
| | AMENDMENTS AND CORRIGENDA TO VOLUMES 1,2 AND 3 | | |
| .256 | /4 3 2 1 | / | .3 |
| | AMENDMENTS AND CORRIGENDA TO VOLUMES 1,2,3 AND 4 | | |
| . | | | • |
| | : | | • |
| | . | | • |
| | VS | TS | RS |
| | . | | R |

1
.

. registration

monographs

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)

(

2
hydrated anhydrous

"

(bleomycins)

"High-pressure liquid chromatography

1

Version

.²373-387 2 1

."High performance liquid chromatography

"

)

Praziquantel

(

.1984 704

1

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2

()

¹Specifications for pharmaceutical Preparations

non-aqueous

titrations

)

2 1 (...

specific

$(A_{1\text{ cm}}^{1\%})$ absorbance

$(E_{1\text{ cm}}^{1\%})$ extinction

Acknowledgements

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7
10
379

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| 64 | 30 |
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| 140 | 80 |
| 142 | 83 |
| 145 | 86 |
| 147 | 89 |
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| 165 | 104 |
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| 375..... | |

MONOGRAPHS

ALUMINII HYDROXIDUM

Aluminium hydroxide

$\text{Al}(\text{OH})_3$:Molecular formula

78.00 :Relative molecular mass

Aluminium hydroxide CAS Reg. No. 21645-51-2 :Chemical name

| | | |
|--------------|-----|--------------|
| . | () | :Description |
| TS (/ 750~) | | :Solubility |
| .TS (/ 80~) | | TS (/ 70~) |
| . | | :Category |
| . | | :Storage |

REQUIREMENTS

| | | | | |
|-------------------------|--------------|------|------------------------------|----------------------|
| %71.9 | | | | :General requirement |
| | | | . $\text{Al}(\text{OH})_3$ | %94.9 |
| .TS (/ 80~) | 5 | 0.10 | | :Identity test |
| . | | R | 0.5 | |
| 5 | 0.5 | | | :Heavy metals () |
| 4-3 | (pH) | . | 10 | TS (/ 300~) |
| " | | () | . | 40 |
| (129 | 1 |) A | "Limit test for heavy metals | () |
| | | | . | / 60 |
| 35 | TS (/ 100~) | 20 | 3.3 | :Arsenic |
| "Limit test for arsenic | | " | | |
| . | / | 5 | | (130 1) |

| | | | | |
|----------|----------------------|----------------------|--|----------------------------|
| 25 | 5.0 | :Ammonium salts | | |
| | 100 | 200 | TS (/ 200~) | |
| | | | .VS (/ 0.1) | 25.0 |
| TS | / | | VS (/ 0.1) | |
| | | | .VS (/ 0.1) | 22.5 |
| | | TS (/ 130~) | 2 | 0.10 |
| | | " | | :Chlorides |
| | | | | 10 |
| | / 10 | | (129 1) | "Limit test for chlorides |
| | | TS (/ 70~) | 5 | 0.10 |
| | | " | | :Sulfates |
| Limit | | | | 10 |
| | / 5 | | (125 1) | "test for sulfates |
| | | | | :Neutralizing capacity |
| | 200 | 0.50 | 150 | |
| ° 37 | | | ° 37 | VS (/ 0.05) |
| () | | 3.0 2.3 1.8 | 20 15 10 | |
| ° 37 | | VS (/ 0.5) | 10 | .4.0 |
| (/ 0.1) | | .° 37 | | |
| | %83.3 | | .3.5 (pH) | VS |
| 0.1) | | y | $A \times W \times 38.46 / (y - 150) (1000)$ | |
| | W | Al (OH) ₃ | A | VS (/ |
| | .Al(OH) ₃ | | 38.46 | |
| | / 0.04 | (pH) | | :Alkaline impurities |
| | | | .10.0 | R |
| " | | | 0.15 | :Assy |
| | 1 | (137 1) | | "Complexometric titrations |
| | | .Al(OH) ₃ | 3.900 | VS (/ 0.5) |

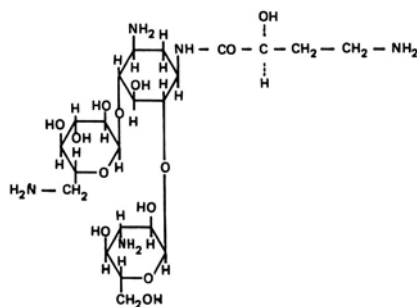
AMIKACINUM

Amikacin –

$C_{22}H_{43}N_5O_{13}$:Molecular formula

585.6 :Relative molecular mass

:Graphic formula



:Chemical name

O-3-Amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)-*O*-[6-amino-6-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)]-*N*³-(4-amino-L-2-hydroxybutyryl)-2-deoxy-L-streptamine; (*S*)-*O*-3-amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)-*O*-[6-amino-6-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)]-*N*¹-(4-amino-2-hydroxyoxobutyl)-2-deoxy-D-streptamine; CAS Reg. No. 37517-28-5.

:Description

:Solubility

:Category

:Storage

REQUIREMENTS

900

:General requirement

1 $C_{22}H_{43}N_5O_{13}$

:Identity testes

| | | | | |
|------------------|---|---|------|----|
| TS (/ 80 ~) | 1 | 1 | 10 | :A |
| TS (/ 10) (II) | | | 2 | |
| (Anthrone TS) TS | 4 | 3 | 0.05 | :B |

/ 20 :Specific optical rotation
 $[\alpha]_D^{20^\circ} = 97 \text{ to } +105^\circ$:
 1000~) 2 () :Sulfated ash
 . / 10 TS (/ 1760 ~) 2.0 TS (/
 Determination of water " : Water
 2.0 (145 1) A " by the karl Fischer method
 . / 85
 .11.5-9.5 / 10 :pH Value
 " :Assay
Bacillus (a) (155 1) "Microbiological assay of antibiotics
 6.7-6.5 (pH) Cml (ATCC 6633) *Subtilis*
 20-5) TS3 TS2 TS1 (pH) 6.0
 ATCC) *Staphylococcus aureus* (b) ° 35-32 (/
 (29737
 (/ 10)
 %105 %95 estimated potency ($P= 0.95$) fiducial limits
 / 900 ($P= 0.95$)
 .anhydrous

AMIKACINI SULFAS

Amikacin Sulfate

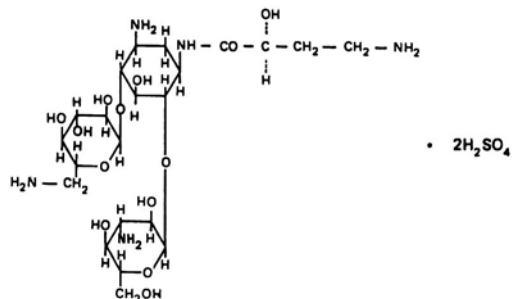
(non-injectable)

Sterile

$C_{22}H_{43}N_5O_{13} \cdot 2H_2SO_4$:Molecular formula

781.8 :Relative molecular mass

:Graphic formula



:Chemical name

O-3-Amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)-*O*-[6-amino-6-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)]-*N*³-(4-amino-L-2-hydroxybutyryl)-2-deoxy-L-streptamine sulfate (1:2) (salt); (*S*)-*O*-3-amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)-*O*-[6-amino-6-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)]-*N*¹-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-D-streptamine sulfate (1:2) (salt); CAS Reg. No. 39831-55-5.

:Description

R

R

R

:Solubility

.R

:Category

:Storage

:Labelling

REQUIREMENTS

650

:General requirement

1

:Identification tests

TS (/ 80~)

1

1

10

:A

(/ 10) (II)

2

Anthron TS

4

3

0.05

:B

| | | | | |
|--|----------|------------|---------|--|
| General | " | A | / 20 | :C |
| | (123 | 1 |) | "identification tests |
| / 10 | | | | |
| | | | | :Specific optical rotation |
| | | | | $[\alpha]_D^{20^\circ} = +69 \text{ to } 79^\circ$ |
| (/ 1000~) | 2 | () | | :Sulfated ash |
| | / 10 | TS (1760~) | 0.2 | TS |
| Determination of water by | | " | | :Water |
| 0.2 | (145 | 1 |) A | "the Karl Fischer method |
| | | | / 50 | |
| .7.5-6.0 | / 10 | | | :pH Value |
| Microbiological | | " | | :Assay |
| ATCC) <i>Bacillus Subtilis</i> | (a) | (155 | 1 |) "assay of antibiotics |
| 6.7-6.5 | (pH) | Cm1 | | (6633 |
| (/ 20-5) | | TS3 | TS2 | TS1 (pH) 6.0 |
| (TCC 29737) <i>Staphylococcus aureus</i> | | (b) | ° 35-32 | |
| 10) | | | | |
| fiducial limits | | | | (/ |
| (P=0.95) | %105 | %95 | | estimated potency (P=0.95) |
| / 650 | (P=0.95) | | | |
| | | | | .anhydrous |

Additional Requirements for Sterile Amikacin Sulfate

| | | |
|----------------------|---|------------|
| | | :Storage |
| Sterility testing of | " | :Sterility |

membran filtration (162 1) "antibiotics

Additional requirements for Amikacin sulfate for parenteral use

(56 4) "

"

:Bacterial endotoxins

(30 5) "Test for bacterial endotoxins

. 1 RS 0.33

Additional requirements for Amikacin sulfate for sterile use

Test for sterility of non-

.(32 5) "injectable preparations

AMILORIDI HYDROCHLORIDUM

Amiloride hydrochloride

anhydrous

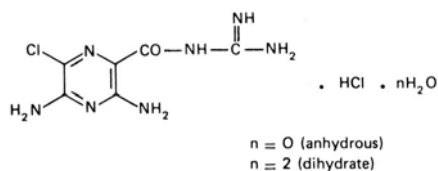
dihydrate

() $C_6H_8ClN_7O, HCl, 2H_2O$ () $C_6H_8ClN_7O, HCl$:Molecular formula

.(

.() 302.1 () 266.1 :Relative molecular mass

:Graphic formula



| | | | | | |
|---------|--|--------------|--|--|--|
| | | | | | :Chemical name |
| | | | | | <i>N</i> -Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride; 3,5-diamino- <i>N</i> -(aminoiminomethyl)-6-chloropyrazinecarboxamide monohydrochloride; 3,5-diamino-6-chloro- <i>N</i> -(diaminomethylene)pyrazinecarboxamide monohydrochloride; CAS Reg. No. 2016-88-8 (anhydrous). <i>N</i> -Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride dihydrate; 3,5-diamino- <i>N</i> -(aminoiminomethyl)-6-chloropyrazinecarboxamide monohydrochloride dihydrate; 3,5-diamino-6-chloro- <i>N</i> -(diaminomethylene)pyrazinecarboxamide monohydrochloride dihydrate; CAS Reg. No. 17440-83-4 (dihydrate). |
| | | | | | :Description |
| | | | | | |
| R | | TS (/ 750~) | | | :Solubility |
| | | | | | R |
| | | | | | :Category |
| | | | | | :Storage |
| | | | | | |
| | | | | | REQUIREMENTS |
| | | | | | |
| | | %98.0 | | | :General requirement |
| | | | | | C ₆ H ₈ ClN ₇ O ₂ ·HCl 101.0 |
| | | | | | :Identity tests |
| | | | | | |
| | | | | | C B C A |
| | | | | | " |
| | | | | | :A |
| | | | | | (43 1) "Spectrophotometry in the infrared region |
| RS | | | | | |
| | | | | | <i>reference spectrum</i> |
| | | | | | |
| | | VS (/ 0.1) | | | / 5.0 :B |
| | | 285 | | | 380 230 |
| | | 285 | | | 1 361 |
| | | | | | 0.31 0.28 361 |
| General | | " | | | A / 5 :C |

.(121 1) "identification tests
 . 0.1 :Sulfated ash
 Determination of water " :Water
 0.2 (145 1) A "by Karl Fischer method
 . / 130 / 110
 50 R 50 1.0 :Free acid
 . 0.3 Potentiometrically VS (/ 0.1)
 Thin- " :Related substances
 Silica gel R1 (84 1) "layer chromatography
 . TS (/ 50~) 2 R 15
 R 1 R 4 5
 . 1 4.0 :B 1 0.4 :A
 A .(365)
 .B
 15 R1 100 0.45 :Assay
 0.1) TS / 10 R
 " VS (/
 (/ 0.1) 1 .(142 1) A "Non-aqueous titration
 .C₆H₈ClN₇O₃HCl 26.61 VS

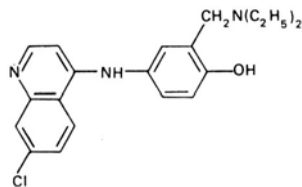
AMODIAQUINUM

Amodiaquine

C₂₀H₂₂ClN₃O :Molecular formula

355.9:Relative molecular mass

:Graphic formula



:Chemical name

4-[(7-Chloro-4-quinolyl)amino]-*a*-(diethylamino)-*o*-cresol;
4-[(7-chloro-4-quinolinyl)amino]-2-[(diethylamino)methyl]phenol; CAS Reg.
No. 86-42-0.

:Description

.R

:Solubility

:Category

:Storage

REQUIREMENTS

% 103.0

%97.0

:General requirement

$C_{20}H_{22}ClN_3O$

:Identity test

.C B

A

•

Spectrophotometry in

"

:A

. (43 1) " the infrared region

free base

reference spectrum

RS

TS (II)

/

0.5

0.1

20

:B

A

. "Substances Related

"

:C

.B

. / 2.0

:Sulfated ash

Determination of water by

"

:Water

0.8 (145 1) A "the Karl Fischer method
. / 5.0

"

:Related substances

. (84 1) "Thin-layer chromatography
TS (/ 260~) R

19 9 Silica gel R2
0.15 . dehydrated
40 reference . (A) 10
2.0 RS
. (B) . 2
10 . (C) 200 B 1.0
. C B A
. (254) chromatogram
. C A
(/ 0.1) 0.3 **:Assay**
. 1000 10.0 200 VS
0.1) 1 RS 15
342 1 . VS (/
. VS (/ 0.1) Solvent cell
355.9 (355.9/428.8)(20C)(A_u/A_s) C₂₀H₂₂C1N₃O ()
C 428.8
RS anhydrous 1
. A_s A_u

AMPHOTERICINUM B

(Amphotericine B) B

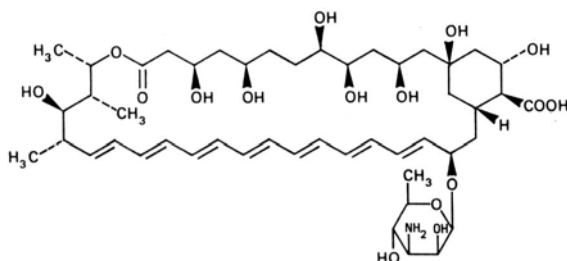
parenteral

B

C₄₇H₇₃NO₁₇ **:Molecular formula**

924.1 :Relative molecular mass

:Graphic formula



:Chemical name

(1*R*,3*S*,5*R*,6*R*,9*R*,11*R*,15*S*,16*R*,17*R*,18*S*,19*E*,21*E*,23*E*,25*E*,27*E*,29*E*,31*E*,33*R*,35*S*,36*R*,37*S*)-33-[(3-Amino-3,6-dideoxy-β-D-mannopyranosyl)-oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid; [1*R*-(1*R**,3*S**,5*R**,6*R**,9*R**,11*R**,15*S**,16*R**,17*R**,18*S**,19*E*,21*E*,23*E*,25*E*,27*E*,29*E*,31*E*,33*R**,35*S**,36*R**,37*S**)]-33-[(3-amino-3,6-dideoxy-β-D-mannopyranosyl)oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid; (3*R*,5*R*,8*R*,9*R*,11*S*,13*R*,15*S*,16*R*,17*S*,19*R*,34*S*,35*R*,36*R*,37*S*)-19-(3-amino-3,6-dideoxy-β-D-mannopyranosyloxy)-16-carboxy-3,5,8,9,11,13,15,35-octahydroxy-34,36-dimethyl-13,17-epoxyoctatriaconta-20,22,24,26,28,30,32-heptaen-37-olide; CAS Reg. No. 1397-89-3.

:Description

R R TS (/ 750~)

:Solubility

.R R 20 R 200

:Category

B

:Storage

.° 8 2

B

:Labelling

B

B

:Additional information

.(pH)

REQUIREMENTS

| 750 | | B | | :General requirement | | 1 | |
|--|------|-------|--------------------------------|-------------------------------|---|-----|--------|
| :Identity tests | | | | | | | |
| R | | R | | 5 | 25 | :A | |
| | | .R | | 200 | 2.0 | | 50 |
| 381 | 362 | | | 450 | 300 | | |
| 381 | | 362 | | 1 | | | 405 |
| .0.9 | | 405 | | 381 | | 0.6 | |
| 1440~) | | 5 | R | | 2.0 | 1 | :B |
| | | | | | | | TS (/ |
| | | | | 15 | | | |
| | | | . / | 30 | :Sulfated ash | | |
|) | ° 60 | | | :Loss on drying | | | |
| | | | . / | 50 | (| 5mm | 0.6kpa |
| 5 | | 0.05 | :Content of tetraenes | | | | |
| 50 | 4 | 50 | R | | R | | |
| B | | | 0.05 | | .(A |) R | |
| Nystatin RS | | 25 | | .(B |) | | RS |
| 250 | R | | R | | 25 | | |
| | | | .(C |) R | 50 | 4 | |
| 282 | | C B A | | 1 | | | |
| 50 | R | | 5 | blank | | | 304 |
| | | .R | | 50 | | 4 R | |
| F+1000(B ₁ A ₂ - : | | | C B A | | A _{1cm} ^{1%} | | |
| 304 | 282 | | A _{1cm} ^{1%} | A ₂ A ₁ | B ₂ A ₁)/(C ₂ B ₁ -C ₁ B ₂) | | |

304 282 RS B $A_{1\text{cm}}^{1\%}$ B2 B1
 F 304 282 RS $A_{1\text{cm}}^{1\%}$ C₂ C₁
 RS B
 . / 150
 shaking R 0.060 :Assay
 R 100 10 . 100 R
 "Microbiological assay of antibiotics "
 (NCTC 10716 or ATCC 9763) *Saccharomyces cerevisiae* (145 1)
 10.5 (pH) 6.1 (pH) Cm3
 (/ 10.0 0.5) B TS1
 (P=0.95) fiducial limits .° 33-29
 . %105 %95 estimated potency
 . / 750 (P=0.95)

B

Additional requirements for Amphotericin B for Parenteral use

.(56 4) "Parenteral preparations "
 . / 5.0 :Sulfated ash
 . / 100 :Content of tetraenes
 " :Bacterial endotoxins
 (30 5) "Test for bacterial endotoxins
 . 1 RS 0.9

ARGENTI NITRAS

Silver nitrate

AgNO₃ : Molecular formula

169.9 :Relative molecular mass

Silver (1+) nitrate; CAS.Reg. No.7761-88-8 **:Chemical name**

:Description

.TS (/ 750~)

0.5

:Solubility

.Antiinfective

:Category

:Storage

:Additional informations

REQUIREMENTS

%100.5

%99.0

:General requirement

AgNO₃

:Identity tests

TS (/ 100~)

1.0

20

:A

TS

0.1

TS (/ 80~)

1.0

20

:B

.TS (/ 1000~)

TS (/ 100~)

2 TS (/ 15) ferrous Sulfate ()

2

:C

"

A

/ 0.05

.(122 1)

"General identification tests

10 0.4

:Clarity and colour

2

10 0.4

:Acidity or alkalinity

TS

/

0.1

TS /

0.1

2

70~)

7.5

30

1.2

:Foreign salts

20 . 5 TS (/
. 2.0 ° 105
2 5 1.0 :Bismuth, Copper, and Lead
TS (/ 100~)
. 130~) 2 50 0.3 :Asaay
.TS (/ 45) ferric ammonium sulfate 4 TS (/
1 . VS (/ 0.1)
.AgNO₃ 16.99 VS (/ 0.1)

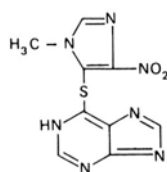
AZATHIOPRINUM

Azathioprine

C₉H₇N₇O₂S :Molecular formula

277.3 :Relative molecular mass

:Graphic formula



:Chemical name

6-[(1-Methyl-4-nitroimidazol-5-yl)thio]purine; 6-[(1-methyl-4-nitro-1*H*-imidazol-5-yl)thio]-1*H*-purine; CAS Reg. No. 446-86-6.

:Description

TS (/ 750)

:Solubility

R

.Immunosuppressive

:Category

| | | | |
|--------------------|------------------------|----------------------------|--|
| | | .() | |
| Thin- | " | :Related substances | |
| |) Cellulose R3 | (84 1) | "layer chromatography |
| | TS (/ 100~) | 1-butanol R | (|
| 10 | :(A) TS (/ 100~) | 3 | 10 |
| 0.15 | :(C) 1 | 0.15 | :(B) 1 |
| | | . 1 | RS |
| A | | .(254) | |
| | .B | | |
| | R 50 | 0.5 | :Assay |
| Potentiometrically | | .VS (/ 1.0) | |
| 1) B | "titration Non-aqueous | " | |
| 27.73 | VS (/ 1.0) | 1 | .(132 |
| | | | .C ₉ H ₇ N ₇ O ₂ S |

BACITRACINUM

Bacitracin

(non-injectable)

Sterile

Poly peptide

:Composition

.*Bacillus subtilis*

licheniformis

organism

.CAS Reg.No. 1405-87-4 .B₂ B₁ A

:Description

TS (/ 750~) R R

:Solubility

.R R R

| | | | |
|---------------------|-----------------------------|---|------------------------|
| .Antiinfective drug | | :Category | |
| | | :Storage | |
| | | .° 15 | |
| | | .microorganisms | |
| | | :Labelling | |
| | | | |
| .hygroscopic | | :Additional information | |
| | | | |
| REQUIREMENTS | | | |
| 1 | 55 | :General requirement | |
| | | | |
| | | :Identity tests | |
| 1 |) "Thin-layer Chromatograph | | |
| R (1-butanol) | -1 | 60 | Silica gel R1 (84 |
| 5 | R | R 15 | 6 10 |
| | | 1 | TS (/ 750~) |
| | 6.3 (B) | 1 | 6.0 (A) : TS (/ 10) |
| B A | | 1 (C) | . 1 bacitracin Zinc RS |
| | | | |
| 10 | ° 110 | TS (triketohydrindene/pyridine/butanol) | |
| | | | |
| .C | .B | A | |
| | | . / 20 | |
| | | :Sulfated ash | |
| 0.6 kpa |) | ° 60 | :Loss on drying |
| | | . / 50 | 3 (5 |

R 10 1.0 :pH Value
 .7.5 5.5 (pH)
 0.05) 100 30 : F
 .0.15 252 290 .VS (/
 0.5 5 0.05 :Assay
 . 100 TS (/ 70~)
 " 30
Micrococcus luteus (155 1) "Microbiological assay of antibiotics
 7.1-7.0 (pH) Cm1 (NCTC 7743 or ATCC 10240)
 6.0 7.0 (pH) TS 6.6-6.5
 .° 35-32 ° 39-35 (1 4-1)
 %105 %95 estimated potency ($P=0.95$)
 55 ($P=0.95$) .
 . 1

Additional Requirement for Sterile Bacitracin

:Storage
 .° 15
 Sterility testing of " :Stirility
 . (162 1) "antibiotics

Additional Requirements for Bacitracin for sterile use

Test for sterility of non- "
 (32 5) "injectable Preparations
 " :Bacterial endotoxins
 (30 5) "Test for bacterial endotoxin
 . 1 RS 0.01

BACITRACINUM ZINCUM

Bacitracin Zinc

(non-injectable)

Sterile

:Composition

B₁ A₁

.*Bacillus subtilis*

licheniformis

.CAS Reg. No. 1405-89-6 .B2

:Description

.

(/ 750~)

500

900

:Solubility

.R

R

.antiinfective

:Category

:Storage

.° 25

.

:Labelling

.

.hygroscopic

:Additional information

55

:General requirement

.

1

:Identity tests

1) "Thin-layer chromatography

"

:A

1-)

-1

60

Silica gel R1

(84

5 R

15 R

6

10 R (butanol

1

TS (/ 750~)

6.0 (B)

1

6.0 (A) :

TS (/ 10)

| | | | | | | |
|---|---------|---------|---------------|---|------------------------|----------------|
| | B | A | 1 | (C) | 1 | RS |
| | 10 | ° | 110 | TS (triketohydrindene/pyridine/butanol) | | |
| | | A | | | | |
| | | | C | | B | |
| TS (/ 70) | | | 1.0 | | 30 () | :B |
| | | | | TS (/ 45) | | 1.0 |
| (/ 1) (II) | | | 0.05 | TS (/ 100~) | | 1.0 |
| | | | | ammonium mercurithiocyanate TS | | 2.0 TS |
| 0.6 kpa | | | | | | |
| | | | ° | 60 | :Loss on drying | |
| | | | | / 50 | 3 (5mm | |
| R | | | 10 | 1.0 | :pH Value | |
| | | | | | .7.5-6.0 | (pH) |
| (/ 0.05) | | | 100 | 30 | : | F |
| .0.15 | | | 252 | | 290 | .VS |
| 50 | 50 | | TS (/ 60~) | 5 | 0.20 | :Zinc |
| 2.0 | | | methenamine R | | xlenol orange R | |
| | | | VS (/ 0.01) | | methenamine R | |
| | | | 0.6537 | VS (/ 0.01) | 1 | |
| | | | | / 60 | / 40 | |
| | | | 0.5 | 5 | 0.05 | :Assay |
| 30 | | | | 100 | | TS (/ 70~) |
| Microbiological assay of | | | | | " | |
| (NCTC 7743 or ATCC 10240) <i>Micrococcus luteus</i> | | | | (145 | 1 |) "antibiotics |
| TS | 6.6-6.5 | 7.1-7.0 | (pH) | Cml | | |
| (1 | 4-1 |) | | 6.0 | 7.0 | (pH) |
| | | | | ° | 35-32 | ° 39-35 |

1 . %105 %95 estimated potency ($P=0.95$)
55 ($P=0.95$)

Additional Requirements for Sterile Bacitracin Zinc

Sterility testing of " :Storage
° 25
:Sterility
(162 1) "antibiotics
R TS1 (/ 1) Peptone

Additional Requirements for Bacitracin Zinc for sterile use

Test for sterility of non- "
(32 5) "injectable preparations

BARIUM SULFAS

Barium sulfate

BaSO₄ :Molecular formula

233.4 :Relative molecular

Barium sulfate (1:1);CAS Reg.No. 7727-43-7 :Chemical name

grittiness :Description

:Solubility

.radiocontrast :Category

:Additional information

:Identity tests

| | | | | | | |
|------------------------|--------------|---|---|-------|-----|--------------|
| 10 | 5 | 5 | R | 5.0 | 0.2 | :A |
| 5 | TS (/ 70~) | | | 5 | .(B |) |
| General identification | | | " | A | | |
| | | | | .(123 | 1 |) |
| | | | | | | "tests |
| 5 | . | | | A | | :B |
| | TS (/ 100~) | | | 0.3 | | TS (/ 70~) |
| | | | | | | .TS (/ 80~) |

7 TS (/ 130~) 3 1.0 **:Phosphates**
 TS 5 . 10 . 5
 5 ammonium molybdate/vanadate
 10
 .TS (/ 5)
 30 5 1.0 **:Oxidizable sulfur compounds**
 1 R 0.1 TS 0.1 .
 1 TS (/ 3.6) Potassium iodate
 VS (/ 1)
 .
 (/ 300~) 15 5 **:Acid-soluble substances**
 5 10 TS
 . 15 ° 105
 . / 20 ° 600 1.0 () **:Loss on ignition**
 20 5.0 **:Acidity or alkalinity**
 bromothymol 0.05 10 . 5 R
 0.5 VS (/ 0.01) 0.5 blue/ethanol TS
 VS (/ 0.01)
 .()

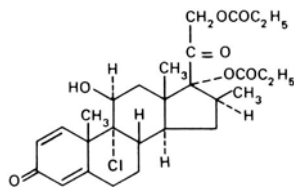
BECLOMETASONE DIPROPIONAS

Beclometasone dipropionate

$C_{28}H_{37}ClO_7$ **:Molecular formula**

521.0 **:Relative molecular mass**

:Graphic formula



:Chemical name

9-Chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate; 9-chloro-11β-hydroxy-16β-methyl-17,21-bis(1-oxopropoxy)pregna-1,4-diene-3,20-dione; CAS Reg. No. 5534-09-8.

:Description

8 TS (/ 750~)

60

:Solubility

.R

.Antiasthmatic

:Category

:Storage

REQUIREMENTS

%96.0

:General requirement

$C_{28}H_{37}ClO_7$ %104.0

:Identity tests

"

:A

.(43 1) "Spectro photometry in the infrared region

reference spectrum

RS

1) "Thin-layer chromatography

"

:B

1

RI()

(84

. 5

R

9 R

16

Toluene 1 R 4 .

9 2 . R

(B) 1 2.5 (A) R 1 R

. 1 RS 2.5

15 ° 120

. 10 ° 120 TS /

. (365)

.B A

R / 10 :**Specific optical rotation**

. $[a]_D^{20^\circ} = +88 \text{ to } 94^\circ$:

. / 1.0 :**Sulfated ash**

. / 5.0 :**Loss on drying**

Thin- "

Silica gel RI (84 1) "layer chromatography

. 0.2 R 5 R 95

R 1 R 9 10

. 1 0.30 (B) 1 15 (A) :

10 ° 105

TS /

A

.B

:**Assay**

. •

TS (/ 750~) 20

TS (/ 750~) 20 . 100

25 10.0 100

TS / 2.0

TS / 2.0 .R
 .R
 750~) .° 30
 525 1 25 TS (/
 10 Solvent cell
 C₂₈H₃₇ClO₇ . TS (/ 750~)
 . RS

BENZATHINI BENZYL PENICILLINUM

Benzathin benzylpenicillin

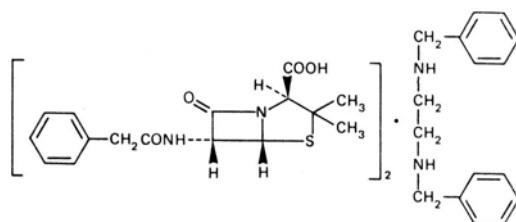
(non-injectable)

sterile

(anhydrous) (C₁₆H₁₈N₂O₄S)₂.C₁₆H₂₀N₂ :Molecular formula

() 909.1 :Relative molecular mass

:Identity tests



:Chemical name

N,N'-Dibenzylethylenediamine compound with (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:2); *N,N'*-bis(phenylmethyl)-1,2-ethanediamine compound with [2*S*-(2*α*,5*α*,6*β*)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:2); *N,N'*-dibenzylethylenediamine salt of benzylpenicillin; CAS Reg. No. 1538-09-6 (anhydrous).

.(Penicillin G benzathine) G

:Other name

| | | | |
|--|--------------|--|---------------|
| | | :Description | |
| TS (/ 750~) | | :Solubility | |
| | | .R | R |
| .Antibacterial | | :Category | |
| | | :Storage | |
| | | .° 30 | |
| | | :Labelling | |
| | | | |
| :Additional information | | | |
| . Water of crystallization | | | |
| REQUIREMENTS | | | |
| %96.0 | | :General requirement | |
| (C ₁₆ H ₁₈ N ₂ O ₄ S) ₂ .C ₁₆ H ₂₀ N ₂ | | Penicillins | %100.5 |
| . | | C ₁₆ H ₂₀ N ₂ | %27.0 %24.0 |
| :Identity tests | | | |
| (/ 1760~) | 2 | 1 | 2 :A |
| . | 1 | . | TS |
| TS / | 2 | 1 | 2 |
| . — | | | |
| . | | | |
| 1 | | | |
| 2 | TS (/ 1) | 2 | 0.1 :B |
| 1 | | R | 3 |
| 5 ° 90 | TS (/ 7) | 5 | .TS (/ 375~) |
| / 10 | TS (/ 150~) | . | |
| .(Picrate) ° 214 | | R | |

Determination of water " **:Water**

0.5 (145 1) A "by Karl Fischer method

80 / 50

10 0.05 (pH) **:pH Value**

7.5-5.0 R

:Assay

10 0.065 *:For total penicillins* :A

1000 R

10.0 2.0

25 ° 60 TS /imidazol

10.0 .(A) ° 20 .

.(B)

325 1

A TS / 10.0 2.0

.B

$(C_{16}H_{18}N_2O_4S)_2, C_{16}H_{20}N_2$ B A

RS 0.050

1.275 $(C_{16}H_{17}N_2O_4S)$ RS 1

$(C_{16}H_{18}N_2O_4S)_2, C_{16}H_{20}N_2$

$.0.03 \pm 0.62$

400) 30 1 $:C_{16}H_{20}N_2$:B

TS (/ 150~) 10 TS (/

10 .R 50

25

R () dehydrated 2

R 50

.1-naphtholbenzein/acetic acid TS VS (/ 0.1)

1 .liberated base

.C₁₆H₂₀N₂ 12.02 VS (/ 0.1)

Additional Requirements for Sterile Benzathin Benzylpenicillin

:Storage

.° 30

Sterility testing of

"

:Sterility

Penicillinase TS

(162 1) "antibiotics

.

Additional requirements for Benzathine benzylpenicillin for parenteral use

(56 4) "Parenteral preparations"

:Bacterial endotoxins

(30 5) "Test for bacterial endotoxins"

. 1 RS 0.01

Additional requirements for Benzathin benzylpenicillin for Sterile use

Test for Sterility of non-

"

.(32 5) "injectable preparations

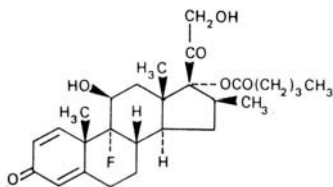
BETAMETHASONI VALERAS

Betamethason Valerate

C₂₇H₃₇FO₆ :Molecular formula

476.6 :Relative molecular mass

:Graphic formula



:Chemical name

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate; 9-fluoro-11β,21-dihydroxy-16β-methyl-17-[(1-oxopen-tyl)oxyl]pregna-1,4-diene-3,20-dione; CAS Reg. No. 2152-44-5.

:Description

TS (/ 750~)

:Solubility

.R R

.Antiinflammatory

:Category

:Storage

REQUIREMENTS

%96.0

:General requirement

$C_{27}H_{37}FO_6$ %104.0

:Identification tests

.E C D

B A

•

"

:A

.(43 1) "Spectrophotometry in the infrared region

reference spectrum

RS

20

2

TS (/ 750~)

20

20

:B

/

10

2

20

° 60

TS

.0.25

423 nm

1

"Related steroids" :C
 .B C A
 .B A
 1) "Oxygen flask method" :D
 0.01) 0.5 7 (132
 0.1 0.1 .absorbing 20 VS (/
 Zirconyl nitrate TS 0.1 TS (/ 1) Sodium alizarin sulfonate
 .
 . 5 TS1 / 2.0 0.05 :E
 1 TS (/ 100~) 2.0
 . /
 / 10 **:Specific optical rotation**
 . $[\alpha]_D^{20^\circ} = +75 \text{ to } +81^\circ$
 . / 2.0 () 0.1 **:Sulfated ash**
 . / 5.0 ° 105 **:Loss on drying**
 Thin- " **:Related steroids**
 Silica gel R1 (84 1) "layer chromatography
 . 0.2 R 5 R 95
 R 1 R 9 1
 RS 15 :(B) 1 15 :(A)
 A (C) 2 1
 1 0.15 (D) 1 B
 .B A
 / 10 ° 105 .
 A TS
 .
 .D

| | | | |
|--------------|---|--------|--|
| | | :Assay | |
| TS (/ 750~) | 20 | | |
| TS (/ 750~) | 20 | 100 | |
| 25 | 10.0 | 100 | |
| .R | TS / | 2.0 | |
| TS / | 0.2 | | |
| 1 | .R | | |
| TS (/ 750~) | .° 30 | | |
| 525 | 1 | 25 | |
| (/ 750~) | 10 | | |
| RS | C ₂₇ H ₃₇ FO ₆ | | |

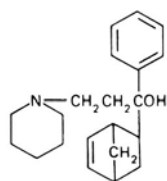
BIPERIDENUM

Biperiden البيبيريدين

C₂₁H₂₉NO :Molecular formula

311.5 :Relative molecular mass

:Graphic formula



:Chemical name

α -5-Norbornen-2-yl- α -phenyl-1-piperidinepropanol; α -bicyclo[2.2.1]hept-5-en-2-yl- α -phenyl-1-piperidinepropanol; CAS Reg. No. 514-65-8.

Potassium idobismuthate

A

TS2

.B

0.15 R1 30 0.4 :Assay
VS (/ 0.1) 1-naphtholbenzein/acetic acid TS
) A "Non-aqueous titration"
.C₂₁H₂₉NO 31.5 VS (/ 0.1) 1 (142 1

Additional requirement for Biperiden for parenteral use

(56 4) "Parenteral preparations"

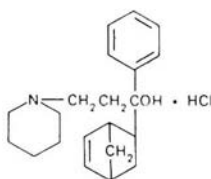
BIPERIDENI HYDROCHLORIDUM

Biperiden hydrochloride

C₂₁H₂₉NO, HCl :Molecular formula

347.9 :Relative molecular mass

:Graphic formula



:Chemical name

α -5-Norbornen-2-yl- α -phenyl-1-piperidinepropanol hydrochloride; α -bicyclo[2.2.1]hept-5-en-2-yl- α -phenyl-1-piperidinepropanol hydrochloride; CAS Reg. No. 1235-82-1.

:Description

R TS (/ 750~) R

:Solubility

.R

| | | | | | |
|------------------------------|--|--|---|--|--------|
| .Antiparkinsonism | | | :Category | | |
| . | | | :Storage | | |
| REQUIREMENTS | | | | | |
| %98.0 | | | :General requirement | | |
| . | | | C ₂₁ H ₂₉ NO,HCl | | %101.0 |
| :Identification tests | | | | | |
| .D C B | | | D A | | • |
| " | | | A | | |
| .(43 1) | | | "Spectrophotometry in the infrared region | | |
| reference spectrum | | | RS | | |
| . | | | . | | |
| TS (/ 1440~) | | | 5 20 | | B |
| bromine TS1 | | | 5 50 0.10 | | C |
| . | | | . | | |
| TS1 | | | . | | |
| General " | | | B / 20 | | D |
| .(121 1) chlorides | | | "identification tests | | |
| . / 1.0 | | | :Sulfated ash | | |
| . / 5 ° 105 3 | | | :Loss on drying | | |
| " | | | :Related substances | | |
| Silica (84 1) | | | "Thin-layer chromatography | | |
| 96.5 VS (/ 0.5) | | | gel R1 | | |
| :(A) R 10 | | | .R | | 3.5 |
| . 1 0.10 | | | :(B) 1 | | 20 |
| potassium iodobismuthate TS2 | | | | | |
| A | | | | | |
| . | | | | | |
| .B | | | | | |
| R1 30 | | | 0.4 | | :Assay |
| : 0.15 TS / | | | 10 | | |

| | | | | |
|---|---|-------|-------------|----------------------------------|
| 1 | VS (/ 0.1) | 1 | VS (/ 0.1) | 1-naphtholbenzein/acetic acid TS |
| 1 | (142 | 1 |) A | "Non-aqueous titration" |
| | .C ₂₁ H ₂₉ NO,HCl | 34.79 | VS (/ 0.1) | |

BLEOMYCINI HYDROCHLORIDUM

Bleomycin hydrochloride

(non-injectable)

Sterile

:Composition

CAS Reg. B₂

A₂

.*Streptomyces verticillus*

.No. 67763-87-5

.C₅₅H₈₄N₁₇O₂₁S₃,Cl :A₂

:Molecular formula

.C₅₅H₈₄N₂₀O₂₁S₂,HCl :B₂

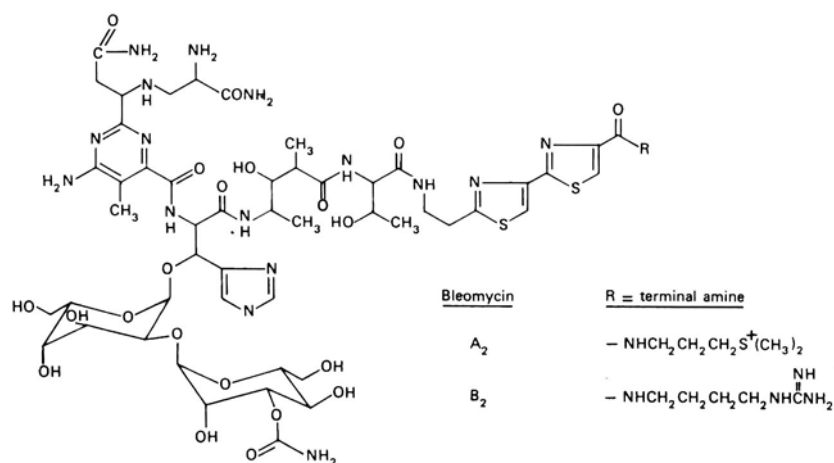
1452 :A₂

:Relative molecular mass

1461 :B₂

:A₂/B₂ bases

B₂/A₂



:Chemical name

Bleomycin A₂ hydrochloride: *N*¹-[3-(Dimethylsulfonio)-propyl]bleomycinamide chloride; [3-[2'-[2-[(2*S*,3*R*)-2-[(2*S*,3*S*,4*R*)-4-[(2*S*,3*R*)-2-[6-amino-2-[(1*S*)-1-[(2*S*)-2-amino-2-carbamoylethyl]amino]-2-carbamoylethyl]-5-methyl-4-pyrimidinecarboxamido]-3-[[2-*O*-(3-*O*-carbamoyl- α -D-mannopyranosyl)- α -L-gulopyranosyl]oxy]-3-imidazol-4-ylpropionamido]-3-hydroxy-2-methylvaleramido]-3-hydroxybutyramido]ethyl][2,4'-bithiazole]-4-carboxamido]propyl]dimethylsulfonium chloride; CAS Reg. No. 49830-49-1.

Bleomycin B₂ hydrochloride: *N*¹-(Guanidinobutyl)bleomycinamide hydrochloride; (β *S*)-4-amino- β -[[[(2*S*)-2-amino-2-carbamoylethyl]amino]-6-[[[(1*S*,2*R*)-2-[[2-*O*-(3-*O*-carbamoyl- α -D-mannopyranosyl)- α -L-gulopyranosyl]oxy]-1-[[[(1*R*,2*S*,3*S*)-3-[[[(1*S*,2*R*)-1-[[2-[4-[(4-guanidinobutyl)carbamoyl][2,4'-bithiazol]-2'-yl]ethyl]carbamoyl]-2-hydroxypropyl]carbamoyl]-2-hydroxy-1-methylbutyl]carbamoyl]-2-imidazol-4-ylethyl]carbamoyl]-5-methyl-2-pyrimidinepropionamide hydrochloride; *N*¹-[4-[(aminoiminomethyl)amino]butyl]bleomycinamide hydrochloride; CAS Reg. No. 55658-44-1.

:Description

TS (/ 750~)

R

R

R

.Cytotoxic

:Category

:Storage

:Labelling

:

REQUIREMENTS

A

:General requirement

1

B₂/A₂

2000

1500

%55.0

B

B₂

%32.0

%25.0

A₂

%70.0

%7.0

A₅

.%85

B₂

A₂

14 .orbital shaker
0.5 inoculated plates .° 5
.° 27 Cm8
International TS 7.0 reference solution
.(1 200 10) B₂/A₂ Reference Preparation
estimated potency (*P*= 0.95)
(*P*= 0.95) . %105 %95
1 B₂/A₂ 2000 1500
.
A .Content of the bleomycin components :B
.packing material
1 ¹377-373
25 "High performance liquid chromatography "
10-5 4.6
linear .octadecyl silyl groups
R 1 1-pentanesulfonic acid TS 9 gradient development
1-pentane sulfonic acid TS 6
R 4
1.86 :) . 60
detector .(1 R
5 .(20-8) 254
. 1 5
gradient elution
. A₂ 80
bleomycin acid void :
. A₂ B₄ A₅ B₂ A₂
.()

1

areas

peaks

Additional Requirements for Sterile Bleomycin Hydrochloride

:Storage

"

:Histamine-like substances

1 (167 1) "Test for histamine-like substances

. 1 500 TS 1

Sterility testing of

"

:Sterility

(162 1) "antibiotics

Additional requirements for Bleomycin hydrochloride for Sterile use

Test for Sterility of non-

"

.(32 5) "injectable preparations

"

:Bacterial endotoxins

(30 5)"Test for bacterial endotoxins

. 1 RS 10.0

BLEOMYCINI SULFAS

Bleomycin sulfate

(non-injectable)

Sterile

:Composition

CAS Reg. No. 9041- :B₂ A₂

.*Streptomyces verticillus*

.93-4

C₅₅H₈₄N₁₇O₂₁S₃.HSO₄ :A₂

:Molecular formula

.C₅₅H₈₄N₂₀O₂₁S₂.HCl :B₂

:B₂

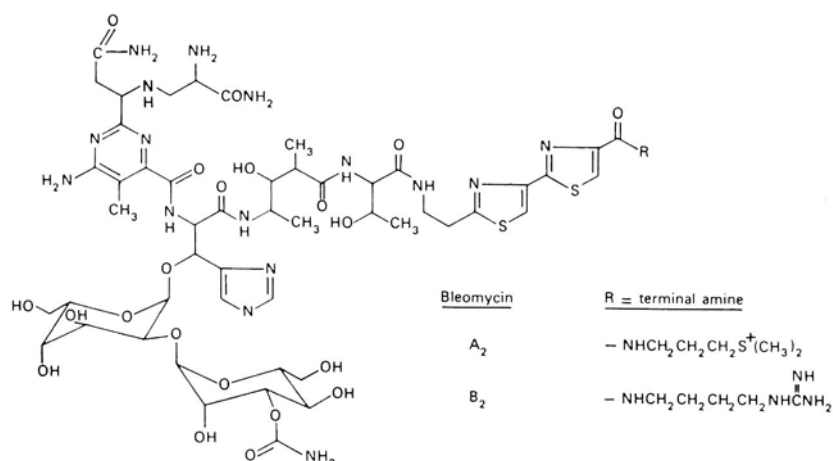
1514 :A₂

:Relative molecular mass

.1524

:A₂/B₂ bases

B₂/A₂



:Chemical name

Bleomycin A₂ sulfate: *N*¹-[3-(Dimethylsulfonio)propyl]bleomycinamide hydrogen sulfate; [3-[2'-[2-[(2*S*,3*R*)-2-[(2*S*,3*S*,4*R*)-4-[(2*S*,3*R*)-2-[6-amino-2-[(1*S*)-1-[(2*S*)-2-amino-2-carbamoylethyl]amino]-2-carbamoylethyl]-5-methyl-4-pyrimidinecarboxamido]-3-[[2-*O*-(3-*O*-carbamoyl- α -D-mannopyranosyl)- α -L-gulopyranosyl]oxy]-3-imidazol-4-ylpropionamido]-3-hydroxy-2-methylvaleramido]-3-hydroxybutyramido]ethyl][2,4'-bithiazole]-4-carboxamido]propyl]dimethylsulfonium hydrogen sulfate.

Bleomycin B₂ sulfate: *N*¹-(Guanidinobutyl)bleomycinamide; (β *S*)-4-amino- β -[(2*S*)-2-amino-2-carbamoylethyl]amino]-6-[[[(1*S*,2*R*)-2-[[2-*O*-(3-*O*-carbamoyl- α -D-mannopyranosyl)- α -L-gulopyranosyl]oxy]-1-[[[(1*R*,2*S*,3*S*)-3-[[[(1*S*,2*R*)-1-[[2-[4-[(4-guanidinobutyl)carbamoyl][2,4'-bithiazol]-2'-yl]ethyl]carbamoyl]-2-hydroxypropyl]carbamoyl]-2-hydroxy-1-methylbutyl]carbamoyl]-2-imidazol-4-ylethyl]carbamoyl]-5-methyl-2-pyrimidinepropionamide sulfate (salt); *N*¹-[4-[(aminoiminomethyl)amino]butyl]bleomycinamide sulfate (salt).

:Description

:Solubility

.Cytotoxic

:Category

:Storage

:Labelling

:

REQUIREMENTS

A

:General requirement

1

B₂/A₂

2000

1500

%55.0

B

B₂

%32.0

%25.0

A₂

%70.0

B₄

%7.0

A₅

%.85

B₂

A₂

%.3.0

demethylbleomycin

A₂

%1.0

:Identification tests

TS (/ 160) (II)

5

10

5

A

100

268

290

242

General

"

A

/ 10

B

.(123 1)

"identification tests

0.6

)

° 60

:Loss on drying

. / 60

4 (

5

.6.0-4.5 / 5.0

:pH value

10

60

75

:Copper content

TS2

10

.TS (/ 0.1)

. 1

Zinc bis (dibenzylthio carbamate TS

10

R

1

435 1 .

.R

$$A_o = (A_o \times 15) / (A_s \times W) \quad /$$

W TS2 A_s

. / 0.2

:Assay

" **:Microbiological assay** A

(155 1) "Microbiological assay of antibiotics

: inoculum . *Mycobacterium smegmatis* (ATCC 607)

50 Cm9 ° 27 48-40

Orbital 5 ° 27-25

.° 5 14 .shaker

inoculated plaks

reference Solution .° 27 Cm8

International Reference Preparation 7.0 TS

. (1 200 10) B2/A2

%95 estimated potency ($P = 0.95$)

1500 ($P = 0.95$) . %105

1 B₂/A₂ 2000

.

A *Content of the bleomycin components* :B

377-373 .packing material

"High performance liquid chromatography " 1

10-5 4.6 25

.Octadecyl silyl groups

1 1-pentanesulfonic acid TS 9 linear gradient development

1- TS 6 R

4 pentanesulfonic acid
) . 60
 detector . (1 R 1.86 :
 20-8) 254
 5 5 . (gradient elution . 1
 . A2 80
 bleomycin acid Void :
 . A₂ B₄ A₅ B₂ A₂
 areas
 . peaks

Additional Requirements for Sterile Bleomycin Sulfate

. :Storage
 :Histamine-like substances
 (167 1) "Test for histamine-like substances "
 . 1 500 TS 1 1
 Sterility testing of "
 . (162 1) "antibiotics :Sterility

Additional Requirements for Bleomycin Sulfate for Sterile use

Test for Sterility of non- "
 . (32 5) "injectable preparations
 "
 :Bacterial endotoxins
 (30 5) "Test for bacterial endotoxins
 . 1 RS 10.0

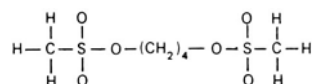
BUSULFANUM

Busulfan

$C_6H_{14}O_6S_2$:Molecular formula

246.3 :Relative molecular mass

:Graphic formula



:Chemical name

1,4-Butanediol dimethanesulfonate; tetramethylene dimethanesulfonate; CAS Reg. No. 55-98-1.

.Myelosanum

:Other name

:Description

R

:Solubility

.TS (/ 750~)

.Cytotoxic

:Category

:Storage

: :Additional information

REQUIREMENTS

%100.5

%98.5

:General requirement

$C_6H_{14}O_6S_2$

:Identification tests

VS (/ 1)

5

10

0.1

:A

methanesulfonic acid

.B

0.05

A

:B

TS (/ 10)

0.05 TS (/ 100~) 2 A

TS (/ 10)

0.5 TS 1.0 0.10 :C

TS (/ 60~) 0.5 TS (/ 260~)

5 .2 blank .1

4.0 TS (/ 70~) 1.0

1 2 TS (/ 50)

.° 118-115 :Melting range

. / 1.0 :Sulfated ash

) ° 60 :Loss on drying

. / 20 (5 0.6

25 0.25 :Assay

condenser . 30 reflux

.phenolphthalein/ethanol TS VS (/ 0.1)

0.1) 1 .

.C₆H₁₄O₆S₂ 12.32 VS (/

CALCII CARBONAS

Calcium carbonate

CaCO₃ :Molecular formula

100.1 :Relative molecular mass

.Calcium carbonate (1:1); CAS Reg. No. 471-34-1 :Chemical name

:Description

. TS (/ 750~)

:Solubility

| | | | |
|----------------------------------|-------------------------|-----------------------|-------------------|
| TS (/ 130~) | TS (/ 70~) | TS (/ 60~) | |
| | .Antacid | :Category | |
| | | :Storage | |
| REQUIREMENTS | | | |
| %98.0 | | :General requirement | |
| | | CaCO ₃ | %100.5 |
| | | :Identification tests | |
| 2 TS (/ 70~) | 0.3 | 20 | :A |
| "General identification tests | " | | |
| | (120 | 1 |) |
| TS (/ 300~) | 1.0 | 0.01 | :B |
| TS | | | |
| TS (/ 60~) | 80 | / 5 | :Heavy metals () |
| TS (/ 60~) | 100 | 2 | |
| |) Sintered glass filter | | |
| |) 20 | (| |
| Limit test for heavy | " | (| |
| | / 30 | (126 1) A | "metals |
| TS (/ 70~) | 35 | 3.3 | :Arsenic |
| (130 1) "Limit test for arsenic | | " | |
| | / | 3 | |
| 10 () | 10 | :Barium | |
| (B) 10 | 10 | (A) TS | |
| .B | opalescent | A | 15 |
| 40 TS (/ 70~) | 10 | 0.20 | :Iron |

(129 1) "Limit test for iron "

. / 200

10 1.0 :Magnesium and alkali metals ()

R 1 20 TS (/ 70~)

TS (/ 100~) .TS / 0.1

40 . 2

0.25 . 100 4 .TS (/ 50~)

. 50 TS (/ 100~)

. 5 ° 600 ()

:Substances insoluble in acetic acid

° 105 5 ()

. 10 1

20 ° 200 :Loss on drying

. /

20 TS (/ 70~) 3 0.15 :Assay

. 50 2

1 .(138 1) "Complexometric titration "

.CaCO₃ 5.004

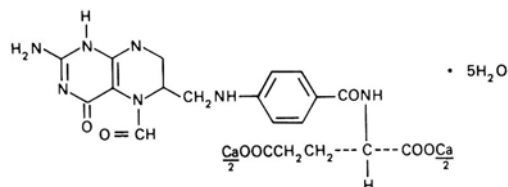
CALCII FOLINAS

Calcium folinate

C₂₀H₂₁CaN₇O₇·5H₂O :Molecular formula

601.6 :Relative molecular mass

:Graphic formula



:Chemical name

Calcium *N*-[*p*-[[[(2-amino-5-formyl-5,6,7,8-tetrahydro-4-hydroxy-6-pteridiny)methyl]amino]benzoyl]-L-glutamate (1 : 1) pentahydrate; calcium *N*-[4-[[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridiny)methyl]amino]benzoyl]-L-glutamate (1 : 1) pentahydrate; CAS Reg. No. 6035-45-6 (pentahydrate).

.Leucovorin calcium

:Other name

:Description

TS (/ 750~)

:Solubility

.Cytotoxic

:Category

:Storage

:Additional information

REQUIREMENTS

%95.0

:General requirement

.anhydrous

C₂₀H₂₁CaN₇O₇ %105.0

:Identification tests

.D C B
"

C A

•
:A

. (43 1) "Spectrophotometry in the infrared region
reference spectrum RS

0.5 TS (/ 70~)

0.5

3.0

20

:B

| | | | | |
|-----|--------------------------|-------------------------|---|------|
| RS | | System suitability test | | (B) |
| 1 | 1 | 175 | | |
| | | | (C) A | 4 |
| | | 1 | 2-1 | |
| | | | 254 | |
| | C | 15 | replicate injections | 6 |
| | 3.6 | | resolution factor | |
| | relative retention times | | %2.0 | peak |
| B A | 15 | | 1.6 1.0 | |
| | | | peak responses | |
| | C | 100(0.1C)(ru/rs) : | C ₂₀ H ₂₁ CaN ₇ O ₇ | |
| B A | | rs ru A | RS | 1 |
| | | | | . |

| | | | | |
|---|--|---|----------------------------------|------|
| | Additional requirements for Calcium folinat for parenteral use | | | |
| 4 |) "Prenteral preparations | " | | |
| | | | | (56 |
| | " | | | |
| | | | :Bacterial endotoxins | |
| (| 30 | 5 |) "Test for bacterial endotoxins | |
| | | 1 | RS | 0.51 |

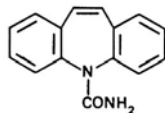
CARBAMAZEPINUM

Carbamazepine

C₁₅H₁₂N₂O :Molecular formula

236.3 :Relative molecular mass

:Graphic formula



:Chemical name

5H-Dibenz[b,f]azepine-5-carboxamide; CAS Reg. No. 298-

46-4.

:Description

(/ 750~)

R

:Solubility

.R

TS

.Antiepileptic

:Category

:Storage

REQUIREMENTS

%102.0

%98.0

:General requirement

C₁₅H₁₂N₂O

:Identification tests

.D C B

A

•

"

:A

.(43 1) "Spectrophotometry in the infrared region

RS

reference spectrum

. "Related substances

"

:B

.D

C

(365 mm)

:C

.

—

3

TS (/ 1000~)

2

0.1

:D

. ° 193-189 :Melting range
 1.0 :Heavy metals ()
 1) 3 "Limit test for heavy metals () "
 . / 10 (128 1) A (127
 . / 1.0 :Sulfated ash
 5.0 ° 105 :Loss on drying
 . /
 R 20 1.0 :Acidity or alkalinity
 TS / 0.1 10 . 15
 0.5 VS (/ 0.01)
 0.01) TS / 0.15 .pink
 . 1.0 VS (/
 Thin- "
 :Related substances
 Silica gel R6 (84 1) "layer chromatography
 5 2 . R 14 R 86
 0.050 :(A) R TS (/ 750~)
 iminodibenzyl R 0.050 :(B) 1
 5.0 :(D) 1 5.0 :(C) 1
 . 1 RS 5.0 :(E) 1 RS
 TS3
 A .
 15 ° 140 .B
 A .(254)
 .E
 TS (/ 750~) 0.1 :Assay

| | | | |
|----|--|---------------|-------------|
| 10 | 100 | 10 | 100 |
| 1 | | .TS (/ 750~) | 100 |
| RS | C ₁₅ H ₁₂ N ₂ O | . | 285 |
| | | . | |
| | | . | 0.02 ± 0.49 |

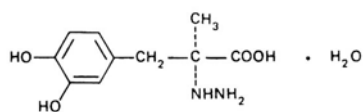
CARBIDOPUM

Carbidopa

C₁₀H₁₄N₂O₄·H₂O :Molecular formula

244.2 :Relative molecular mass

:Graphic formula



:Chemical name

(-)-L- α -Hydrazino-3,4-dihydroxy- α -methylhydrocinnamic acid monohydrate; (S)- α -hydrazino-3,4-dihydroxy- α -methylbenzenepropanoic acid monohydrate; CAS Reg. No. 38821-49-7 (monohydrate).

:Description

TS (/ 750~)

:Solubility

.R

R

.Antiparkinsonism

:Category

:Storage

REQUIREMENTS

101.0

%99.0

:General requirement

C₁₀H₁₄N₂O₄

:Identity tests

11

: A

40 1) "Spectrophotometry in the infrared region

reference spectrum

RS

R 4 - 5 R 1 1 5 :B

3

TS (/ 200) 0.1

/ 10

:Specific optical rotation

$$[\alpha]_D^{20^\circ\text{C}} = -22.0 \text{ to } -26.5^\circ$$

TS

1.0

:Heavy metals

()

1) 3 "Limit test for heavy metals () "

$$. / 20 \quad (128 \quad 1) \text{ A} \quad (127$$

. / 1.0

:Sulfated ash

Determination of water the

11

:Water

0.5 (135 1) A "by the Karl Fischer method

. / 79 / 69

A :Methyldopa and 3-*O*-Methylcarbidopa -0-3

377-373

.Packing material

"High performance liquid chromatography

11

1

4 20

octadecyl silyl

10

Silica gel

98 . () groups

1 1.5 R 2 TS (/ 13.6)

282

. (10)

0.050 : (A) VS (/ 0.1)

0.10 (-)-3-(4-hydroxy-3-methoxyphenyl)-2-hydrazino-2-methylalanine RS : 0.050 RS

1 (-)-3-(4-hydroxy-3-methoxyphenyl)-2-methylalanine RS
 10 : (C) 1 10 : (B) internal standard
 . 1 0.1
 : (b) : (a) peaks A
 (-)-3-(4-hydroxy-3-methoxyphenyl)- : (C) (-)-3-(4-hydroxy-3-methoxyphenyl)-2-methylalanine
 (C) (a) . 2-hydrazino-2-methylalanine
 .C
 VS (/ 0.1) 25.0 0.3 : Assay
 /
 " VS (/ 0.1)
 0.1) 1 . (142 1) A "Non-aqueous titration
 .C₁₀H₁₄N₂O₄ 22.62 VS (/

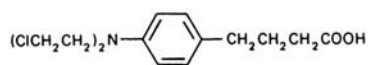
CHLORAMBUCILUM

Chlorambucil

C₁₄H₁₉Cl₂NO₂ :Molecular formula

304.2 :Relative molecular mass

:Graphic formula



:Chemical name

4-[p-[Bis(2-chloroethyl)amino]phenyl]butyric acid; 4-[bis(2-chloroethyl)amino]benzenebutanoic acid; CAS Reg. No. 305-03-3.

:Description

R TS (/ 750~)

:Solubility

.R

:Category

: Additional information

:General requirement

C₁₄H₁₉Cl₂NO₂ %101.0

| | | | |
|-----|------|----|----|
| TS2 | 0.20 | 20 | :A |
|-----|------|----|----|

0.05 . 10 R 5 0.05 :B

ionizable) . (ion)

| | | | | |
|----|-------------|----|-----|----|
| 30 | TS (/ 70~) | 10 | 0.4 | :C |
|----|-------------|----|-----|----|

$$3 \quad R \quad \left(\quad 5 \quad \quad 0.6 \quad \right)$$

. / 1.0 :Melting range

:Water

11

silica gel R2 (84 1) "Thin-layer chromatography

$$\mathbb{R} \quad 4 \mathbb{R} \quad 4 \mathbb{R} \quad 5 \mathbb{R}$$

| | | | |
|-----|--|-------------|-------------|
| 20 | :(A) | R | 10 |
| . | 1 | 0.4 | :(B) 1 |
| .(| 254) | | |
| .B | | A | |
| 10 | R | 10 | 0.2 |
| .TS | / | VS (/ 0.1) | :Assay |
| | 1 | . | |
| | .C ₁₄ H ₁₉ Cl ₂ NO ₂ | 30.42 | VS (/ 0.1) |

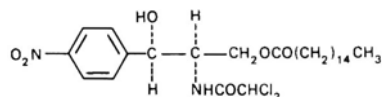
CHLORAMPHENICOLI PALMITAS

Chloramphenicol Palmitate

C₂₇H₄₂Cl₂N₂O₆ :Molecular formula

561.5 :Relative molecular mass

:Graphic formula



:Chemical name

D-threo-(-)-2,2-Dichloro-N-[β-hydroxy-α-(hydroxymethyl)-p-nitrophenethyl]acetamide α-palmitate; [*R-(R*,R*)*]-2-[(dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl)propyl hexadecanoate; CAS Reg. No. 530-43-8.

| | | |
|--------------|---------------------|-------------------------|
| . | unctuous | :Description |
| TS (/ 750~) | | :Solubility |
| | | .R R |
| | .Antibacterial drug | :Category |
| . | | :Storage |
| | | :Additional information |

polymorph B %90

polymorph B %90

REQUIREMENTS

%98.0

:General requirement

$C_{27}H_{42}Cl_2N_2O_6$ %102.0

:Identification tests

1) "Thin-layer chromatography" :A
R 9 silica gel R4 (84

10 0.1 R 1
10 :(B) 1 10 :(A) R
1 RS

A .(254)

.B

TS (/ 100~) 1.0 TS (/ 750~) 4 10 :B
. 10 R 0.05

2 TS (/ 100~) 0.5
2.0 2-naphtol TS1 1.0 R 1.0
R TS (/ 400~)

/ 50

:Specific optical rotation

$[a]_D^{20^{\circ}C} = + 22.5 \text{ to } + 25.5^{\circ}$ R

. / 1.0

:Sulfated ash

:Loss on drying

)
5.0 R (5 0.6
. /

5 ° 35 1.0 :Acidity

.TS / R TS (/ 750~)

TS / VS (/ 0.1)

. 0.4 30

80 1.0 :Free chloramphenicol

15 xylene R

R 10 . 50

blank 278 1

.005

. / 0.45 ($A_{1cm}^{1\%} = 298$) 29.8 :

100 R 0.03 :Assay

. 100 10

$C_{27}H_{42}Cl_2 N_2O_6$ 271 1

. ($A_{1cm}^{1\%} = 178$) 17.8 :

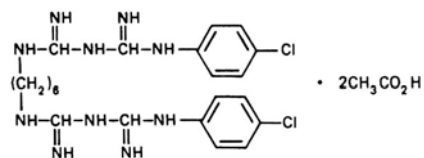
CHLORHEXIDINI DIACETAS

Chlorhexidine diacetate

$C_{22}H_{30}Cl_2 N_{10}, 2C_2H_4O_2$:Molecular formula

625.6 :Relative molecular mass

:Graphic formula



:Chemical name

1,1'-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide] diacetate; *N,N''*-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamide diacetate; CAS Reg. No. 56-95-1.

:Description

TS (/ 750~)

15

55

:Solubility

.R

.Disinfectant

:Category

:Storage

REQUIREMENTS

%97.5

:General requirement

$C_{22}H_{30}Cl_2 N_{10}, 2C_2H_4O_2$ %101.0

:Identification tests

2

R

10

0.1

:A

TS1

2

TS (/ 150~)

TS / (II)

0.15

10

0.1

:B

TS / (II)

0.5

TS (/ 1760~)

1

TS (/ 750~)

1

0.2

:C

. ()

. / 2.0

:Sulfated ash

35

° 105

:Loss on drying

. /

5

30

0.20

:Chloraniline

ammonium

2 TS (/ 35)

1 VS (/ 1)

N-(1-naphthyl)ethylenediamine :

5

TS (/ 50) sulfamat

TS (/ 750~)

1

TS (/ 1) hydrochloride

R 0.10 30 . 30 . 50
 . TS (/ 70~)

"Colour of liquids"

.(/ 0.5) (53 1)

"

:Related substances

Silica gel R4 (84 1) "Thin-layer chromatography

16 R4 8 : slurry

50 . 0.5 sodium formate R 1

7 TS (/ 750~) 50 R

20 4 . TS (/ 1080~)

.(A) 1 72 TS (/ 90~)

.(254 nm)

15 R 5

. 256 1

blank solution

0.14 : B .

50 200 100 TS (/ 90~)

.B eluted A .R

0.15 R1 30 0.45 **:Assay**

VS (/ 0.1) 1-naphtholbenzein/acetic acid TS

1) A "Non-aqueous titration"

.C₂₂H₃₀Cl₂N₁₀2C₂H₄O₂ 15.64 VS (/ 0.1) 1 .(142

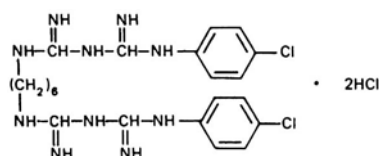
CHLORHEXIDINI DIHYDROCHLORIDUM

Chlorhexidin dihydrochloride

$C_{22}H_{30}Cl_2N_{10} \cdot 2HCl$:Molecular formula

578.4 :Relative molecular mass

:Graphic formula



:Chemical name

1,1'-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide] dihydrochloride; *N,N'*-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecane-diimidamide dihydrochloride; CAS Reg. No. 3697-42-5.

:Description

.TS (/ 750~)

450

:Solubility

:Category

:Storage

REQUIREMENTS

:General requirement

$C_{22}H_{30}Cl_2N_{10} \cdot 2HCl$ %101.0 %98.0

:Identification tests

| | | | | | | | |
|----|-------|--------------|-----|-----|-----|----|--------------------------------|
| TS | /(II) | 0.15 | 2 | R | 10 | 20 | :A |
| | | | | | | | TS1 |
| | TS | /(II) | 0.5 | 10 | 0.1 | 2 | TS (/ 150~) |
| | | | | | | | :B |
| 1 | A | TS (/ 130~) | 50 | 0.1 | : | : | C |
| | | | | | | | "General identification tests" |

.(121

. / 1.0 :Sulfated ash
 20 ° 130 :Loss on drying
 . /
 5 . 30 0.20 :Chloraniline
 sulfamate 2 TS (/ 35) 1 VS (/ 1)
 (/ 1) N-(1-naphthyl)ethylenediamin hydrochloride 5 . TS (/ 50)
 50 TS (/ 750~) 1
 R 0.10 30 . 30
 . TS (/ 70~)
 1) "Colour of liquids "
 .(/ 0.5) (53
 "
 :Related substances
 Silica gel R4 (84 1) "Thin-layer chromatography
 16 R4 8 : slurry
 50 . 0.5 Sodium formate R 1
 7 TS (/ 750~) 50 R
 35 1.1 A . TS (/ 1080~)
 2-propanol R 100 TS (/ 330~)
 100 200 TS (/ 200~)
 R .R
 R 50 R
 0.56 30 ° 65 R
 4 . 100 TS (/ 90~)
 .A 20
 .(254)

blank solution . 15 R 5
 256 1
 TS (/ 90~) 0.11 : B
 .R 50 200 100
 .B eluted A
 10 R1 30 0.4 :Assay
 VS (/ 0.1) TS /
 A "Non-aqueous titration "
 C₂₂H₃₀Cl₂ 14.46 VS (/ 0.1) 1 .(142 1)
 .N₁₀,2HCl

CHLORTETRACYCLINI HYDROCHLORIDUM

Chlortetracycline hydrochloride

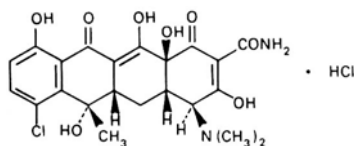
(non-injectable)

sterile

C₂₂H₂₃ClN₂O₈·HCl :Molecular formula

515.4 :Relative molecular mass

:Graphic formula



:Chemical name

(4*S*,4*aS*,5*aS*,6*S*,12*aS*)-7-Chloro-4-(dimethylamino)-
1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,6,10,12,12*a*-pentahydroxy-6-methyl-1,11-di-
oxo-2-naphthacenecarboxamide monohydrochloride; [4*S*-(4*α*,4*αα*,5*αα*,6*β*,12*αα*)]-
7-chloro-4-(dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,6,10,12,12*a*-pen-
tahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochlo-
ride; CAS Reg. No. 64-72-2.

| | | | |
|--------------|-------------------------|-----|--------------|
| | | | :Description |
| TS (/ 750~) | 250 | 100 | :Solubility |
| | .R | R | R |
| | .Antiinfective drug | | :Category |
| | | | :Storage |
| | | | :Labelling |
| | :Additional information | | |

REQUIREMENTS

| | | | |
|----------------------------|----------------------|---|--------------------|
| 900 | :General requirement | | |
| | 1 | | |
| | :Identity tests | | |
| "Thin-layer chromatography | " | | :A |
| R1 | 25 | : | keiselguhr (84 1) |
| | 47.5 | R | 2.5 50 keiselguhr |
| | .TS (/ 100~) | | 7 VS (/ 0.1) |
| | 90-70 | | |
| R | 1 | R | 2 R 2 200 |
| 7 | VS (/ 0.1) | | 25 |
| 3 | 1 | . | TS (/ 100~) |

| | | | | | | | | |
|---------|---------------------------------------|---------------|----------------------------|-----------------|---|---------------|------|----------------|
| 0.50 | : | (B) | 1 | 0.50 | : | (A) | R | |
| | 0.50 | : | (C) | 1 | RS | | | |
| 0.50 | 1 | RS | | 0.50 | 1 | RS | | |
| | | | | . | 1 | RS | | |
| .(| 365) | | | | TS (/ 260~) | | | |
| .B | | | | A | | | | |
| . | | | C | | | | | |
| | 1 | ° 100 | 7.6 | TS | | 10 | 10 : | B |
| | | | . | | (| 365) | | |
| | | TS (/ 1760~) | | 2 | 1 | | : | C |
| | | . | 1 | | | | | |
| General | | " | | B | / 0.05 | | : | D |
| | | .(121 | 1 |) | | | " | identification |
| | | 0.125 | :Specific optical rotation | | | | | |
| | ° 25 | | . | 30 | | | 25.0 | |
| | | | | | . $[a]_D^{20^{\circ}C} = -235 \text{ to } -250^{\circ}$ | | | |
| | | | 0.5 | :Heavy metals | | (|) | |
| | (127 | 1 |) 3 | (| |) | " | |
| | . | / | 50 | (128 | | 1 |) A | |
| | | | . | / | 5.0 | :Sulfated ash | | |
| | 0.6 |) | ° 60 | :Loss on drying | | | | |
| . | / | 20 | 3 | R | | (| 5 | |
| | | 3.3-2.3 | / | 10 | :pH value | | | |
| 10 | :Absorption in the ultraviolet region | | | | | | | |
| | 10 | . | 100 | VS (/ 0.5) | | | | |
| 25 | | | | 10 | . | VS (/ 0.5) | | 100 |
| | | | | . | 8 | | | 200 |

0.76 0.70 274 1

"

:Assay

NCTC) (a) (155 1) "Microbiological assay of antibiotics

Cm1 *Bacillus pumilus* (8241 or ATCC 14884

20 2) 4.5 TS 6.5-6.5

Bacillus cereus (ATCC : (b) ° 39-35 (1

TS 6.0-5.9 Cm1 11778)

(0.2 0.05) 4.5

estimated ($P = 0.95$) .° 33-29

. %105 %95 potency

. 1 900 ($P = 0.95$)

Additional Requirements for Sterile Chlortetracycline Hydrochloride

:Storage

Sterility testing of "

(162 1) "antibiotics

Additional requirement for Chlortetracycline hydrochloride for sterile use

Test for sterility of non-

.(32 5) "injectable preparation

"

:Bacterial endotoxins

(30 5) "Test for bacterial endotoxins

. 1 RS 1.0

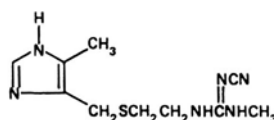
CIMETIDINUM

Cimetidine

$C_{10}H_{16}N_6S$:Molecular formula

252.3 :Relative molecular mass

:Graphic formula



:Chemical name

2-Cyano-1-methyl-3-[2-[[[(5-methylimidazol-4-yl)methyl]-thio]ethyl]guanidine; *N''*-cyano-*N*-methyl-*N'*-[2-[[[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]guanidine; 1-cyano-2-methyl-3-[2-[[[(5-methylimidazol-4-yl)methyl]thio]ethyl]guanidine; *N*-cyano-*N'*-methyl-*N''*-[2-[[[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]guanidine; CAS Reg. No. 51481-61-9.

:Description

.R

:Solubility

.Antiulcer

:Category

:Storage

:Additional information

.RS

polymorph

.polymorphic

REQUIREMENTS

%101.0

%98.5

:General requirement

$C_{10}H_{16}N_6S$

:Identity tests

"

:A

. (43 1) "Spectrophotometry in the infrared region

RS

| | | | | | |
|----------------------|---|-------------------|----------------------------|-----------------------------|-------------|
| | peak | shoulder | <i>reference spectrum</i> | | |
| | | (polymorphic form | |) 1180 cm ⁻¹ | discernable |
| | | | ° 142 | | :B |
| | | 1.0 | :Heavy metals | () | |
| 3 | "Limit test for heavy metals | () | | " | |
| | (128 1) A | () | | (127 1) | |
| | | | | . / | 20 |
| | | . / 1.0 | :Sulfated ash | | |
| 10.0 | ° 105 | | :Loss on drying | | |
| | | | | . / | |
| 9.5- R | | / 5.0 | :pH value | | |
| | | | | | .8.0 |
| | .Packing material | A | :Related substances | | |
| | 1 | 377-373 | | | |
| 25 | "High performance liquid chromatography | | | " | |
| | ceramic | porous | | 4.6 | |
| | .Octadecyl silyl groups | | | | 10-5 |
| . 200 | | R | | 1 : | |
| | .TS (/ 2) | | 10 | | 190 |
| .R | 16 | | 84 | | |
| 24 RS | 18 | | system suitability | | |
| | .(A) | | 1 | caffeine RS | |
| | .(B) | | 1 | 18 | |
| | | detector | . 1 | 1 | |
| replicate injections | 6 . | | 228 | | |
| | peak responses | | .A | | 10 |
| | | | | relative standard deviation | |

| | | | | | |
|---|------------|---|------------------------|--------|------|
| | resolution | %2.0 | | | |
| 10 | . | 1.4 | 1.0 | | .3.0 |
| | | | | : | B |
| | | | . 0.99 | | |
| R1 | | 30 | 0.25 | :Assay | |
| " | | | VS (/ 0.1) | | |
| 1 | .(142 | 1) A | "Non-aqueous titration | | |
| | | .C ₁₀ H ₁₆ N ₆ S | 25.23 VS (/ 0.1) | | |
| Additional requirement for Cimetidine for parenteral use | | | | | |
| .(56 | 4 |) "parenteral preparation | | " | |

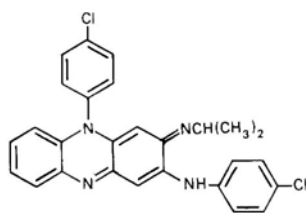
CLOFAZIMINUM

Clofazimine

C₂₇H₂₂Cl₂ N₄ :Molecular formula

473.4 :Relative molecular mass

:Graphic formula



:Chemical name

3-(p-Chloroanilino)-10-(p-chlorophenyl)-2,10-dihydro-2-(iso-propylimino)phenazine; N,5-bis(4-chlorophenyl)-3,5-dihydro-3-[(1-methyl-ethyl)imino]-2-phenazinamine; CAS Reg. No. 2030-63-9.

:Description

" . /
) silica gel R6 (84 1) "Thin-layer chromatography
 30 (
 .TS (/ 17~) shallow
 .R -1 4 R 85
 20 :(A) R 3 5
 0.10 :(C) 1 0.16 :(B) 1
 . 12 . 1
 . 5
 5 12
 A .(254)
 .B C
 R 50 R 20 0.4 :Assay
 Non- " VS (/ 0.1)
 (/ 0.1) 1 .(142 1) A "aqueous titration
 .C₂₇H₂₂Cl₂N₄ 47.34 VS

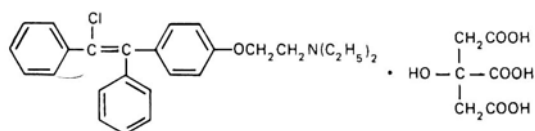
CLOMIFINI CITRAS

Clomifen citrate

C₂₆H₂₈ClNO₇·C₆H₈O₇ :Molecular formula

598.1 :Relative molecular mass

:Graphic formula



| | | | | | |
|--------------------|-----------|-------------------------|--|--|--------|
| | | | | :Chemical name | |
| | | | | 2-[<i>p</i> -(2-Chloro-1,2-diphenylvinyl)phenoxy]triethylamine citrate (1:1); 2-[4-(2-chloro-1,2-diphenylethenyl)phenoxy]- <i>N,N</i> -diethylethanamine 2-hydroxy-1,2,3-propanetricarboxylate (1:1); CAS Reg. No. 50-41-9. | |
| | | | | :Description | |
| R | | R | | :Solubility | |
| | | . R | | TS (/ 750~) | |
| | | .ovulation inducer | | :Category | |
| | | | | :Storage | |
| Z E | | :Additional information | | | |
| | | . (geometric isomers) | | | |
| REQUIREMENTS | | | | | |
| %97.0 | | :General requirement | | | |
| (Z-isomer) Z- | %50.0 | %30.0 | C ₂₆ H ₂₈ ClNO ₇ , C ₆ H ₈ O ₇ | | %101.0 |
| :Identity tests | | | | | |
| | | .C B | A | | • |
| | | " | | | :A |
| .(43 | | 1) | "Spectrophotometry in the infrared region | | |
| reference spectrum | | RS | | | |
| | | / 25 | | :B | |
| 392 | 235 | 350 | 220 | VS (/ 0.1) | |
| . | 0.44 0.79 | 1 | | | |
| General | " | B | / 10 | :C | |
| | | .(121 1) | | "identification tests | |

1.0 :Heavy metals ()

1) 3 "Limit test for heavy metals () "

. / 20 (128 1) A (127

R 30 1.0 :solution in methanol

Determination of water by " :Water

1 (145 1) A "the Karl Fischer method

. / 10

Thin-layer " : (Z-isomer) Z-

90 Silica gel R2 (84 1) "chromatography

100 . 1 R 10

(A) TS (/ 750) 1 R 30 50

.(B) 50 RS Z- 50

B 100 A 100 syringe

.blank

bands .(254)

B A Z -

10 . blank

1 . TS (/ 750~)

.TS (/ 750~) 240

: Z -

Z- A_2 A_1 $(A_1)(W_2)(1000)/(A_2)(W_1)$:

Z- W_2 W_1 RS

. / 500 / 300 Z- RS

R1 30 1.0 :Assay

"Non-aqueous titration " VS (/ 0.1)

59.81 VS (/ 0.1) 1 .(142 1) A

.C₂₆H₂₈ClNO,C₆H₈O₇

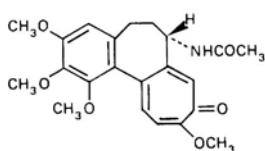
COLCHICINUM

Colchicine

C₂₂H₂₅NO₆ :Molecular formula

399.4 :Relative molecular mass

:Graphic formula



:Chemical name

(S)-N-(5,6,7,9-Tetrahydro-1,2,3,10-tetramethoxy-9-oxobenzo[a]heptalen-7-yl)acetamide; CAS Reg. No. 64-86-8.

scales

:Description

R

TS (/ 750~)

:Solubility

.R

.Antigout

:Category

:Storage

colchicum

alkaloid

:Additional information

(Liliaceae) *autumnale*

:

REQUIREMENTS

%103.0

%97.0

:General requirement

C₂₂H₂₅NO₆

| :Identity tests | | | | |
|--|---|------------------|---------------|---|
| | .D | C | B | A |
| | " | | | • |
| | | | | :A |
| | (43 | 1 |) | "Spectrophotometry in the infrared region |
| | reference spectrum | | RS | |
| | TS (/ 750~) | / | 10 | :B |
| 350 | 243 | | 400 | 230 |
| | TS (/ 25) | 1 | TS (/ 750~) | 30 :C |
| | TS (/ 1760~) | | 0.2 | 1 :D |
| | | | TS (/ 1000~) | 0.1 |
| | | | | TS (/ 80~) |
| | / 10 | | | |
| :Specific optical rotation | | | | |
| | . $[a]_D^{20^\circ C} = -425$ to -460° | | | |
| | / 1.0 | | | :Sulfated ash |
| 4 ° 130 | | | | :content of solvent and water |
| | 0.3 | | | 0.5 |
| "Determination of water by the Karl Fischer method | | | | " |
| | R | (145 | 1 |) A |
| | / 145 | / 115 | / | |
| 0.2 | 4 | 0.05 | | :Colchcaine |
| | | 6 | TS (/ 25) | |
| cobalt colour | 1 iron colour TS | 2 | | |
| | | | | TS |
| TS (/ 70~) | 0.70 | copper colour TS | | 2 |

| | | | | | |
|----------------|------|-------|--|--------------|-----------------------------|
| | (53 | 1 |) "colour of liquids | " | |
| | | | | | :Related substances |
| | | | (84 | 1 |)"Thin-layer chromatography |
| R | 20 | R | 25 | 254 | |
| | 2 | | . | TS (/ 260~) | 0.4 |
| 2.5 | :(B) | 1 | 50 | :(A) | TS (/ 750~) |
| | | | | . | 1 |
| | A | | .(| 254) | |
| | | | .B | | |
| acetic anhydre | | | | 0.05 | :Assay |
| " | | | | VS (/ 0.02) | |
| | 1 | .(142 | 1 |) A | "Non-aqueous titration |
| | | | .C ₂₂ H ₂₅ NO ₆ | 7.988 | VS (/ 0.20) |

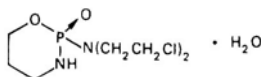
CYCLOPHOSPHAMIDUM

Cyclophosphamide

C₇H₁₅Cl₂N₂O₂P.H₂O :Molecular formula

279.1 :Relative molecular mass

:Graphic formula



:Chemical name

2-[Bis(2-chloroethyl)amino]tetrahydro-2*H*-1,3,2-oxazaphosphorine 2-oxide monohydrate; *N,N*-bis(2-chloroethyl)tetrahydro-2*H*-1,3,2-oxazaphosphorin-2-amine 2-oxide monohydrate; CAS Reg. No. 6055-19-2 (monohydrate).

| | |
|------------------|-------------|
| .Cyclophosphanum | :Other name |
|------------------|-------------|

| | | | |
|---------------------------|-------------------------------|---------------------------------|-------------------------|
| | | .Description | |
| .R | TS (/ 750~) | :Solubility | |
| | | .cytotoxic | :Category |
| .° 30 2 | | :Storage | |
| | | : | :Additional information |
| | | | |
| REQUIREMENTS | | | |
| %98.0 | :General requirement | | |
| .anhydrous | C7H15Cl2N2O2P | | %101.0 |
| :Identity tests | | | |
| . | TS (/ 40) | 5 | 10 0.1 :A |
| TS (/ 100~) | TS (/ 130~) | | |
| .TS (/ 130~) | | | |
| fumes | TS (/ 100~) | 1 | 20 :B |
| TS (/ 100~) | | 5 | . |
| " | A | TS (/ 130~) | |
| .(122 1) | "General identification tests | | |
| | | ° 53- 49 :Melting range | |
| 10 | 0.20 | :Clarity and colour of solution | |
| | | | |
| Determination of water by | " | | :Water |
| 0.3 | (145 1) A | " the Karl Fischer method | |
| | | . / 70 | / 55 |
| R | / 20 | :pH Value | |

7.0 - 4.0 30

"

:Related substances

(84 1)"Thin-layer chromatography

Silica gel R1

R 25 R 25 R 50

25 :(A) 10

5.0 0.125 :(B) R 1

° 20 30 reflux condenser

.triketohydrindene/methanol TS

0.25 0.10 R_f B

5.50 3.50 R_f A —

/ 20 0.2 **:Assay**

3 30 1 .VS (/ 0.5)

.VS (/ 0.1) 20.0 TS (/ 1000~)

VS (/ 0.1) diethyl phthalate R 5

. TS (/ 45) ferric ammonium sulfate 5

13.05 VS (/ 0.1) 1 .

.C₇H₁₅Cl₂N₂O₂P

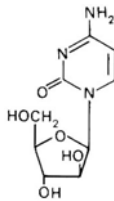
CYTARABINUM

Cytarabine

.C₉H₁₃N₃O₅ **:Molecular formula**

243.2 **:Relative molecular mass**

:Graphic formula



:Chemical name

l-β-D-Arabinofuranosylcytosine; 4-amino-l-β-D-arabinofuranosyl-2(1*H*)-pyrimidone; CAS Reg. No. 147-94-4.

:Description

.R TS (/ 750~)

:Solubility

.cytotoxic

:Category

:Storage

.° 15

:Additional information

REQUIREMENTS

%100.5

%99.0

:General requirement

C₉H₁₃N₃O₅

:Identity tests

"

:A

.(43 1) "Spectrophotometry in the infrared region

. *reference spectrum*

RS

VS (/ 0.1)

/ 10

:B

280

350

230

.0.55

1

+ 154 to + 160° / 10

:Specific optical rotation

. $[a]_D^{20^{\circ}} =$

. / 5.0

:Sulfated ash

| | | | |
|---|-------|---|------|
| .C ₉ H ₁₃ N ₃ O ₅ | 24.32 | 1 | (142 |
|---|-------|---|------|

N-[5-[3-[(5-Aminopentyl)hydroxycarbamoyl]propionamido]pentyl]-3-[[5-(*N*-hydroxyacetamido)pentyl]carbamoyl]propionohydroxamic acid monomethanesulfonate (salt); *N'*-[5-[[4-[[5-(acetylhydroxyamino)pentyl]amino]-1,4-dioxobutyl]hydroxyamino]pentyl]-*N*-(5-aminopentyl)-*N*-hydroxybutanediamide monomethanesulfonate (salt); CAS Reg. No. 138-14-7.

.Desferrioxamine mesylate

:Other name

:Description

TS (/ 750~)

5

:Solubility

.R

R

R

antidote

:Category

:Storage

. ° 4

REQUIREMENTS

%98.0

:General requirement

$C_{25}H_{48}N_6O_8, CH_4O_3S$ %102.0

:Identity tests

TS (/ 2)

2

5

5

:A

TS (/ 5) 1,2- naphthoquinone-4- sulfonate

1

2

5

:B

2

5

benzyl alcohol R

R

1.0

:Heavy metals

()

3

"Limit test for heavy metals

()

"

. / 20

(128

1) A

TS (/ 130~)

2

0.7

:Chlorides

(124

1) "Limit test for chlorides

"

. / 0.35

| | | | |
|---|-------------------------|-------------------|---------------------------------|
| " | 40 | 0.85 | :sulfates |
| . / 0.6 | (125 | 1 |) "Limit test for sulfates |
| 10 | 1.0 | | :Clarity and colour of solution |
| .0.10 | 420 | 1 | |
| . / 0.1 | | | :Sulfated ash |
| Determination of water by | " | | :Water |
| 1 | (145 | 1 |) A "the Karl Fischer method |
| | | | . / 20 |
| R | / 0.10 | | :pH Value |
| | | | .6.0 -3.5 |
| 2 | 15 | 0.3 | :Assay |
| VS (/ 0.1) | ferric ammonium sulfate | | .VS (/ 0.05) |
| .calomel refrence electrode | | platinum eletrode | |
| C ₂₅ H ₄₈ N ₆ O ₈ .CH ₄ O ₃ S | 65.68 | VS (/ 0.1) | ferric ammonium sulfate 1 |
| | | | .(B) |

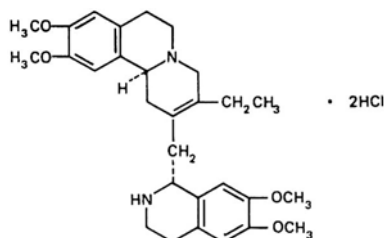
DIHYDROCHLORIDUM DEHYDROMETINI

Dehydroemetine dihydrochloride

C₂₉H₃₈N₂O₄.2HCl :Molecular formula

551.6 :Relative molecular mass

:Graphic formula



| | | | |
|-----------------|---------------|--|----|
| | | :Chemical name | |
| | | (±)-2,3-Didehydroemetine dihydrochloride; (±)-2,3-didehydro-6′,7′,10,11-tetramethoxyemetan dihydrochloride; (±)-(11bR*)-3-ethyl-1,6,7,11b-tetrahydro-9,10-dimethoxy-1-[[[(1bS*)-1,2,3,4-tetrahydro-6,7-dimethoxy-1-isoquinolyl]methyl]-4 <i>H</i> -benzo[<i>a</i>]quinolizine dihydrochloride; CAS Reg. No. 3317-75-7. | |
| | | :Description | |
| .R | | :Solubility | |
| .Antiamoebic | | :Category | |
| | | :Storage | |
| REQUIREMENTS | | | |
| %98.0 | | :General requirement | |
| | | C ₂₉ H ₃₈ N ₂ O ₄ ·2HCl %101.0 | |
| :Identity tests | | | |
| VS (/ 0.1) | | / 0.040 | :A |
| . 282 | | 350 240 | |
| | | .0.49 1 | |
| 5 | TS (/ 1760~) | 1 | :B |
| | | . Molybdenum trioxide R | |
| General | " | B / 0.1 | :C |
| .(121 1) | | "identification tests | |
| 10 0.30 | | :Clarity and colour of solution | |
| " | | Yw2 | |
| | | .(53 1) "Colour of liquids | |
| | | . / 0.1 :Sulfated ash | |
| 70 | ° 105 | :Loss on drying | |
| | | . / | |

| | | | | | | |
|---------|-------|---------|-------|--|-------|----------------------------|
| | | 5.0-3.5 | / | 30 | | pH Value |
| | " | | | | | Related substances |
| 9 | R4 | | (84 | 1 |) | "Thin-layer chromatography |
| 5 | | . | R | 1 | R | |
| | :(B) | 1 | 20 | :(A) | R | 3 |
| emetine | | 0.10 | :(C) | 1 | | 0.10 |
| | | | | . | 1 | hydrochloride RS |
| | | 10 | ° 120 | TS | / | |
| | | A | | . | (| 365) |
| | | . | | C | | B |
| 10 | R1 | | 75 | 0.4 | | Assay |
| | | VS (| / | 0.1) | / | |
| | .(142 | 1 |) | A | | "Non-aqueous titration |
| | | | | .C ₂₉ H ₃₈ N ₂ O ₄ ·2HCl | 27.58 | 1 |

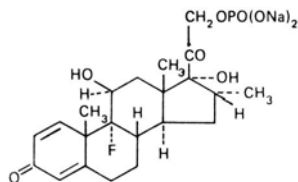
DEXAMETHASONI NATRII PHOSPHAS

Dexamethason sodium phosphate

C₂₂H₂₈FN₂O₈p :Molecular formula

516.4 :Relative molecular mass

:Graphic formula



:Chemical name

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-(dihydrogen phosphate) disodium salt; 9-fluoro-11β,17-dihydroxy-16α-methyl-21-(phosphonooxy)pregna-1,4-diene-3,20-dione disodium salt; CAS Reg. No. 2392-39-4.

Description

TS (/ 750~)

Solubility

.R R

.Adrenal hormone

Category

Storage

Additional information

.hygroscopic

REQUIREMENTS

%96.0

General requirement

C₂₂H₂₈FN₂O₈p %103.0

Identity tests

"Thin-layer chromatograph

"

:A

-1 3

R1

(84 1)

1 R ()

1 R

1

2.5

:(A)

R

4

2

:(C)

1

RS

2.5 :(B)

2.5

A

:(D)

(B) (A)

1 RS

90 TS (/ 1760~)

10

10 ° 120

TS (/ 750~)

A (365)
 C .B
 D
 5 TS 0.5 :B
 3 .greasiness
 5
 TS (/ 1760~) 2 0.04 :C
 (/ 1000~)
 2 TS (/ 100~) 10
 " A .D .R
 .(122 1) " General identification tests
 General " B C :D
 .(123 1) "identification tests
 / 10 :Specific optical rotation
 $[a]_D^{20^\circ C} = +74^\circ \text{ to } +82^\circ$
 10 0.10 :Clarity and colour of solution
 . R
 Determination of " :Water
 . 0.3 (145 1) A "water by the Karl Fischer methode
 . / 160 / ()
 "Gas chromatography " :Ethanol
 R -1 10 :(1) 3 (101 1)
 R 10 internal standard 1
 0.10 :(3) 1 0.10 :(2) 1
 . 1 10
 (2) peak (1) R

porous polymer 4 1.5
 ° 135 .(100-80)
 .flame ionization detector R
 0.790 ° 20 1 /
 . / 80
 R / 10 **:pH Value**
 .10.5-7.5

:Free dexamethasone and other related substances

1) "Thin-layer chromatography "
 2 . R R (84
 :(B) 1 10 :(A)
 1 RS 0.20
 R 10 R 3 5
 .(365) 1 ° 125
 .B A
 . 200 0.2 **:Assay**
 . 241 1 5
 . $(A_{1\text{ cm}}^{1\%} = 297) 29.7$ $\text{C}_{22}\text{H}_{28}\text{FNa}_2\text{O}_8\text{p}$

Additional requirments for Dexamethason sodium phosphate for Parenteral use

4) "*Pranenteral Preparations* "
 .(56
 "
:Bacterial endotoxins
 (30 5) "Test for bacterial endotoxins
 . 1 RS 31.3

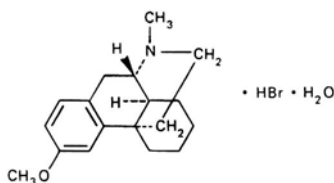
DEXTROMETHORPHANI HYDROBROMIDUM

Dextromethorphan hydrobromide

$C_{18}H_{25}NO \cdot HBr \cdot H_2O$:Molecular formula

370.3 :Relative molecular mass

:Graphic formula



:Chemical name

(+)-3-Methoxy-17-methyl-9 α ,13 α -14 α -morphinan hydrobromide monohydrate; (+)-*cis*-1,3,4,9,10,10 α -hexahydro-6-methoxy-11-methyl-2*H*-10,4a-iminoethanophenanthrene hydrobromide monohydrate; CAS Reg. No. 6700-34-1 (monohydrate).

:Description

R

TS (/ 750~)

:Solubility

. R

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

$C_{18}H_{25}NO \cdot HBr$ %101.0

:Identity tests

.E D C B

E A

•

0.6)

4

:A

"

R

(

5

. (43 1) "Spectrophotometry in the infrared region

| | | | | | | | |
|---|--------------------|-------------------------------|--------------------------|---------------|----|--|--|
| RS | | | | | | | |
| | | reference spectrum | | | | | |
| VS (/ 0.1) | | / 0.10 | | | :B | | |
| 280 | | 350 | 230 | | | | |
| | | .0.50 | 1 | | | | |
| / | 1 | .TS (/ 100~) | 2 | 0.05 | :C | | |
| | | | | TS | | | |
| | | | 10 | | | | |
| | | | ° 125 | | :D | | |
| B | | TS (/ 130~) | / 5 | | :E | | |
| | | "General identification tests | | " | | | |
| | | | | .(120 1) | | | |
| / 20 | | :Specific optical rotation | | | | | |
| .[a] _D ^{20° C} = + 28.0 to +30.0° | | VS (/ 0.1) | | | | | |
| | | . / 1.0 | | :Sulfated ash | | | |
| Determination of water by | | " | | :Water | | | |
| 0.2 | (145 1) | A | "The Karl Fischer method | | | | |
| | | / 55 | / 35 | | | | |
| R | | 50 0.4 | :pH Value | | | | |
| .6.5 5.2 | | ° 20 | 20 | | | | |
| | 5 0.5 | :Dimethylaniline | | | | | |
| TS (/ 10) | | 1 TS (/ 60~) | 4 | | | | |
| 25 N,N-dimethylaniline R | 5 | | 25 | | | | |
| | | | | | | | |
| (53 1) | "Colour of liquids | | " | | | | |
| | | / 10 | | | | | |
| (/ 70~) | 5 | :Phenolic substances | | | | | |

0.2 TS (/ 50) 0.2 1 TS
15 5 (/ 50)
.
R1 40 0.5 :Assay
TS / 10
Non-aqueous " VS (/ 0.1)
35.23 VS (/ 0.1) 1 .(142 1) A "titration
.C₁₈H₂₅NO, HBr

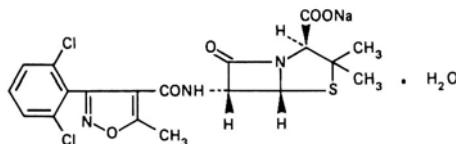
DICLOXACILINUM NATRICUM

Dicloxacillin sodium

C₁₉H₁₆Cl₂N₃NaO₅S·H₂O :Molecular formula

510.3 :Relative molecular mass

:Graphic formula



:Chemical name

Monosodium (2*S*,5*R*,6*R*)-6-[3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; monosodium [2*S*-(2*α*,5*α*,6*β*)]-6-[[[3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; monosodium [3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolyl]penicillin monohydrate; CAS Reg. No. 13412-64-1 (monohydrate).

:Description

TS (/ 750~)

R

:Solubility

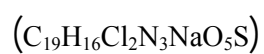
.R

:Storage

:Additional information

:General requirement

%88.0



:Identity tests

11

 $\vdash A$

1) "Spectrophotometry in the infrared region"

reference spectrum

RS

TS (/ 1760~)

1

R

10

:B

2

1

.()

.TS(/ 60~)

20 ()

$$:\mathbf{C}$$

)

"General identification tests

11

B

.(123 1

/ 10

:Specific optical rotation

$$[\alpha]_D^{20^\circ\text{C}} = +128 \text{ to } +143^\circ$$

Determination of water by

11

:Water

0.25

$$(145 \quad 1) \text{ A}$$

"the Karl Fischer method

. / 50

/ 30

.75-4.5 / 10

:pH Value

oxygen flask " :Chlorine

10 25 (132 1) "method

VS (/ 0.1)

TS (/ 130~) 20 30

silver/silver VS (/ 0.01)

VS (/ 0.01) 1 . .chloride electrode

/ .Cl 0.3546

. / 142 / 130

10 0.12 :Free chlorides

. 30 20 VS (/ 0.1)

VS (/ 0.01) TS (/ 130~) 20

.silver/silver chloride electrode

Cl 0.3546 VS (/ 0.01) 1 .

. / 5

. 1000 20 :Assay

2.0- ml aliquots 2.0

imidazol/mercuric chloride TS 10.0 .

.(A) ° 20 . 25 ° 60

.(B) 10.0

343 1

imidazol/mercuric chloride TS 10.0 2.0

.B A

C₁₉H₁₆Cl₂N₃NaO₅S B A

. RS

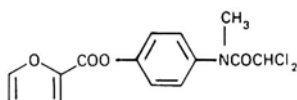
DILOXANIDI FUROAS

Diloxanide furoate

$C_{14}H_{11}Cl_2NO_4$:Molecular formula

328.2 :Relative molecular mass

:Graphic formula



:Chemical name

2,2-Dichloro-4'-hydroxy-*N*-methylacetanilide 2-furoate (ester);
4-[(dichloroacetyl)methylamino]phenyl 2-furancarboxylate; 2,2-dichloro-*N*-(4-hydroxyphenyl)-*N*-methylacetamide 2-furoate; CAS Reg. No. 3736-81-0.

:Description

2.5 TS (/ 750~)

100

:Solubility

.R

130

R

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

$C_{14}H_{11}Cl_2NO_4$ %102.0

:Identity tests

.C B

A

•

"

:A

.(43 1) "Spectrophotometry in the infrared region

reference spectrum

RS

TS (/ 750~)

/

7.0

:B

258

350

240

| | | | | |
|------|--|----------------------------|------------------------|------------------------------|
| | | 0.49 | 1 | |
| 1 |) "oxygen flask method | " | | :C |
| | VS (/ 1) | 10 | 20 | (132 |
| A | TS (/ 130~) | | | . |
|) | "General identification tests | | " | |
| | | | (121 | 1 |
| | | 116–114 | :Melting range | |
| | | / 1.0 | :Sulfated ash | |
| | / 5 | ° 105 | :Loss on drying | |
| R | | 50 | 3.0 | :Free acidity |
| | 20 | R | | |
| TS | / | VS (/ 0.1) | | |
| | | | 1.3 | |
| | " | :Related substances | | |
| | R2 | (84 | 1 |) "Thin-layer chromatography |
| 5 | | | 1 R | 24 |
| :(B) | 1 | 0.10 | :(A) | R |
| | | | 1 | 2.5 |
| A | | .(254) | | |
| | | .B | | |
| R | | 50 | 0.3 | :Assay |
| | | VS (/ 0.1) | | |
| 1 | .(142 | 1 |) B | "Non-aqueous titration |
| | .C ₁₄ H ₁₁ Cl ₂ NO ₄ | 32.82 | VS (/ 0.1) | " |

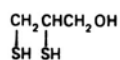
DIMERCAPROLUM

Dimercoprol

$C_3H_8OS_2$:Molecular formula

124.2 :Relative molecular mass

:Graphic formula



:Chemical name

2,3-Dimercapto-1-propanol; CAS Reg. No. 59-52-9.

:Description

.Mercaptan

.R TS (/ 750~)

20

:Miscibility

:Category

:Storage

.° 5

REQUIREMENTS

/ %98.0

:General requirement

. $C_3H_8OS_2$ / %101.5

:Identity tests

0.05 5 TS (/ 30) (II)

0.5 :A

TS (/ 80)

4 0.1 :B

$n_D^{20} = 1.568-1.574$:Refractive index

. $d_{20}^{20} = 1.239-1.259$:Reactive density

TS1 /

25 2.0 :Halides

20 . 2

10 40 TS (/ 330~) 10 .

5 TS (/ 130~) 10 .

ferric ammonium VS (/ 0.1) VS (/ 0.1)

sulfat

. 0.1 . TS (/ 45)

.6.8- 4.6 R / 0.5 :pH Value

VS (/ 0.1) 20 0.12 :Assay

. TS VS (/ 0.05)

6.211 VS (/ 0.05) 1 .

.C₃H₈OS₂

Additional requirements for Dimercaprol for Parenteral use

. (56 4) *Parenteral preparations*

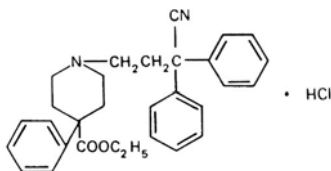
DIPHENOXYLATI HYDROCHLORIDUM

Diphenoxylate hydrochloride

C₃₀H₃₂N₂O₂·HCl : Molecular formula

489.1 :Relative molecular mass

:Graphic formula



:Chemical name

| | | | |
|-----------------------------|----------------|--|---------------|
| | | :Description | |
| TS (/ 750~) | R | :Solubility | |
| | | R | R |
| | | :Category | |
| | | :Storage | |
| REQUIREMENTS | | | |
| :General requirement | | | |
| | | C ₃₀ H ₃₂ N ₂ O ₂ ·HCl | %101.0 |
| :Identity test | | | |
| | | D C B | E A |
| | | " | :A |
| (43 | 1 |) "Spectrophotometry in the infrared region | |
| rum | RS | | |
| 1 | / | 0.50 | :B |
| 50 | 230 | R | 99 VS (/ 1) |
| 265 | 258 | 252 | |
| | 0.50 0.65 0.55 | 1 | |
| Potassio-mercuric iodide TS | 0.1 | 5 | 25 :C |
| | | | |
| | | .° 223 | :D |
| " | B | / 20 | :E |
| (121 | 1 |) "identification tests | |
| | / | 1.0 | :Sulfated ash |

| | | | |
|---------------------------|------------------------------|---------------------------|---|
| | | :Description | |
| R | R | :Solubility | |
| | | .R | R |
| .sympathomimetic | Cardiovascular | :Category | |
| | | :Storage | |
| REQUIREMENTS | | | |
| %98.0 | :General requirement | | |
| | | $C_8H_{11}NO_2 \cdot HCl$ | %101.0 |
| :Identity test | | | |
| | .D C B | D A | • |
| | " | | :A |
| .(43 | 1 |) | "Spectrophotometry in the infrared region |
| <i>reference spectrum</i> | | RS | |
| | | | |
| VS (/ 0.1) | / | 0.020 | :B |
| 280 | | 350 | 230 |
| 280 | 1 | | 249 |
| | | | .0.54 |
| TS2 | -4 | 10 | 5 |
| | | | 0.05 |
| | | | :C |
| | | | |
| General | " | A | / 20 |
| | | | :D |
| | .(121 | 1 |) |
| | | | "identification tests |
| | 1.0 | :Heavy metals | () |
| 1 | "Limit test for heavy metals | () | " |
| (128 | 1 |) A | (127 |
| | | | 1 |
| | | |) |
| | | | . / |
| | | | 20 |

| | | | |
|---|------------------------|------------------------------------|-------------|
| 10 | 1.0 | : Clarity and colour of solution | |
| . | | | |
| 5.0 | ° 105 | : Sulfated ash | |
| . / | | | |
| " | | :Related substances | |
| silica gel R1 | | (84 1) "Thin-layer chromatography | |
| (/ 300~) | 4 R | 9 R | 13 |
| 30 : (A) | R | 10 | . TS |
| . 1 RS | 0.3 | :(B) | 1 |
| 1 TS (/ 50) | | 2 | |
| A | . TS (/ 50) | | |
| 3 | | | |
| .B | | | |
| 10 | R1 | 140 | 0.4 :Assay |
| VS (/ 0.1) | | TS | / |
| .(142 1) A | "Non-aqueous titration | | " |
| .C ₈ H ₁₁ NO ₂ HCl | | 18.96 | VS (/ 0.1) |
| | | | 1 |

Additional requirments for Dopamine hydrochloride for Parenteral use

.(56 4) *Pranenteral preparations*

"

:Bacterial endotoxins

(30 5) "Test for bacterial endotoxins

. 1 RS 16.67

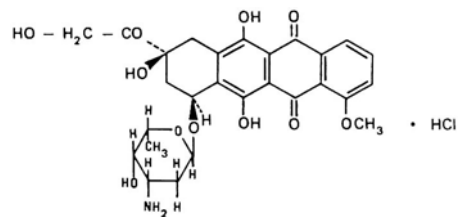
DOXORUBICINI HYDROCHORIDUM

Doxorubicin hydrochloride

C₂₇H₂₉NO₁₁.HCl : Molecular formula

580.0 :Relative molecular mass

:Graphic formula



:Chemical name

(8*S*,10*S*)-10-[(3-Amino-2,3,6-trideoxy- α -*L*-lyxo-hexopyranosyl)oxy]-8-glycoloyl-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-naphthacenedione hydrochloride; (8*S*-*cis*)-10-[(3-amino-2,3,6-trideoxy- α -*L*-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-5,12-naphthacenedione hydrochloride; CAS Reg. No. 25316-40-9.

:Description

:Solubility

:Category

:Storage

:Additional information

:

REQUIREMENTS

%97.0

:General requirement

C₂₇H₂₉NO₁₁.HCl %102.0

:Identity test

R / 20 :A
/ 20 600 220

| | | | | | | | |
|---------------------------|-------|-----|---|------|-------|-----------|----------------------------|
| 477 | 290 | 253 | 233 | |) R | RS | |
| | | (| 350 | 280 | 245 | | 530 495 |
| 1 | | | | %3 | | | |
| | | | 0.24 | 0.44 | 0.46 | 0.30 0.88 | 1.32 |
| | | " | Related substances | | " | | :B |
| | | | .B | | | A | |
| | | | 0.05 | 2 | R | 2 | 2 :C |
| | | | | | | | TS (/ 80~) |
| General | | " | | B | / | 0.05 | :D |
| | | | (121 | 1 |) | | "identification tests |
| Determination of water by | | | | | " | | :Water |
| | | | 0.25 | (145 | 1 |) A | " the Karl Fischer method |
| | | | | | | | . / 40 |
| | | | .6.5-3.8 | / | 5.0 | | :pH Value |
| | | " | | | | | :Related substances |
| 80 | | R1 | | (84 | 1 |) | "Thin-layer chromatography |
| | | R | | 5 | R | 20 | R |
| | | 2.0 | : (A) | R | 4 | 10 | |
| | : (C) | 1 | RS | | 2.0 | : (B) | 1 |
| | | 1 | | 0.40 | : (D) | 1 | 20 |
| | | | | | | | |
| | | .D | | | | C | |
| 100 | | R | | | 20 | | :Assay |
| | 1 | | | | 100 | | 10 |
| | | | C ₂₇ H ₂₉ NO ₁₁ .HCl | | 495 | | |
| | | | | | RS | | |

.0.02 ± 0.44

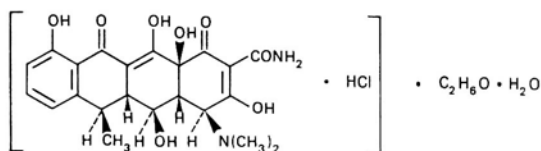
DOXYCYCLINIHYCLAS

Doxycycline hyclate

$(C_{22}H_{24}N_2O_8 \cdot HCl)_2 \cdot C_2H_6O \cdot H_2O$:Molecular formula

1026 :Relative molecular mass

:Graphic formula



:Chemical name

(4*S*,4*aR*,5*S*,5*aR*,6*R*,12*aS*)-4-(Dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,5,10,12,12*a*-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate; [4*S*-(4*α*,4*αα*,5*α*,5*αα*,6*α*,12*αα*)]-4-(dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,5,10,12,12*a*-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethanol (2:1), monohydrate; CAS Reg. No. 24390-14-5.

:Description

R

R

4

3

:Solubility

.R

:Category

:Storage

:Additional information

REQUIREMENTS

880

:General requirement

1

| | | | | | | | | | |
|---------------------------------------|-----------|--|--|--|-----------------------|--------------------------|----------------------|----|--|
| | | | | | :Identity tests | | | | |
| . TS (/ 1760~) | | | | | 2 | 5 | :A | | |
| TS (/ 25~) | | | | | 0.05 | 2 | 5 | :B | |
| | | | | | . | | | | |
| Potassio-mercuric iodide TS | | | | | 0.25 | 2.0 | 5 | :C | |
| | | | | | . | | | | |
| General | " | | | | B | / | 20 | :D | |
| .(121 1) | | | | | "identification tests | | | | |
| . / 4.0 | | | | | :Sulfated ash | | | | |
| Determination of water by | | | | | " | | | | |
| | | | | | :Water | | | | |
| 1.2 (145 1) | | | | | A | "the Karl Fischer method | | | |
| | | | | | . / 28 | / 14 | | | |
| "Gas chromatography | | | | | " | | | | |
| 0.50 | | | | | :(1) | 3 | (101 1) | | |
| 1 | 10 | | | | :(2) | 1 | dehydrated ethanol R | | |
| . | | | | | 0.5 1 | 10 | :(3) | | |
| porous polymer | | | | | 4 | 1.5 | | | |
| ° 135 | | | | | .(| 100-80 |) | | |
| .flame ionization | | | | | R | | | | |
| 60 | / 43 | | | | 0.790 ° 20 | 1 | / | | |
| | | | | | . / | | | | |
| .3.0-2.0 / 10 | | | | | :pH Value | | | | |
| :Absorption in the ultraviolet region | | | | | | | | | |
| 99 | VS (/ 1) | | | | 1 | / | 10 | | |
| . | | | | | 349 | R | | | |
| | | | | | 0.31 | 0.28 | 1 | | |

1 / 10 :light- absorbing impurities

1 R 99 VS (/ 1)

0.12 490

" :Assay

Bacillus cereus (NCTC (155 1) "Microbiological assay of antibiotics

6.6 Cm10 10320 or ATCC 11778)

2.0 0.2) TS(/ 13.6)

.° 39-35 (1

. %105.0 %95 estimated potency ($P = 0.95$)

1 880 ($P = 0.95$)

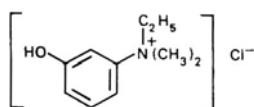
EDROPHONII CHLORIDUM

Edrophonium chloride

$C_{10}H_{16}ClNO$:Molecular formula

201.7 :Relative molecular mass

:Graphic formula



:Chemical name

Ethyl(*m*-hydroxyphenyl)dimethylammonium chloride;
N-ethyl-3-hydroxy-*N,N*-dimethylbenzenaminium chloride; CAS Reg. No. 116-38-1.

:Description

TS (/ 750~)

5

0.5

:Solubility

.R

R

.Diagnostic agent

:Category

:Storage

REQUIREMENTS

%98.5

:General requirement

C₁₀H₁₆ClNO %101.0

:Identity tests

VS (/ 0.1) / 0.050 :A
273 350 230

.0.55 1
(/ 0.1) / 10 :B
240 350 230 VS
0.17 0.55 1 294

TS(/ 25) 0.05 2 0.05 :C

General " A / 20 :D
:E

.(121 1) "identification tests

. / 1.0 **:Sulfated ash**

0.6)
. / 5.0 24 R (5
:Loss on drying

.5.0-4.0 / 0.10 **:pH Value**

5 10 0.1 **:Dimethylaminophenol**

.R 20 TS 8.0
(/ 0.1) 10 10
293 1 .VS
.0.25

R1 20 0.2 :Assay
 TS / 0.25 TS / 10
 Non- " VS (/ 0.1)
 VS (/ 0.1) 1 .(142 1) A "aqueous titration
 .C₁₀H₁₆ClNO 20.17

EMETINI HYDROCHLORIDUM

Emetine hydrochloride

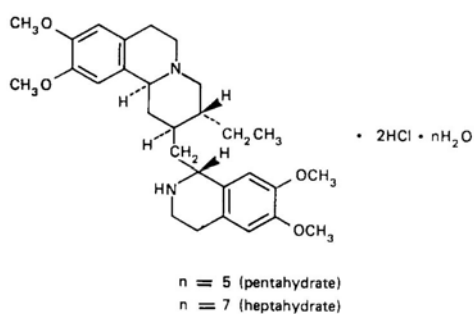
Emetine hydrochloride pentahydrate

Emetine hydrochloride heptahydrate

C₂₉H₄₀N₂O₄, C₂₉H₄₀N₂O₄, 2HCl, 7H₂O (heptahydrate) :Molecular formula
 .2HCl, 5H₂O (pentahydrate)

.643.6 (pentahydrate); 679.7 (heptahydrate) :Relative molecular mass

:Graphic formula



:Chemical name

Emetine dihydrochloride pentahydrate; 6',7',10,11-tetramethoxyemetan dihydrochloride pentahydrate; CAS Reg. No. 79300-07-5 (pentahydrate).

Emetine dihydrochloride heptahydrate; 6',7',10,11-tetramethoxyemetan dihydrochloride heptahydrate; CAS Reg. No. 79300-08-6 (heptahydrate).

:Description

.R TS (/ 750~)

:Solubility

.Antiamoebic

:Category

:Storage

:Labelling

:Additional information

cephaëline

ipecacuanha

REQUIREMENTS

%98.0

:General requirement

$C_{29}H_{40}N_2O_4 \cdot 2HCl$ %101.5

:Identity tests

.D C B

D A

•

"

:A

.(43 1) "Spectrophotometry in the infrared region

reference spectrum

RS

. " Related alkaloides

"

:B

.D

A

| | | | | |
|------------|-------------|------------------------------------|----------------|--|
| TS | / | 1 | 5 | :C |
| General | " | B | / 0.05 | :D |
| | .(121 | 1 |) | "identification tests |
| | / 50 | :Specific optical rotation | | |
| | | | | $[a]_D^{20^{\circ}} = +16 \text{ to } +19^{\circ}$ |
| | | . / 1.0 | :Sulfated ash | |
| | ° 105 | :Loss on drying | | |
| | . / 150 | 110 | | |
| | | . / 190 | / 150 | |
| | R | 10 | 0.10 | :Acidity |
| 0.5 | TS | / | VS (/ 0.02) | |
| | | .(|) | |
| | " | :Related alkaloids | | |
| 100 | R1 | (84 | 1 |) "Thin-layer chromatography |
| 2 R | 5 | ethylene glycol monomethyl ether R | 20 | R |
| 4 | 10 | . | R | 0.5 |
| 0.50 | :(A) | R | 99 TS (/ 17~) | 1 |
| cephaeline | | 10 | :(B) | 1 |
| :(D) | 1 | 5.0 | :(C) | 1 hydrochlorid R |
| | | . 1 | RS | 0.50 |
| 15 | ° 60 | TS | / | |
| A | | .(| 365) | |
| | A | | .B | |
| | | | .C | |
| 10 | R1 | 30 | 0.2 | :Assay |
| | VS (/ 0.1) | TS | / | |

(142 1) A "Non-aqueous titration"
 $C_{29}H_{40}N_2O_4 \cdot 2HCl$ 27.68 VS (/0.1) 1

EPHEDRINUM

Ephedrine

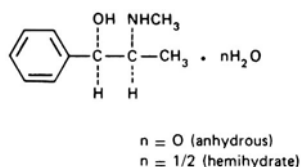
Ephedrine, anhydrous

Ephedrine, hemihydrate

$C_{10}H_{15}NO$ (anhydrous); $C_{10}H_{15}NO \cdot \frac{1}{2} H_2O$ (hemihydrate) :**Molecular formula**

174.2 (hemihydrate) 165.2 (anhydrous) :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

(-)-Ephedrine; [*R*-(*R**,*S**)]- α -[1-(methylamino)ethyl]benzene-methanol; CAS Reg. No. 299-42-3 (anhydrous).

(-)-Ephedrine hemihydrate; [*R*-(*R**,*S**)]- α -[1-(methylamino)ethyl]benzene-methanol hemihydrate; CAS Reg. No. 50906-05-3 (hemihydrate).

:**Description**

TS (/ 750~)

R

:**Solubility**

:**Category**

:**Storage**

:**Labelling**

| | | | | | | | | | | |
|---------------------------|-------------------------|-----|----------------------------|--|------------------------------------|------|--|----|-----------------------------|--|
| R | :Additional information | | | | | | | | | |
| | 1 | | 10 | | | | | | | |
| | . ° 42 | | | | ° 38 | | | | | |
| REQUIREMENTS | | | | | | | | | | |
| %101.0 | %98.5 | | :General requirement | | | | | | | |
| | | | | | C ₁₀ H ₁₅ NO | | | | | |
| | | | :Identity tests | | | | | | | |
| | VS (/ 0.1) | | / 0.05 | | :A | | | | | |
| | 263 | 257 | 251 | | 350 | 230 | | | | |
| 2 | TS (/ 80) (II) | | 0.1 | | 1 | 10 | | :B | | |
| | R | 1 | | | TS (/ 80~) | | | | | |
| | | | | | | | | | | |
| 4 | TS (/ 80~) | | | | 5 | 0.05 | | :C | | |
| | | | | | TS (/ 50) | | | | | |
| 15 | 2.25 | | :Specific optical rotation | | | | | | | |
| | | | 50 | | TS (/ 70~) | | | | | |
| | | | | | | | . [α] _D ^{20°C} = − 41 to − 43° | | | |
| 20 | TS (/ 130~) | | 2 | | 0.7 | | :Chlorides | | | |
| "Limit test for chlorides | | | | | | | | | | |
| | | | / 0.35 | | | | (124 | | 1) | |
| " | | | | | 20 | | 1.2 | | :Sulfates | |
| / 0.4 | | | (125 | | 1) | | "Limit test for Sulfates | | | |
| | | | / 1.0 | | | | :Sulfated ash | | | |
| Determination of water | | | | | | | :Water | | | |
| 2 | | | (145 | | 1) | | A | | "by the Karl Fischer method | |

1 . / 10
. / 55 / 45
50.0 TS (/ 750~) 5 0.5 :Assay
VS (/ 0.1) VS (/ 0.1)
16.52 VS (/ 0.1) 1 .TS /
.C₁₀H₁₅NO

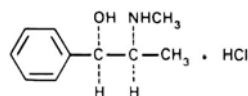
EPHEDRINI HYDROCHLORIDUM

Ephedrine hydrochloride

C₁₀H₁₅NO, HCl :Molecular formula

201.7 :Relative molecular mass

:Graphic formula



:Chemical name

(-)-Ephedrine hydrochloride; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzenemethanol hydrochloride; CAS Reg. No. 50-98-6.

:Description

TS (/ 750~)

4

:Solubility

.R

R

:Category

:Storage

:Additional information

REQUIREMENTS

| | | | |
|------------------------------|----------------------|--|-----------|
| %99.0 | | :General requirement | |
| | | C ₁₀ H ₁₅ NO, HCl %101.0 | |
| :Identity tests | | | |
| 350 | 230 | / 0.05 | :A |
| 1 | | 263 257 251 | |
| | | 0.36 0.48 0.37 | |
| 2 | TS (/ 80) (II) | 0.1 1 10 | :B |
| | 1 | TS (/ 80~) | |
| 4 | TS (/ 80~) | 5 0,05 | :C |
| | | TS (/ 50) | |
| . ° 220 – 217 :Melting range | | | |
| – 33.0 to -35.5° | / 50 | :Specific optical rotation | |
| | | . [a] _D ^{20°C} = | |
| TS (/ 70~) | 1.5 | 40 0.050 | :Sulfates |
| | 10 | TS (/ 50) | 1 |
| 10 | 1.0 | :Clarity and colour of solution | |
| | opalescence standard | | |
| | / 1.0 | :Sulfated ash | |
| 5.0 | ° 105 | :Loss on drying | |
| . / | | | |
| | .01 10 1.0 | :Acidity and alkalinity | |
| 0.1 | VS(/ 0.1) | 0.1 | TS / |
| | .() | VS(/ 0.1) | |
| TS | / | 10 0.2 | :Assay |
| | TS / | 1 R | 50 |

| | | |
|-------|-------------------------|---|
| A | "Non-aqueous titration" | VS(/ 0.1) |
| 20.17 | VS(/ 0.1) | 1 .(142 1) |
| | | .C ₁₀ H ₁₅ NO,HCl |

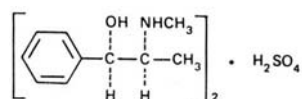
EPHEDRINI SULFAS

Ephedrine sulfate

(C₁₀H₁₅NO)₂,H₂SO₄ :Molecular formula

428.5 :Relative molecular mass

:Graphic formula



:Chemical name

(-)-Ephedrine sulfate (2:1) (salt); [*R*-(*R**,*S**)]-α-[1-(methyl-amino)ethyl]benzenemethanol sulfate (2:1) (salt); CAS Reg. No. 134-72-5.

:Description

.TS (/ 750~)

:Solubility

:Category

:Storage

:Additional information

REQUIREMENTS

%98.0

:General requirement

(C₁₀H₁₅NO)₂,H₂SO₄ %101.0

| | | | | | | | | | |
|-----------------|----------------------------|---|---------------------------------|---------------------------|------|----|--|--|---|
| :Identity tests | | | | | | | | | |
| 350 | 230 | / 1.0 | | :A | | | | | |
| | | 262 | 257 | 251 | | | | | |
| | | | 0.61 | 0.76 | 0.61 | 1 | | | |
| 2 | TS (/ 80) (II) | | 0.1 | 1 | 10 | :B | | | |
| | 1 | TS (/ 80~) | | | | | | | |
| 4 | TS (/ 80~) | | | 5 | 0.05 | :C | | | |
| | | TS (/ 50) | | | | | | | |
| General | " | | A | / 20 | :D | | | | |
| | (123 | 1 |) | "identification tests | | | | | |
| | | | ° 245 | :E | | | | | |
| | / 50 | :Specific optical rotation | | | | | | | |
| | | . [a] _D ^{20°C} = - 33.5 to -32.5° | | | | | | | |
| | | 0.20 | :Chlorides | | | | | | |
| | (124 | 1 |) | "Limit test for chlorides | | | | | " |
| 1.4 | VS (/ 0.02) | | 0.40 | | | | | | |
| | . / | | | | | | | | |
| | 10 | 1.0 | :Clarity and colour of solution | | | | | | |
| | . opalescence standard TS2 | | | | | | | | |
| | | / 1.0 | :Sulfated ash | | | | | | |
| 20 | ° 105 | | :Loss on drying | | | | | | |
| | . / | | | | | | | | |
| | 0.1 | 10 | 1.0 | :Acidity and alkalinity | | | | | |
| 0.1 | VS (/ 0.1) | | 0.1 | TS | / | | | | |
| | .() | | VS (/ 0.1) | | | | | | |

| | | | |
|-----------|---|------------------------|--------|
| 3 | 10 | 0.3 | :Assay |
| VS (/ 1) | 5 | | R |
| 10 | .R | 25 | |
| 10 | .R | | R |
| TS / | 0.25 | | R |
| " | VS (/ 0.1) | / | |
| / | 1 .(142 1) A | "Non-aqueous titration | |
| | .(C ₁₀ H ₁₅ NO) ₂ , H ₂ SO ₄ | 21.43 VS (/ 0.1) | |

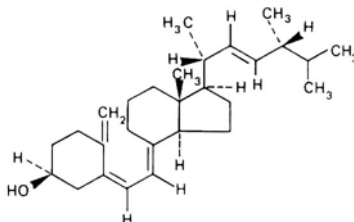
ERGOCALCIFEROLUM

Ergocalciferol

C₂₈H₄₄O :Molecular formula

396.7 :Relative molecular mass

:Graphic formula



:Chemical name

(5Z,7E,22E)-9,10-Secoergosta-5,7,10(19),22-tetraene-3β-ol;
24-methyl-9,10-secocholesta-5,7,10(19),22-tetraene-3β-ol; CAS Reg.
No. 50-14-6.

.D₂ :Other name

:Description

:Solubility

.antirachitic

:Category

:Storage

inert

:Additional information

REQUIREMENTS

:Identity tests

: A

1) Spectrophotometry in the infrared region

reference spectrum

RS

5 1.0 .TS (/ 750~) 10 2 :B
 colecalciferol) TS (/ 750~)

| | | | |
|----|----------------|-----|--------------|
| .(| colecalfiferol |) | TS (/ 750~) |
| R | () | 0.5 | R 5 5 :C |

| | |
|----------------|-----|
| .TS (/ 1760~) | 0.1 |
|----------------|-----|

4 1 .R 40 1 :D
antimony trichloride TS

◦ 117–112 : **Melting range**

0.2 : Specific optical rotation

30 . 25 TS(/ 750~)

$$.[a]_D^{20^\circ\text{C}} = +103 \text{ to } +107^\circ$$

%95.0

:General requirement

| | |
|------------------------------------|--------|
| .C ₂₈ H ₄₄ O | %105.0 |
|------------------------------------|--------|

Thin-layer " **:Ergosterol**

R1 (84 1) "chromatography

0.10 R R

10 . 1 butylated hydroxytoluene R

butylated 0.10 squalane 10 R

:(B) 1 0.050 :(A) : 1 hydroxytoluene R

ergosterol R 0.10 :(C) 1 RS 0.050

(D) 20 1

.C B

. 4-3 .antimony trichloride TS

— A

R_f A .B

A .C

.C B

. D

10 0.10 **:Reducing substances ()**

0.5 TS / 0.5 TS (/ 750~)

.R 1 5 .TS /

525 1

. TS (/ 750~) 10

hydroquinone R / 0.2 10

.TS (/ 750~)

0.05 **:Assay**

. 250 5.0 100 TS (/ 750~)

1 30

RS C₂₈H₄₄O . 265

.0.03 ± 0.48

ERYTHROMYCINUM

Erythromycin

streptomyces

:composition

.C B

A

.erythreus

A

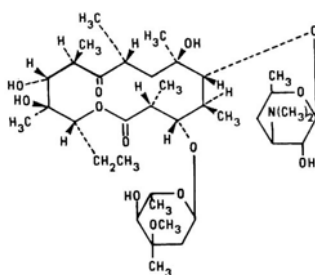
:

•

C₃₇H₆₇O₁₃ :Molecular formula

733.9 :Relative molecular mass

:Graphic formula



:Chemical name

[3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-Dideoxy-3-*C*-methyl-3-*O*-methyl- α -L-*ribo*-hexopyranosyl)oxyl]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[[3,4,6-trideoxy-3-(dimethylamino)- β -D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione; CAS Reg. No. 114-07-8.

:Description

1000

:Solubility

.R

R TS (/ 750~)

:Category

:Storage

| | | | |
|---------------------------|--------------------|---|--------------------------------------|
| .hygroscopic | | :Additional information | |
| REQUIREMENTS | | | |
| 1 | 870 | :General requirement | |
| . | | | |
| :Identity tests | | | |
| | .D C B | A | • |
| | " | | :A |
| | (43 1) | "Spectrophotometry in the infrared region | |
| . | reference spectrum | RS | |
| | TS (/ 1760~) | 2 | 5 :B |
| | | | . |
| TS (/ 420~) | | 2 | R 2 3 :C |
| R 2 | . | | |
| | | Xanthidrol | 5 5 :D |
| | / 20 | :Specific optical rotation | |
| - 71 to -78° | | 30 | R |
| | | | . [a] _D ^{20°C} = |
| | / 2.0 | :Sulfated ash | |
| Determination of water by | | " | :Water |
| 1 | (145 1) | A | "the Karl Fischer method |
| | | | . / 100 |
| 19 R | 1 | 50 0.1 | :pH Value |
| | .10.5 8.0 | | |
| | " | :Assay | |
| Bacillus Pumilus | (155 1) | "Microbiological assay of antibiotics | |

8.1-8.0 Cml (NCTC 8241 or ATCC 14884)
 25 5) TS2 TS 8.0
 . ° 39-35 (1
 . %105 %95 estimated potency ($P = 0.95$)
 1 870 ($P = 0.95$)

ERYTHROMYCINI ETHYLSUCCINAS

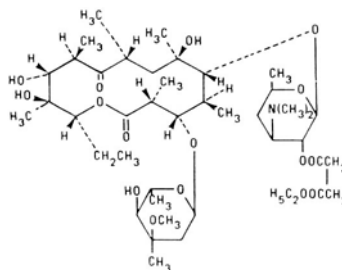
Erythromycin ethylsuccinate

for parenteral use

$C_{43}H_{75}NO_{16}$:Molecular formula

862.1 :Relative molecular mass

:Graphic formula



:Chemical name

Erythromycin 2'-(ethylsuccinate); erythromycin 2'(ethyl butanedioate); [3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-di-deoxy-3-*C*-methyl-3-*O*-methyl-α-*L*-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-tri-hydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-*D*-xyllo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione 2'-(ethyl butanedioate); CAS Reg. No. 1264-62-6.

:Description

:Solubility

TS (/ 750~)

:Labelling

:Category

:Storage

REQUIREMENTS

740

:General requirement

1

:Identity tests

.D C B

A

•

11

 $\vdash A$

1) "Spectrophotometry in the infrared region"

reference spectrum

RS

TS (/ 1760~)

2

5

:B

TS (/ 420~)

2

R

2

3

$$:\mathbf{C}$$

R

2

Xanthidrol TS

5

5

:D

. / 10

:Sulfated ash

Determination of water by

11

:Water

0.5

$$(145 \quad 1) \text{ A}$$

"the Karl Fischer method

. / 30

| | | | | | | |
|-----|-------|--|-----|-----|-----------|----------|
| | | | 50 | 0.5 | :pH Value | |
| | | | | | | .8.5-6.0 |
| | | 100 | R | | 50 | :Assay |
| 1 |) | "Microbiological assay of antibiotics | | | | " |
| | | (NCTC 8241 or ATCC 14884) <i>Bacillus Pumilu</i> | | | | (155 |
| | | TS2 | TS1 | 8.0 | 8.1-8.0 | Cml |
| | . ° | 39-35 | | (1 | 25 5 |) |
| | %95.0 | estimated potency ($P = 0.95$) | | | | |
| 740 | | ($P = 0.95$) | | | | %105 |
| | | | | | 1 | |

Additional requirements for Erythromycin ethylsuccinate for Parenteral use

(56 4) "Pranenteral Preparations"

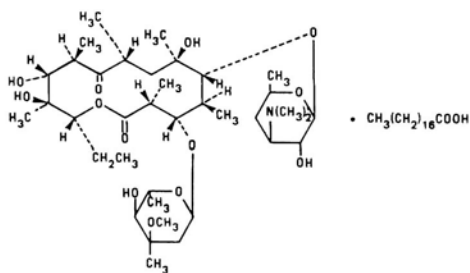
ERYTHROMYCINI STEARAS

stearate Erythromycin

$C_{37}H_{67}NO_{13}, C_{18}H_{36}O_2$:Molecular formula

1018 :Relative molecular mass

:Graphic formula



:Chemical name

Erythromycin stearate (salt); erythromycin octadecanoate (salt); [3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl- α -*L*-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)- β -*D*-xyl-o-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione octadecanoate (salt); CAS Reg. No. 643-22-1.

:Description

R

TS (/ 750~)

.opalescent

:Solubility

R R

:Category

:Storage

REQUIREMENTS

550

:General requirement

$C_{37}H_{67}NO_{13}$, $C_{18}H_{36}O_2$ %77.0

1

:Identity tests

.D C B

A

•

"

:A

. (43 1) "Spectrophotometry in the infrared region

reference spectrum

RS

TS (/ 420~)

2

R

2

3

:B

R 2 .

Xanthidrol TS 5 5 :C

10 TS (/ 70~) 5 0.1 :D

3 .

10 .gel VS (/ 0.1)

TS (/ 55~) 1 1 ()

.TS (/ 250~)

.R 30 0.5 :Erythromycin stearate

VS (/ 0.1) R1 50

R 25

washings filtrate R filter

VS (/ 0.1) R1 50 . 30

1 . VS (/ 0.1)

$C_{37}H_{67}NO_{13}, C_{18}H_{36}O_2$ 101.8 VS (/ 0.1)

. / 0.770

Determination of water by " :Water

0.5 (145 1) A "the Karl Fischer method

. / 40

neutralized 50 0.4 :Free stearic acid

. VS (/ 0.1) ethanol TS

1 VS (/ 0.1)

28.45 1 . 1 VS (/ 0.1)

. / 185 $C_{18}H_{36}O_2$

2.0 :Sodium stearate

TS (/ 1760~) () TS (/ 1760~)

| | | | | |
|---|--|-------|---------|---------|
| ° / 60 | C ₁₈ H ₃₅ NaO ₂ | 4.317 | 1 | ° 800 |
| :Total stearic acid, stearates and water | | | | |
| %98.0 | (| |) | |
| | | | | %.103.0 |
| 100 | R | 50 | :Assay | |
| "Microbiological assay of antibiotics | | " | | |
| (NCTC 8241 or ATCC 14884) <i>Bacillus Pumilus</i> | | | (155 | 1) |
| TS2 | TS1 | 8.0 | 8.1-8.0 | Cml |
| ° 39-35 | (1 | | 25 5 |) |
| %95 | estimated potency (<i>P</i> =0.95) | | | |
| (<i>P</i> = 0.95) | | | | %105 |
| | | 1 | | 550 |

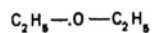
ETHER ANAESTHESICUS

Anaesthetic Ether

C₄H₁₀O :Molecular formula

74.12 :Relative molecular mass

:Graphic formula



:Chemical name

Ethyl ether; 1,1'-oxybis[ethane]; diethyl ether; CAS Reg.

No. 60-29-7.

:Description

.R TS (/ 750~)

10 :Miscibility

:Category

| | | | | | |
|--------------|----|---|------------------------|-------------|------|
| Highly | " | :Storage | | 1 | ° 15 |
| | | :Labelling | | " flammable | |
| | | antioxidant | | | |
| | | :Additional information | | | |
| | 24 | | | | |
| | | :explosive concentrations nitrous oxide | | | |
| REQUIREMENTS | | | | | |
| | | :Distillation range | | • | |
| | | | | .Peroxides | |
| | | ° 35.0 34.0 | test liquid | | |
| | | $d_{20}^{20} = 0.713 - 0.716$ | :Relative density | | |
| | | :Non-volatile residue | | • | |
| | | | | .Peroxides | |
| / | 20 | 1 | ° 105 | 5 | |
| 50 | | TS (/ 750~) | 10 | :Acidity | |
| TS | / | 0.5 | glass- stoppered flask | | |
| 30 | | | VS (/ 0.02) | 25 | |
| VS (/ 0.02) | | | | | |
| 0.4 | | 30 | | | |

| | | | | |
|----------------------------------|-----|------------------------------|-----------------------|-------------|
| / | 2.0 | 10 | :Peroxides | |
| | 1.0 | reference solution | | TS |
| / | 2.0 | 0.10 | 100 | TS (/ 60~) |
| | | | | .TS |
| | | (53 1) | "Colour of liquids" | |
| alkalin potassio-mercuric iodide | 2 | :Aceton and aldehydes | | |
| | 10 | 1.5 | 12 | TS |
| | | 5 | 10 | |
| | | | 40 | |
| | | | .distillate | 5 |
| | 10 | | :Foreign odour | |

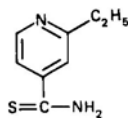
ETHIONAMIDIUM

Ethionamid

$C_8H_{10}N_2S$ **:Molecular formula**

166.2 **:Relative molecular mass**

:Graphic formula



:Chemical name

2-Ethylthioisonicotinamide; 2-ethyl-4-pyridinecarbothioamide; CAS Reg. No. 536-33-4.

:Description

| | | | |
|----------------------|------------------------------|---|---------|
| R | | :Solubility | |
| . R | | TS (/ 750~) | |
| .Antileprosy | | :Category | |
| . | | :Storage | |
| . | | :Additional information | |
| REQUIREMENTS | | | |
| %101.0 | %98.0 | :General requirement | |
| | | C ₈ H ₁₀ N ₂ S | |
| | | :Identity tests | |
| .D C B | | D A | • |
| " | | :A | |
| .(43 1) | | "Spectrophotometry in the infrared region | |
| . reference spectrum | | RS | |
| 10 | 2,4-dinitro chlorobenzene R | 0.10 | 0.05 :B |
| TS1 / | 3 | . | |
| VS (/ 1) | | 5 | 0.1 :C |
| | | . R | |
| .° 162 | | :D | |
| 1.0 | | :Heavy metals () | |
| 1) 3 | "Limit test for heavy metals | () | " |
| . / 20 | (128 1) A | (127 | |
| . / 1.0 | | :Sulfated ash | |
| ° 105 | | :Loss on drying | |
| | | . / 5.0 | |

| | | | |
|-------------|---------|--|--------------|
| " | | :Related substances () | |
| R4 | (84 1) | "Thin-layer chromatography | |
| 10 | . | R | 1 R 9 |
| 0.10 | :(B) | 1 | 20 :(A) R |
| . | 1 | 0.04 | :(C) 1 |
| 254) | | | |
| .B | | A | .(|
| | .C | | |
| R1 | 50 | 0.15 | :Assay |
| Non-aqueous | " | VS (/ 0.1) | |
| VS (/ 0.1) | 1 | .(142 1) | A "titration |
| | | .C ₈ H ₁₀ N ₂ S | 16.62 |

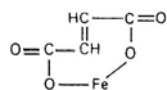
FERROSI FUMARAS

Ferrous fumarate

C₄H₂FeO₄ :Molecular formula

169.9 :Relative molecular mass

:Graphic formula



:Chemical name

Iron(2+) fumarate (1:1); iron(2+) (*E*)-2-butenedioate (1:1);
CAS Reg. No. 141-01-5.

:Description

.TS (/ 750~)

:Solubility

.Iron supplement

:Category

:Storage

REQUIREMENTS

%93.0

:General requirement

$C_4H_2FeO_4$ %101.0

:Identity tests

| | | | | | |
|------------|---------------|-----------|----------------------|-----------------|-----------------------|
| 1.0 |) . | VS (/ 1) | 10 | 0.4 | :A |
| .VS (/ 1) | | | 15 | | .(B |
| | TS | / | 0.2 | | . |
| 2.0 | .(|) | | VS (/ 1) | |
| | | | TS (/ 45) (II) | | 2.0 |
| General | " | | C | A | :B |
| | .(121 | 1 |) | | "identification tests |
| 0.15 | | 0.5 | .R | 1 | 0.5 :C |
| | | | | TS (/ 1760~) | |
| | .fluorescence | | - | | |
| 5 | | 1.0 () | :Heavy metals | () | |
| | | | TS (/ 420~) | | |
| 6 | TS (/ 1000~) | 4 | TS (/ 420~) | | 15 |
| | . 20 | R | | 1 | |
| | | | | | 20 |
| (/ 100~) | pbR | | 1 | | |
| | | 40 | pbTS | 1 | pbTS |
| Limit test | () | " | | () | |
| | . / | 100 | (128 | 1 |) A |
| | 10 | R | | 1.5 | 0.2 |
| | | | | :Arsenic | |
| 20 | | () | | | AsTS |

. 10 brominated hydrochloric acid AsTS
 stannous chloride AsTS
 " 22
 . / 5 (130 1) "Limit test for arsenic
 10 100 3 **:Ferric iron**
 3 . TS (/ 420~)
 . 15 R
 . TS VS (/ 0.1)
 1 . VS (/ 0.1)
 5.585 VS (/ 0.1)
 . / 20
 20 TS (/ 70~) 8 0.15 **:Sulfates**
 Limit test " "for sulfates
 . / 2 (125 1)
 10 ° 105 **:Loss on drying**
 . /
 TS (/ 100~) 7.5 0.3 **:Assay**
 ceric ammonium 25
 1 . TS 0.1 VS (/ 0.1) sulfate
 .C₄H₂FeO₄ 16.99 VS (/ 0.1)

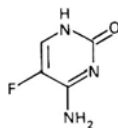
FLUCYTOSINUM

Flucytosine

C₄H₄FN₃O **:Molecular formula**

129.1 **:Relative molecular mass**

:Graphic formula



:Chemical name

5-Fluorocytosine; 4-amino-5-2(1-*H*)-pyrimidinone; CAS. Reg.No. 2022-85-7

:Description

TS (/ 750~)

:Solubility

.R R

.Antifungal

:Category

:Storage

.° 295

:Additional information

REQUIREMENTS

%101.0

%98.5

:General requirement

C₄H₄FN₃O

:Identity tests

.D C B

C A

•

Spectro

"

:A

.(43 1) "photometry in the infrared region

reference spectrum

RS

VS (/ 0.1)

/ 5.0

:B

286

350

230

.0.36

1

A

. "Fluorouracil

"

:C

.B

TS1

0.15

5

0.05

:D

1.0

:Heavy metals

()

(125 1) "Limit test for heavy metals () "

. / 20 (128 1) A

. / 1 :Sulfated ash

15 ° 105 :Loss on drying

. /

Thin- " :Fluorouracil

) R6 (84 1) "layer chromatography

(/ 750~) 20 R 70 (

1 . TS (/ 10) 10 TS

10 :(A) 10 R 15

1 RS 10 :(B) 1

20 :(C) 10

. 1 RS 20 :(D) 1

.unsaturated

D .(254)

.C

R () 50 0.3 :Assay

(/ 0.1) R1 100

Non-aqueous "

VS (/ 0.1) 1 .(142 1) A "titration

.C₄H₄FN₃O 12.91

Additional requirement for Flucytosine for parenteral use

.(56 4) "parenteral preparation "

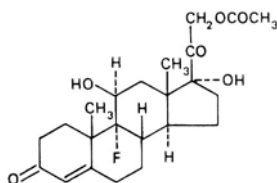
FLUDROCORTISONI ACETAS

Fludrocortisone acetate

$C_{33}H_{31}FO_6$:Molecular formula

422.5 :Relative molecular mass

:Graphic formula



:Chemical name

9-Fluoro-11 β ,17,21-trihydroxypregn-4-ene-3,20-dione 21-acetate; 21-(acetyloxy)-9-fluoro-11 β ,17-dihydroxypregn-4-ene-3,20-dione ; CAS Reg. No. 514-36-3.

:Description

R

TS (/ 750~)

:Solubility

.R

.Adrenal hormone

:Category

:Storage

.hygroscopic

:Additional information

REQUIREMENTS

%96.0

:General requirement

$C_{33}H_{31}FO_6$ %104.0

:Identity tests

.C B

A

•

"

:A

.(43 1) "Spectrophotometry in the infrared region

| | | |
|----------------------------|--|----------------------------|
| <i>reference spectrum</i> | RS | |
| "Thin-layer chromatography | " | :B |
| 10 | R1() | (84 1) |
| | 5 | 90 R |
| | | 16 |
| | 2 | |
| .R | 25 R | 75 |
| R | 1 R | 9 |
| 2.5 | : (B) | 1 |
| | 15 | 2.5 : (A) |
| | | 1 RS |
| 15 ° 120 | | |
| . 10 ° 120 | TS / | |
| .(365) | | |
| .B | A | |
| 5 | | 0.5 :C |
| | 3 | |
| | | 5 |
| / 10 | :Specific optical rotation | |
| | . [a] _D ^{20°C} = +148 to +156° R | |
| | . / 1.0 | :Sulfated ash |
| ° 105 | :Loss on drying | |
| | | . / 10 |
| 1 | :Ultraviolet absorption | |
| .0.42-0.39 240 | (dehydrated) R | / 10 |
| " | | |
| Silicagel R2 | (84 1) | "Thin-layer chromatography |

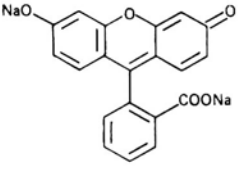
. 0.2 R 5 R 95
 1 R 9 1
 0.30 : (B) 1 15 : (A) R
 . 1
 10 ° 105
 A . (254)
 .B
 : Assay
 .
 TS (/ 750~) 25
 TS (/ 750~) 10 . 250
 2.0 25 10.0 . 50
 .R TS /
 TS / 2.0
 1 .R
 . 25 TS (/ 750~) . ° 30
 525 1
 C₂₃H₃₁FO₆ . TS (/ 750~) 10
 . RS

FLUORESCEIN NATRICUM

Fluorescein sodium

C₂₀H₁₀Na₂O₅ : **Molecular formula**

376.3 : **Relative molecular mass**

| | | | | | |
|--|--|--|--|--|---|
| | | | | | :Graphic formula |
| | | | |  | |
| | | | | | :Chemical name |
| | | | | Fluorescein disodium salt; 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid disodium salt; 3',6'-dihydroxyspiro[isobenzofuran-1(3 <i>H</i>),9'-[9 <i>H</i>]xanthene]-3-one disodium salt; CAS Reg. No. 518-47-8. | |
| | | | | | :Description |
| | | | | TS (/ 750~) | 1.5 :Solubility |
| | | | | | .R |
| | | | | | :Category |
| | | | | | :Storage |
| | | | | .hygroscopic | :Additional information |
| | | | | REQUIREMENTS | |
| | | | | %98.0 | :General requirement |
| | | | | | C ₂₀ H ₁₀ Na ₂ O ₅ %100.5 |
| | | | | | :Identity tests |
| | | | | | :A |
| | | | | .TS (/ 60~) | 20 () :B |
| | | | | "General identification tests | " B |
| | | | | | .(123 1) |
| | | | | 0.05 | 2 1 :C |
| | | | | TS (/ 260~) R | 1 R |

| | | | | |
|-------------------|--------------------------|----------------------------|---------------------|----------------------------|
| 20 | TS (/ 130~) | 2 | 0.07 | :Chlorides |
| " | Limit test for Chlorides | " | | |
| . | / 3.5 | (124 | 1 |) |
| " | | 20 | 0.05 | :Sulfates |
| . | / 10 | (125 | 1 |) "Limit test for Sulfates |
| TS (/ 420~) | | 2 | 10 | 0.10 :Zinc |
| . | | TS (/ 45~) | | 0.1 |
| 10 | 0.20 | :Chloroform-soluble matter | | |
| .R | | 10 | VS (/ 0.1) | |
| 1 | | . | R | |
| .0.10 | | R | | 480 |
| 1 | (/ 750~) | 20 | 0.2 | :Ethanol-insoluble matter |
| TS (/ 750~) | | | | Sintered glass filter |
| . | 2.0 | 1 | ° 105 | |
| 100 | ° 105 | | | :Loss on drying |
| | | | | . |
| .9.0-7.0 | | / 20 | | :pH Value |
| " | | | | :Dimethyl formamide |
| internal standard | | .(101 | 1 |) "Gas chromatography |
| (1) : | . | 100 | dimethylacetamide R | 20 |
| (2) | | 10 | 10 R | 2 |
| | 10 | 1.0 | | retention time |
| 0.1 | 15 | VS (/ 0.5) | | 10 |
| 10 | | (3) | 5 R | |
| | VS (/ 0.05) | | 10 | |
| . | | 5 R | | 0.10 |
| | | | | 15 |

4 1.5
silanized diatomaceous 9 macrogol 1000R 1 adsorbent
.° 120 acid-washed support R
.flam ionization detector

peak area ratio

.1

Thin- " **:Resorcinol**
) R1 (84 1) "layer Chromatography
R 4 R 6 (
1.0 (A) : 5 .
VS (/ 0.5) 10 10
. 10 R 2.5 (B) 15
. 30 R

.A B .
" **:Related substances ()**
) R1 (84 1) "Thin-layer chromatography
2 R 8 (
0.1) / 5 . R
20 :(B) 1 10 :(A) VS (/
. 1
A . 30 R

.B

:Assay
TS (/ 70~) 5 20 0.5
R -2 20
5 10 .R

| | | | |
|--|-------|--------------|----------------------------|
| | | TS (/ 750~) | 10 |
| .C ₂₀ H ₁₀ Na ₂ O ₅ | 1.132 | 1 | .° 105 |
| Additional requirement for Fluorescein sodium for sterile use | | | |
| test for sterility of non- | | | " |
| | . (| 32 5 |) "injectable preparations |

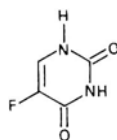
FLUOROURACILUM

Fluorouracil

C₄H₃FN₂O₂ :Molecular formula

130.1 :Relative molecular mass

:Graphic formula



:Chemical name

5-Fluorouracil; 5-fluoro-2,4(1*H*,3*H*)-pyrimidinedione; CAS
Reg. No. 51-21-8.

:Description

TS (/ 750~)

:Solubility

.R R

:Category

:Storage

: . ° 282

:Additional information

REQUIREMENTS

%98.5

:General requirement

$C_4H_3FN_2O_2$ %101.0

:Identity tests

.D C B

A

•

"

:A

"Spectrophotometry in the infrared region

RS

reference spectrum

TS 4.7

/

10

:B

qualitatively similar

350

220

) RS

TS 4.7

/

10.0

.(232

266

.0.54

266

1

%.3

5

TS

0.5

:C

3

5

TS1

1

5

0.05

:D

1.0

:Heavy metals

(

)

1) 3

"Limit test for heavy metals

()

"

. / 20

(128

1

) A

(127

. / 1.0

:Sulfated ash

0.6)

° 80

:Loss on drying

. / 5.0

4

R

(

5

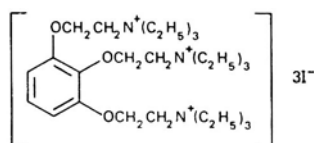
CALLAMINI TRIETHIODIDUM

Gallamine triethiodide

$C_{30}H_{60}I_3N_3O_3$:Molecular formula

891.5 :Relative molecular mass

:Graphic formula



:Chemical name

[*m*-Phenyltris(oxyethylene)]tris[triethylammonium] triiodide;
2,2',2''-[1,2,3-benzenetriyltris(oxy)]tris[*N,N,N*-triethylethanaminium] triiodide;
1,2,3-tris(2-diethylaminoethoxy)benzene triethiodide; CAS Reg. No. 65-29-2.

:Description

TS (/ 750~)

:Solubility

.R

R

:Category

:Storage

.hygroscopic

:Additional information

REQUIREMENTS

%98.0

:General requirement

$C_{30}H_{60}I_3N_3O_3$ %101.0

:Identity tests

.D C B

D A

•

"

:A

.(43 1) "Spectrophotometry in the infrared region

RS

| | | | | |
|---|---|-------------------------|----|---------------|
| | | | | :Assay |
| | 15 | R | 40 | 0.5 |
| | | VS (/ 0.1) | | .TS / |
| 1 |) A | "Non- aqueous titration | | " |
| | .C ₃₀ H ₆₀ I ₃ N ₃ O ₃ | 29.72 VS (/ 0.1) | 1 | .(142 |

GENTAMYCINI SULFAS

Gentamycin sulfate

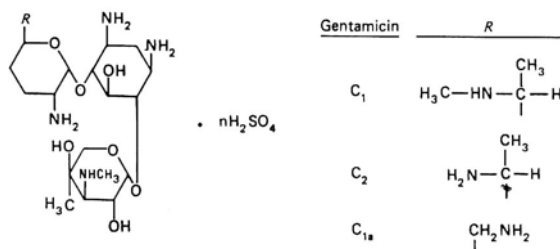
(Non- injectable)
sterile

Cl_{1a} C₂ C₁

:composition

.*Micromonaspora purpurea*; CAS Reg. No. 1405-41-0

:Graphic formula



:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

:Labelling

hygroscopic

:Additional information

REQUIREMENTS

590

:General requirement

1

:Identity tests

"Thin-layer chromatography" :A
) R5 (84 1)
 (/ 260~) 1 R 1 R 1 (TS
 1 .
 20 : (B) 1 20 : (A)
 triketo . 1 RS
 . 2 ° 105 hydrindene/pyridine/acetone TS

.B

A

General " A / 10 :B
 . (123 1) "identification tests

/ 0.10

:Specific optical rotation

. $[a]_D^{20^\circ} = +107 \text{ to } +121^\circ$:

. / 10

:Sulfated ash

Determination of water by

"

:Water

0.2 (145 1) A "the Karl Fischer method
 . / 150

.5.5-3.5 / 40

:pH Value

"

:Assay

Bacillus pumilus (155 1) "Microbiological assay of antibiotics
 (ATCC 6633) *Bacillus subtilis* (NCTC 8241; ATCC 14884)
 7.8 Cm1 (ATCC 6538P) *Staphylococcus aureus*

20 2) TS2 TS1 8.0
 .° 39-35 (1
 . %105 %95 estimated potency ($P=0.95$)
 . 1 590 ($P=0.95$)

Additional Requirements for Sterile for Gentamycin sulfate

Sterility testing of " : :S terility
 . (162 1) "antibiotics

Additional Requirements for Gentamycin sulfate for sterile use

Test for sterility of non- "
 . (32 5) "injectable Preparations

Additional Requirements for Gentamycin sulfate for parenteral use

.(56 4) "Parenteral Preparations
 " :Bacterial endotoxins
 (30 5) "Test for bacferial endotoxins
 . 1 RS 1.70

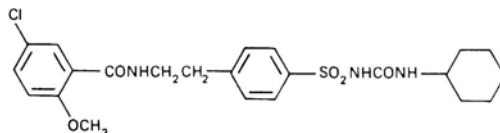
GLIBENCLAMIDUM

Glibenclamide

$C_{23}H_{28}ClN_3O_5S$:Molecular formula

494.0 :Relative molecular mass

:Graphic formula



:Chemical name

1-[[p-[2-(5-Chloro-*o*-anisamido)ethyl]phenyl]sulfonyl]-3-cyclohexylurea; 5-chloro-*N*-[2-[4-[[[(cyclohexylamino)carbonyl]amino]sulfonyl]phenyl]ethyl]-2-methoxybenzamide; 1-[4-[2-(5-chloro-2-methoxybenzamido)ethyl]-phenylsulfonyl]-3-cyclohexylurea; CAS Reg. No. 10238-21-8.

:Description

TS (/ 750~)

R

:Solubility

.R

R

:Category

:Storage

REQUIREMENTS

%101.0

%98.5

:General requirement

C₂₃H₂₈ClN₃O₅S

:Identity tests

.C B

A

•

"

A

:A

.(43 1) "Spectrophotometry in the infrared region

reference spectrum

RS

VS (/ 0.01)

/ 0.10

:B

230

350

230

.0.63

300

1

275

.° 172

:C

1.0

:Heavy meatals

()

1) 3 "Limit test for heavy metals () "

. / 20 (125

. / 1.0 :Sulfated ash

10 ° 105 :loss on drying

. /

"

:Related substances

45 R4 (84 1) "Thin-layer chromatography

5 TS (/ 750~) 5 R 45 R

10 R

0.05 : (B) 1 10 : (A) R

. 1

A . (254)

.B

TS 100 0.5 :Assay

TS / VS (/ 0.1)

1 .

.C₂₃H₂₈ClN₃O₃S 49.40 VS (/ 0.1)

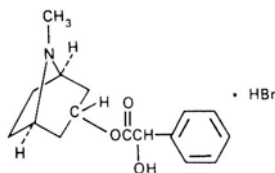
HOMATROPINI HYDROBROMIDUM

Homatropine hydrobromide

C₁₆H₂₁NO₃·HBr :Molecular formula

356.3 :Relative molecular mass

:Graphic formula



1*aH*,5*aH*-Tropan-3*a*-ol mandelate (ester) hydrobromide; (±)-*endo*-8-methyl-8-azabicyclo[3.2.1]oct-3-yl α-hydroxybenzeneacetate hydrobromide; CAS Reg. No. 51-56-9.

TS (/ 750~)

$$\mathbb{R} \quad \mathbb{R}$$

:Storage

%98.0

C₁₆H₂₁NO₃,HBr %101.0

TS (/ 100~)

1 10 :A

1.5

.R 5

TS /

General

" A / 20 :B

120 1) bromides "identification tests

$$^{\circ} 215 \qquad \qquad \qquad :C$$

. / 1.0 :Sulfated ash

| | ° 105 | % loss on drying |
|----|-------|------------------|
| 15 | | |

. /

7.0-5.5 / 20 :pH Value

| | | | |
|------|---|----|-------------------|
| 0.25 | 2 | 10 | Foreign alkaloids |
|------|---|----|-------------------|

TS(/ 50)

| | | | |
|---|------|---|--------------------|
| R | 0.25 | 5 | :Related alkaloids |
|---|------|---|--------------------|

| | | | | | |
|--|------------------------|-------------|-------------|--------|-----|
| | 1 | 0.1 | R | 0.1 | . |
| | TS (/ 750~) | 4 | VS (/ 0.5) | / | . |
| 10 | R1 | 30 | 0.3 | :Assay | |
| | VS (/ 0.1) | TS | / | | |
| A | "Non-aqueous titration | " | | | |
| C ₁₆ H ₂₁ NO ₃ ,HBr | 35.63 | VS (/ 0.1) | 1 | .(142 | 1) |

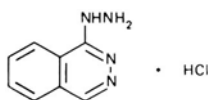
HYDRALAZINI HYDROCHLORIDUM

Hydralazine hydrochloride

C₈H₈N₄,HCl :Molecular formula

196.6 :Relative molecular mass

:Graphic formula



:Chemical name

1-Hydrazinophthalazine monohydrochloride; 1(2*H*)-phthalazinone hydrazone monohydrochloride; CAS Reg. No. 304-20-1.

:Description

TS (/ 750~)

25

:Solubility

.R

:Category

:Storage

° 275

:Additional information

REQUIREMENTS

| | | | | | | | | | | | |
|-----------------|--|---|--|-----------------------------|--|-------|--|---------------|--|------------------------------|--|
| %98.0 | | :General requirement | | | | | | | | | |
| | | C ₈ H ₈ N ₄ ·HCl | | | | | | | | %101.0 | |
| :Identity tests | | | | | | | | | | | |
| 220 | | / 10 | | | | | | | | :A | |
| | | 315 | | 303 | | 260 | | 240 | | 350 | |
| | | 0.21 | | 0.27 | | 0.54 | | 0.58 | | 1 | |
| 20 | | TS (/ 70~) | | | | 8 | | 100 | | 0.5 :B | |
| | | | | 10 | | | | TS (/ 10) | | | |
| | | | | | | | | . ° 210 | | ° 105 | |
| General | | " | | | | A | | / 20 | | :C | |
| | | | | (121 | | 1 | |) | | "identification tests | |
| 250 | | 2.0 | | :Water-insoluble substances | | | | | | | |
| | | | | | | 30 | | | | 100 | |
| | | | | | | | | | | | |
| | | (/ 5) | | 10 | | | | 3 ° 105 | | 10 | |
| | | | | | | / 1.0 | | :Sulfated ash | | | |
| 0.6 | |) | | :loss on drying | | | | | | | |
| | | / 5.0 | | 8 | | R | | (5 | | | |
| | | " | | :Related substances | | | | | | | |
| | | R1 | | | | (84 | | 1 | |) "Thin-layer chromatography | |
| 8 | | TS (/ 260~) | | 2 | | R | | 2 | | | |
| | | 0.10 | | | | | | | | R | |
| | | TS (/ 420~) | | | | 1 | | R | | 100 | |
| | | TS | | 1.0 | | | | 2.0 | | 20 | |
| | | 10 R | | | | 25.0 | | | | (A) | |

| | | | | |
|------|--|--------------|--------------|-----|
| R | 100 | TS (/ 420~) | 1 | 100 |
| TS | 1.0 | 2.0 | 100 | 1.0 |
| .B A | 40 | (B) | | |
| .TS6 | -4 | | | |
| A | (254) | .B | | |
| 25 | 25 | 0.15 | :Assay | |
| R | 5 | TS (/ 420~) | | |
| | | VS (/ 0.05) | | |
| 1 | 5 | | | |
| | .C ₈ H ₈ N ₄ .HCl | 9.832 | VS (/ 0.05) | |

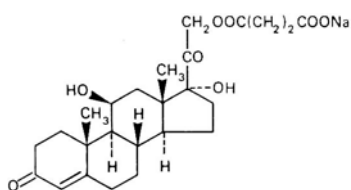
HYDROCORTISONI NATRII SUCCINAS

Hydrocortisone sodium succinate

C₂₅H₃₃NaO₈ :Molecular formula

484.5 :Relative molecular mass

:Graphic formula



:Chemical name

Cortisol 21-(sodium succinate); 21-(3-carboxy-1-oxopropoxy)-11β,17-dihydroxypregn-4-ene-3,20-dione monosodium salt; CAS Reg. No. 125-04-2.

:Description

200 TS (/ 750~)

24

:Solubility

| | | | |
|----------------------------|---------------------|---|--------------|
| .R | R | dehydrated ethanol R | |
| .Adrenal hormone | | :Category | |
| . | | :Storage | |
| | | :Additional information | |
| | | | .hygroscopic |
| | | | . |
| REQUIREMENTS | | | |
| | | :General requirement | |
| . | $C_{25}H_{33}NaO_8$ | %103.0 | %97.0 |
| | | :Identity tests | |
| | " | | :A |
| .(43 | 1 |) "Spectrophotometry in the infrared region | |
| <i>refernce spectrum</i> | RS | | |
| | | . | |
| "Thin-layer chromatography | " | | :B |
| -1 | 3 | R1 (84 | 1) |
| . | | 1 R () | 1 R |
| 1 | 2.5 | :(A) R | 2 |
| . | 1 | RS | 2.5 :(B) |
| 10 | | | |
| ° 120 | TS (/ 750~) | 90 TS (/ 1760~) | |
| .(| 365) | | 10 |
| | .B | | A |
| " | | | :C |
| . | (123 | 1) "General identification tests | |
| | / | 20 | B |

[illegible]

HYDROXOCOBALAMINUM

Hydroxocobalamin

anhydrous

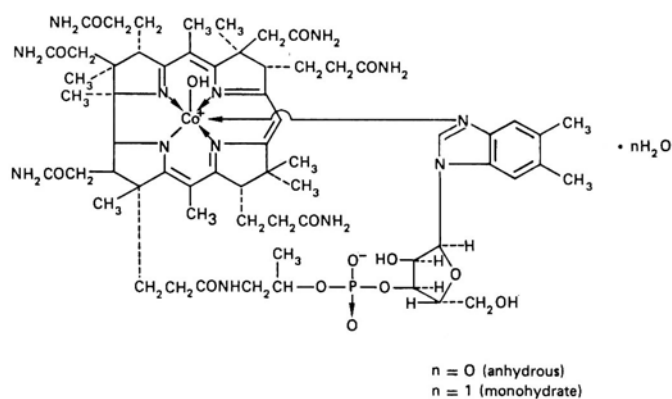
hydrate

:Molecular formula

$C_{62}H_{89}CoN_{13}O_{15}P$ (anhydrous); $C_{62}H_{89}CoN_{13}O_{15}P \cdot H_2O$ (monohydrate)

.1346 (anhydrous); 1365 (monohydrate) :Relative molecular mass

:Graphic formula



:Chemical name

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosylbenzimidazole; cobinamide dihydrogen phosphate (ester)-mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosyl-1*H*-benzimidazole; Co α -[α -(5,6-dimethylbenzimidazolyl)]-Co β -hydroxocobamide; CAS Reg. No. 13422-51-0 (anhydrous). Cobinamide dihydroxide monohydrate, dihydrogen phosphate (ester), mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosylbenzimidazole; cobinamide dihydroxide monohydrate, dihydrogen phosphate (ester), mono(inner salt) 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosyl-1*H*-benzimidazole; Co α -[α -(5,6-dimethylbenzimidazolyl)]-Co β -hydroxocobamide monohydrate; CAS Reg. No. 13422-52-1 (monohydrate).

B_{12b}

B_{12a}

:other name

:Description

| | | |
|----------------------|-------------------------------|-------------|
| R | TS (/ 750~) | :Solubility |
| | | .R |
| | .Antianaemia | :Category |
| | | :Storage |
| | | |
| | | :Labelling |
| | | |
| | :Additional information | |
| .hydrated ionic form | hydroxocobamide | |
| | .hygroscopic | |
| | | |
| REQUIREMENTS | | |
| %96.0 | :General requirement | |
| | $C_{62}H_{89}CoN_{13}O_{15}P$ | %102.0 |
| | :Identity tests | |
| TS 4.5 | / 40 | :A |
| 525 351 274 | 550 230 | |
| 351 | 525 1 | |
| 351 | 274 0.34 | |
| | | .0.80 |
| TS (/ 1760~) | 2 | :B |
| | 0.05 | |
| | - | R |
| 5 2 | 100 2 | :C |
| 2 1 | .TS (/ 1440~) | |
| 4 | .TS / | 1 |

) ()
) ° 100 :Loss on drying
 . / 180 / 140 2 (5 0.6
 10.0- R / 20 :pH Value
 .8.0
 " :Other cobalamins
 diethylaminoethylcellulose R 20 (86 1) "Column Chromatography
 VS (/ 0.5) 200
 .
 alkali
 .stopcock 1.2 22 adsorbent
 elute . 14
 .
 0.5) R VS (/
 .
 1.2 22 acid washings
 . 10 .stopcock
 .
 elute
 drain
 .
 effluent diethylaminoethylcellulose
 .
 20 0.05
 diethyl lamino .4.0 TS (/ 70~)
 . ethyl cellulose
 50 .TS (/ 70~) 4.0
 1 .

$(A_{1\text{cm}}^{1\%} = 207)$ / 361

. / 30 20.7

diethylaminoethylcellulose

:Acidic impurities

. 50 TS (/ 10)

361 351 1

. / 30 $(A_{1\text{cm}}^{1\%} = 190)$ 19.0 /

:Assay

TS 4.5

20

351

1

. 500

. $(A_{1\text{cm}}^{1\%} = 195)$ 19.5

$\text{C}_{62}\text{H}_{89}\text{CoN}_{13}\text{O}_{15}\text{P}$

Additional requirements for Hydroxocobalamin for Parenteral use

. (56 4) " *Parenteral Preparations* "

"

:Bacterial endotoxins

(30 5) "Test for bacterial endotoxins

. 1 RS 0.41

HYDROXOCOBALAMINI CHLORIDUM

HYDROXOCOBALAMINI SULFAS

Hydroxocobalamin chloride

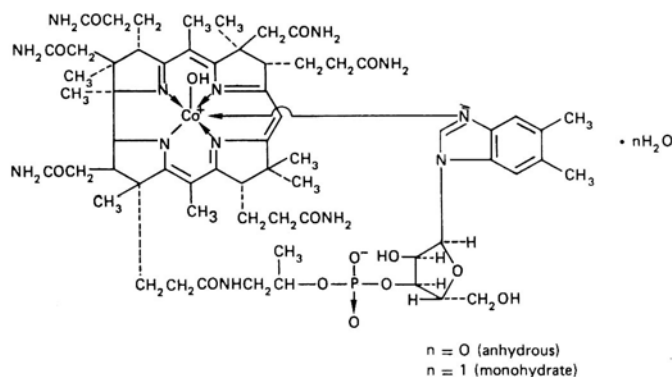
Hydroxocobalamin sulfate

$\text{C}_{62}\text{H}_{90}\text{ClCoN}_{13}\text{O}_{15}\text{P}$; $\text{C}_{124}\text{H}_{180}\text{Co}_2\text{N}_{26}\text{O}_{34}\text{P}_2\text{S}$:Molecular formula

:Relative molecular mass

1383 (hydroxocobalaminchloride); 2791 (hydroxocobalamin sulfate)

:Graphic formula



:Chemical name

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosylbenzimidazole monohydrochloride; cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosyl-1*H*-benzimidazole monohydrochloride; *Co* α -[α -(5,6-dimethylbenzimidazolyl)]-*Co* β -hydroxocobamide chloride; CAS Reg. No. 59461-30-2.

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosylbenzimidazole sulfate (salt) (2:1); cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosyl-1*H*-benzimidazole sulfate (salt) (2:1); 2(*Co* α -[α -(5,6-dimethylbenzimidazolyl)]-*Co* β -hydroxocobamide) sulfate (salt) (2:1).

:Description

:Solubility

.Antianaemia

:Category

:Storage

:Labelling

:Additional information

REQUIREMENTS

%96.0

:General requirement

alkali

elute .stopcock 1.2 22 adsorbent

14

0.5) R

VS (/

1.2 22 acid washings

. 10 .stopcock

elute

drain

effluent diethylaminoethylcellulose

20 0.05

diethylaminoe- .4.0 TS (/ 70~)

thylcellulose

50 .TS (/ 70~) 4.0

1

207) 20.7 / 361

. / 30 ($A_{1\text{cm}}^{1\%} =$

diethylaminoethylcellulose :Acidic impurities

50 TS (/ 10)

361 351 1

. / 30 ($A_{1\text{cm}}^{1\%} = 290$) 19.0 /

:Assay

| | | |
|------|------|---|
| 4.5 | TS | 20 |
| 351 | 1 | 500 |
| 18.9 | 19.0 | $C_{124}H_{180}Co_2N_{26}O_{34}P_2S$ $C_{62}H_{90}ClCoN_{13}O_{15}P$ $(A_{1cm}^{1\%} = 190 \text{ or } 188)$ |

IPECACUANHAE RADIX

Ipecacuanha root

:Molecular formula

Cephaelis ipecacuanha (Brotero)

. *Cephaelis acuminata* karsten () A.Richard

.cephaeline emetine

() :Description

:Category

:Storage

:Additional information

REQUIREMENTS

%2.0 :General requirement

:Macroscopic characteristics

:*cephaelis ipecacuanha*

6 15

wood bark fracture

pith 2

:cephaëlis acuminaata

1-0.5 3-1

•

.cephaëlis ipecacuanha

phelloderm

parenchymatous

xylem

vessels

phloem

tracheids

collenchymatous

pericycle

:cephaëlis acuminata

:Identity tests

11

93

R1

(84

1

TS (/ 260~)

0.5 R

10

 $3 \times$

20

0.1

A

R

5 TS (/ 260~)

0.05

R

25

A

1

B

30

cephaëlin 6 RS 5 C
 . 20 R hydrochlorid R
 . 10 ° 60 R 10 R 0.05
 .
 (365)
 A
 B
cephaëlis ipecacuanha .C
cephaëlis .C A
 .C A *acuminata*
 1) "Determination of ash " :Ash
 . / 60 (173
 "
 :Acid-insoluble ash
 . / 30 (173 1) "Determination of acid-insoluble ash
 . 200 :Foreign matter
 10 (6× lens)
 . /
 7.5 :Assay
 TS (/ 100~) 5 . 5 R 100
 5 1
 R 25 .adsorbent cotton
 .
 (/ 710~) 5 .
 15 previously neutralized TS
 VS (/ 0.1) VS (/ 0.1)

0.1) 1 .TS / 0.5
24.03 VS (/

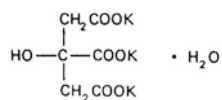
KALII CITRAS

Potassium Citrate

$C_6H_5K_3O_7 \cdot H_2O$:Molecular formula

324.4 :Relative molecular mass

:Graphic formula



:Chemical name

Tripotassium citrate monohydrate; tripotassium 2-hydroxy-1,2,3-propanetricarboxylate monohydrate; CAS Reg. No. 6100-05-6 (monohydrate).

:Description

TS (/ 750~)

:Solubility

systemic ()

:Category

.rehydration salt

:Storage

deliquescent

:Additional information

REQUIREMENTS

%99.0

:General requirement

$C_6H_5K_3O_7$ %101.0

| | | | |
|-------------------------------|---------|--|--------------------------|
| | | :Identity tests | |
| TS (/ 80~) | 2 | / 0.1 | :A |
| "General identification tests | " | | |
| A | / 0.1 | :B .(123 | 1) |
| .(121 | 1) | "General identification tests | " |
| 1) 1 | 1.0 | :Heavy meatal | () |
| "Limit test for heavy metals | () | " | |
| . / 10 | (128 | 1) A | (127 |
| potassium antimonate TS | 6 | 10 | 1 :Sodium |
| .TS2 | 15 | | |
| 4 | 1 | :Oxalates and tartrates | |
| TS (/ 55) | 1.0 | TS (/ 750~) | 4 TS (/ 70~) |
| 10 | 1.0 | :Clarity and colour of solution | |
| | | R | |
| 10 | 0.20 | :Readily carbonized substances | |
| 1 | ° 90-80 | TS (/ 1760~) | |
| Colour | " | Gn6 Yw5 | |
| | | .(53 | 1) "of liquids |
| Determination of water by | " | :Water | |
| 0.5 | (145 | 1) A | "the Karl Fischer method |
| 1 | 15 | dehydrated methanol R | |
| | . / 70 | / 40 | |
| R | 10 | 1 :Acidity or alkalinity | |
| 0.2 | TS | / | 0.1 |
| VS (/ 0.1) | 0.2 | VS (/ 0.1) | |

| | | | |
|--|------------------------|-------------|--------|
| R1 | 20 | 0.15 | :Assay |
| 1-naphtholbenzein/acetic acid TS | 0.25 | | ° 50 |
| | | VS (/ 0.1) | |
| 1 (142 1) A | "Non-aqueous titration | | " |
| .C ₆ H ₅ K ₃ O ₇ | 10.21 | VS (/ 0.1) | |

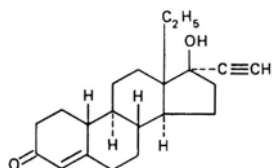
LEVONORGESTRELUM

Levonorgestrel

C₂₁H₂₈O₂ :Molecular formula

312.5 :R elative molecular mass

:Graphic formula



:Chemical name

(-)-13-Ethyl-17-hydroxy-18,19-dinor-17 α -pregn-4-en-20-yn-3-one; CAS Reg. No. 797-63-7.

:Description

R

:Solubility

.R (/ 750~)

.contraceptive

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

C₂₁H₂₈O₂ %102.0

:Identity tests

.C B A •

" :A

1) "Spectrophotometry in the infrared region"

refernce spectrum

RS

Related substances " :B

.C B

$$.^\circ 236 \quad :C$$

R / 10

:Specific optical rotation

$$.[a]_{\text{D}}^{20^{\circ}\text{C}} = -30.0 \text{ to } -35.0$$

. / 1.0 :Sulfated ash

5.0 ° 105

:loss on drying

. /

dehydrated

30 0.10

:Acidity of alkalinity

0.15 TS / 0.5 ethanol R

0.01) 0.30 VS (/ 0.01)

VS (/

:Related substances

8 R1 (84 1) "Thin-layer chromatography

10 R 2 R

0.10 : (B) 1 10 : (A) R 3

$$. \quad 1 \quad \text{RS} \quad 0.10 \quad :(\text{C}) \quad 1$$

50

TS (/ 1760~) 10 R

A .(365)

.B

40 0.2 :Ethynyl group
 VS (/ 0.1) TS (/ 100) 10 .R
 calomel electrode
 1 . .electrolyte
 -C \equiv CH 2.503 VS (/ 0.01)
 . / 81.8 / 78.1
 R 0.05 :Assay
 1 . 100 2.0 100
 C₂₁H₂₈O₂ . 241
 . RS
 .0.03 \pm 0.54

LEVOTHYROXINUM NATRICUM

Levothyroxin sodium

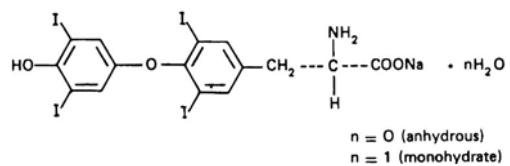
:Molecular formula

(); C₁₅H₁₀I₄NNaO₄, H₂O(monohydrate) C₁₅H₁₀I₄NNaO₄(anhydrous)

:Relative molecular mass

. (); 816.9 (monohydrate) 798.9 (anhydrous)

:Graphic formula



| | | | | | | | |
|-------------------|------------|--|--|--|--|-------------|--|
| | | | | :Chemical name | | | |
| | | | | Monosodium L-thyroxine; monosodium O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine; 3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-L-alanine monosodium salt; CAS Reg. No. 55-03-8 (anhydrous); Monosodium L-thyroxine monohydrate; monosodium O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine monohydrate; 3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-L-alanine monosodium salt monohydrate; CAS Reg. No. 31178-59-3 (monohydrate). | | | |
| .Thyroxin sodium | | | | :Other name | | | |
| | | | | :Description | | | |
| | | | | . | | | |
| TS (/ 750~) | | | | :Solubility | | | |
| . | | | | .R R R | | | |
| | | | | .thyroid hormone | | | |
| | | | | :Category | | | |
| | | | | :Storage | | | |
| | | | | :Additional information | | | |
| .hygroscopic | | | | crystalization | | | |
| REQUIREMENTS | | | | | | | |
| %97.0 | | | | :General requirement | | | |
| | | | | C ₁₅ H ₁₀ I ₄ NNaO ₄ %101.0 | | | |
| | | | | :Identity tests | | | |
| | | | | TS (/ 130~) 2.0 5 :A | | | |
| | | | | R 1.0 | | | |
| 0.2 TS (/ 750~) | | | | 2.0 5 :B | | | |
| 15 | TS (/ 10) | | | 0.25 | | TS (/ 70~) | |
| (/ 100~) | | | | 3-2 | | | |
| | | | | | | | |
| .() liothyronine | | | | :C | | | |

0.15 10 . 5 TS (/ 130~)
 0.15 TS (/ 40)
 10 VS (/ 0.02) 0.10 TS (/ 40)
 .(/ 7)
 "oxygen flask method " :Assay
 10 25 (132 1)
 .absorbing liquid TS (/ 10)
 1 (134 1) "Determination of iodine "
 .C₁₅H₁₀I₄NNaO₄ 1.665 VS (/ 0.05)

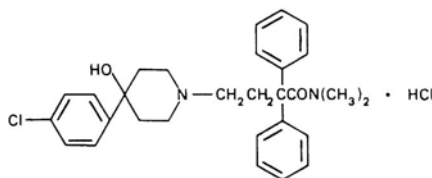
LOPERAMIDI HYDROCHLORIDUM

hydrochloride Loperamide

C₂₉H₃₃ClN₂O₂·HCl :Molecular formula

513.5 :R elative molecular mass

:Graphic formula



:Chemical name

4-(*p*-Chlorophenyl)-4-hydroxy-*N,N*-dimethyl- α,α -diphenyl-1-piperidinebutyramide monohydrochloride; 4-(4-chlorophenyl)-4-hydroxy-*N,N*-dimethyl- α,α -diphenyl-1-piperidinebutanamide monohydrochloride; CAS Reg. No. 34552-83-5.

:Description

R

:Solubility

.R

:Storage

%98.0

$$\text{C}_{29}\text{H}_{33}\text{ClN}_2\text{O}_2, \text{HCl} \quad \%102.0$$

.D C B

●

1) "Spectrophotometry in the infrared region"

RS

100

:B

VS (/ 0.1)

R

-2

.R

-2

350

230

.(273 265 259 253

RS

```

.%3

```

◦ 224

$$:\mathbf{C}$$

11

A

/ 10

:D

$$\begin{pmatrix} 121 & 1 \end{pmatrix}$$

"identification tests

. / 2.0

:loss on drying

0.6

◦ 80

:loss on drying

. / 5.0

4 (5

11

R1

(84

1) "Thin-layer chromatography

TS (/ 1080~)

5 R

10 R

10 : (A) R 10 .
 . 1 0.10 : (B) 1
 .
 .B A
 10 R1 30 0.38 : **Assay**
 1-naphtholbenzein/acetic acid TS 0.15 TS /
 Non- " VS (/ 0.01)
 (/ 0.01) 1 . (142 1) A " aqueous titration
 .C₂₉H₃₃ClN₂O₂.HCl 51.35

MAGNESII HYDROXIDUM

Magnesium hydroxide

Mg(OH)₂ : **Molecular formula**

58.32 : **Relative molecular mass**

Magnesium hydroxide; CAS Reg. No. 1309-42-8. : **Chemical name**

: **Description**

TS (/ 750~)

: **Solubility**

: **Category**

: **Storage**

REQUIREMENTS

%95.0

: **General requirement**

Mg(OH)₂ %100.5

: **Identity tests**

1.0 TS (/ 70~)

1.0 10 : A

1.0 TS (/ 100)
 .TS (/ 300~)

2.0 TS (/ 70~)

0.5 TS (/ 100)
 TS (/ 100~)

1.0 10 :B
 TS (/ 80~)
 .TS (/ 80~)

TS (/ 250~) TS 15 1.0 :Heavy metals ()
 . 2 R 25

" 15 .
 (127 1) 1 "Limit test for heavy metals ()
 . / 30 (119 1) A

35 TS (/ 100~) 20 3.3 :Arsenic
 1) "Limit test for arsenic "

. / 3 (130

50 TS (/ 300~) 50 5.0 :calcium
 .TS (/ 120~) 100 2

. porosity

.(150 1.3
 0.8 TS (Ca / 100~) 0.20
 15 TS (/ 120~) 1 1 .TS (/ 50)

(ca / 10) 10

15 . 5 TS
 .(/ 15)

. 10 TS (/ 70~) 5 0.15 :Iron
 " 4.0
 . / 700 (129 1) "Limit test for heavy iron

. 5 100 2.0 :water-soluble substances

| | | | | |
|---|-------|------------------------|--------------------------|---------------|
| | 50 | . | 100 | |
| | . | 20 | | ° 105 |
| :substances insoluble in acetic acid | | | | |
| | | . | 5 | ° 600 () |
| () | ° 900 | 0.5 | :loss on ignition | |
| | | . | / 0.325 | / 0.300 |
| | ° 105 | :loss on drying | | |
| | | | . | / 0.33 |
| TS (/ 70~) | 2 | 0.05 | :Assay | |
| Complexometric | " | | | |
| (/ 0.05) | 1 | (138 | 1 |) "titrations |
| | | .Mg(OH) ₂ | 2.916 | VS |

MAGNESII OXIDUM

Magnesium oxide

Light

Heavy

MgO **:Molecular formula**

40.30 **:R elative molecular mass**

Magnesium oxide; CAS Reg. No. 1309-48-4. **:Chemical name**

:Description

.

TS (/ 750~)

:Solubility

:Category

| | | | |
|--------------------------------------|---------------|----------|----------------------------|
| 10 | TS (/ 100~) | 0.10 | |
| 150 | () | 1.3 | :calcium |
| 0.8 | TS (Ca / 100) | 0.20 | |
| 15 | TS (/ 120~) | 1 | 1 TS (/ 50) |
| (Ca / 10) | 10 | | |
| | | 15 | 5 TS |
| | | | (/ 15) |
| 10 | TS (/ 70~) | 5 | 0.15 :Iron |
| " | | 4.0 | |
| / | 500 | (129 1) | "Limit test for heavy iron |
| 5 | 100 | 2.0 | :water-soluble substances |
| 50 | 100 | | |
| 20 | | ° 105 | |
| :substances insoluble in acetic acid | | | |
| | | 5 | ° 600 |
| | ° 900 | 1.0 () | :loss on ignition |
| | | | / 100 |
| TS (/ 70~) | 20 | 0.35 | :Assay |
| Complexometric | " | | |
| (/ 0.05) | 1 | (138 1) | "titrations |
| | | .MgO | 2.015 VS |

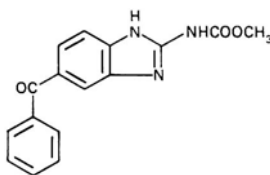
MEBENDAZOLUM

Mependazol

$C_{16}H_{13}N_3O_3$:Molecular formula

295.3 :R elative molecular mass

:Graphic formula



:Chemical name

Methyl 5-benzoyl-2-benzimidazolecarbamate; methyl (5-benzoyl-1*H*-benzimidazol-2-yl)carbamate; CAS Reg. No. 31431-39-7.

:Description

TS (/ 750~)

:Solubility

.TS (/ 1080~)

R

:Category

:Storage

REQUIREMENTS

%102.0

%98.0

:General requirement

$C_{16}H_{13}N_3O_3$

:Identity tests

.C B

A

•

"

:A

. (43 1) "Spectrophotometry in the infrared region

refernce spectrum

RS

TS (/ 80~)

2.0

20

:B

TS (/ 100~)

TS (/ 160) (II)

TS (/ 1760~)

2 20 :C

TS (/ 40)

1.0

3

.TS (/ 100~)

1.0

:Heavy metals

()

1) 3

"Limit test for heavy metals

()

"

. / 20

(128 1) A

(127

. / 1.0

:Sulfated ash

0.6)

° 105

:Loss on drying

. / 5.0

4 (5

"

:Related substances

) R6

(84

1

) "Thin-layer chromatography

5 R

5 R

90

(

10

. TS (/ 1080~)

1.0

50

:(A)

R

10

TS (/ 1080~)

1 R

9

200 A

1.0 :(B)

.TS (/ 1080~)

A

.(254)

.B

R1

30

0.22

:Assay

"

VS (/ 0.1)

1

.(142

1

) A

" Non-aqueous titration

.C₁₆H₁₃N₃O₃

29.53

VS (/ 0.1)

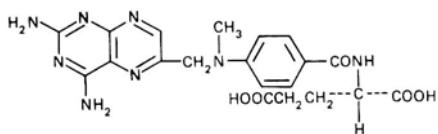
METHOTREXATUM

Methotrexate

$C_{20}H_{22}N_8O_5$:Molecular formula

454.4 :Relative molecular mass

:Graphic formula



:Chemical name

(+)-*N*-[*p*-[[[(2,4-Diamino-6-pteridiny)l)methyl]methylamino]benzoyl]-L-glutamic acid; *N*-[4-[[[(2,4-diamino-6-pteridiny)l)methyl]methylamino]benzoyl]-L-glutamic acid; CAS Reg. No. 59-05-2.

:Description

R

TS (/ 750~)

:Solubility

R

:Category

:Storage

:Additional information

REQUIREMENTS

%96.0

:General requirement

$C_{20}H_{22}N_8O_5$ %102.0

:Identity tests

"

:A

(43 1) "Spectrophotometry in the infrared region

reference spectrum

RS

(/ 0.1) / 10.0 :B
 3 380 230 VS
 2.8 371 303 371 303 258
 .3.3

12 0.25 :Specific optical rotation
 $[a]_D^{20^\circ} = +19 \text{ to } +24^\circ$ 25 TS (/ 10)
 . / 1.0 :Sulfated ash
 Determination of water by " :Water
 0.5 (145 1) A "the Karl Fischer method
 . / 120

.packing material A :Assay
 1 377-373
 10 high performance liquid chromatography
 5 6
 .octadecyl silyl groups
 / 92 R 8
 .TS 6.0

0.10 :(A)
 0.10 :(C) 1 RS 0.10 :(B) 1
 . 1 RS 0.10 RS
 . 1 1.4
 303
 . (10)
 resolution factor . 20 C 6
 peak relative standard deviation 5.0
 .() %2.5
 peak responses .B A 20

$$.100(A_1 M_2 T) / (A_2 M_1) : \quad C_{20}H_{22}N_8O_5 : \quad (\%)$$

$$M_2 \quad M_1 \quad A_2 \quad A_1$$

.RS purity T

Additional requirement for Methotrexate for parenteral use
 .(56 4) " *parenteral preparation* "

METHYLTHIONINII CHLORIDUM

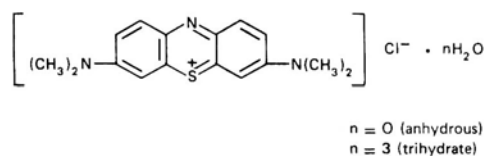
Methylthioninium chloride

:Molecular formula

.() $C_{16}H_{18}ClN_3S$, $3H_2O$ (trihydrate) $C_{16}H_{18}ClN_3S$ (anhydrous)

319.9 (anhydrous); 373.9 (trihydrate) :**Relative molecular mass**

:Graphic formula



:Chemical name

C.I. Basic Blue 9; 3,7-bis(dimethylamino)phenothiazin-5-ium chloride; CAS Reg. No. 61-73-4 (anhydrous).
 C.I. Basic Blue 9 trihydrate; 3,7-bis(dimethylamino)phenothiazin-5-ium chloride trihydrate; CAS Reg. No. 7220-79-3 (trihydrate).

.Methylene blue

:Other name

:Description

R TS (/ 750~)

:Solubility

.R

| | | |
|-------------------------------|----------------------|-------------------------|
| .Antidote | | :Category |
| .hygroscopic | | :Storage |
| | | :Additional information |
| REQUIREMENTS | | |
| %97.0 | :General requirement | |
| | $C_{16}H_{18}ClN_3S$ | %101.0 |
| :Identity tests | | |
| TS (/ 70~) | / | 5 :A |
| 745 680 288 258 | 4 | 800 230 |
| 2.0 | | 10 1 :B |
| | R | 0.25 TS (/ 70~) |
| | | |
| | R | 0.5 0.05 :C |
| TS (/ 130~) | 10 | 10 |
| "General identification tests | | " A |
| | | .(121 1) |
| 1.0 () | :Copper and Zinc | |
| (/ 130~) | 15 | |
| 200 R (II) | | 5 TS |
| 5 | TS (/ 130~) | 15 Cu |
| | 10 | |
| TS (/ 100~) | | |
| | 50 | |
| 25 | | |
| 5 | hydrogen sulfide TS | 10 |
| | | () |

. (/ 0.20)
 15 200 4 :Iron
 TS (/ 1000~)
 . TS (/ 1760~) 10 . 20
 TS (/ 1000~)
 .
 TS (/ 1000~)
 . R 25
 " 5 50
 . / 0.10 (129 1) "Limit test for heavy iron
 . / 10 :Sulfated ash
 / 80 ° 105 :loss on drying
 . / 220
 Thin-layer " :dyes foreigne
 R1 slurry (84 1) "chromatography
 TS (/ 27.2)
 4 R -1 20 .TS (/ 28.4)
 25 2 . 1 R
 . 10 R
 0.5 *Rf* 4-3 . ° 105
 .
 30 100 0.3 :Assay
 50.0
 10 . VS (/ 0.0167)
 40 50.0 . 20
 R 1 TS (/ 190~)

TS VS (/ 0.1) 100 . 5

.C₁₆H₁₈ClN₃S 10.66 VS (/ 0.0167) 1 .

Additional requirement for Methylthionium chloride for parenteral use

(56 4) "parenteral preparation"

"

:Bacterial endotoxins

(30 5) "Test for bacterial endotoxins"

. 1 RS 2.5

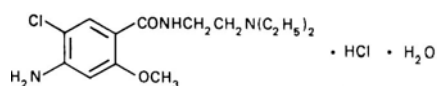
METOCLOPRAMIDI HYDROCHLORIDUM

Metoclopramide hydrochloride

C₁₄H₂₂ClN₃O₂·HCl·H₂O :Molecular formula

354.3 :R elative molecular mass

:Graphic formula



:Chemical name

4-Amino-5-chloro-*N*-[2-(diethylamino)ethyl]-*o*-anisamide monohydrochloride monohydrate; 4-amino-5-chloro-*N*-[2-(diethylamino)ethyl]-2-methoxybenzamide monohydrochloride monohydrate; CAS Reg. No. 54143-57-6 (monohydrate).

:Description

TS (/ 750~)

:Solubility

.R R

:Category

:Storage

95 R4 (84 1) "Thin-layer chromatography
 5 TS (/ 260~) 5 R -1
 : (B) 1 50 : (A) R
 . 1 0.50
 A . (254)
 .B
 10 R 80 0.3 :Assay
 VS (/ 0.1) TS /
 1) A "Non-aqueous titration "
 .C₁₄H₂₂ClN₃O₂.HCl 33.63 VS (/ 0.1) 1 . (142

Additional Requirements for Metoclopramide hydrochloride for parenteral use

. (56 4) "Parenteral Preparations

"

:Bacterial endotoxine

(30 5) "Test for bacterial endotoxins

. 1 RS 2.5

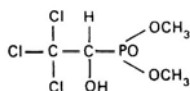
METRIFONATUM

Metrifonate

.C₄H₈Cl₃O₄P :Molecular formula

257.4 :Relative molecular mass

:Graphic formula



Dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate; CAS
Reg. No. 52-68-6.

TS (/ 750~)

.Antischistosomal

:Storage

•

%101.0

:General requirement

$$\text{C}_4\text{H}_8\text{Cl}_3\text{O}_4\text{P}$$

R

0.2

0.1

 $\vdash A$

3

R

.B

2

.TS (/ 1000~)

3

7

TS (/ 95)

2

5

VS (/ 0.1)

1

A

2

:B

.TS (/ 100~)

3

2

◦ 85

6.2

:Congealing temperature

11

○ 80

R

◦ 73

(27

1

) "Determination of congealing point

15

R

20

1.0

:Aceton-insoluble matter

1

◦ 105

10

. / 5.0
 . / 3.0 :Sulfated ash
 Determination of water by " :Water
 1 (145 1) A "the Karl Fischer method
 . / 7.5
 .3.5-2.0 / 5.0 :pH Value
 10 .R 90 1.0 :Assay
 10 . 1 ° 0.5±20 monoethanolamine R
 0.1) ° 20 TS (/ 1000~) 20
) () VS (/
 VS (/ 0.1) 1 .calomel reference electrode (
 .C₄H₈Cl₃O₄P 25.74

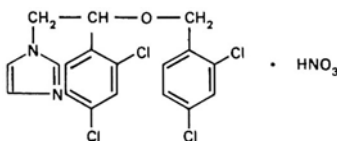
MICONAZOL NITRAS

Miconazole Nitrate

C₁₈H₁₄Cl₄N₂O₃.HNO₃ :Molecular formula

479.2 :Relative molecular mass

:Graphic formula



:Chemical name

1-[2,4-Dichloro-β-[(2,4-dichlorobenzyl)oxy]-phenethyl]imidazole mononitrate; 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]-ethyl]-1*H*-imidazole mononitrate; CAS Reg. No. 22832-87-7.

:Description

| | | | |
|--------------|---------|---|---|
| TS (/ 750~) | 140 | R | :Solubility |
| | | | .R |
| | | | :Category |
| | | | :Storage |
| | ° 182 | | :Additional information |
| REQUIREMENTS | | | |
| %98.5 | | | :General requirement |
| | | C ₁₈ H ₁₄ Cl ₄ N ₂ O,HNO ₃ | %101.5 |
| | | | :Identity testes |
| | | .C B | A |
| | | " | :A |
| | (40 | 1 |) "Spectrophotometry in the infrared region |
| | | | RS |
| R | 9 | / | 0.40 :B |
| | 350 230 | | VS (/ 0.1) |
| 1 | | | 280 272 264 |
| | | | 0.58 0.48 0.40 |
| | 0.4 | | 5 10 :C |
| 5 | TS | / | 0.1 TS (/ 100) |
| | | | TS (/ 1760~) |
| | | / 2 | :Sulfated ash |
|) | ° 100 | | :Loss on drying |
| | / 5 | (| 5 0.6 |
| " | | | :Related substances |
| R1 | (84 | 1 |) "Thin-layer chromatography |

R 10 R 30 R 60
 50 TS (/ 260~)
 25 (B) 10 (A) :R R
 / .
 (A) TS
 .B
 R1 50 0.35 :Assay
 Potentionetrically .VS (/ 0.1)
 .(142 1) A "Non-aqueous titration"
 .C₁₈H₁₄C₁₄N₂O₃.HNO₃ 47.92 VS (/ 0.1)

NALOXONI HYDROCHLORIDUM

Naloxone hydrochloride

Naloxone hydrochloride, anhydrous

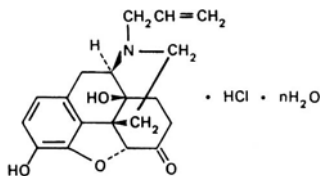
Naloxone hydrochloride, dihydrate

) C₁₉H₂₁NO₄.HCl.2H₂O () C₁₉H₂₁NO₄.HCl :Molecular formula

.(

.() 399.9 () 363.8 :Relative molecular mass

:Graphic formula



n = 0 (anhydrous)
 n = 2 (dihydrate)

| | | |
|-------|--|--|
| | | :Chemical name |
| | | (-)-17-Allyl-4,5 <i>a</i> -epoxy-3,14-dihydroxymorphinan-6-one hydrochloride; 4,5 <i>a</i> -epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one hydrochloride; (-)-12-allyl-7,7 <i>a</i> ,8,9-tetrahydro-3,7 <i>a</i> -dihydroxy-4 <i>aH</i> -8,9 <i>c</i> -imino-ethanophenanthro[4,5- <i>bcd</i>]furan-5(6 <i>H</i>)-one hydrochloride; CAS Reg. No. 357-08-4 (anhydrous). (-)-17-Allyl-4,5 <i>a</i> -epoxy-3,14-dihydroxymorphinan-6-one hydrochloride dihydrate; 4,5 <i>a</i> -epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one hydrochloride dihydrate; (-)-12-allyl-7,7 <i>a</i> ,8,9-tetrahydro-3,7 <i>a</i> -dihydroxy-4 <i>aH</i> -8,9 <i>c</i> -imino-ethanophenanthro[4,5- <i>bcd</i>]furan-5(6 <i>H</i>)-one hydrochloride dihydrate; CAS Reg. No. 51481-60-8 (dihydrate). |
| | | :Description |
| R | (/ 750~) | :Solubility |
| | | .R |
| | | :Category |
| | | :Storage |
| | | :Labelling |
| | | :Additional information |
| | ° 177 | |
| | REQUIREMENTS | |
| %98.0 | | :General requirement |
| | | C ₁₉ H ₂₁ NO ₄ .HCl %102.0 |
| | | :Identity testes |
| | .C B A • | |
| | " | :A |
| | .(43 1) "Spectrophotometry in the infrared region | |
| | RS | |
| 0.3 | VS (/ 0.1) | 5 0.05 :B |
| | | TS (/ 25) |

Additional Requirements for Naloxone hydrochloride for parenteral use

(56 4) "Parenteral preparations"

"

:Bacterial endotoxins

(30 5) "Test for Bacterial endotoxins"

500 RS

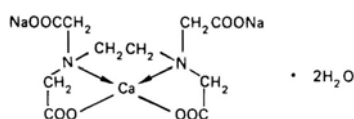
NATRII CALCII EDETAS

Sodium Calcium edetate

$C_{10}H_{12}CaN_2Na_2O_8 \cdot 2H_2O$:Molecular formula

410.3 :Relative molecular mass

:Graphic formula



:Chemical name

Disodium [(ethylenedinitrilo)tetraacetato]calcate(2-) dihydrate; (OC-6-21)-disodium [[N,N'-1,2-ethanediylbis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',O'',O''']calcate(2-) dihydrate; calcium chelate of the disodium salt of ethylenediamine-N,N,N',N'-tetraacetic acid dihydrate; CAS Reg. No. 6766-87-6 (dihydrate).

:Description

TS (/ 750~)

:Solubility

.R R

:Category

:Storage

:Additional information

REQUIREMENTS

%97.0

:General requirement

$C_{10}H_{12}CaN_2Na_2O_8$ %102.0

:Identification tests

6 TS (/ 100) 2.0 25 2.0 :A
 .(C) TS (/ 80)
 TS (/ 75) 0.15 TS (/ 25) 0.15 :B
 . 0.05
 TS (/ 100~) A :C
) TS (/ 25) 5 .R
 .(:D
 General " :D
 () B . (123 1) "identification tests
 .TS (/ 60~)

"

1.0

:Heavy metals

(127 1) "Limit test for heavy metals
 . / 20 (128 1) A

4 R

1.0

50

1.0

:Cyanide

VS (/ 0.01)

0.10 TS (/ 100~)

1.0 TS (/ 130)

1

.VS (/ 0.1)

0.10

9 VS (/ 0.0001)

.

10

20

5.0

:Disodium edetate

0.1)

R

11 mordant black

0.2 TS2

.VS (/ 0.1)

1.5

.VS (/

.

40

0.5 ()

:Iron

80 (129 1) "Limit test for iron "

. /

Determination of water by " :**Water**

0.2 (145 1) A "the Karl Fischer method

. / 130

.8.0-6.5 R / 0.2 :**pH**

5 R 7 90 0.5 :**Assay**

VS (/ 0.05) .TS (/ 70~)

18.71 VS (/ 0.05) 1 .R

.C₁₀H₁₂CaN₂Na₂O₈

Additional Requirements for Sodium Calcium edetate for parenteral use

(56 4) "Parenteral preparations "

" :**Bacterial endotoxins**

(30 5) "Test for Bacterial endotoxins

0.2 RS

NATRII CITRAS

Sodium citrate

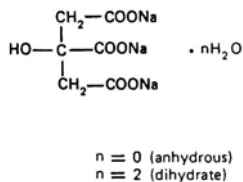
Sodium citrate, anhydrous

Sodium citrate, dihydrate

.() C₆H₅Na₃O₇·2H₂O () C₆H₅Na₃O₇ :**Molecular formula**

.() 294.1 () 258.1 :**Relative molecular mass**

:Graphic formula



:Chemical name

Trisodium citrate; trisodium 2-hydroxy-1,2,3-propanetricarboxylate; CAS Reg. No. 68-04-2 (anhydrous).
Trisodium citrate dihydrate; trisodium 2-hydroxy-1,2,3-propanetricarboxylate dihydrate; CAS Reg. No. 6132-04-3 (dihydrate).

:Description

:Solubility

.R TS (/

:Category

:Storage

:Labelling

:Additional information

REQUIREMENTS

:General requirement

$\text{C}_6\text{H}_5\text{Na}_3\text{O}_7$ %101.0

:Identification tests

General

"

:A

B

(123 1) "identification tests

. / 20

General

"

B

/

20

:B

. (121 1) "identification tests

| | | |
|---|--|-------------------------------|
| " | 1.0 | :Heavy metals |
| (127 1) | "Limit test for heavy metals | |
| . / 10 | (128 1) A | |
| (/ 420~) | 3 4 0.5 | :Oxalates |
| 2 . | R | 1 TS |
| . TS (/ 10) | 0.25 | |
| 0.25 (/ 420~) | | |
| 30 | .TS (/ 50) | |
| .TS (/ 0.05) | 4 | |
| 10 1 | :Clarity and colour of solution | |
| | . | R |
| Determination of water by | " | :Water |
| 1 | (145 1) A | "the Karl Fischer method |
| 0.3 | . / 10 | |
| | . / 0.13 / 0.10 | |
| R | 10 1 | :Acidity or alkalinity |
| (/ 0.1) | 0.2 TS / | 0.1 |
| . | VS (/ 0.1) | 0.2 VS |
| R1 | 20 | 0.15 |
| -1 0.25 | | :Assay |
| VS (/ 0.1) | TS | ° 50 |
|) A "Non-aqueous titration | " | /(1-naphtholbenezein) |
| .C ₆ H ₅ Na ₃ O ₇ 8.603 VS (/ 0.1) | 1 .(142 1 | |

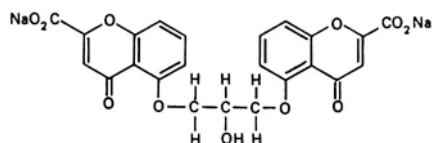
NATRII CROMOGLICAS

Sodium Cromoglicate

C₂₃H₁₄Na₂O₁₁ **:Molecular formula**

512.3 :Relative molecular mass

:Graphic formula



:Chemical name

Disodium 5,5'-[(2-hydroxytrimethylene)dioxy]bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; disodium 5,5'-[(2-hydroxy-1,3-propanediyl)bis(oxy)]-bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; CAS Reg. No. 15826-37-6.

:Description

R

:Solubility

.R R

TS (/ 750~)

:Category

:Storage

:Additional information

REQUIREMENTS

%98.0

:General requirement

$C_{23}H_{14}Na_2O_{11}$ %101.0

:Identification tests

.D C B

D A

•

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

. "Related substances

"

:B

.C

B

TS1

4

3

R

0.5

5

:C

5

"

B (123 1) "General identification tests
. / 20

" 1.0 **:Heavy metals**
(127 1) 3 "Limit test for heavy metals
. / 20 (128 1) A

TS 5.0 20 0.10 **:Oxalates**
0.35 480 50
. R

) ° 100 **:Loss on drying**
. / 100 (5 0.6

R 25 1 **:Acidity or alkalinity**
0.1) 0.25 TS / 0.1
.() VS (/ 0.1) 0.25 VS (/

" **:Related substances**
R4 (84 1) "Thin-layer chromatography
9 .
10 . R 9 R
) R 4 R
20 (A) : 6 (alumina
. RS 0.10 (C) 0.10 (B)

ahead A .(254)
.B

5 R 25 0.18 **:Assay**
0.1) / .R 30 R -2
Non- " VS (/

0.1) / 1 .(142 1) A "aqueous titration
 $\text{C}_{23}\text{H}_{14}\text{Na}_2\text{O}_{11}$ 25.62 VS (/

NATRII FLUORIDUM

Sodium fluoride

NaF :Molecular formula

41.99 :Relative molecular mass

.CAS Reg NO. 7681-49-4

:Chemical name

:Description

.TS (/ 750~)

:Solubility

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

NaF %101.0

:Identification tests

General

"

:A

B

(123 1) "identification tests

. / 20

1760~)

1

0.10 :B

15

TS (/

0.10

:C

TS

0.10 TS (/ 10)

" 0.5 **:Heavy metals**

(127 1) 3 "Limit test for heavy metals

. / 40 (128 1) A

. / 10 ° 130 **:Loss on drying**

20 1.0 **:Acidity or alkalinity**

0.15 .° 0 R 3

1.0 VS (/ 0.05) 2.0 TS /

() .() VS (/ 0.05)

.(

:Fluorosilicates

VS (/ 0.05)

.VS (/ 0.05) 1.5

15 . 1.0 30 **:Assay**

R

VS (/ 0.1) Reflux condenser

.(142 1) A "Non-aqueous titration "

.NaF 4.199 VS (/ 0.1) 1

NATRII NITRIS

Sodium nitrite

NaNO₂ **:Molecular formula**

69.00 **:Relative molecular mass**

CAS Reg. NO. 7632-00-0

:Chemical name

:Description

.

| | | | |
|---------------|------------------------------|------------------------------|---------------|
| .TS (/ 750~) | | :Solubility | |
| | | :Category | |
| | | :Storage | |
| | | :Additional information | |
| REQUIREMENTS | | | |
| %98.0 | | :General requirement | |
| | | NaNO ₂ %100.5 | |
| | | :Identification tests | |
| General | " | :A | |
| B | (123 1) " | identification tests | |
| | .TS (/ 300~) | / 0.10 | |
| TS (/ 15~) | 1.0 | 1 | 0.10 :B |
| | | | |
| TS (/ 100~) | 1.0 | 1 | 0.20 :C |
| | TS / | | |
| TS (/ 70~) | 10 | 1.0 | :Heavy metals |
| | "Limit test for heavy metals | | |
| 1) 1 | (128 1) A | (127 | |
| . / 20 | | | |
| 2 | 3 | 2.5 | :Chlorides |
| Limit | " | TS (/ 1000~) | |
| | . / 0.1 | (124 1) "test for chlorides | |
| 4 R | :Loss on drying | | |
| | . / 5.0 | | |

0.1 10 0.5 :Acidity or alkalintiy
 0.3 . TS / 0.25 VS (/ 0.01)
 . VS (/ 0.01)
 . 100 0.4 :Assay
 10 VS (/ 0.02) 20 10.0
 swirl R 0.5 10 .TS (/ 1760~)
 . TS VS (/ 0.1)
 .NaNO₂ 3.450 VS (/ 0.1)

Additional Requirements for Sodium nitrite for parenteral use

(56 4) " Parenteral preparations "

"

:Bacterial endotoxins

(30 5) "Test for Bacterial endotoxins

0.33 RS

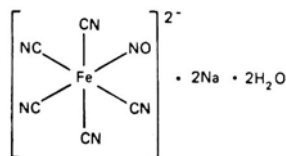
NATRII NITROPRUSSIDUM

Sodium nitroprusside

Na₂[Fe(CN)₅NO],2H₂O :Molecular formula

298.0 :Relative molecular mass

:Graphic formula



:Chemical name

Disodium pentacyanonitrosylferrate(2-) dihydrate; disodium (OC-6-22)-pentakis(cyano-C)nitrosylferrate(2-) dihydrate; CAS Reg. No. 13755-38-9 (dihydrate).

| | | | |
|---------------------------|--------------|---|-----------------------|
| | | :Other names | |
| | | :Description | |
| TS (/ 750~) | | :Solubility | |
| | | .R | |
| | | :Category | |
| | | :Storage | |
| REQUIREMENTS | | | |
| %99.0 | | :General requirement | |
| | | Na ₂ [Fe(CN) ₅ NO] %100.5 | |
| | | :Identification tests | |
| 600 | 350 | / 4 | :A |
| 1.10 | 1 | 395 | |
| General | " | | :B |
| B | . | (123 1) | "identification tests |
| .TS (/ 300~) | | / 0.10 | |
| 80~) | 0.5 R | 1 | 2.0 5 :C |
| . | TS (/ 300~) | 2 | . TS (/ |
| 30 TS (/ 130~) | 2 | 1.20 | :Chlorides |
| "Limit test for chlorides | " | | |
| | . / 0.2 | (124 1) | |
| " | | 40 5.0 | :Sulfates |
| . / 0.1 | .(125 1) | "Limit test for sulfates | |
| TS 4.62 | 20 | 0.50 | :Ferricyanide |
| (/ 50) | 1 B | .B A | |
| . 50 | TS (/ 1) | 5 | |

50 TS 4.62 10 0.25

. 720 .

. (/ 0.2) A B A

.B A 40 2 :Ferrocyanide

0.2 TS (/ 100) 2 B

. 5 . 50 TS (/ 50)

695 . 50 1.0

0.2) A B A .

. (/

30 50 10.0 :Insoluble matter

° 105

. / 0.1

Determination of water by " :Water

1 (145 1) A "the Karl Fischer method

. / 150 / 90

0.1 . 100 0.35 :Assay

VS (/ 0.1) .TS (/ 750~) 20 TS (/ 100~)

. /

.Na₂[Fe(CN)₅NO] 13.10 VS (/ 0.1)

NATRII STIBOGLUCONAS

Sodium stibogluconate

:Composition

C₆H₉Na₂O₉Sb

| | | | |
|--------------|--------------|--|----------------------|
| | | :Chemical name | |
| | | D-Gluconic acid cyclic ester with antimononic acid (H ₈ Sb ₂ O ₉) (2:1), trisodium salt, nonahydrate; 2,4:2',4'-O-(oxydistibylidyne)bis-D-gluconic acid, Sb,Sb'-dioxide, trisodium salt, nonahydrate; CAS Reg. No. 16037-91-5. | |
| | | :Description | |
| .R | TS (/ 750~) | :Solubility | |
| | | :Category | |
| | | :Storage | |
| REQUIREMENTS | | | |
| %30.0 | | :General requirement | |
| | | %34 | |
| | | :Identification tests | |
| TS (/ 60~) | | | :A |
| General | " | B | |
| | | .(123 1) "identification tests | |
| TS | 10 | 0.5 | :B |
| | | .TS (/ 80~) | |
| | | . / 10 :C | |
| TS (/ 130~) | 2 | 50 | 2.5 :Chlorides |
| VS (/ 0.1) | | .TS 5.0 75 | |
| .VS (/ 0.1) | | 3.0 Potentiometrically | |
| 6 |) | ° 130 :Loss on drying | |
| | | . / 150 (5 | |
| 10 | | 0.3 | :Colour and pH value |
| 30 | | (70) | |
| | | .5.6 5.0 | |

15 30 2.0 : Trivalent antimony
 TS / VS (/ 0.00833) TS (/ 250~)
 .VS (/ 0.00833) 1.3
 10 300 0.25 :Assay
 TS (/ 1760~) 5 TS (/ 1000~)
 1 .
 R 1 . TS (/ 1000~)
 . 60 R 1
 5 R 1
 15) TS (/ 400~) .
 . TS (/ 100~) (TS
 VS (/ 0.02) R
 . 2.435 VS (/ 0.02)

NATRII SULFAS

Sodium sulfate

$\text{Na}_2\text{SO}_4 \cdot 10\text{H}_2\text{O}$:Molecular formula

322.2 :Relative molecular mass

:Chemical name

Disodium sulfate decahydrate; sulfuric acid disodium salt, decahydrate; CAS Reg. No. 7727-73-3 (decahydrate).

:Other name

:Description

.TS (/ 750~)

:Solubility

:Category

:Storage

. ° 30

:Additional information

. ° 33

REQUIREMENTS

%99.0

:General requirement

. Na₂SO₄ %100.5

:Identification tests

General " :A
B . .(123 1) "identification tests
 / 0.05

General " A / 0.05 :B
.(123 1) "identification tests

" 1.0 **:Heavy metals**

(127 1) 1 . "Limit test for heavy metals
 / 20 (128 1) A

0.3 1 **:Ammonium salts**

. R () R

35 5 **:Arsenic**

(130 1) . "Limit test for arsenic "
 / 2

100) 0.2 **:Calcium**

TS (/ 25) 1.5 TS (Ca /

.TS (/ 120~) 1

TS (Ca / 100) 10 15 0.5
15 . 5

NATRII SULFAS ANHYDRICUS

Sodium sulfate, anhydrous

Na₂SO₄ :Molecular formula

142.0 :Relative molecular mass

:Chemical name

Disodium sulfate; sulfuric acid disodium salt, anhydrous; CAS
Reg. No. 7757-82-6 (anhydrous).

:Description

.TS (/ 750~)

:Solubility

:Category

:Storage

:Additional information

REQUIREMENTS

%99.0

:General requirement

Na₂SO₄ %100.5

:Identification tests

General " :A
20 B . (123 1) "identification tests
/

General " A / 20 :B
.(123 1) "identification tests

0.5 :Heavy metals

(127 1) 1 "Limit test for heavy metals "
/ 45 (128 1) A

0.3 0.5 :Ammonium salts

| | | | | | | |
|---------------------------|------------|---------|--------|---------|----------------------|---------------------------------|
| | | | R () | | | R |
| | " | | | 35 | 2.0 | :Arsenic |
| | / | 5 | (130 | 1 |) | "Limit test for arsenic |
| 100) | | | 0.2 | | | :Calcium |
| | | TS (/ | 25) | | 1.5 | TS (Ca / |
| | | | | .TS (/ | 120~) | 1 |
| TS (Ca / | | 10) | | 10 | | 15 0.22 |
| | | | | 15 | | 5 |
| | | | | (/ | 450) | |
| 30 TS (/ | | 130~) | | 2 | 0.55 | :Chlorides |
| "Limit test for chlorides | | | | " | | |
| | / | 0.45 | | | (124 | 1) |
| " | | | 40 | | 0.44 | :Iron |
| / | 90 | | (129 | 1 |) | "Limit test for iron |
| 0.15 R | | 1 | | 10 | 0.22 | :Magnesium |
| 5 TS (/ | | 50) | | | 0.25 TS Titan yellow | |
| | | | | | TS (/ | 80~) |
| | 5 TS (Mg / | | 10) | | | 5 |
| 10 | 0.22 | | | | | :Clarity and colour of solution |
| | | | | | | R |
| | 1 | 5 | 0.25 | | | :Reducing substances |
| 15 | | .VS (/ | 0.002) | | 0.20 TS (/ | 100~) |
| | | | | | .discoloration () | |
| 50 | | ° 130 | | | | :Loss on drying |
| | | | | | | / |
| | | | 10 | 0.22 | | :Acidity or alkalinity |

| | | | | | |
|-------------|--------------|----------------------------------|------------------|-------------|---|
| | 0.5 | TS | / | 0.1 | R |
| 0.5 | VS (/ 0.01) | carbonate-free | sodium hydroxide | | |
| | .() | | VS (/ 0.01) | | |
| 10 | | 250 | 0.1 | :Assay | |
| .TS (/ 50) | | | | TS (/ 70~) | |
| . 600 | | | | 30 | |
| | | .Na ₂ SO ₄ | 0.608 | | |

NATRII THIOSULFAS

Sodium thiosulfate

Na₂S₂O₃·5H₂O :Molecular formula

248.2 :Relative molecular mass

:Chemical name

Disodium thiosulfate pentahydrate; disodium thiosulfate (Na₂S₂O₃) pentahydrate; thiosulfuric acid (H₂S₂O₃), disodium salt, pentahydrate; CAS Reg. No. 10102-17-7 (pentahydrate).

:Description

.TS (/ 750~)

:Solubility

:Category

:Storage

:Additional information

. ° 49

° 33

REQUIREMENTS

%99.0

:General requirement

.Na₂S₂O₃·5H₂O %101.0

| :Identification tests | | | | | | | | | |
|-----------------------|-------------|----|------------|------|--------------------------|-------------------------------|-------------------------------|----|--|
| 1.0 | 2 | .(| C | B |) | 10 | | :A | |
| | | | TS (/ 50) | | 0.25 | | TS | | |
| | TS (/ 70~) | | | 1.0 | A | | 2 | :B | |
| | | | .(|) | | | | | |
| | VS (/ 0.1) | | | 2 | A | | 2 | :C | |
| | | | " | | | | | :D | |
| | B | | | (123 | 1 |) | "General identification tests | | |
| | | | | | | | / 0.10 | | |
| | | | 5 | 10 | 1.0 | :Heavy metals | | | |
| | | | 15 | | | TS (/ 70~) | | | |
| | 0.05 | | | | | | | | |
| | 4-3 | | .VS (/ 1) | | | TS / | | | |
| | " | | | 40 | | TS (/ 60~) | | | |
| | (128 | | 1 |) | A | "Limits test for heavy metals | | | |
| | | | | | | / | 20 | | |
| (/ 130~) | | 2 | 20 | | 1.20 | :Chlorides | | | |
| | " | | | | | 4-3 | TS | | |
| | / 0.2 | | (124 | 1 |) | "Limit test for chlorides | | | |
| TS | 5 | | 10 | 0.25 | :Sulfates and sulfites | | | | |
| | | | | | | TS | | | |
| | (125 | | 1 |) | "Limit test for sulfates | | " | | |
| | | | | | | / 2 | | | |
| sodium | | | 0.05 | | 10 | 1 | :Sulfides | | |
| | | | | | | | TS (/ 45) nitroprusside | | |

| | | | |
|--------------|----|---|---------------------|
| R | 10 | 1.0 | :Clarity and colour |
| .8.4-6.0 R | | / 0.10 | :pH value |
| 0.05) iodine | 25 | 0.5 | :Assay |
| VS (/ 0.05) | 1 | TS | VS (/ |
| | | .Na ₂ S ₂ O ₃ .5H ₂ O | 24.82 |

Additional Requirements for Sodium thiosulfate for parenteral use

| | | | |
|-----|----|----------------------------|----------------------------------|
| (56 | 4 |) "Parenteral preparations | " |
| " | | :Bacterial endotoxins | |
| (| 30 | 5 |) "Test for Bacterial endotoxins |
| | | 0.03 RS | |

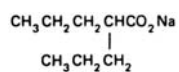
NATRII VALPROAS

Sodium valproate

C₈H₁₅NaO₂ :Molecular formula

166.2 :Relative molecular mass

:Graphic formula



:Chemical name

Sodium 2-propylvalerate; sodium 2-propylpentanoate; CAS
Reg. No. 1069-66-5.

:Description

.TS (/ 750~)

:Solubility

:Category

1

•

REQUIREMENTS

%98.0

:General requirement

$$\text{C}_8\text{H}_{15}\text{NaO}_7 \quad \%101.0$$

Identification tests

(/ 70~) 1 R 5 5 0.5 :A

R TS

.(43 1) "Spectrophotometry in the infrared region

RS

| TS (/ 100) (II) | 1 | 5 | 0.5 | 0.1 |
|------------------|---|---|-----|-----|
| TS (/ 100) (II) | 1 | 5 | 0.5 | 0.1 |

.R

General " B / 20 :C
 .(125 1) "identification tests

1.0 :Heavy metals

(127 1) 3 "Limit test for heavy metals

$$\cdot / \quad 20 \quad (128 \quad 1) \text{ A}$$

35 5.0 :Arsenic

2 (130 1) "Limit test for arcinico

| | | | | |
|----|--------------|---|------|------------|
| 20 | TS (/ 130~) | 2 | 1.20 | :Chlorides |
|----|--------------|---|------|------------|

1) "Limit test for chlorides"

$$\cdot / 0.2 \quad (124)$$

| | | | |
|---|----|-----|-------|
| " | 40 | 0.2 | :Iron |
|---|----|-----|-------|

50 (129 1) "Limit test for iron

" 20 2.5 :Sulfates
. / 0.2 (125 1) "Limit test for sulfates
10 2.0 :Clarity and colour of solution
. TS2 R
° 105 :Loss on drying
. / 20
20 2.0 :Acidity or alkalinity
0.1) 1.5 TS / 0.1 R
VS (/ 0.1) 1.5 VS (/
.()
Gas " :Related substances
: 3 (101 1) "chromatography
1 (internal standard) octanoic acid R 0.20 :I
.(dichloromethane) R
TS (/ 190~) 10 0.50 .2
combined . 20 R 3
° 30 R 10
. 10
10 R 2.0 10 0.50 .3
3 TS (/ 190~) VS (/ 0.1)
10 combined . 20 R
° 30 R
. 10
0.4 1.5
1 M 20 15
silanized R 84 TS (/ 1440~)
R ° 170 .(180-150) diatomaceous support

| | | | | |
|--|------------------------|-------------|--------|------|
| R1 | 30 | 0.25 | :Assay | |
| VS (/ 0.1) | TS | / | -1 | 0.15 |
| 1) A | "Non-aqueous titration | " | | |
| .C ₈ H ₁₅ NaO ₂ | 16.62 | VS (/ 0.1) | 1 | (142 |

NEOMYCINI SULFAS

Neomycin sulfate

:Composition

.C B *Streptomyces fradiae*

:Chemical name

Neomycin sulfate; CAS Reg. No. 1405-10-3.

:Description

TS (/ 750~)

:Solubility

.R R R

:Category

:Storage

.° 30

:Additional information

REQUIREMENTS

600

:General requirement

:Identification tests

"Thin-layer chromatography" :A

TS (/ 40) R3 (84 1)

20 (A) : (1)

RS B 20 (B)

/ ° 105 10

5 ° 105 .TS

.B A

2 R 0.1 5 10 :B

10 ° 70 65 TS (/ 1)

General " A / 0.05 :C

.(123 1) "identification tests

. / 10 **:Sulfated ash**

0.6) ° 60 **:Loss on drying**

3 phosphorus pentoxide R (5

. / 80

.7.5-5.0 R / 0.10 **:ph value**

Thin-layer " **:Neamine**

R 0.3 : (84 1) "chromatography

7 . 240

.R3 30 TS (/ 80~)

° 110 0.75

.TS (/ 100)

0.05 (B) 2.5 (A) : 10

. RS

15 ° 110 TS /

A .

.B

3 200 1 :Content of sulfates

.TS (/ 50) 25 TS (/ 420~)

4

. / 310 / 250 411.6

"

:Assay

NCTC) *Bacillus pumilus* (a) (155 1) "Microbiological assay of antibiotics

8.1-8.0 Cm1 (8241; ATCC 14884

(14 2) TS2 TS1 8.0

(ATCC 29737) *Staphylococcus aureus* (b) ° 39-35

TS2 TS1 8.0 8.0-7.8 Cm1

(C) ° 39-35 (1 20 2)

8.1- Cm1 (ATCC 12228) *Staphylococcus epidermidis*

2 0.5) TS2 TS1 8.0 8.0

.° 39-35 (1

%105 %95 ($P = 0.95$) fiducial limits of error of the estimated potency

600 ($P = 0.95$)

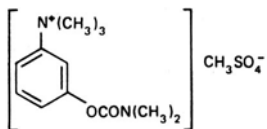
NEOSTIGMINI METILSULFAS

Neostigmine metilsulfate

$C_{13}H_{22}N_2O_6S$:Molecular formula

334.4 :Relative molecular mass

:Graphic formula



:Chemical name

(*m*-Hydroxyphenyl)trimethylammonium methyl sulfate dimethylcarbamate; 3-[[[(dimethylamino)carbonyl]oxy]-*N,N,N*-trimethylbenzenaminium methyl sulfate; CAS Reg. No. 51-60-5.

:Description

.TS (/ 750~)

:Solubility

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

$C_{13}H_{22}N_2O_6S$ %100.5

:Identification tests

.D C B
"

D A

●

:A

.(43 1) "Spectrophotometry in the infrared region

RS

. "Related substances

"

:B

.C

B

TS (/ 750~)

2 R

0.4

0.05

:C

2

2

TS (/ 750~)

3

TS

R

0.5

20

:D

TS

0.2

10

A

TS (/ 70~)

| | | | | |
|----------|--------------|--------------------------------|-----------|--|
| 1 |) | "General identification testes | " | |
| | | | | .(123 |
| | | 3 ° 105 | ° 149-144 | :Melting range |
| 1 | TS (/ 130~) | 1 | 10 0.20 | :Chlorides |
| | | | | .TS (/ 40) |
| | TS (/ 70~) | 1.5 | 10 0.20 | :Sulfates |
| | | | | .TS (/ 50) 1 |
| | | 10 0.20 | | :Clarity and colour of solution |
| | " | | Bn1 | |
| | | | | .(53 1) "Colour of liquids |
| | | | . / 1.0 | :Sufated ash |
| | | ° 105 | | :Loss on drying |
| | | | | . / 10 |
| | TS / | 0.1 | 10 0.20 | :Acidity |
| | | VS (/ 0.01) | 0.30 | |
| | " | | | :Related substances |
| 67 | R1 | (84 1) | | "Thin layer chromatography |
| |) | R | 3 R | 30 |
| | 10 | .(| | |
| 0.10 (C) | | 0.10 (B) | | 20 (A) : |
| | | | | RS |
| | .VS (/ 0.1) | | | TS2 -4 |
| | | | TS 2 | |
| .B | | | | A |
| | | 20 | 0.15 | :Assay |

| | | | |
|--------|---------------|----|--|
| | .TS (/ 400~) | 25 | semi-micro |
| . 200 | VS (/ 0.01) | | 50 |
| . TS / | VS (/ 0.02) | | |
| 6.688 | VS (/ 0.01) | 1 | . |
| | | | .C ₁₃ H ₂₂ N ₂ O ₆ S |

Additional Requirements for Neostigmini metilsulfate for parenteral use

.(56 4) "Parenteral preparations"

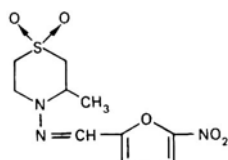
NIFURTIMOXUM

Nifurtimox

C₁₀H₁₃N₃O₅S :Molecular formula

287.3 :Relative molecular mass

:Graphic formula



:Chemical name

3-Methyl-4-[(5-nitrofurfurylidene)amino]thiomorpholine 1,1-dioxide; 3-methyl-*N*-[(5-nitro-2-furanyl)methylene]-4-thiomorpholinamine 1,1-dioxide; CAS Reg. No. 23256-30-6.

:Description

R

R

:Solubility

.R

R

.Antitrypanosomal drug

:Category

:Storage

REQUIREMENTS

%102.0

%98.0

:General requirement

$C_{10}H_{13}N_3O_5S$

:Identification tests

. C B A •
" :A

.(43 1) "Spectrophotometry in the infrared region
RS

. "Related substances " :B

.C B
0.25 . 2.0 R 2.0 20 :C

R 5 . R 4 TS (/ 160) (II)

. ° 182-178 :Melting range

. / 1.0 :Sulfated ash

5.0 ° 105 :Loss on drying

. /

" :Related substances

) R6 (84 1) "Thin layer chromatography
R R (

10 10 (A) :R
2 (C) 1.0 2 (B)

. RS 1.0

. 10

A .(254)
.B

| | | | | |
|------|------|--|--------------|---------------|
| 80 | R | 20 | 0.1 | :Assay |
| | | TS (/ 250~) | 5 | .TS (/ 750~) |
| | 30.0 | 3 | | R |
| 15 | | .TS (/ 200) | 3 | VS (/ 0.1) |
| 0.1) | | 1 | .VS (/ 0.1) | |
| | | .C ₁₀ H ₁₃ N ₃ O ₅ S | 4.788 | VS (/ |

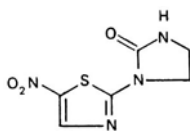
NIRIDAZOLUM

Niridazole

C₆H₆N₄O₃S **:Molecular formula**

214.2 **:Relative molecular mass**

:Graphic formula



:Chemical name

1-(5-Nitro-2-thiazolyl)-2-imidazolidinone; CAS Reg. No. 61-

57-4.

:Description

R

R

R

:Solubility

.R

TS (/ 750~)

R

:Category

:Storage

REQUIREMENTS

%103.0

%97.0

:General requirement

C₆H₆N₄O₃S

:Identification tests

| D C B | | A | | |
|-----------------------|------------------------------|---|-----------------|----|
| (43 1) | | "Spectrophotometry in the infrared region | | :A |
| . "Related substances | | RS | | :B |
| TS (/ 80~) | 2.0 | R | 2.0 20 | :C |
| | | 10 | | |
| | | ° 264 | | :D |
| " 1.0 | | :Heavy metals | | |
| (127 1) 3 | "Limit test for heavy metals | | | |
| / 20 | (128 1) | A | | |
| (/ 70~) | 2.0 | 0.5 | :Sulfates | |
| 10 | | | 8.0 TS | |
| VS (/ 0.5) | | 1.0 | | |
| 2.0 VS (/ 0.01) | 0.10 | | | |
| VS (/ 0.5) | 1.0 | 8.0 TS (/ 70~) | | |
| 10 0.10 | | :Solution in dimethylformamide | | |
| | | R | | |
| / 3.0 | | :Sufated ash | | |
| 0.6) | ° 100 | | :Loss on drying | |

. / 5.0 3 (5
 " :Related substances
) R6 (84 1) "Thin layer chromatography
 R 8 R 12 (5
 10 (A) :R 4
 RS 10 (B) ()
 (D) RS -5- -2 20 (C) ()
 . RS 40
 (365)
 A . 15
 . 15 D C
 R 4 40 :Assay
 100 5.0 200 dehydrated ethanol R
 359 1 .
 . RS C₆H₆N₄O₃S .
 .003±0.70 RS / 10

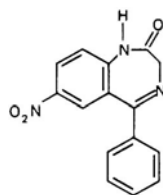
NITRAZEPAMUM

Nitrazepam

C₁₅H₁₁N₃O₃ :Molecular formula

281.3 :Relative molecular mass

:Graphic formula



:Chemical name

1,3-Dihydro-7-nitro-5-phenyl-2*H*-1,4-benzodiazepin-2-one;
CAS Reg. No. 146-22-5.

:Description

R

:Solubility

TS (/ 750~)

:Category

:Storage

REQUIREMENTS

%101.0

%98.5

:General requirement

$$\text{C}_{15}\text{H}_{11}\text{N}_3\text{O}_3$$

:Identification tests

$$I_{\text{max}} = 0.005 \text{ A}$$

R 9 VS (/ 1)

| | | | | |
|---|---|-----|-----|-----|
| 1 | . | 280 | 350 | 230 |
|---|---|-----|-----|-----|

. 0.45

| | | | | |
|------|---|---|----|----|
| 0.05 | R | 1 | 10 | :B |
|------|---|---|----|----|

TS (/ 80~)

5 10 TS (/ 420~) 5 20 :C

1 .TS (/ 1) 2

| | | |
|----------------|---|-----------|
| N-(1-naphthyl) | 1 | TS (/ 5) |
|----------------|---|-----------|

TS (/ 1) ethylenediamine hydrochloride

◦ 227 :D

11

1.0 :Heavy metals

(127 1) 3 "Limit test for heavy metals

. / 20 (128 1) A
 . / 1.0 :Sulfated ash
 . / 5.0 4 ° 105 :Loss on drying
 " :Related substances
 R4 (84 1) "Thin layer chromatography
 . R 15 R 85
 (A) :R R 10
 . 25 (B) 25
 . 12
 A . (254)
 .B
 R 30 0.25 :Assay
 potentiometrically VS (/ 0.1)
 1 . (142 1) A "Non-aqueous titration "
 .C₁₅H₁₁N₃O₃ 28.13 VS (/ 0.1)

NITROFURANTOINUM

Nitrofurantion

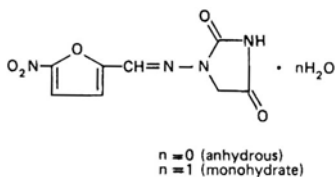
Nitrofurantion, anhydrous

Nitrofurantion, monohydrate

() C₈H₆N₄O₅·H₂O () C₈H₆N₄O₅ :Molecular formula

.() 256.2 () 238.2 :Relative molecular mass

:Graphic formula



:Chemical name

1-[(5-Nitrofurfurylidene)amino]hydantoin; 1-[(5-nitro-2-furanyl)methylene]amino]-2,4-imidazolidinedione; CAS Reg. No. 67-20-9 (anhydrous).

1-[(5-Nitrofurfurylidene)amino]hydantoin monohydrate; 1-[(5-nitro-2-furanyl)methylene]amino]-2,4-imidazolidinedione monohydrate; CAS Reg. No. 17140-81-7 (monohydrate).

.Furadoninum

:Other name

—

:Description

TS (/ 750~)

:Solubility

.R

:Category

:Storage

.° 25

:Labelling

. ° 271

:Additional information

. Stainless steel

REQUIREMENTS

%102.0

%98.0

:General requirement

. $C_8H_6N_4O_5$

:Identification tests

.D C B

A

●

"

:A

.(43 1) "Spectrophotometry in the infrared region

.° 105

RS

:

:B

0.3 20 R 3.6

R 50 0.12 . 200 R

. 100 5 . 1000

0.05 10

400 220 .R

0.46 0.32 1 . 367 266

.1.42 1.36 266 367 .

.R R 10 0.2 :C

0.2 TS (/ 80) (II) 0.15 2 0.5

. R 3 R

. VS(/ 0.1) 5 5 :D

—

. / 1.0 :Sulfated ash

10 ° 105 :Loss on drying

. / 71 / 50 . /

"

:Related substances

90 R2 (84 1) "Thin layer chromatography

10 . R 10 R

10 R 0.25 (A) :

.R 100 A 1 (B) R

/ . 5 ° 105

10 ° 105 TS

| | | | | |
|------|--------|--|------------------------|-------------------|
| | | A | | . (254) |
| | | | | .B |
| 10 R | | 10 | 0.4 | :Assay |
| | TS | / | 0.10 | R |
| " | | | VS (/ 0.1) | Lithium methoxide |
| 1 | . (142 | 1) B | "Non-aqueous titration | |
| | | .C ₈ H ₆ N ₄ O ₅ | 23.82 | VS (/ 0.1) |

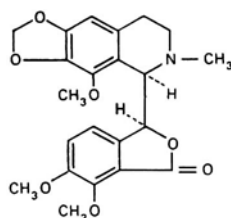
NOSCAPINUM

Noscapine

C₂₂H₂₃NO₇ :Molecular formula

413.4 :Relative molecular mass

:Graphic formula



:Chemical name

Narcotine; (5*R*)-5-[(1*S*)-6,7-dimethoxyphthalidyl]-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinoline; [*S*-(*R*^{*},*S*^{*})]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl)-1(3*H*)-isobenzofuranone; CAS Reg. No. 128-62-1.

:Description

R

:Solubility

.R TS (/ 750~)

:Category

•

of

%98.5

•



A

●

 $\cdot A$

.(43

•

R

:B

310

291

•

0.5

: C

:D

/ 20

 $\cdot [a]_D^{20^\circ\text{C}}$

:Sulfated ash

◦ 105

:Related substances

R5

(84

7 R

45 R

10

TS (/ 260~)

20 (A)

A

| | | | | | | |
|--------|------|---|----|--------|------|--|
| | R1 | | 40 | | 0.5 | :Assay |
| Non- | | " | | VS (/ | 0.1) | |
| VS (/ | 0.1) | | 1 | (142 | 1 |) A "aqueous titration |
| | | | | | | .C ₂₂ H ₂₃ NO ₇ 41.34 |

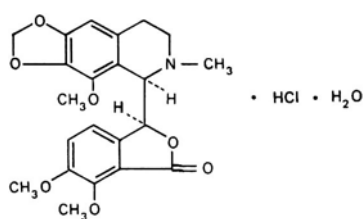
NOSCAPINI HYDROCHLORIDUM

Noscapine hydrochloride

C₂₂H₂₃NO₇,HCl,H₂O :Molecular formula

467.9 :Relative molecular mass

:Graphic formula



:Chemical name

Narcotine hydrochloride monohydrate; (5*R*)-5-[(1*S*)-6,7-dimethoxyphthalidyl]-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinoline hydrochloride monohydrate; [*S*-(*R*^{*},*S*^{*})]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl)-1(3*H*)-isobenzofuranone hydrochloride monohydrate; CAS Reg. No. 912-60-7 (anhydrous).

:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

:Additional information

REQUIREMENTS

%98.5

:General requirement

$C_{22}H_{23}NO_7, HCl$ %101.0

:Identification tests

| | | | D C B | | D A | | • |
|-------------------------------------|-----|--------------|-------|-------------|-----|-----|---|
| .R | 10 | TS (/ 100~) | | | 10 | 0.1 | :A |
| | | | | | 5 | | |
| | | | | | R | | 1 |
| "ophotometry in the infrared region | | | | | | " | |
| RS | | | | | | (43 | 1) |
| | 1 | R | 100 | TS (/ 35~) | | 5 | :B |
| / | | / | 0.050 | | .R | | 100 |
| 310 | 291 | | | 350 | 230 | | |
| 310 | | | | 263 | | | |
| | | | | 1.3 1.2 | 291 | | |
| TS(/ 1760~) | | | | | 0.1 | | :C |
| General | | " | | A | / | 20 | :D |
| | | | | (121 | 1 | | "identification tests |
| | / | 20 | | | | | |
| | | | | | | | :Specific optical rotation |
| | | | | | | | $[a]_D^{20°C} = + 38.5 \text{ to } + 44.0°$ |
| | | | | | | | VS (/ 0.01) |
| | | | | / | 1.0 | | :Sulfated ash |
| | / | 65 | | ° 105 | | | :Loss on drying |
| | | " | | | | | :Related substances |
| 45 | | R5 | | (84 | 1 | | "Thin layer chromatography |

3 TS (/ 750~) 7 R 45 R
:TS (/ 750~) 10 . TS(/ 260~)
. 0.20 (B) 20 (A)
VS (/ 0.1)
.B A .
7 50 0.5 :Assay
TS / 10 R1 3 R
Non-aqueous " VS (/ 0.1)
44.99 VS (/ 0.1) 1 .(142 1) A "titration
.C₂₂H₂₃NO₇,HCl

NYSTATINUM

Nystatin

Streptomyces

:

.A₁

noursei

.CAS Reg.NO.1400-61-9

:Chemical name

:Description

R TS (/ 750~)

:Solubility

.R R

:Category

:Storage

.° 5

:Additional information

%1

| 1 | | 4400 | | :General requirement | |
|---------------------------------|------|-----------------|-------------------|-----------------------|--------------------------------------|
| | | | | :Identification tests | |
| | R | 5 | R | 50 | 0.10 :A |
| | | .R | 100 | 1 | 100 R |
| 305 | 291 | | | 350 | 240 |
| | 291 | | 1 | | 319 |
| 305 | | 319 | | 0.73 | 0.61 305 |
| | | | | .0.96 | 0.83 |
| R | 0.1 | | 2 | 2 | 5 30 :B |
| | | | | | TS 100 |
| . | | | | | |
|) | ° 60 | :Loss on drying | | | |
| | | . | / | 50 | (5 kPa 0.6 |
| R | | | 10 | 0.3 | :pH value |
| | | | | | .8.0-6.5 |
| " | | | | | |
| :Assay | | | | | |
| | | .(155 | 1 |) " | Microbiological assay of antibiotics |
| <i>Saccharomyces cerevisiae</i> | | 6.2-6.0 | | Cm3 | 2-1 |
| 300 25) | | | | | (NCYC 87; ATCC 9763) |
| 75 | | . | ° 33-29 | (| 1 |
| | 200 | 10 | 50 | R | |
| fiducial | | | | | .TS3 6.0 |
| | %105 | %95 | estimated potency | (P = 0.95) | limits |
| | 4400 | (P = 0.95) | | | . |

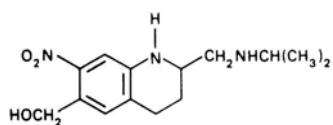
OXAMNIQUINUM

Oxamniquine

$C_{14}H_{21}N_3O_3$:Molecular formula

279.3 :Relative molecular mass

:Graphic formula



:Chemical name

1,2,3,4-Tetrahydro-2-[(isopropylamino)methyl]-7-nitro-6-quinolinemethanol; 1,2,3,4-tetrahydro-2-[[[1-methylethyl]amino]methyl]-7-nitro-6-quinolinemethanol; CAS Reg. No. 21738-42-1.

:Description

.R R R

:Solubility

:Category

:Storage

REQUIREMENTS

%97.0

:General requirement

$C_{14}H_{21}N_3O_3$ %103.0

:Identification tests

.C B A •
" :A

spectro-

.(43 1) " photometry in the infrared region

| | | | | | | | |
|---------------------------|------------------------|------|-----|------------------------------|--------------------------|------------------------------|-------------|
| | | | | RS | | | |
| | 0.5 | 1.0 | R | 10 | 10 | :B | |
| | 1 | | 5 | | .TS (/ 250~) | | |
| 0.5 | .TS (/ 50) | | | | TS (/ 100) | | |
| | TS (/ 80~) | 2.0 | TS1 | -2 | 0.5 | | |
| | | | | | | | |
| | | | | .° 151 | | :C | |
| " | | | | 0.5 | :Heavy metals | | |
| | (127 | 1 |) 3 | "Limit test for heavy metals | | | |
| | . / | 50 | | (128 | 1 |) A | |
| 30 | FeTS (/ 250~) | 5 | | 1.0 | :Iron | | |
| 1 |) "Limit test for iron | | | " | | | |
| | | . / | 50 | | (129 | | |
| | | . / | 2.0 | :Sulfated ash | | | |
| Determination of water by | | | " | :Water | | | |
| | 0.5 | (145 | 1 |) A | "the Karl Fischer method | | |
| | | | | | . / | 20 | |
| R | | | | 10 | 0.1 | :pH value | |
| | | | | | | | .10.0 - 8.0 |
| | " | | | :Related substances | | | |
| |) | R6 | | (84 | 1 |) "Thin layer chromatography | |
| 2 | R | 10 | R | 20 | (| | |
| 10 | | | | R | 0.5 | R | -2 |
| | 25 (A) | :R | R | | | | |
| | | | | | | 0.25 (B) | |
| | | | | | | 10 | |
| A | | | | | 365 | | 254 |

| | | | | | | |
|---|-------------|--|-------|------------------------|------------------|--------|
| | | | | | .B | |
| | R1 | | 30 | | 0.3 | :Assay |
| | VS (/ 0.1) | | .TS | | /R (oracet blue) | |
| 1 | .(142 | 1 |) A | "Non-aqueous titration | " | |
| | | .C ₁₄ H ₂₁ N ₃ O ₃ | 27.93 | VS (/ 0.1) | | |

XYTETRACYCLINI DIHYDRAS

Oxytetracycline dihydrate

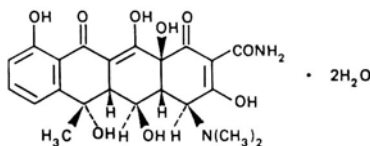
Oxytetracycline dihydrate (non-injectable) ()

Oxytetracycline dihydrate, sterile

C₂₂H₂₄N₂O₉·2H₂O :Molecular formula

496.5 :Relative molecular mass

:Graphic formula



:Chemical name

(4*S*,4*aR*,5*S*,5*aR*,6*S*,12*aS*)-4-(Dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,5,6,10,12,12*a*-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide dihydrate; [4*S*-(4*α*,4*αα*,5*α*,5*αα*,6*β*,12*αα*)]-4-(dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,5,6,10,12,12*a*-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide dihydrate; CAS Reg. No. 6153-64-6 (dihydrate).

:Description

TS (/ 750~)

:Solubility

:Category

:Storage

:Labelling

:Additional information

2

REQUIREMENTS

920

:General requirement

1

:Identification tests

"Thin layer chromatography

"

:A

25 : () (84 1)

47.5 R 2.5 50 R1 ()

.TS (/ 100~) 7 VS (/ 0.1)

90-70

R

2 R

2

200

7

VS (/ 0.1)

25

R

1

TS (/ 100~)

0.50 (B)

0.50 (A) :R

0.50

RS

0.50

(C)

RS

0.50

RS

TS (/ 260)

.(365)

. B

A

C

TS (/ 1760~)

2

1

:B

0.1

| | | | | | | | |
|---------------------------------------|------------------------------|--|---------------|--|--|--|--|
| | 0.25 | :Specific optical rotation | | | | | |
| | . | 60 | 25 | VS (/ 0.1) | | | |
| | | | | . [a] _D ^{20°C} = −203 to -216° | | | |
| | . | / 5.0 | :Sulfated ash | | | | |
| Determination of water by | " | | :Water | | | | |
| 0.25 | (1454 | 1 |) A | "the Karl Fischer method | | | |
| | . | / 75 | / 40 | | | | |
| .7.5-4.5 | / 10 | :pH value | | | | | |
| :Absorption in the ultraviolet region | | | | | | | |
| | VS (/ 0.1) | / 20 | | | | | |
| . | 353 | 268 | 400 | 230 | | | |
| | .0.58 | 0.54 | 353 | 1 | | | |
| / 2.0 | :Light-absorbing impurities | | | | | | |
| R | 99 | VS (/ 1) | | | | | |
| .0.25 | 430 | 1 | | | | | |
| R | 99 | VS (/ 1) | / 10 | | | | |
| .0.20 | 490 | 1 | | | | | |
| " | :Assay | | | | | | |
| <i>Bacillus</i> | (a) | (155 | 1 |)"Microbiological assay of antibiotics | | | |
| 6.6-6.5 | Cml | (NCTC 8241 or ATCC 14884) <i>pumilus</i> | | | | | |
| 20 2 |) | TS 4.5 | | | | | |
| (ATCC 11778) <i>Bacillus cereus</i> | (b) | ° 39-37 | (| | | | |
| TS 4.5 | 6.0-5.9 | Cml | | | | | |
| .° 33-30 | (| 2 0.5 |) | | | | |
| %95 | estimated potency (P = 0.95) | fiducial limits | | | | | |
| (P = 0.95) | . | %105 | | | | | |
| . | 900 | | | | | | |

Additional Requirements for Sterile Oxytetracycline Dihydrate

| Test | " | :Undue toxicity |
|----------------|-------------------------------------|---------------------------------|
| 40 | : | 0.5 (165 1) "for undue toxicity |
| R | | VS (/ 0.1) 2.0 |
| | | . 20 |
| 1 |) "Sterility testing of antibiotics | " :Sterility |
| R (macrogol P- | 1 | (162 |
| | .TS (/ 1) | isooctylphenyl ether) |

Additional requierments for Oxytetracycline dihydrate for sterile use

| Test for non injectable | " |
|-------------------------|--------------------------------|
| | .(32 5) "preparations |
| " | :Bacterial endotoxins |
| (30 5) | "Test for Bacterial endotoxins |
| . | 0.4 RS |

OXYTETRACYCLINI HYDROCHLORIDUM

Oxyetracycline hydrochloride

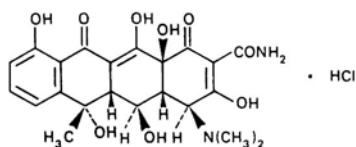
Oxyetracycline hydrochloride (non-injectable) ()

Oxyetracycline hydrochloride, sterile

$C_{22}H_{24}N_2O_9 \cdot HCl$:Molecular formula

496.9:Relative molecular mass

:Graphic formula



:Chemical name

(4*S*,4*aR*,5*S*,5*aR*,6*S*,12*aS*)-4-(Dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,5,6,10,12,12*a*-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide monohydrochloride; [4*S*-(4*α*,4*α*,5*α*,5*α*,6*β*,12*α*)]-4-(dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,5,6,10,12,12*a*-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide monohydrochloride; CAS Reg. No. 2058-46-0.

:Description

TS (/ 750~)

45

:Solubility

.R

R

:Category

:Storage

:Labelling

:Additional information

base

2

REQUIREMENTS

870

:General requirement

| | | | |
|----------------------------|-----------------------------------|------------------------------|--|
| | | :Identification tests | |
| "Thin layer chromatography | " | :A | |
| 25 | : | (| (84 1) |
| 47.5 | R | 2.5 | 50 R1 () |
| | .TS (/ 100~) | 7 | VS (/ 0.1) |
| . | | 90-70 | |
| R | 2 R | 2 | 200 |
| 7 | VS (/ 0.1) | 25 | R |
| 1 | . | | TS (/ 100~) |
| | 0.50 (B) | 0.50 (A) | :R |
| 0.50 | RS | 0.50 | (C) RS |
| . | | 0.50 | |
| | TS (/ 260) | | |
| A | . | (365) | |
| | | .B | |
| | | . | C |
| | TS (/ 1760~) | 2 | 1 :B |
| | | . | 0.1 |
| General | " | B | / 0.05 :C |
| | .(121 1) | | "identifications tests |
| 0.25 | :Specific optical rotation | | |
| . | 60 | 25 | VS (/ 0.1) |
| | | | . $[\alpha]_D^{20^\circ C} = -188$ to -200° |
| | / 5.0 | :Sulfated ash | |
| Determination of water by | " | :Water | |
| 20 | 0.25 | (145 1) A | "the Karl Fischer method |
| | | | . / |

0.4 RS

Sterility testing of " :Sterility

(162 1) "antibiotics

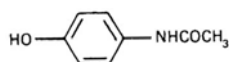
PARACETAMOLUM

Paracetamol

$C_8H_9NO_2$:Molecular formula

151.2 :Relative molecular mass

:Graphic formula



:Chemical name

4'-Hydroxyacetanilide; *N*-(4-hydroxyphenyl)acetamide; CAS
Reg. No. 103-90-2.

.Acetaminophen

:Other name

:Description

R TS (/ 750~)

:Solubility

. R

:Category

:Storage

REQUIREMENTS

%101.0

%98.5

:General requirement

$C_8H_9NO_2$

:Identity tests

(/ 0.1) 0.5 .R 100 0.05 :A
. 100 1 VS
.0.88 249 1
TS (/ 25) 0.05 10 0.1 :B
. 10 TS (/ 70~) 1 0.1 :C
VS (/ 0.0167) 0.05 .
.(Phenacetin)
. ° 172-168 :Melting range
85 1.0 :Heavy metals ()
Limit test for " 15 R
. / 10 (128 1) A "heavy metals
. / 1.0 :Sulfated ash
5.0 ° 105 :Loss on drying
. /
R 0.5 :4-Aminophenol -4
TS 0.2 . 10
-4 R 0.5 . 30
. R -4 / 0.050 0.5
.(/ 0.05)
" :Related substances
65 R4 silica gel "Thin-layer chromatography
. toluene R 10 R 25 R
. 14
1.0 (A) :
. 30 R 5
10 A 1 (B) . supernatant

750~) R -4 25 (C) .TS (/ 750~)

0.1 R -4 0.25 (D) .TS (/

200 . 100 TS (/ 750~)

40 A

.(254)

.C A -4

-4 B

D .C

R_f -4

10 0.25 :Assay

30 . TS (/ 70~)

combined solution R 1

.VS (/ 0.1) (143 1) "Nitrite titration"

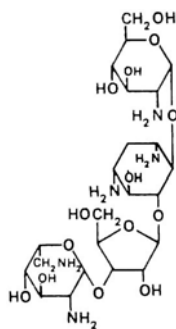
. $C_8H_9NO_2$ 15.12 VS (/ 0.1)

PAROMOMYCINI SULFAS

Paromomycin sulfate

$C_{23}H_{45}N_5O_{14} \cdot xH_2SO_4$:Molecular formula

:Graphic formula



O-2,6-Diamino-2,6-dideoxy- β -L-idopyranosyl-(1 \rightarrow 3)-*O*- β -D-ribofuranosyl-(1 \rightarrow 5)-*O*-[2-amino-2-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)]-2-deoxy-streptamine sulfate (salt); *O*-2-amino-2-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)-*O*-[*O*-2,6-diamino-2,6-dideoxy- β -L-idopyranosyl-(1 \rightarrow 3)- β -D-ribofuranosyl-(1 \rightarrow 5)]-2-deoxy-D-streptamine sulfate (salt); CAS Reg. No. 1263-89-4.

| R | TS (/ 750~) | Solubility |
|---|--------------|------------|
|---|--------------|------------|

Category

:Additional information

675 :General requirement

"Thin-layer chromatography" : A

$$\left(\begin{array}{cc} / & 40 \end{array} \right) \quad \text{R3} \quad \left(\begin{array}{cc} 84 & 1 \end{array} \right)$$

20 (A) : 1 . TS

RS 20 (B)

$$/ \quad \circ 105 \quad 10$$

5 ° 105 .TS (triketohydrindene /butanol)

.B

General " A / 0.05 B

.(123 1) "identification tests

/ 50 :Specific optical rotation
 $[\alpha]_D^{20^\circ C} = + 50 \text{ to } +55^\circ$
 . / 20 :Sulfated ash
) ° 50 :Loss on drying
 . / 50 (5 0.6
 .7.5 – 5 R / 30 :pH Value
 " :Assay
Bacillus (a) (155 1) "Microbiological assay of antibiotics
 8.0 (pH) Cml test organism (NCTC 10400) *subtilis*
 37 (/IU 4 1) TS 7.8
 test organism (ATCC 6633) *Bacillus subtilis* (b) ° 39 –
 TS2 TS1 8.0 7.8 Cml
 fiducial .° 38 – 36 (/IU 8 2)
 %105 %95 ($P = 0.95$) estimated potency limits
 / IU 675 ($P = 0.95$) .

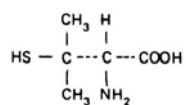
PENICILLAMINUM

Penicillamine

$C_5H_{11}NO_2S$:Molecular formula

149.2 :Relative molecular mass

:Graphic formula



:Chemical name

| | | | |
|--|--------------|--|--|
| No. 52-67-5. | | 3-Mercapto-D-valine; 3,3-dimethyl-D-cysteine; CAS Reg. | |
| . | | :Description | |
| TS (/ 750~) | | 9 | :Solubility |
| | | .R R | |
| | | .antidote | :Category |
| . | | | :Storage |
| :Additional information | | | |
| . | | | |
| REQUIREMENTS | | | |
| %100.5 | %95 | :General requirement | |
| | | . | C ₅ H ₁₁ NO ₂ S |
| :Identity testes | | | |
| | TS | 2 | 4 20 :A |
| . | | | |
| 20 | TS (/ 200~) | 0.05 | 5 20 :B |
| . | | | |
| R | | | |
| / 50 | | | |
| :Specific optical rotation | | | |
| . [a] _D ^{20°C} = - 58 to - 68° VS (/ 1) | | | |
| . / 1 | | | |
| :Sulfated ash | | | |
|) ° 60 | | | |
| :Loss on drying | | | |
| . / 5 (5 0.6 | | | |
| .6.0 – 4.0 / 10 | | | |
| :pH Value | | | |
| :Mercury | | | |
| . | | | |
| : | | | |
| 650 | | 0.5 | |

TS (/ 1000~) 2.5 °45

TS (/ 1760~) 2.5 . (30 – 5)

TS (/ 1000~) 2.5 .

50 .

250 . (25)

1 TS (/ 20) 1 . 50

R R

10 90 VS (/ 0.125) 50 .

TS .TS (/ 200)

. 10 0.5 – 0.3

TS .

TS

20

5 50 0.1 :Assay

1 .VS (/ 0.02) TS 0.2 VS (/ 1)

.C₅H₁₁NO₂S 5.968 VS (/ 0.02)

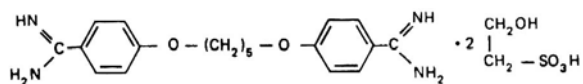
PENTAMIDINI ISETIONAS

Pentamidine isetionate

C₁₉H₂₄N₄O₂·2C₂H₆O₄S :Molecular formula

592.7 :Relative molecular mass

:Graphic formula



| | | | |
|--------------|--|--|---------------------|
| | | :Chemical name | |
| | | 4,4'-(Pentamethylenedioxy)dibenzamidine bis(2-hydroxyethanesulfonate); 4,4'-[1,5-pentanediylbis(oxy)]bis[benzenecarboximidamide]-bis(2-hydroxyethanesulfonate); CAS Reg. No. 140-64-7. | |
| | | :Description | |
| TS (/ 750~) | | 10 | :Solubility |
| | | .R | R |
| | | :Category | |
| | | :Storage | |
| | | :Additional information | |
| | | REQUIREMENTS | |
| %98.5 | | :General requirement | |
| | | $C_{19}H_{24}N_4O_2 \cdot 2C_2H_6O_4S$ %102.5 | |
| | | :Identification tests | |
| VS (/ 0.01) | | / | :A |
| | | 262 | 350 230 |
| | | | 0.47 1 |
| 10 | | ° 80 | 5 0.5 :B |
| (/ 1000~) | | 0.2 2 | TS (/ 50~) |
| | | TS ceric | 0.2 TS |
| | | ° 190 | :C |
| | | / 1.0 | :Sulfated ash |
| 40 | | ° 105 | :Loss on drying |
| | | | / |
| | | .6.5 – 4.5 / 0.05 | :pH Value |
| | | " | :Related substances |

R6 silica gel (84 1) "Thin-layer chromatography
 () ° 105
 . R R -1 8 10
 50 (A) :R 10
 0.25 (B)
 A .(254)
 .B
 Determination of " A :Assay
 9 0.4 (147 1) "nitrogen
 VS (/ 0.05) 1 .TS (/ 1760~)
 .C₁₉H₂₄N₄O₂·2C₂H₆O₄S 14.82

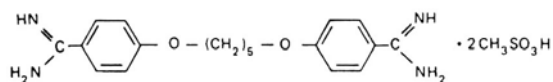
PENTAMIDINI MESILAS

Pentamidine mesilate

C₁₉H₂₄N₄O₂·2CH₃SO₃H :Molecular formula

532.6 :Relative molecular mass

:Graphic formula



:Chemical name

4,4'-(Pentamethylenedioxy)dibenzamidine dimethanesulfonate; 4,4'-[1,5-pentanediylobis(oxy)]bis[benzenecarboximidamide] dimethanesulfonate; CAS Reg. No. 6823-79-6.

:Description

R R TS (/ 750~) :Solubility

. R

:Storage

%98.5

$$\text{C}_{19}\text{H}_{24}\text{N}_4\text{O}_2, 2\text{CH}_4\text{O}_3\text{S} \quad \%102.5$$

| | | | | |
|-----|--------------|-------------|---------------|----|
| 10 | ° 80 | 5 | 0.5 | :A |
| 0.2 | 2 | TS (/ 50~) | | |
| | TS ceric | 0.2 | TS (/ 1000~) | |
| | TS (/ 400~) | 1 | 0.5 | :B |

TS (/ 50~) 10 ° 80 10 1 :C
 ° 105 10 (D)
 , ° 188

60~) 2.5 C 10 :D
1 1 . TS (/
() R
70~) . 5 .
" A 30 . 3 TS (/
(123 1) "General identification tests

15 ◦ 105

.6.5 – 4.5 / 0.05 :pH Value

278

R6 silica gel (84 1) "Thin-layer chromatography
 () ° 105
 . R R -1 8 10
 50 (A) :R 10
 . 0.25 (B) ()
 . (254)
 .B A
 Determination of " A :Assay
 9 0.4 (147 1) "nitrogen
 VS (/ 0.05) 1 .TS (/ 1760~)
 .C₁₉H₂₄N₄O₂·2CH₄O₃S 13.32

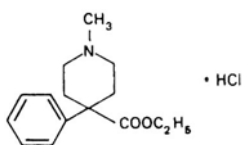
PETHIDINI HYDROCHLORIDUM

Pethidine hydrochloride

C₁₅H₂₁NO₂·HCl :Molecular formula

283.8 :Relative molecular mass

:Graphic formula



:Chemical name

Ethyl 1-methyl-4-phenylisonipeccate hydrochloride; ethyl 1-methyl-4-phenyl-4-piperidinecarboxylate hydrochloride; CAS Reg. No. 50-13-5.

:Other name

:Description

. R TS (/ 750~) :Solubility

•

•

•

%98.0

•



%101.0

•

0.1

5

TS (/ 1760~)

15

5

:B

.(C

) .(picrate

)

◦ 190

5

◦ 20

11

/ 10

$$\cdot \begin{pmatrix} 121 & 1 \end{pmatrix}$$

"identification tests

:Melting range

:Clarity and colour of solution

:Sulfated ash

◦ 105

/

:pH Value

:Related substances

R1 () (84 1) "Thin-layer chromatography
 5 R 9 R -2
 15
 .
 .
 R -2 8 R1 100 R
 0.5 5 0.10
 . R 2 TS (/ 400~)
 .B 50 A 0.5 .A
 .B A 5
 . 12 10
 5 .TS 10
 .
 A .(365)
 .B
 10 R1 30 0.20 :Assay
 VS (/ 0.1) TS /
 1 .(142 1) A "Non-aqueous titration "
 .C₁₅H₂₁NO₂.HCl 28.38 VS (/ 0.1)

Additional requirements for Pethidine hydrochloride for parenteral use

.(56 4) "Parenteral preparations "

"

:Bacterial endotoxins

(30 5) "Test for Bacterial endotoxins

2.4 RS

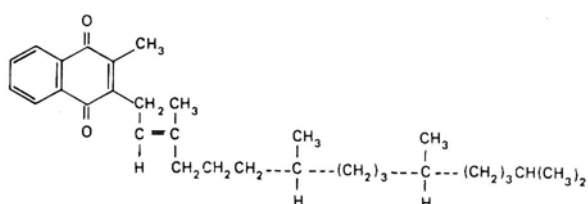
PHYTOMENADIONUM

Phytomenadione

$C_{31}H_{46}O_2$:Molecular formula

450.7 :Relative molecular mass

:Graphic formula



:Chemical name

Phylloquinone; [*R**,*R**-(*E*)]-2-methyl-3-(3,7,11,15-tetramethyl-2-hexadecenyl)-1,4-naphthalenedione; 2-methyl-3-phytyl-1,4-naphthoquinone; CAS Reg. No. 84-80-0.

.K₁

Phytonadione

:Other name

:Description

TS (/ 750~)

:Miscibility

.R

R

:Category

:Storage

REQUIREMENTS

102.0

%97.0

:General requirements

.C₃₁H₄₆O₂

:Identity tests

R

-4 2 2

/

10

:A

261

249

243

4

350

230

0.42 0.40 1 . 270
 266 254 246 . 0.39 0.38
 0.70 249 254 .
 .0.75
 R -4 2 2 / 0.10 :B
 243 350 230
 . 0.22 0.70 1 . 285
 1.0 TS (/ 750~) 5 0.05
 15 . TS1 /

. n_D^{20} = 1.525–1.529 :Refractive index

R 20 1 :Acidity or alkalinity
 .R

:Related substances

silica (84 1) "Thin-layer chromatography "
 R 20 R 80 R4 gel
 :R -4 2 2 10 . R
 . R 0.05 (B) 5 (A)
 .(254)
 B
 .B

:Assay

. :
 . 100 R -4 2 2 0.1
 100 10 R -4 2 2 100 10
 249 1 .
 . $(A_{1cm}^{1\%} = 420)$ 42 C31H46O2

| | |
|---|-------------------------------------|
| Additional requierments for Phytomenadione for parenteral use | |
| (56 | 4) "Parenteral preparations" |
| " | |
| | :Bacterial endotoxins |
| (30 | 5) "Test for Bacterial endotoxins" |
| | 14 RS |
| PIX LITHANTHRACIS | |
| Coal tar | |
| | :Composition |
| CAS Reg. No. | |
| | .8007-45-2 |
| | :Description |
| (/ 750~) | |
| | :Solubility |
| | .R R R TS |
| | :Category |
| | :Storage |
| | :Additional information |
| | sooty |

REQUIREMENTS

| | |
|----|----------------|
| | :Identity test |
| 30 | R1 |
| 10 | 0.5 |
| .(| 365) |
| | / 20 |
| | :Sulfated ash |

PRAZIQUANTELUM

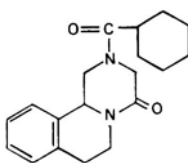
Praziquantel

9 :

$C_{19}H_{24}N_2O_2$:Molecular formula

312.4 :Relative molecular mass

:Graphic formula



:Chemical name

2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4*H*-pyrazino-[2,1-*a*]isoquinolin-4-one; CAS Reg. No. 55268-74-1.

:Description

.R TS (/ 750~)

:Solubility

:Category

:Storage

REQUIREMENTS

%101 %98.5

:General requirement

$C_{19}H_{24}N_2O_2$

:Identity tests

.C B A •

" :A

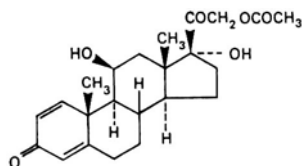
.(43 1) "Spectrophotometry in the infrared region

RS

A . "Related substances " :B

.B

:Graphic formula



:Chemical name

11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 21-acetate;
21-(acetyloxy)-11β,17-dihydroxypregna-1,4-diene-3,20-dione; CAS Reg. No. 52-21-1.

:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

:Additional information

° 235

REQUIREMENTS

%96.0

:General requirement

$C_{23}H_{30}O_6$ %104.0

:Identity test

.C B

C A

•

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

"Thin-layer chromatography

"

:B

10

R1 ()

(84 1)

5

R

90 R

| | | | | |
|--|---|---------------|------------------------------|----|
| 2 | .R | 25 | R | 75 |
| 2.5 (A) | :R | R | 9 | |
| 15 | RS | 2.5 (B) | | |
| 15 ° 120 | | | | |
| (/ 750~) | 80 TS (/ 190~) | 20 | | |
| 365) | | 10 ° 120 | | |
| .B | A | . (| | |
| TS (/ 700~) | 2 TS (/ 750~) | 2 0.05 | :C | |
| | . () | | | |
| R / 10 | :Specific optical rotation | | | |
| | . [a] _D ^{20°C} = + 112 to +119° | | | |
| 10 ° 105 | :Loss on drying | | | |
| | . / | | | |
| " | :Related substances | | | |
| R1 silica gel | (84 | 1 |) "Thin-layer chromatography | |
| 0.2 R | 5 | R | 95 | |
| R | 9 | 1 | | |
| 0.30 (B) | 15 (A) | :R | | |
| 10 ° 105 | TS | / | | |
| | A | | | |
| | .B | | | |
| 5 100 R | 20 | :Assay | | |
| 1 | 100 | | | |
| C ₂₃ H ₃₀ O ₆ | 243 | | | |

0.02 ± 0.37

RS

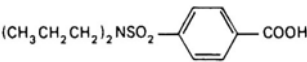
PROBENECIDUM

Probenecid

C₁₃H₁₉NO₄S :Molecular formula

285.4 :Relative molecular mass

:Graphic formula



:Chemical name

p-(Dipropylsulfamoyl)benzoic acid; 4-[(dipropylamino)sulfonyl]benzoic acid; CAS Reg. No. 57-66-9.

:Description

12 TS (/ 750~)

25

:Solubility

R

R

:Category

:Storage

REQUIREMENTS

%101.0

%98.0

:General requirement

C₁₃H₁₉NO₄S

:Identity tests

.C B

A

●

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

A

." "

:B

.B

()

.° 199

:C

"

1.0

:Heavy metals

(127 1) 3

"Limit test for heavy metals"

. / 20

(128 1) A

. / 1.0

:Sulfated ash

5.0

° 105

:Loss on drying

. /

30

100 2

:Acidity

TS /

0.15

0.5

VS (/ 0.1)

"

:Related substances

R4

(84 1) "Thin-layer chromatography

.

TS (/ 17~)

3 R

-1

15

(A) :TS (/ 750~)

9 TS (/ 17~)

0.050 (C)

RS

10 (B)

10

20

.B A

1

.C A

A

.(254)

() A

.B

.C

TS

50

1.0

:Assay

TS / VS (/ 0.1)

.C₁₃H₁₉NO₄S 28.54 VS (/ 0.1)

PROCAINI BENZYL PENICILLINUM

Procaine benzylpenicillin

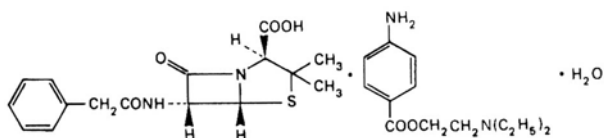
Procaine benzylpenicillin (non-injectable) ()

Procaine benzylpenicillin, sterile

C₁₆H₁₈N₂O₄S, C₁₃H₂₀N₂O₂, H₂O :Molecular formula

588.7 :Relative molecular mass

:Graphic formula



:Chemical name

2-(Diethylamino)ethyl *p*-aminobenzoate compound with (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylic acid (1:1) monohydrate; 2-(diethylamino)ethyl 4-aminobenzoate compound with [2*S*-(2*α*,5*α*,6*β*)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:1) monohydrate; CAS Reg. No. 6130-64-9 (monohydrate).

G

:Other names

:Description

.R TS (/ 750~)

:Solubility

:Category

:Storage

:Labelling

REQUIREMENTS

| | | | |
|-------|----------------------|---|---|
| %96.0 | :General requirement | | |
| %41.5 | %38.5 | C ₁₆ H ₁₈ N ₂ O ₄ S;C ₁₃ H ₂₀ N ₂ O ₂ | %100.5 |
| | | . | C ₁₃ H ₂₀ N ₂ O ₂ |

| | | | | |
|---------------|---|---|------|----|
| TS (/ 1760~) | 2 | 2 | 0.05 | :A |
|---------------|---|---|------|----|

TS / 2 2 .

TS / 0.5 10 10 :B
1.0 VS (/ 0.01)

General " 0.05 :C (119 1) "identification

| Determination of water by | | "the Karl Fisher Method" | |
|---------------------------|------|--------------------------|-----|
| 0.5 | (145 | 1 |) A |
| | . | / | 42 |
| | | / | 28 |

:pH Value

.7.5 – 5.0 R

:Assay

1000 0.045 :

10.0 2.0

25 ° 60 TS /

10.0 (A) ° 20 .

(B)

314 1

A TS / 10.0 2.0

.B

B A $C_{16}H_{18}N_2O_4S, C_{13}H_{20}N_2O_2$

0.050

$C_{16}H_{18}N_2O_4S, C_{13}H_{20}N_2O_2$ 1.601 ($C_{16}H_{17}N_2NaO_4S$) RS

0.03 ± 0.62

5 10 0.5 :

R 25 TS (/ 75)

20.0 .

TS / 0.25 . VS (/ 0.1)

23.63 VS (/ 0.1) 1 .VS (/ 0.1)

$C_{13}H_{20}N_2O_2$

Additional Requirements for Sterile Procaine Benzyl penicillin

"Test for non injectable preparations"

(32 5)

"

:Bacterial endotoxins

(30 5) "Test for Bacterial endotoxins"

0.01 RS

Sterility testing of

"

:Sterility

TS

(162 1) "antibiotics"

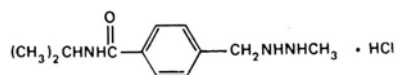
PROCARBAZINI HYDROCHLORIDUM

Procarbazine hydrochloride

$C_{12}H_{19}N_3O \cdot HCl$:Molecular formula

257.8 :Relative molecular mass

:Graphic formula



:Chemical name

N-Isopropyl- α -(2-methylhydrazino)-*p*-toluamide monohydrochloride; *N*-(1-methylethyl)-4-[(2-methylhydrazino)methyl]benzamide monohydrochloride; CAS Reg. No. 366-70-1.

:Description

TS (/ 750~)

R

:Solubility

.R

R

:Category

:Storage

° 223

:Additional information

REQUIREMENTS

%98.5

:General requirement

$C_{12}H_{19}N_3O \cdot HCl$ %100.5

:Identity tests

Spectrophotometry in " :A
 .(43 1) "the infrared region
 RS
 General " B / 0.10 :B
 .(121 1) "identification tests
 " 1.0 :Heavy metals
 (127 1) 1 "Limit test for heavy metals"
 . / 20 (128 1) A
 . / 1.0 :Sulfated ash
 5 ° 105 :Loss on drying
 . /
 .4.5 – 3.0 / 0.05 :pH Value
 1080~) 5 0.125 :Assay
 TS / 5 R1 20 TS (/
 Non- " VS (/ 0.1)
 VS (/ 0.1) 1 .(142 1) A "aqueous titration
 .C₁₂H₁₉N₃O₃·HCl 25.78

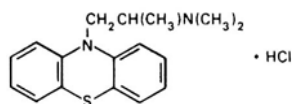
PROMETHAZINI HYDROCHLORIDUM

Promethazine hydrochloride

C₁₇H₂₀N₂S·HCl :Molecular formula

320.9 :Relative molecular mass

:Graphic formula



:Chemical name

10-[2-(Dimethylamino)propyl]phenothiazine monohydrochloride; *N,N*, α -trimethyl-10*H*-phenothiazine-10-ethanamine monohydrochloride; CAS Reg. No. 58-33-3.

.Diprazinum

:Other name

:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

:Additional information

REQUIREMENTS

%98.5

:General requirement

C₁₇H₂₀N₂S₂HCl %101

:Identity tests

| | | | | |
|--------|------|---|----|----|
| R (IV) | 0.05 | 5 | 20 | :A |
|--------|------|---|----|----|

| | | | | |
|--------|----|----|------|----|
| (/ 7) | 25 | 25 | 0.25 | :B |
|--------|----|----|------|----|

10 TS

. () ° 160 TS (/ 750~)

| | | | | |
|---------------|---|---|------|----|
| TS (/ 1000~) | 2 | 5 | 0.05 | :C |
|---------------|---|---|------|----|

11

A

.(121 1) "General identification tests

| | | | |
|---|----|-----|-------------------------|
| R | 10 | 1.0 | :Solution in chloroform |
|---|----|-----|-------------------------|

Ywl

Additional Requirements for Promethazine hydrochloride for parenteral use

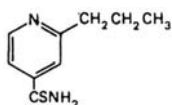
PROTIONAMIDUM

Protionamide

$C_9H_{12}N_2S$:Molecular formula

180.3 :Relative molecular mass

:Graphic formula



:Chemical name

2-Propylthioisonicotinamide; 2-propyl-4-pyridinecarbothioamide; CAS Reg. No. 14222-60-7.

:Description

R TS (/ 750~)

:Solubility

.R R

:Category

:Storage

REQUIREMENTS

%101.0

%98.0

:General requirement

$C_9H_{12}N_2S$

:Identity tests

.D C B

D A

•

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

230

TS (/ 750~)

/

10

:B

1 291 350
.0.39
VS (/ 1) 5 0.1 :C
. R
.° 141 :D
" 1 :Heavy metals
(127 1) 3 "Limit test for heavy metals"
. / 20 (128 1) A
. / 1.0 :Sulfated ash
5.0 ° 105 :Loss on drying
. /
20 R 20 2.0 :Acidity
TS / VS (/ 0.1)
.() 0.2
" :Related substances
R4 silica gel (84 1) "Thin-layer chromatography
. R R 9
0.25 (B) 50 (A) :R 5
. A .(254)
.B
R1 30 0.45 :Assay
Non-aqueous " VS (/ 0.1)
18.03 VS (/ 0.1) 1 .(142 1) A titration
.C₉H₁₂N₂S

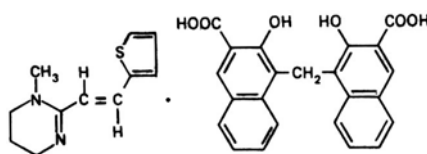
PYRANTELI EMBONAS

Pyrantel embonate

$C_{11}H_{14}N_2S, C_{23}H_{16}O_6$:Molecular formula

594.7 :Relative molecular mass

:Graphic formula



:Chemical name

(*E*)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine compound with 4,4'-methylenedibis[3-hydroxy-2-naphthoate] (1:1); (*E*)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)ethenyl]pyrimidine 4,4'-methylenedibis[3-hydroxy-2-naphthalenecarboxylate] (1:1); CAS Reg. No. 22204-24-6.

.Pyrantel pamoate

:Other name

:Description

R

R

:Solubility

.R

:Category

:Storage

REQUIREMENTS

%97.0

:General requirement

$C_{11}H_{14}N_2S, C_{23}H_{16}O_6$ %103.0

:Identity tests

.D C B

D A

•

Spectrophotometry in

"

:A

(43 1) "the infrared region
 RS
 230 R / 13 :B
 300 288 360
 1.0 300 288
 1.0 TS (/ 70~) 1.0 5 :C
 TS /
 ° 250 :D
 / 5.0 :Sulfated ash
 0.6) ° 60 :Loss on drying
 / 20 3 (5
 " :Related substances
 R2 silica gel (84 1) "Thin-layer chromatography
 R 1.5 R 5 R 20
 5 R 5 100
 0.20 (B) 20 (A) :TS (/ 260~) 0.5 R
 10
 .(254)
 .B A
 :Assay
 interruptions •
 .low actinic
 10 200 0.10
 (/ 140~) TS (/ 100~) 10 R
 . 50 5 10 :TS
 250 25 . TS (/ 140~)
 . R 100

| | | | |
|---|---------------|-----|--------------|
| | R | 100 | |
| | VS (/ 0.05) | 40 | . |
| 40 | | | . |
| 100 | | | VS (/ 0.05) |
| .VS (/ 0.05) | | | |
| 311 | | 1 | |
| C ₁₁ H ₁₄ N ₂ S,C ₂₃ H ₁₆ O ₆ | .VS (/ 0.05) | | |
| | RS | | |

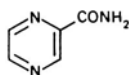
PYRAZINAMIIDUM

Pyrazinamide

C₅H₅N₃O :Molecular formula

123.1 :Relative molecular mass

:Graphic formula



:Chemical name

Pyrazinecarboxamide; CAS Reg. No. 98-96-4.

:Description

.TS (/ 750~)

R

:Solubility

:Category

:Storage

REQUIREMENTS

%101.0

%98.5

:General requirement

C₅H₅N₃O

| | | | | |
|---|-----------------------|-------------|------|---------|
| 54 | R | 15 | 0.07 | :Assay |
| 0.1) | | TS | 0.15 | R |
|) A | Non-aqueous titration | " | | VS (/ |
| .C ₅ H ₅ N ₃ O | 12.31 | VS (/ 0.1) | 1 | .(142 1 |

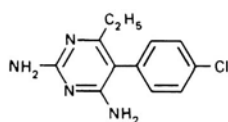
PYRIMETHAMINUM

Pyrimethamine

C₁₂H₁₃ClN₄ :Molecular formula

248.7 :Relative molecular mass

:Graphic formula



:Chemical name

2,4-Diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine; 5-(4-chlorophenyl)-6-ethyl-2,4-pyrimidinediamine; CAS Reg. No. 58-14-0.

:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

REQUIREMENTS

%101.0

%99.0

:General requirement

C₁₂H₁₃ClN₄

:Identity tests

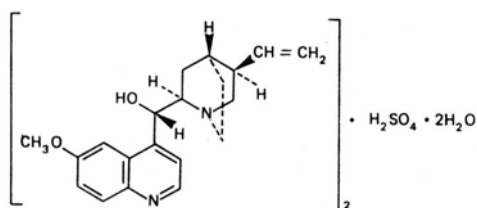
QUINIDINI SULFAS

Quinidine sulfate

$(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4 \cdot 2H_2O$:Molecular formula

783.0 :Relative molecular mass

:Graphic formula



:Chemical name

Quinidine sulfate (2:1) (salt), dihydrate; (9*S*)-6'-methoxycinchonan-9-ol sulfate (2:1) (salt), monohydrate; CAS Reg. No. 6591-63-5 (dihydrate).

:Description

TS (/ 750~)

:Solubility

.R

R

:Category

:Storage

:Additional information

REQUIREMENTS

%99.0

:General requirement

$C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4$

%101.0

:Identity tests

.(B

)

10

0.10

:A

| | | | | | | | | |
|---------------|---|---------------------|---------------------------------|----------------------------|----------|----|--|--|
| General | 5 | | TS (/ 100~) | | 1.0 | | | |
| | 1.0 | TS1 | 0.15 | 4 A | 1.0 | :B | | |
| | TS (/ 40) | | 1 | TS (/ 100~) | | :C | | |
| | .TS (/ 130~) | | 5 0.05 | | | | | |
| | " | | A | / 20 | :D | | | |
| | .(123 1) | | "identification tests | | | | | |
| | / 20 | | :Specific optical rotation | | | | | |
| | .[a] _D ^{20°C} = + 275 to + 290° | | VS (/ 0.1) | | | | | |
| | 10 | 0.20 | :Clarity and colour of solution | | | | | |
| | Yw2 | | VS (/ 0.1) | | | | | |
| .(53 1) | | "Colour of liquids" | | | | | | |
| . / 1 | | :Sulfated ash | | | | | | |
| 30 | ° 130 | | :Loss on drying | | | | | |
| | | . / 50 | | / | | | | |
| .6.8 - 6.0 R | | / 10 | | :pH Value | | | | |
| " | | :Related substances | | | | | | |
| R1 silica gel | | (84 1) | | "Thin-layer chromatography | | | | |
| R | 5 R | | 12 R | 20 | | | | |
| 10 (A) | | :R | 4 | 4 | . | | | |
| 10 (D) | | R | 0.25 (C) | R | 0.25 (B) | | | |
| 15 | | | .C | 1 | | | | |
| 30 ° 105 | | .development | | | | | | |
| | | TS | | | | | | |
| .C | B | A | | | | | | |
| | | A | | | | | | |
| | | D | | | | | | |

| | | | |
|-----------------------|----------------|---|--|
| 20 | 0.2 | :Limit of dihydroquinidine | |
| 0.1 | TS (/ 70~) | 15 | R |
| | VS (/ 0.0167) | TS | / |
| 5 | | 200 | 0.5 |
| | VS (/ 0.1~) | excess | |
| | | TS | 2 |
| | | (C ₂₀ H ₂₄ N ₂ O ₂) ₂ ·H ₂ SO ₄ | 18.67 VS (/ 0.0167) |
| | .%15 | | |
| 20 | R | 10 | 0.20 |
| | | VS (/ 0.1) | |
| Non-aqueous titration | | " | |
| 24.90 | VS (/ 0.1) | 1 | (142 1) A |
| | | | ·(C ₂₀ H ₂₄ N ₂ O ₂) ₂ ·H ₂ SO ₄ |

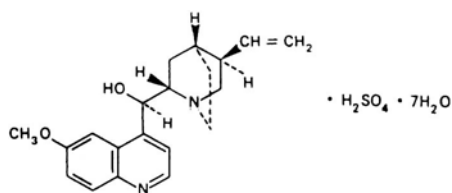
QUININI BISULFAS

Quinine bisulfate

C₂₀H₂₄N₂O₂·H₂SO₄·7H₂O **:Molecular formula**

548.6 **:Relative molecular mass**

:Graphic formula



:Chemical name

Quinine sulfate (1 : 1) (salt), heptahydrate;
 (8αS,9R)-6'-methoxycinchonan-9-ol sulfate (1 : 1) (salt), heptahydrate;
 (8S,9R)-9-hydroxy-6'-methoxycinchonan sulfate (1 : 1) (salt), heptahydrate; CAS
 Reg. No. 6183-68-2 (heptahydrate).

| | | | |
|---|---|---------------------------------|-----------|
| | | :Description | |
| .TS (/ 750~) | | :Solubility | |
| | | :Category | |
| | | :Storage | |
| effloresce | | :Additional information | |
| REQUIREMENTS | | | |
| %98.5 | | :General requirement | |
| C ₂₀ H ₂₄ N ₂ O ₂ ·H ₂ SO ₄ | | %101.5 | |
| :Identity tests | | | |
| TS (/ 100~) | | 0.05 | 10 5 :A |
| | | .(B) | |
| TS (/ 100~) | | 1.0 TS1 | 0.15 A :B |
| TS (/ 40) | | 1 | 5 0.05 :C |
| General | " | A / 20 | :D |
| | | .(123 1) "identification tests | |
| / 30 | | :Specific optical rotation | |
| .[a] _D ^{20°C} = −208 to −216° | | VS (/ 0.1) | |
| 10 0.20 | | :Clarity and colour of solution | |
| Y _w 2 | | VS (/ 0.1) | |
| .(53 1) " | | "Colour of liquids " | |
| | | . / 1.0 :Sulfated ash | |
| 0.6) | | :Loss on drying | |
| . / 240 | | / 190 18 (5 | |

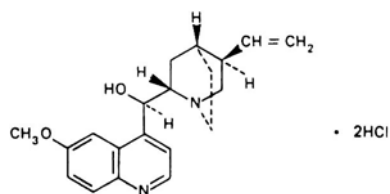
QUININI DIHYDROCHLORIDUM

Quinine dihydrochloride

$C_{20}H_{24}N_2O_2 \cdot 2HCl$:Molecular formula

397.3 :Relative molecular mass

:Graphic formula



:Chemical name

(8*αS*,9*R*)-6'-Methoxycinchonan-9-ol dihydrochloride; (8*S*,9*R*)-9-hydroxy-6'-methoxycinchonan dihydrochloride; CAS Reg. No. 60-93-5.

:Description

(/ 750~)

R

:Solubility

.R

TS

:Category

:Storage

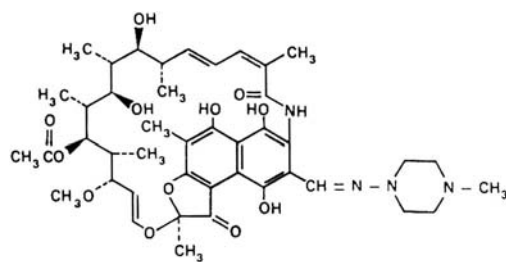
:Additional information

REQUIREMENTS

%99.0

:General requirement

| | | | | | |
|---|---------|---|--------|-----------------------|----|
| | | C ₂₀ H ₂₄ N ₂ O ₂ ·2HCl | | %101.0 | |
| :Identity tests | | | | | |
| TS (/ 100~) | | 0.05 | 10 | 5 | :A |
| .(B) | | | | | |
| TS (/ 100~) | | 1.0 TS1 | 0.15 A | :B | |
| | | | | | |
| TS (/ 40) | | 1 | 5 | 0.05 | :C |
| General | " | A | / 20 | :D | |
| | | .(121 1) | | "identification tests | |
| / 30 | | :Specific optical rotation | | | |
| . [α] _D ^{20C} = −223 to −299° | | VS (/ 0.1) | | | |
| 10 0.20 | | :Clarity and colour of solution | | | |
| Yw2 | | VS (/ 0.1) | | | |
| .(53 1) | | "Colour of liquids" | | | |
| | | . / 1.0 | | :Sulfated ash | |
| 30 | ° 105 | :Loss on drying | | | |
| . / | | | | | |
| | | .3.0-2.0 / 30 | | :pH Value | |
| :Related cinchona alkaloids | | | | | |
| R1 | (84 1) | "Thin-layer chromatography" | | | |
| R | 5 R | 12 R | 20 | | |
| 10 (A) | :R | 4 | 4 | | |
| 10 (D) | R | 0.25 (C) | R | 0.25 (B) | |
| | | .C 1 | | | |
| 30 ° 105 | | .development | | 15 | |
| TS | | | | | |



:Chemical name

(2*S*,12*Z*,14*E*,16*S*,17*S*,18*R*,19*R*,20*R*,21*S*,22*S*,23*S*,24*E*)-5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,20,22-heptamethyl-8-[*N*-(4-methyl-1-piperazinyl)formimidoyl]-2,7-(epoxypentadeca[1,11,13]-trienimino)naphtho[2,1-*b*]-furan-1,11-(2*H*)-dione, 21-acetate; 3-[[4-methyl-1-piperazinyl]imino]methyl]rifamycin; CAS Reg. No. 13292-46-1.

.Rifampin

:Other name

brick red

:Description

R

R

:Solubility

.R TS (/ 750~)

:Category

:Storage

. ° 30

° 15

REQUIREMENTS

%102.0

%97.0

:General requirement

$C_{43}H_{58}N_4O_{12}$

:Identity tests

Spectrophotometry in

"

:A

. (43 1) "the infrared region

RS

50

1

R

50

50

:B

| | | | | | | | | | |
|------|------------------|----------|------------------------------|-----|--------------|-----|----------------------------|------|-----|
| 4 | 500 | 220 | | | | | | .TS | 7.4 |
| | | | 475 | 334 | 254 | 237 | | | |
| | | | | 334 | | | | 1 | |
| | | | | | | | | 1.75 | 475 |
| | 1 | 5 | . | 5 | 25 | 25 | :C | | |
| | | | | | TS | / | | | |
| | | | | | | | | | |
| | 4 | | | 1.0 | | | :Heavy metals | | |
| | | | | | | | .TS | / | |
| | | | ° 800 | | () | . | | | |
| | | | | | TS (/ 100~) | | | | |
| | PbTS (/ 100~) | | | | TS (/ 70~) | | | | |
| | PbTS TS (/ 60~) | | | | 8.5 8 | | | | |
| | | | | 40 | | | 4.0-3.0 | | |
| 1 |) A | | "Limit test for heavy metals | | | | " | | |
| | | | | | . | / | 20 | (128 | |
| | | | | . | / | 1.0 | :Sulfated ash | | |
| 0.6 |) | | 60 | | | | :Loss on drying | | |
| | | . | / | 10 | 4 | (| 5 | | |
| 6.5- | R | | | 10 | 0.10 | | :pH Value | | |
| | | | | | | | | .4.5 | |
| | | | | | | | :Related substances | | |
| | R1 silica gel | | | (84 | 1 |) | "Thin-layer chromatography | | |
| | | .TS | 6.0 | / | | | slurry | | |
| 4 | 20 | | | .R | 15 | R | | 85 | |
| SV | -3 | 0.10 (B) | | | 20 (A) | | :R | | |
| | | 0.20 (D) | | RS | 0.30 (C) | | | RS | |

| | | | | | |
|-----|---------|---|--|--|--|
| A | | A | | .C B | |
| 2 | | .D | | .Assay | |
| 100 | R | 0.10 | | 100 | |
| 1 | | .TS 7.4 | | 475 | |
| | .TS 7.4 | | | | |
| | | . (A ₁ ^{1%} _{cm} = 187) 18.7 | | C ₄₃ H ₅₈ N ₄ O ₁₂ | |

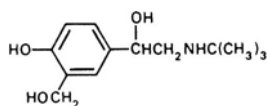
SALBUTAMOLUM

Salbutamol

C₁₃H₂₁NO₃ :Molecular formula

239.3 :Relative molecular mass

:Graphic formula



:Chemical name

α^1 -[[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene- α,α' -diol;
 α^1 -[[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol; CAS
 Reg. No. 18559-94-9.

:Description

TS (/ 750~)

70

:Solubility

.R

:Category

:Storage

REQUIREMENTS

%101.0

%98

:General requirement

$C_{13}H_{21}NO_3$

:Identity tests

.D C B

A

•

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

VS (/ 0.1)

/ 0.080

:B

276

350

230

. 0.56

1

TS (/ 25)

0.1

5

0.05

:C

R

0.05

TS (/ 1760~)

° 155

:D

. / 1.0

:Sulfated ash

0.6

)

50

:Loss on drying

. / 5.0

18 (5

"

:Related substances

R1 silica gel

(84 1) "Thin-layer chromatography

50 R

-2

30

16 TS (/ 260~)

4

(A)

:R

5

R

0.10 (B)

20

(

) TS diazotized

R

A

.B

| | | | |
|-------------|-------------|---------------|--|
| R1 | 30 | 0.4 | :Assay |
| Non-aqueous | " | VS (/ 0.1) | |
| 23.93 | VS (/ 0.1) | 1 .(142 1) A | titration |
| | | | .C ₁₃ H ₂₁ NO ₃ |

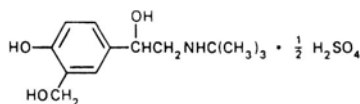
SALBUTAMOLI SULFAS

Salbutamol sulfate

(C₁₃H₂₁NO₃)₂, H₂SO₄ :Molecular formula

288.4 :Relative molecular mass

:Graphic formula



:Chemical name

α '-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene- α,α' -diol sulfate (2:1) (salt); α '-[[1,1-dimethylethylamino]methyl]-4-hydroxy-1,3-benzenedimethanol sulfate (2:1) (salt); CAS Reg. No. 51022-70-9.

:Description

R TS (/ 750~)

4 :Solubility

.R

:Category

:Storage

:Additional information

REQUIREMENTS

%98.0

:General requirement

C₁₃H₂₁NO₃, 1/2H₂SO₄ %101.0

:Identity tests

| | | | | | | |
|------------------------|---------------|-----------------|---------------|--|---------------------------|----|
| | D | C | B | D | A | • |
| | " | | | | | :A |
| | (43 | 1 |) " | Spectrophotometry in the infrared region | | |
| | | | | RS | | |
| VS (/ 0.1) | | / | 0.080 | | | :B |
| | 276 | | 350 | 230 | | |
| | | . | 0.46 | 1 | | |
| TS (/ 25) | | 0.1 | 5 | 0.05 | | :C |
| | R | | 0.05 | . | | |
| | | | TS (/ 1760~) | | | |
| General | " | A | / | 20 | | :D |
| | (123 | 1.0 |) " | identification tests | | |
| | . | / | 1.0 | : | Sulfated ash | |
| 0.6 |) | 100 | : | Loss on drying | | |
| | . | / | 5.0 | 18 (| 5 | |
| | " | | : | Related substances | | |
| | R1 silica gel | (84 | 1 |) " | Thin-layer chromatography | |
| 50 R -2 | 30 | 16 | TS (/ 260~) | 4 | | |
| (A) :R | 5 | . | | R | | |
| | . | 0.10 (B) | | | 20 | |
| | (|) TS diazotized | | R | | |
| | A | | | . | | |
| | | .B | | | | |
| R1 | 30 | 0.9 | : | Assay | | |
| "Non-aqueous titration | " | | VS(/ 0.1) | | | |

57.67 VS (/ 0.1) 1 .(142 1) A
 $\text{C}_{13}\text{H}_{21}\text{NO}_3, \frac{1}{2}\text{H}_2\text{SO}_4$

Additional Requirements for Salbutamol sulfate for parenteral use
 .(56 4) "Parenteral preparations"

SENNAE FOLIUM

Senna leaf ()

Alexandrian Senna leaf
 Tinnevelly Senna leaf

Cassia senna L. :Composition
 (*C. angustifolia* Vahl) Tinnevelly Senna (*C. acutifolia* Delile)

mucilaginous :Description
 :Category
 :Storage
 :Additional information

REQUIREMENTS

%2.5 :General requirement
 .(sennoside B) B
 :Identity test
 TS / 10 0.5
 TS (/ 70~) 10
 TS (/ 100~) 5 .R 10

| | |
|-------------------------------------|----------|
| 15-5 | 40-20 |
| 260 | 20-7 |
| 50-25 | |
| Microscopic examination | |
| 260 | mucilage |
| lacunose | |
| Water-soluble extractive | |
| 0.5 | 5 |
| 300 | 20 |
| 200 | |
| Acid-insoluble ash | |
| (173 | 1 |
| Determination of Acid-insoluble ash | |
| 20 | |
| Stems and foreign matter | |
| 6× | |
| 10 | 20 |
| 30.0 | 100 |
| 0.15 | Assay |
| 90-80 | |
| 20.0 | |
| TS (/ 70~) | 0.1 |
| 150 | |
| 0.10 | R |
| 15 | |

| | | | | | | |
|------|------------|--------------|------|------------|----------------------------------|----|
| | | | 10.0 | | 3 | R |
| | TS (/ 65) | 20 | | 100 | ground glass | |
| | | | | | | 20 |
| | 20 | TS (/ 420~) | | | 1 | |
| R | 25 | 3 | | | | |
| | 15 | | | | | |
| | | 10.0 | R | 100 | | |
| | R | | R | 5 | 10.0 | |
| R | | | 515 | | 1 | |
| 24.0 | B | | | | | |
| | W | 515 | A | W/A 1.25 : | ($A_{1\text{cm}}^{1\%} = 240$) | |

SENNAE FRUCTUS

Senna fruit ()

Alexandrian Senna fruit

Tinnevelly Senna fruit

C.)

Cassia senna L.

C. angustifolia Vahl

mucilaginous

:Composition

(*acutifolia* Delile

:Description

:Category

:Storage

:Additional information

REQUIREMENTS

| | | | |
|--------------|-------------------|-------------------------|--------------------------|
| 3.4% | | General requirement | |
| 2.2% | | B. | |
| | | Identity test | |
| TS | / | 10 | 0.5 |
| TS (/ 70~) | | . | 10 |
| TS (/ 100~) | 5 | .R | 10 |
| | | Macroscopic examination | |
| 25-20 | 50-40 | : | |
| | obovate | 7-6 | |
| 18-14 | 60-35 | : | |
| | obovate | 10 | |
| | | Microscopic examination | |
| | epicarp | | |
| | <i>anomocytic</i> | <i>paracytic</i> | |
| | collenchymatous | <i>Hypodermis</i> | |
| endocarp | | | mesocarp |
| | palisade | . | |
| | .mucilaginous | polyhedral | endosperm |
| R | 0.5 | 5 | Water-soluble extractive |
| | . / 250 | 20 | 200 |
| " | | Acid-insoluble ash | |

20 (173 1) "Determination of Acid-insoluble ash

. /

200 :Foreign matter

. / 10 6×

30.0 . 100 0.15 :Assay

. 15 . ° 90-80

20.0 .

TS (/ 70~) 0.1 . 150

0.10 . .R 15

10.0 . 3 R

. TS (/ 65) 20 . 100 ground glass

20

20 TS (/ 420~) 1

R 25 3 .

. 15 .

10.0 10.0 .R 100

.R R 5

.R 515 1

($A_{1\text{cm}}^{1\%} = 240$) 24.0 B

. W 515 A W/A 1.25 :

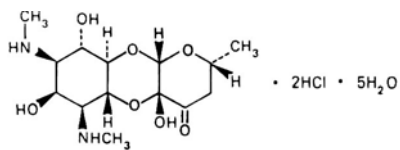
SPECTINOMYCINI HYDROCHLORIDUM

Spectinomycin hydrochloride

$\text{C}_{14}\text{H}_{24}\text{N}_2\text{O}_7 \cdot 2\text{HCl} \cdot 5\text{H}_2\text{O}$:Molecular formula

495.4 :Relative molecular mass

:Graphic formula



:Chemical name

(2*R*,4*aR*,5*aR*,6*S*,7*S*,8*R*,9*S*,9*aR*,10*aS*)-Decahydro-4*a*,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*][1,4]benzodioxin-4-one dihydrochloride pentahydrate; [2*R*-(2*α*,4*αβ*,5*αβ*,6*β*,7*β*,8*β*,9*α*,9*αα*,10*αβ*)]-decahydro-4*a*,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*][1,4]benzodioxin-4-one dihydrochloride pentahydrate; CAS Reg. No. 22189-32-8 (pentahydrate).

:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

.° 30

REQUIREMENTS

600

:General requirement

C₁₄H₂₄N₂O₇

:Identity tests

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

B / 20

/ 20

:B

.(121 1)

"General identification tests

"

| | | | | | | | | | | | |
|---------------------------|------------------------|----------------------------|-------------------------|-----|--|---|--|--|--|--|--|
| | / 0.10 | :Specific optical rotation | | | | . [a] _D ^{20°C} = +15 to + 21° | | | | | |
| | | . / 10 | :Sulfated ash | | | | | | | | |
| Determination of water by | | " | :Water | | | | | | | | |
| | 0.2 | (145 1) A | "the Karl Fisher Method | | | | | | | | |
| | | . / 0.20 | / 0.16 | | | | | | | | |
| | .5.6-3.8 | / 0.10 | :pH Value | | | | | | | | |
| " | | | :Related substances | | | | | | | | |
| R1 | (84 1) | "Thin-layer chromatography | | | | | | | | | |
| R | | 8 R | -1 | 10 | | | | | | | |
| 20 (A) | : | 10 | | R | | | | | | | |
| | | | 0.20 (B) | | | | | | | | |
| 3-2 | TS (/ 25) | | | | | | | | | | |
| A | | | | | | | | | | | |
| | | .B | | | | | | | | | |
| " | | :Histamine-like substances | | | | | | | | | |
| 1 | (167 1) | "Histamine-like substances | | | | | | | | | |
| | | 25 | TS | | | | | | | | |
| Sterility testing of | | " | :Sterility | | | | | | | | |
| | | (162 1) | "antibiotics | | | | | | | | |
| "Gas chromatography | | " | :Assay | | | | | | | | |
| .R | R | 2 | | | | | | | | | |
| 10.0 | RS | 30 | (1) : | | | | | | | | |
| | R hexamethyldisilazane | 1.0 | | | | | | | | | |
| | 1.0 | 10.0 | 30 | (2) | | | | | | | |
| 1.3 | | | . | R | | | | | | | |

/ 5 adsorbent 0.4
 R4 () 95 R
 265 ° 270 ° 215
 A . 90 R . °
 .2 1 2.5 B
 C₁₄H₂₄N₂O₇

Additional Requirements for Spectinomycin hydrochloride for parenteral use

"

:Bacterial endotoxins

(30 5) "Test for Bacterial endotoxins

0.09 RS

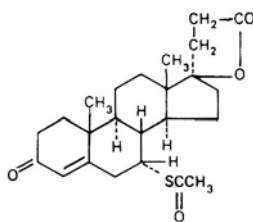
SPIRONOLACTONUM

Spironolactone

C₂₄H₃₂O₄S :Molecular formula

416.6 :Relative molecular mass

:Graphic formula



:Chemical name

17-Hydroxy-7 α -mercapto-3-oxo-17 α -pregn-4-ene-21-carboxylic acid γ -lactone acetate; 7 α -(acetylthio)-17-hydroxy-3-oxo-17 α -pregn-4-ene-21-carboxylic acid γ -lactone; CAS Reg. No. 52-01-7.

:Description

| | | | | |
|-------------------------|-------|--|------|-----------|
| TS (/ 750~) | | :Solubility | | .R |
| | | :Category | | |
| | | :Storage | | |
| :Additional information | | | | 135 |
| REQUIREMENTS | | | | |
| %97.0 | | :General requirement | | |
| | | C ₂₄ H ₃₂ O ₄ S | | %101.5 |
| :Identity tests | | | | |
| .D C B | | A | | • |
| " | | | | :A |
| .(43 1) | | "Spectrophotometry in the infrared region | | |
| | | RS | | |
| 230 | R | / | 10 | :B |
| 1 | | 238 | 350 | |
| | | 0.47 | | |
| TS (/ 700~) | | 2 | 10 | :C |
| | | | | |
| | | .R | | |
| | | 204 | | :D |
| R / 10 | | :Specific optical rotation | | |
| | | . [α] _D ^{20°C} = −33.0 to −37.0° | | |
| R | 0.3 R | 1 | 0.20 | :Chromium |
| 650-600 () | | | | |
| | | 10 | | |

TS (/ 190~) R 0.5 10 . 20

.TS 0.5 20

0.50 TS (/ 190~) 1

0.5 20 100 R 2.83

.TS

. / 1.0 :Sulfated ash

. / 5.0 ° 105 :Loss on drying

"

:Related substances

R5 silica gel (84 1) "Thin-layer chromatography

5 . R ()

0.20 (B) 20 (A) :R

.

15

. 10 ° 105 TS /

A

.B

10 20 2.0 :Mercapto compounds

. TS VS (/ 0.005)

.VS (/ 0.005) 0.1 .

100 R 10 :Assay

1 .R 100 10

$C_{24}H_{32}O_4S$ 238

. ($A_{1cm}^{1\%} = 470$) 47

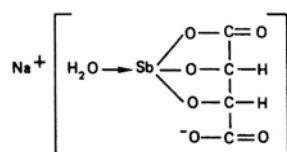
STIBII NATRII TARTRAS

Antimony sodium tartrate

$C_4H_4NaO_7Sb$:Molecular formula

308.8 :Relative molecular mass

:Graphic formula



:Chemical name

Sodium aqua[tartrato(4⁻)-O¹,O²,O³]antimoniate(III); CAS Reg.

No. 34521-09-0.

scale () :Description

.TS (/ 750~) 1.5 :Solubility

:Category

:Storage

:Additional information

REQUIREMENTS

%98.0 :General requirement

$C_4H_4NaO_7Sb$ %101.0

:Identity tests

General " :A

B (123 1) "identification tests

. / 10

1.0 TS (/ 70~) 1.0 0.05 :B

TS - TS

| | | | | | |
|--|--------|--------------|--------|---------------------------------|----------------------|
| General | " | .TS (/ 80~) | 0.2 | 20 | :C |
| | .(123 | 1 |) | " | identification tests |
| stannated | 16 | 10 | 1.3 | :Arsenic | |
| distillate | 20 | | | AsTS (/ 250~) | |
| | 16 | AsTS | 0.05 | | |
| (130 | 1 |) | " | Limit test for arsenic | |
| | | / | 8 | | |
| 10 | 0.50 | | | :Clarity and colour of solution | |
| | / | 60 | ° | 105 | :Loss on drying |
| | 50 | 1.0 | | :Acidity or alkalinity | |
| VS (/ | 0.01) | 2 | TS | / | |
| | () | | VS (/ | 0.01) | |
| | | | | | .4.5 |
| | 5 | 50 | 0.5 | :Assay | |
| TS | VS (/ | 0.05) | .R | 2 | R |
| .C ₄ H ₄ NaO ₇ Sb | 15.44 | VS (/ | 0.05) | 1 | . |

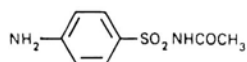
SULFACETAMIDUM

Sulfacetamide

C₈H₁₀N₂O₃S :Molecular formula

214.2 :Relative molecular mass

:Graphic formula



| | | | | | |
|-----------------------|--------------|-------|---|---------------------|------------------------|
| | | | :Chemical name | | |
| | | | N-Sulfanilylacetamide; N-[(4-aminophenyl)sulfonyl]acetamide; CAS Reg. No. 144-80-9. | | |
| | | | :Description | | |
| R | R | | R | :Solubility | |
| | | | .TS (/ 750~) | | |
| | | | .Antiinfective | :Category | |
| | | | :Storage | | |
| REQUIREMENTS | | | | | |
| %101.0 | | %99.0 | :General requirement | | |
| | | | C ₈ H ₁₀ N ₂ O ₃ S | | |
| | | | :Identity tests | | |
| | | | .C B | A | • |
| Spectrophotometry in | | | " | :A | |
| | | | .(43 | 1 |) "the infrared region |
| | | | RS | | |
| . "Related substances | | | " | :B | |
| | | | B | A | |
| 0.2 | TS (/ 750~) | | 5 | 0.10 | :C |
| .(|) | | TS (/ 1760~) | | |
| | | | 184-181 | :Melting range | |
| 1.0 | 10 | | 1.0 | :Heavy metals | |
| 40 | | | TS (/ 300~) | | |
| Limit | | | " | | |
| . / | 20 | (128 | 1 |) A | "test for heavy metals |
| (/ 1) | | 10 | 0.5 | :Solution in alkali | |

| | | |
|------------------------|---|-----------------|
| TS2 | opalescence | VS |
| " | Yw3 | |
| | (53 1) "Color of liquids | |
| 10 1.0 | :Solution in acid | |
| .TS2 | opalescence | VS (/ 1) |
| . / 1.0 | :Sulfated ash | |
| ° 105 | :Loss on drying | |
| | . / 5.0 | |
| " | :Related substances | |
| R3 silica gel | (84 1) "Thin-layer chromatography | |
| R | R | 20 |
| 9 | 10 | . |
| 2.5 (A) | :TS (/ 260~) | TS (/ 750~) |
| RS | 12.5 (C) | RS 2.5 (B) |
| . | | . |
| | 30 ° 105 | TS / |
| TS (/ 700~) | |) 15 |
| .(100 R | 3 R | 10 |
| N-(1- naphthyl) | (-1)-N | 15 |
| | .TS /ethylenediamine hydrochloride | |
| A | . | |
| | .C | |
| 1) "Nitrite titration | " | :Assay |
| 20 | 0.5 | .(143 |
| 0.1) | 1 .VS (/ 0.1) | 50 TS (/ 250~) |
| | .C ₈ H ₁₀ N ₂ O ₃ S | 21.42 VS (/ |

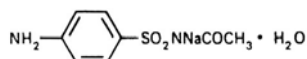
SULFACETAMIDUM NATRICUM

Sulfacetamide sodium

$C_8H_9N_2NaO_3S \cdot H_2O$:Molecular formula

254.2 :Relative molecular mass

:Graphic formula



:Chemical name

N-Sulfanilylacetamide monosodium salt monohydrate; *N*-[(4-aminophenyl)sulfonyl]acetamide monosodium salt monohydrate; CAS Reg. No. 6209-17-2 (monohydrate).

.Sulfacylum-natrium

:Other name

:Description

TS (/ 750~)

1.5

:Solubility

.R

R

.Antiinfective

:Category

:Storage

:Additional information

REQUIREMENTS

%99.0

:General requirement

$C_8H_9N_2NaO_3S$ %101.0

:Identity tests

.D C B

A

•

TS (/ 300)

2

10

1

:A

.° 105

Spectrophotometry in the infrared

"

.(43 1) "region

RS

.() ° 183 A :B

0.2 TS (/ 750~) 5 A 0.1 :C

.() TS (/ 1760~)

General " :D

() B . (115 1) "identification tests

.TS (/ 60~) 0.5

10 0.5 :Clarity and colour of solution

Yw1 R

.(53 1) "Colour of liquids "

Determination of water by " :Water

0.2 (145 1) A "the Karl Fisher Method

. / 80 / 60

.9.5-8.0 R / 0.05 :pH Value

"

:Related substances

R6 silica gel (84 1) "Thin-layer chromatography

25 R -1 50 ()

. TS (/ 260~) 10 25 R

0.50 (B) 0.10 (A) : 5

. RS 0.25 (C) RS

-4

A

.TS5

.C

.B

1) "Nitrite titration "

:Assay

20 50 0.5 (143

1 .VS (/ 0.1) TS (/ 70~)
 .C₈H₉N₂NaO₃S 23.62 VS (/ 0.1)

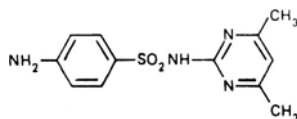
SULFADIMIDINUM

Sulfadimidine

C₁₂H₁₄N₄O₂S :Molecular formula

278.3 :Relative molecular mass

:Graphic formula



:Chemical name

*N*¹-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide; 4-amino-*N*-(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide; CAS Reg. No. 57-68-1.

.sulfamethazine

Sulfadimezinum

:Other names

:Description

TS (/ 750~)

:Solubility

.R

R

:Category

:Storage

REQUIREMENTS

%100.5

%99.0

:General requirement

C₁₂H₁₄N₄O₂S

:Identity tests

.D C B

A

•

Spectrophotometry in

"

:A

.(43 1) "the infrared region

RS

"

0.05

:B

(119 1) "General identification tests

.()

TS (/ 700~)

1

0.5

:C

.R 20

TS (/ 80~)

15

R

.(-6.4- -2) ° 153

° 197

:D

"

1.0

:Heavy metals

(127 1) 4

"Limit test for heavy metals

. / 20

(128 1) A

. / 1.0

:Sulfated ash

° 105

:Loss on drying

. / 5.0

° 70

R

100

2

:Acidity

VS (/ 0.1)

25

5

0.2

TS /

.()

"

:Related substances

15

R3

(84 1)

"Thin-layer chromatography

10

TS (/ 17~)

3

R

-1

0.050 (B)

10 (A)

:R

10

105

RS

A

.TS3

-4

.B

1) "Nitrite titration " :Assay
 TS (/ 70~) 50 0.5 (143
 27.83 VS (/ 0.1) .VS (/ 0.1)
 .C₁₂H₁₄N₄O₂S

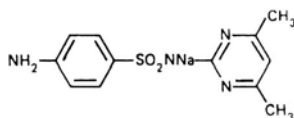
SULFADIMIDINUM NATRICUM

Sulfadimidine sodium

C₁₂H₁₃N₄NaO₂S :Molecular formula

300.3 :Relative molecular mass

:Graphic formula



:Chemical name

*N*¹-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide monosodium
 salt; 4-amino-*N*-(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide monosodium
 salt; CAS Reg. No. 1981-58-4.

:Description

.TS (/ 750~) 60 2.5 :Solubility
 . :Category

:Storage

:Additional information

REQUIREMENTS

%98.0

:General requirement

C₁₂H₁₃N₄NaO₂S %101.0

:Identity tests

| | | | |
|------------------------|--|--------------|-------------|
| (/ 260~) | TS (/ 750~) | 9 | |
| RS | 0.050 (B) | 10 (A) | :TS |
| 9 | TS (/ 260~) | A |) |
| | .(/ | TS (/ 750~) | |
| .TS3 | -4 | 10 ° 105 | |
| | | A | |
| | | | .B |
| 1) "Nitrite titration | " | | :Assay |
| 10 | 75 | 0.5 | (143 |
| 1 | .VS (/ 0.1) | TS (/ 420~) | |
| | .C ₁₂ H ₁₃ N ₄ NaO ₂ S | 30.03 | VS (/ 0.1) |

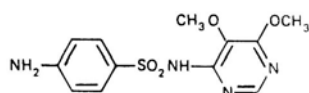
SULFADOXINUM

Sulfadoxine

C₁₂H₁₄N₄O₄S :Molecular formula

310.3 :Relative molecular mass

:Graphic formula



:Chemical name

*N*¹-(5,6-Dimethoxy-4-pyrimidinyl)sulfanilamide; 4-amino-*N*-(5,6-dimethoxy-4-pyrimidinyl)benzenesulfonamide; CAS Reg. No. 2447-57-6.

:Description

R TS (/ 750~)

:Solubility

.R

:Category

:Storage

REQUIREMENTS

%99.0

:General requirement

$C_{12}H_{14}N_4O_4S$ %101.0

:Identity tests

.D C B A •

Spectrophotometry in

" :A
 .(43 1) "the infrared region

RS

" 0.05 :B

. - (119 1) "General identification tests

VS (/ 0.1) 3 50 :C

(/ 80) (II) 1.0

.()

. 199 :D

" 1.0

:Heavy metals

(126 1) 4 "Limit test for heavy metals

. / 20 (128 1) A

10 . 30 2.5 **:Chlorides**

" TS (/ 130~)

. / 0.1 (121 1) "Limit test for chlorides

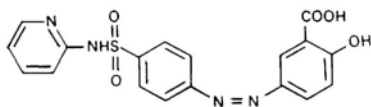
. 40 2.5 **:Sulfates**

(123 1) "Limit test for sulfates "

. / 0.2

10 0.50 **:Clarity and colour of solution**

Yw3 VS (/ 70~)



:Chemical name

5-[[*p*-(2-Pyridylsulfamoyl)phenyl]azo]salicylic acid; 2-hydroxy-5-[[4-[(2-pyridinylamino)sulfonyl]phenyl]azo]benzoic acid; CAS Reg. No. 599-79-1.

Salazosulfapyridine

:Other name

:Description

R R

:Solubility

TS (/ 750~)

:Category

:Storage

° 255

:Additional information

REQUIREMENTS

%93.0

:General requirement

C₁₈H₁₄N₄O₅S %103.0

:Identity tests

.C B A •
" :A

Spectrophotometry in

.(43 1) " the infrared region

RS

600 230

:B

RS

(/ 70~)

4 TS (/750~)

1.0

0.1

:C

| | | | | | | |
|---------------------------|----|--------------------------|------------------------------|---------------|-------------------|---|
| 1.0 | . | 5 | .R | 0.20 | TS | |
| 1.0 | | 1.0 | . | TS (/ 25) | 0.1 | |
| | | 2.0 | . | TS (/ 10) | | |
| | | . | TS1 | -2 | 0.1 TS (/ 80~) | |
| " | | 1.0 | | :Heavy metals | | |
| (127 | 1 |) 3 | "Limit test for heavy metals | | | |
| . | / | 20 | (128 | 1 |) A | |
| . | 5 | ° 70 | 100 | 2.0 | :Chlorides | |
| 1 (| |) | 25 | . | | |
| | . | 5 | TS (/ 1000~) | | | |
| "Limit test for chlorides | | | " | | | |
| | . | / | 0.14 | (121 | 1 |) |
| 1.5 | | | 25 | :Sulfates | | |
| | . | 5 | VS (/ 2) | | | |
| 1 |) | "Limit test for sulfates | | " | | |
| | . | / | 0.4 | (123 | | |
| | . | / | 5.0 | :Sulfated ash | | |
| | ° | 105 | :Loss on drying | | | |
| | | | . | / | 10 | |
| Thin-layer | | " | :Assay | | | |
| 4 | | R2 | (84 | 1 |) "chromatography | |
| | R | | R | -1 | R | |
| 10 | . | 18 | TS (/ 1080) | | | |
| 12 (B) | | | 12 (A) | :R | | |
| . | R | | 10 (C) | RS | | |
| . | 15 | | | | | |
| . | | | | | | |

0.6 R_f (254)

A 3

:) . C B

10 R

R 10.0 .(

1 10

.C 406

.(B) RS (A) C₁₈H₁₄N₄O₅S

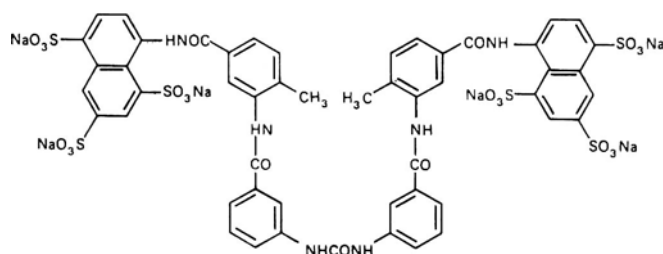
SURAMINUM NATRICUM

Suramin sodium

C₅₁H₃₄N₆Na₆O₂₃S₆ :Molecular formula

1429 :Relative molecular mass

:Graphic formula



:Chemical name

Hexasodium 8,8'-[ureylenebis[*m*-phenylenecarbonylimino(4-methyl-*m*-phenylene)carbonylimino]]di-1,3,5-naphthalenetrisulfonate; hexasodium 8,8'-[carbonylbis[imino-3,1-phenylenecarbonylimino(4-methyl-3,1-phenylene)carbonylimino]]bis[1,3,5-naphthalenetrisulfonate]; CAS Reg. No. 129-46-4.

.Nagananinum

:Other name

:Description

TS (/ 750~)

:Solubility

R

.

:Storage

•

REQUIREMENTS

%96.0

:General requirement

$$\text{C}_{51}\text{H}_{34}\text{N}_6\text{Na}_6\text{O}_{23}\text{S}_6 \quad \%100.5$$

:Identity tests

| | | | | |
|-------------|-----|-----|----|----|
| TS (/ 70~) | 1.0 | 2.0 | 20 | :A |
|-------------|-----|-----|----|----|

TS (/ 10) 0.25 . 5

| | | | | |
|-----|----|------|-------------|---|
| TS1 | -2 | 0.15 | TS (/ 80~) | 1 |
|-----|----|------|-------------|---|

| | | | |
|---|------|----|----|
| R | 0.10 | 20 | :B |
|---|------|----|----|

0.25 . TS (/ 70~) 4 .

2.0 TS (/ 50)

| | | | | | |
|---|---|------|-----|------|----|
| B | R | 0.25 | 2.0 | 0.05 | :C |
|---|---|------|-----|------|----|

1) "General identification tests"

$\cdot(123$

:Heavy metals

(127 1) 3 "Limit test for heavy metals

$$. / 20 \quad (128 \quad 1 \quad) \text{ A}$$

| | | | | |
|--------------|---|----|-----|------------|
| TS (/ 130~) | 5 | 10 | 0.5 | :Chlorides |
|--------------|---|----|-----|------------|

R 3 VS (/ 0.1) 5

TS (/ 45) 2 VS (/ 0.1)

3.6 VS (/ 0.1)

TS (/ 250~) 3 20 0.50 :Sulfates
 1) "Limit test for sulfates "
 . / 1 (123
 10 0.50 :Clarity of solution
 .
 Determination of water by " :Water
 0.2 (145 1) A "the Karl Fisher Method
 . / 0.10
 .7.0-5.5 R / 10 :pH Value
 0.1) 30 30 5 :Free amines
 .R / VS (/
 .
 . 0.4 .electrometrically
 infected :Therapeutic potency
 Trypanosoma equiperdum
 48 . 10 :
 .20 000 1000 .
 cover-slip preparation
 20 1 . 2 0.12 10
 . 20 000 1000
 / 50 0.16 10
 objective-4 ()
 20 5 .
 5 .
 %50 .

| | | | |
|--|---------|-------------|--------|
| TS (/ 700~) | 12 | 0.5 | :Assay |
| 1 | 100 | | |
| VS (/ 0.1) | ° 20 15 | | R |
| | .R | / | |
| .C ₅₁ H ₃₄ N ₆ Na ₆ O ₂₃ S ₆ | 23.82 | VS (/ 0.1) | |

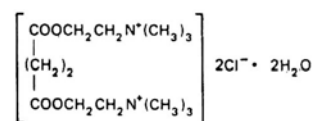
SUXAMETHONII CHLORIDUM

Suxamethonium chloride

C₁₄H₃₀Cl₂N₂O₄·2H₂O :Molecular formula

397.3 :Relative molecular mass

:Graphic formula



:Chemical name

Choline chloride, succinate (2:1), dihydrate; 2,2'-[(1,4-dioxo-1,4-butanediyl)bis(oxy)]bis[*N,N,N*-trimethylethanaminium] dichloride, dihydrate; 2,2'-succinyldioxybis(ethyltrimethylammonium) dichloride, dihydrate; CAS Reg. No. 6101-15-1(dihydrate).

.Succinylcholine chloride

:Other name

:Description

TS (/ 750~)

:Solubility

.R

:Category

:Storage

:Additional information

REQUIREMENTS

| | | | | | |
|---------------------------|----------------|---------------------------------|----|------|----------------------------|
| %98.0 | | :General requirement | | | |
| | | $C_{14}H_{30}Cl_2N_2O_4$ %101.0 | | | |
| | | :Identity tests | | | |
| 0.1 | TS (/ 5) (II) | 0.1 | 1 | 25 | :A |
| | | TS (/ 45) | | | |
| 30 | TS (/ 100~) | 10 | 10 | 0.05 | :B |
| 30 | | TS (/ 10) ammonium reineckate | | | |
| | ° 80 | .R TS (/ 750~) | | | |
| | | .° 183 | | | |
| General | " | A | / | 0.05 | :C |
| | | .(121 1) "identification tests | | | |
| 10 | 1.0 | :Clarity and colour of solution | | | |
| | | . / 1.0 | | | |
| | | :Sulfated ash | | | |
| Determination of water by | | " | | | |
| 80 | 0.15 | (145 | 1 |) A | "the Karl Fisher Method |
| | | . / 100 / | | | |
| | | .5.0-4.0 / 10 | | | |
| | | :pH Value | | | |
| | | " | | | |
| | | :Related substances | | | |
| 4 | R2 | (84 | 1 |) | "Thin-layer chromatography |
| | | 5 TS (/ 300) R -1 | | | |
| 0.10 (B) | | 5.0 (A) : | | | |
| | | 10 | | | |

$2\frac{1}{2}$
 TS2 15 ° 90
 A
 .B
 30 R1 30 0.3 :Assay
 TS / 10 R
 "Non-aqueous titration" VS (/ 0.1)
 18.07 VS (/ 0.1) 1 .(142 1) A
 .C₁₄H₃₀Cl₂N₂O₄

Additional Requirements for Suxamethonium chloride for parenteral use

.(56 4) "Parenteral preparations"
 " :Bacterial endotoxins
 30 5) "Test for Bacterial endotoxins
 . 2.0 RS (

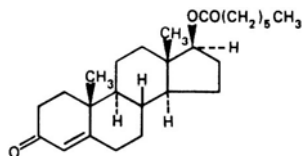
TESTOSTERONI ENANTAS

Testosterone enantate

C₂₆H₄₀O₃ :Molecular formula

400.6 :Relative molecular mass

:Graphic formula



:Chemical name

| | | | |
|----------------------------|-------------------------|--|----------------------|
| | | :Description | |
| R | TS (/ 750~) | :Solubility | |
| | | :Category | |
| | | :Storage | |
| | | . ° 15 | |
| ° 37 | :Additional information | | |
| REQUIREMENTS | | | |
| %97.0 | :General requirement | | |
| | | C ₂₆ H ₄₀ O ₃ | %103.0 |
| :Identity tests | | | |
| .C B | | A | • |
| Spectrophotometry in | | " | :A |
| | | .(43 1) | "the infrared region |
| | | RS | |
| "Thin-layer chromatography | | " | :B |
| 10 | R1 () | (84 1) | |
| . | 5 | R | 90 R |
| | | | 16 |
| | | . | |
| 6 R | | 4 | |
| (A) :R | R | 9 | 2 |
| . | RS | 1.0 (B) | 1.0 |
| | | . | 12 |
| ° 120 | TS / | -4 | 10-5 120 |

.(365) 10
 .B A
 : 293 5
 Related " substances
 TS (/ 1760~) 2.0 5 :C
 TS (/ 750~)
 / 10 :Specific optical rotation
 . $[a]_D^{20^\circ\text{C}} = +77$ to $+83^\circ\text{R}$
) :Loss on drying
 5.0 R (5 0.6
 . /
 10 0.5 :Free heptanoic acid
 TS / TS (/ 750~)
 0.6 TS / VS (/ 0.01)
 .() VS (/ 0.01)
 " :Related substances
 92 R1 (84 1) "Thin-layer chromatography
 . 0.5 R 8 R
 (A) :R R 9 5
 . 0.20 (B) 20
 . 10 110
 10 110 TS /
 A .(365)
 .B
 100 R 20 :Assay

| | | | |
|-------------------|----|-----|-------|
| 1 | . | 100 | 5 |
| $C_{26}H_{40}O_3$ | . | 241 | |
| / | 10 | . | RS |
| ± 0.42 | | R | RS |
| | | | .0.02 |

Additional Requirements for Testosterone enantate for parenteral use

| | | | |
|-----|---|----------------------------------|---|
| (56 | 4 |) "Parenteral preparations | " |
| " | | | |
| | | :Bacterial endotoxins | |
| (30 | 5 |) "Test for Bacterial endotoxins | |
| | | 3.5 RS | |

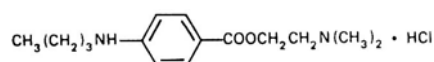
TETRACAINI HYDROCHLORIDUM

Tetracaine hydrochloride

$C_{15}H_{24}N_2O_2 \cdot HCl$:Molecular formula

300.8 :Relative molecular mass

:Graphic formula



:Chemical name

2-(Dimethylamino)ethyl *p*-(butylamino)benzoate monohydrochloride; 2-(dimethylamino)ethyl 4-(butylamino)benzoate monohydrochloride; CAS Reg. No. 136-47-0.

.Dicainum Amethocaine :Other names

:Description

TS (/ 750~) 8 :Solubility
.R R

| | | | |
|---------------------------------|----|---|----------------------------|
| | | :Category | |
| | | :Storage | |
| | | :Additional information | |
| | | | |
| | | ° 134 | |
| . ° 147-134 | | . ° 139 | ° 134 |
| REQUIREMENTS | | | |
| %98.0 | | :General requirement | |
| | | C ₁₅ H ₂₄ N ₂ O ₂ .HCl %101.0 | |
| | | :Identity tests | |
| .TS (/ 75) | | 1 | 10 0.2 :A |
| . ° 131 | | ° 80 | |
| General | " | A | / 20 :B |
| | | . (121 1) "identification tests | |
| 10 0.20 | | | |
| :Clarity and colour of solution | | | |
| R | | | |
| . / 1.0 | | | |
| :Sulfated ash | | | |
| ° 105 | | | |
| :Loss on drying | | | |
| . / 10 | | | |
| .6.0-4.5 R | | / 10 :pH Value | |
| " | | :Related substances | |
| 80 | R4 | (84 1) | "Thin-layer chromatography |
| R | | 4 R | 16 R |
| 12 | | 5 | |

0.050 (B) 0.10 (A) : 5
 10 R -4
 10 105
 A .(254)
 .() .B
 1) "Nitrite titration " :Assay
 5 50 0.5 (143
 1 .VS (/ 0.1) TS (/ 420~)
 .C₁₅H₂₄N₂O₂.HCl 30.08 VS (/ 0.1)

Additional Requirements for Tetracaine hydrochloride for parenteral use
Test for non-injectable "
 .(32 5) "preparations

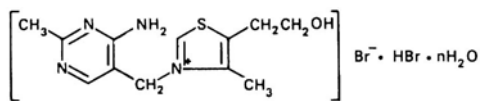
THIAMINI HYDROBROMIDUM

Thiamine hydrobromide

Thiamine hydrobromide, anhydrous

Thiamine hydrobromide, hemihydrate

) C₁₂H₁₇BrN₄OS.HBr (anhydrous) :Molecular formula
 .C₁₂H₁₇BrN₄OS.HBr,½H₂O (hemihydrate)
 .435.2 426.2 :Relative molecular mass
 :Graphic formula



n = 0 (anhydrous)
n = 1/2 (hemihydrate)

:Chemical name

Thiamine bromide, monohydrobromide; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium bromide, monohydrobromide; CAS Reg. No. 4234-86-0 (anhydrous).

Thiamine bromide, monohydrobromide, hemihydrate; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium bromide, monohydrobromide, hemihydrate; CAS Reg. No. 62084-87-1 (hemihydrate).

:Description

TS (/ 750~)

R

:Solubility

.R

.B

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

C₁₂H₁₇BrN₄OS, HBr %101.0

:Identity tests

0.5 TS (/ 80~)

1

1

10

:A

R

-2

5

TS (/ 10)

(365)

-2

10-5

:B

General

"

A

/ 20

:C

(120 1)

"identification tests

"

1.0

:Heavy metals

| | | | | | |
|--|-----|---------------------------------|------------------------------|--------|-----------|
| (127 | 1 |) 1 | "Limit test for heavy metals | | |
| . | / | 20 | (128 | 1 |) A |
| 10 | 0.6 | :Clarity and colour of solution | | | |
| | | | | | |
| . | / | 1.0 | :Sulfated ash | | |
| . | ° | 105 | :Loss on drying | | |
| . | / | 25 | . | / | 5.0 |
| | | | | | |
| | | 3.4-2.7 | / | 0.06 | :pH Value |
| 10 | R1 | 30 | 0.30 | :Assay | |
| VS (| | / | 0.1) | TS | / |
| .(142 | 1 |) A | ."Nom-aqueous titration | | " |
| .OS,HBr ₄ BrN ₁₇ H ₁₂ C | | 21.31 | VS (| / | 0.1) |
| 1 | | | | | |

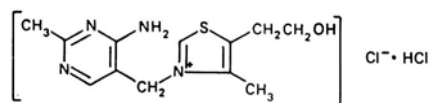
THIAMINI HYDROCHLORIDUM

Thiamine hydrochloride

C₁₂H₁₇ClN₄OS,HCl :Molecular formula

337.3 :Relative molecular mass

:Graphic formula



:Chemical name :

Thiamine chloride, hydrochloride; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium chloride, mono-hydrochloride; CAS Reg. No. 67-03-8.

:Description

| | | | | |
|-------------------------|-------------|---|---------------|-------|
| TS (/ 750~) | | 100 | :Solubility | |
| | | | .R | R |
| | | .B | :Category | |
| | | | :Storage | |
| . | | | | |
| :Additional information | | | | |
| . | | | | |
| | | 284 | 100 | 4 |
| | | | | 4.0 |
| . | | | | |
| REQUIREMENTS | | | | |
| %98.0 | | :General requirement | | |
| | | C ₁₂ H ₁₇ ClN ₄ OS, HCl %101.0 | | |
| . | | | | |
| Identity test | | | | |
| 0.5 | TS (/ 80~) | 1 | 1 | 10 :A |
| 10- | R -2 5 | TS (/ 10) | | |
| . | (365) | R | -2 | 5 |
| . | | | | |
| :B | | | | |
| General | " | A | / 0.05 | :C |
| | | .(121 1) "identification tests | | |
| " | | | | |
| | | 1.0 | :Heavy metals | |
| (127 1) 1 | | "Limit test for heavy metals | | |
| . / 20 | | (128 1) A | | |
| . | | | | |
| 10 2.0 | | :Clarity and colour of solution | | |
| Colour | " | Yw2 | | |
| | | .(53 1) "of liquids | | |
| . / 1.0 | | :Sulfated ash | | |

| | | | | | |
|--------|--|------------------------|-------------|-----------------|--------|
| | . / 50 | ° 105 | | :Loss on drying | |
| | | .3.3-2.7 | / 25 | :pH Value | |
| R1 | | 30 | | 0.25 | :Assay |
| | VS (/ 0.1) | | TS | / | 10 |
| . (142 | 1) A | "Non-aqueous titration | | " | |
| | .C ₁₂ H ₁₇ ClN ₄ OS,HCl | 16.86 | VS (/ 0.1) | | 1 |

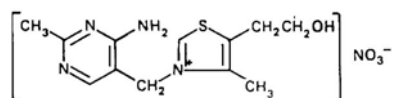
THIAMINI MONONITRAS

Thiamine mononitrate

C₁₂H₁₇N₅O₄S : Molecular formula

327.4 :Relative molecular mass

:Graphic formula



:Chemical name :

Thiamine nitrate (salt); 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium nitrate (salt); CAS Reg. No. 532-43-4.

:Description

TS (/ 750~)

:Solubility

.R

.B

:Category

:Storage

:Additional information

REQUIREMENTS

| | | | |
|----------------|--|---|-----------------|
| %98.0 | | :General requirement | |
| | | C ₁₂ H ₁₇ N ₅ O ₄ S | %101.0 |
| :Identity test | | | |
| 10-5 | 0.5 TS (/ 80~) | 1 | 10 :A |
| | R -2 5 | TS (/ 10) | |
| | (365) | R -2 | |
| :B | | | |
| A | TS (/ 15) | 2 / 0.05 | 2 :C |
| 1) | "General identification tests | | " |
| | | .(122 | |
| " | 1.0 | :Heavy metals | |
| (127 | 1) 1 | "Limit test for heavy metals | |
| | . / 20 | (128 | 1) A |
| 10 | 0.2 | :Clarity and colour of solution | |
| Colour | " | Yw2 | |
| | | .(53 1) "of liquids | |
| | | . / 1.0 | :Sulfated ash |
| | . / 10 | ° 105 | :Loss on drying |
| | | .7.5-6.0 / 20 | :pH Value |
| R1 | 30 | 0.1 | :Assay |
| VS (/ 0.1) | TS | / -1 | 0.15 |
| .(142 | 1) A | "Non-aqueous titration | |
| | .C ₁₂ H ₁₇ N ₅ O ₄ S | 16.37 VS (/ 0.1) | 1 |

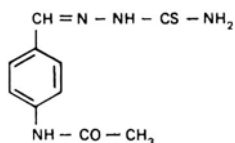
THIOACETAZONUM

Thioacetzone

$C_{10}H_{12}N_4OS$: Molecular formula

236.3 :Relative molecular mass

:Graphic formula



:Chemical name :

4'-Formylacetanilide 4'-(thiosemicarbazone); *N*-[4-[(amino-thioxomethyl)hydrazono]methyl]phenyl]acetamide; CAS Reg. No. 104-06-3.

:Description

R TS (/ 750~)

:Solubility

.R 10

:Category

:Storage

REQUIREMENTS

%102.0 %98.0

:General requirement

$C_{10}H_{12}N_4OS$

Identity test

" :A

.(42 1) "Spectrophotometry in the infrared region

RS

dehydrated / 3.0 :B

328 350 230

. 0.58 1

0.25 VS (/ 5) 1 10 :C

TS (/ 80)

| | | | | | | | | | |
|--------------------------|---------|--|---------|-------|-------------------------------|----------------------------|-------|------|-------|
| " | | | | 10 | :D | | | | |
| | | (119 | 1 |) | "General identification tests | | | | |
| " | | 1.0 | | | :Heavy metals | | | | |
| | (127 | 1 |) | 3 | "Limit test for heavy metals | | | | |
| | . | / | 10 | (128 | 1 |) A | | | |
| | . | / | 2.0 | | :Sulfated ash | | | | |
| . | / | 5.0 | ° | 105 | :Loss on drying | | | | |
| " | | | | | :Related substances | | | | |
| | R4 | | (84 | 1 |) | "Thin layer chromatography | | | |
| R | 9 | | 10 | | R | | | | |
| (P-acetamidobenzalazine) | 4.0 (B) | | 0.2 (A) | : | | | | | |
| | | | | | RS | | | | |
| . | (| 365) | | TS (| / | 130~) | | | |
| | .B | | | A | | | | | |
| 2 | | | | | :Thiosemicarbazide | | | | |
| | | | . | 50 | | | | | |
| | | 25 | | | | | | | |
| | VS (| / | 0.1) | ceric | TS(| / | 100~) | . | 250 |
| 0.8 | | | | | TS (o-phenanthroline) | | | | |
| | . | (| / | 1.0 |) | VS (| / | 0.1) | ceric |
| ° | 60 | R | 60 | 1.0 | :Assay | | | | |
| ° | 60 | | TS | / | 20 | . | | | |
| | | | | | | | | | |
| ° | 105 | | | R | | | | | |
| | | .C ₁₀ H ₁₂ N ₄ OS | 460.6 | 1 | . | | | | |

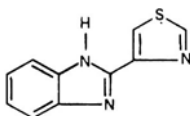
TIABENDAZOLUM

Tiabendazole

$C_{10}H_7N_3S$:Molecular formula

201.3 :Relative molecular mass

:Graphic formula



:Chemical name :

2-(4-Thiazolyl)benzimidazole; 2-(4-thiazolyl)-1*H*-benzimidazole; CAS Reg. No. 148-79-8.

:Description

TS (/ 750~)

150

:Solubility

.R

R

:Category

:Storage

REQUIREMENTS

%101.0

%98.0

:General requirement

$C_{10}H_7N_3S$

:Identity tests

.D C B

A

●

"

:A

.(43 1) "Spectrophotometry in the infrared region

RS

VS (/ 0.1) / 4.0 :B
302 234 350 230
. 0.49 0.23 1
-4 1 3 VS (/ 0.1) 5 5 :C
R 0.1 R
TS (/ 45) 10 2
. / 1.0 :Sulfated ash
. / 5.0 ° 105 :Loss on drying
" :Related substances
50 R4 (43 1) "Thin layer chromatography
2 R 8 R 20 R
10 (A) :R 10 .
0.15 (B)
.(254)
.B A
R1 30 0.16 :Assay
Non- " VS (/ 0.1)
VS (/ 0.1) 1 .(142 1) A "aqueous titration
.C₁₀H₇N₃S 20.13

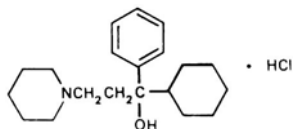
TRIHXYPHENIDYLI HYDROCHLORIDUM

Trihexyphenidyl hydrochloride

C₂₀H₃₁NO₃HCl: **Molecular formula**

337.9 **Relative molecular mass:**

:Graphic formula



:Chemical name :

α-Cyclohexyl-α-phenyl-1-piperidinepropanol hydrochloride;
CAS Reg. No. 52-49-3.

:Other names

:Description

.R R TS (/ 750~)

:Solubility

:Category

:Storage

REQUIREMENTS

%98.0

:General requirement

$C_{20}H_{31}NO, HCl$ %101.0

:Identity tests

.D C B A •

" :A

.(42 1) "Spectrophotometry in the infrared region

RS

VS (/ 0.1) R 5 0.5 :B

R TS (/ 80~)

0.6) R

) 115 2 R (5

.(

General " B / 0.05 :C

.(121 1) "identification tests

| | | | | |
|------|---|-------|------------------------|------------------------|
| | | | 1.0 | :Sulfated ash |
| 5.0 | ° 105 | | | :Loss on drying |
| | | | | |
| | | 100 | 1.0 | :pH Value |
| | | | | .6.0-5.0 |
| 1 | 40 | 0.10 | | :Piperidylpropiofenone |
| | 100 | | | VS (/ 1) |
| | .0.5 | 247 | | 1 |
| R1 | | 30 | 0.5 | :Assay |
| | VS (/ 0.1) | TS | / | 10 |
| (142 | 1 |) A | "Non-aqueous titration | " |
| | .C ₂₀ H ₃₁ NO,HCl | 33.79 | VS (/ 0.1) | 1 |

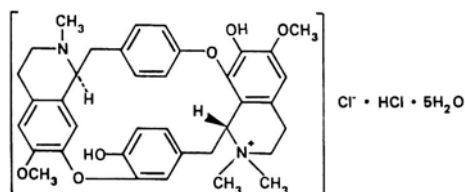
TUBOCURARINI CHLORIDUM

Tubocurarine Chloride

C₃₇H₄₁ClN₂O₆·HCl·5H₂O: **Molecular formula**

771.7 : **Relative molecular mass**

: **Graphic formula**



: **Chemical name** :

(+)-Tubocurarine chloride hydrochloride, pentahydrate; 7',12'-dihydroxy-6,6'-dimethoxy-2,2',2'-trimethyltubocuraranium chloride hydrochloride pentahydrate; CAS Reg. No. 6989-98-6 (pentahydrate).

: **Description**

| | | | | | | |
|--|--------------|--|--------------------------------|---------------|-------------|----|
| 270 | TS (/ 750~) | | 30 | 20 | :Solubility | |
| | | | | .R | R | R |
| | | | | | :Category | |
| | | | | | :Storage | |
| Additional information: | | | | | | |
| REQUIREMENTS | | | | | | |
| %98.0 | | :General requirement | | | | |
| | | C ₃₇ H ₄₁ ClN ₂ O ₆ .HCl | | | %102.0 | |
| Identity test | | | | | | |
| General | TS | | 1 | 1 | 10 | :A |
| | TS (/ 25) | | 0.1 | 1 | 10 | :B |
| | " | | B | / | 20 | :C |
| | .(121 1) | | "identification tests | | | |
| 3 | / | 10 | :Specific Optical rotation: | | | |
| . [α] _D ^{20°C} = +210 to +220° | | | | | | |
| 150 | | 0.25 | :Chloroform-soluble substances | | | |
| 20 | 3 | | R | 5 | | |
| | | 10 | .R | | | |
| | | 5 | R | | | |
| | | ° 105 | | | | |
| 1 | | | 10 | .(%2.0) | | 5 |
| | | | | TS (/ 70~) | | |
| | | / | 2.5 | :Sulfated ash | | |

| | | | |
|---|-------|-------------------------|-------------|
|) ° 100 | | :Loss on drying | |
| . / 120 | / 90 | (5 | 0.6 |
| .6.0-4.0 / 10 | | :pH Value | |
| R1 | 20 | 0.5 | :Assay |
| .TS | / | 10 R | 60 |
| potentiometrically | | VS (/ 0.1) | |
| . (142 | 1) A | "Non-aqueous titration" | |
| .C ₃₇ H ₄₁ ClN ₂ O ₆ .HCl | | 34.08 | VS (/ 0.1) |
| | | | 1 |

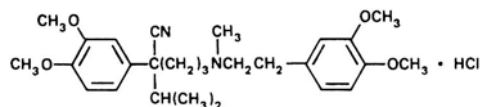
VERAPAMILI HYDROCHLORIDUM

Verapamil Hydrochloride

C₂₇H₃₈N₂O₄.HCl : Molecular formula

491.1 Relative molecular mass:

:Graphic formula



:Chemical name :

5-[(3,4-Dimethoxyphenethyl)methylamino]-2-(3,4-dimethoxyphenyl)-2-isopropylvaleronitrile hydrochloride; α-[3-[[2-(3,4-dimethoxyphenyl)ethyl]methylamino]propyl]-3,4-dimethoxy-α-(1-methylethyl)benzeneacetonitrile monohydrochloride; CAS Reg. No. 152-11-4.

:Description

TS (/ 750~)

20

:Solubility

.R

:Category

:Storage

REQUIREMENTS

%99.0

:General requirement



Identity test

.E D C B A ●

" :A

1) Spectrophotometry in the infrared region

RS

VS (/ 0.1) / 20 :B

278 229 350 230

0.24 0.63 1

0.2 TS (/ 570~) 0.5 2.5 20 :C

TS (/ 10)

General identification " B / 20 :D

.(121 1) "tests

143 E

| | | |
|----|------|---------------------------------|
| 10 | 0.50 | :Clarity and colour of solution |
|----|------|---------------------------------|

10 0.50

:Readily carbonizable substances

5 0.10

5 .TS (/ 1760~)

1) Colour of liquids " Yw2

/ 1.0 :sulfated ash

:Loss on drying

5.0 105

. /

.6.5-4.5 R / 0.05 :pH Value

Related substances

"Thin-layer chromatography () R5 (84 1) :A
 . R 15 R 85
 25 (B) 50 (A) :R 10
 . 50 (C)
 . 10
 5 110
 . 15-10 TS (/ 200) 50 R 2 R
 .
 B
 A .C
 .B
 5 R 20 R 70 A :B
 .A . R 5 R
 10 R1 30 0.5 :Assay
 TS / -1 0.15 TS /
 " VS (/ 0.1)
 VS (/ 0.1) 1 .(142 1) A "Non-aqueous titration
 .C₂₇H₃₈N₂O₄.HCl 49.11

Additional requirements for Verapamil hydrochloride for parenteral use

(56 4) "Parenteral preparations "
 "
 :Bacterial endotoxins
 (30 5) "Test for Bacterial endotoxins
 . 16.7 RS

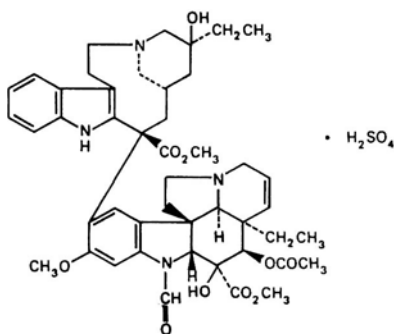
VINCRIPTIN SULFAS

Vincristin sulfate

$\cdot C_{46}H_{56}N_4O_{10}, H_2SO_4$:Molecular formula

923.0 Relative molecular mass:

:Graphic formula



:Chemical name :

Leurocristine sulfate (1 : 1) (salt); 22-oxovincalcaleukoblastine sulfate (1 : 1) (salt); CAS Reg. No. 2068-78-2.

:Description

.R

TS (/ 750~)

:Solubility

:Category

:Storage

.° 10 2

:Additional information

:

REQUIREMENTS

%95.0

:General requirement

$C_{46}H_{56}N_4O_{10}, H_2SO_4$ %105.0

:Identity test

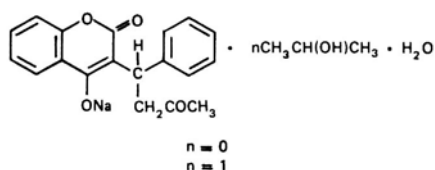
WARFARINUM NATRICUM

Warfarin sodium

$C_{19}H_{15}NaO_4$; $C_{19}H_{15}NaO_4 \cdot C_3H_8O \cdot H_2O$ (Hyclate) : **Molecular formula**

330.3; 408.4 (Hyclate) : **Relative molecular mass**

: **Graphic formula**



: **Chemical name** :

3-(α -Acetonylbenzyl)-4-hydroxycoumarin sodium salt; 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2*H*-1-benzopyran-2-one sodium salt; CAS Reg. No. 129-06-6.

3-(α -Acetonylbenzyl)-4-hydroxycoumarin sodium salt compound with 2-propanol monohydrate; 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2*H*-benzopyran-2-one sodium salt 2-propanol monohydrate.

: **Description**

TS (/ 750~)

: **Solubility**

.R R

: **Category**

: **Storage**

: **Labelling**

.clathrate form

Additional information:

REQUIREMENTS

%98.0

: **General requirement**

-2

$C_{19}H_{15}NaO_4$ %102.0

| Identity test | | | | |
|---------------------------------|------|----------------|---|----------------------------------|
| TS (/ 70~) | 1 | 25 | 0.1 | :A |
| ° 105 | (C | |) | |
| | (B | |) .(| ° 162 |
| " | A | | | :B |
| (43 | 1 |) | "Spectrophotometry in the infrared region | |
| . | RS | | | |
| " | B | A | | :C |
| | (123 | 1 |) | "General identification tests |
| TS (/ 1000~) | 5 | 10 | 1 | :D |
| clathrate | 5 | VS (/ 0.0167) | | 2 |
| :Clarity and colour of solution | | | | |
| 10 | 0.50 | | | |
| | .TS2 | R | | |
| Determination of water | " | | | .Water |
| 45 | 0.4 | (145 | 1 |) "by the Karl Fischer method |
| | | | | . / |
| .8.3-7.2 R | | / 10 | | :pH Value |
| " | | | | : Related substances |
| 5 | R4 | (84 | 1 |) "Thin-layer chromatography |
| R | | 2 R | 5 R | |
| 20 (A) | :R | 20 | | |
| | | | 0.020 (B) | |
| .(| 254) | | | |
| .B | | | A | |
| 10 | 1.25 | | | :Absorbance in alkaline solution |
| 15 | | TS (/ 50) | | |

385 1
.0.3 TS (/ 50)
25.0 . 25.0 0.8 : -2
10 swirling VS (/ 0.125)
30 . 40 250
20 60 .75° TS3
. 250 TS (/ 80~)
5 . 30 VS (/ 0.1) 20.0
well well TS (/ 420~)
3 VS (/ 0.1)
. -2 1.001 VS (/ 1.0) 1 .
. -2 83 43 3
0.01) 0.1 :Assay
.VS (/ 0.01) 1000 10 100 VS (/
C₁₉H₁₅NaO₄ . 308 1
RS RS
.C₁₉H₁₅NaO₄ 1.071
.0.03±0.47

ZINCI OXYDUM

Zinc oxide

ZnO : Molecular formula

81.38 :Relative molecular mass

:Chemical name :

Zinc oxide; CAS Reg. No. 1314-13-2.

:Description

| | | | |
|-------------------------|--------------|---|------------|
| TS (/ 750~) | | :Solubility | |
| | | .TS (/ 70~) | |
| | | :Category | |
| | | :Storage | |
| :Additional information | | | |
| REQUIREMENTS | | | |
| %100.5 | %99.0 | :General requirement | |
| | | () | ZnO |
| :Identity test | | | |
| | | :A | |
| 0.15 | TS (/ 70~) | 2.0 | 20 :B |
| | | TS (/ 45) | |
| TS (/ 70~) | 35 | 1.6 | :Arsenic |
| (130 | 1 |) "Limit test for arsenic | |
| | | . / 6 | |
| 10 | 2.0 | :Carbonates and acid-insoluble substances | |
| | | TS (/ 100~) | 30 |
| | | | |
| 30 | TS (/ 250~) | 5 | 0.20 :Iron |
| (129 | 1 |) "Limit test for iron | |
| | | . / 200 | |
| R | 5 | 20 | 2 :Lead |
| TS (/ 100) | 0.25 | | |
| | | | |
| 500 | 1.0 () | :Loss on ignition | |

| | | | | | |
|--------------|------------------------------|--------------|------|---|-------------|
| TS | / | 0.1 | 10 | 1 | .Alkalinity |
| | VS (/ 0.1) | | 0.3 | | |
| TS (/ 120~) | | 10 | 0.15 | | :Assay |
| 1 |) "Complexometric titrations | | " | | |
| .ZnO | 4.069 | VS (/ 0.05) | | | .(135 |

**LIST OF REAGENTS, TEST SOLUTIONS,
AND VOLUMETRIC SOLUTIONS**

LIST OF REAGENTS, TEST SOLUTIONS, AND VOLUMETRIC SOLUTIONS

| | | | | | |
|------------|-------|-------------------------------|-------------------|-------------------|--|
| " | | " | | 2 | |
| | | . | | | |
| | | :Acacia R. () | | | |
| | | .Acacia sengl (L.) | | | |
| 3 1 | | :Description | | | |
| | | . | | | |
| | | :Solubility | | | |
| | | .R TS (/ 750~) | | | |
| | | . / 50 :Ash. | | | |
| | | . / 5.0 :Acid-insoluble ash - | | | |
| 10 | 100 | 5 | :Insoluble matter | | |
| | | 15 | TS (/ 70~) | | |
| | | ° 105 | | | |
| | | . / 5 | | | |
| TS (/ 25) | | 0.1 | 10 1 | :Tannin | |
| | | . | | | |
| | | R | 5 | :TS (/ 5) Acacia | |
| | | . | | | |
| | | :RS (p-Acetamidobenzalazine) | | -p | |
| | | :TS 4.5 (Acetate buffer) | | | |
| 8 | 100 R | 10.9 | :Procedure | | |
| | | 1000 | R | | |

| | | | | | |
|------|-----------------|----|---|---|---------------|
| | | | | :TS2 (4-Aminoantipyrine) | -4 |
| 10 | | 30 | R | 4 0.1 :Procedure | |
| | VS (/ 1) | | | 2 TS (/ 200) | |
| | | | | . 100 | |
| | | | | -4 : | |
| | | | | .C ₃ H ₃ N ₃ O ₂ S :R (2-Amino-5-nitrothiazole) | -5- -2 |
| | | | | fluffy :Description | |
| | | | | :Solubility | |
| | | | | .R R TS (/ 750~) | |
| | | | | ° 198 :Melting temperature | |
| | | | | .C ₆ H ₇ NO :R (4-Aminophenol) | -4 |
| | | | | :Description | |
| | | | | ° 184 :Melting temperature | |
| 50 | NH ₃ | | | TS (/ 260~) :TS (/ 50~) Ammonia | |
| | | | | .d~0.977 (/ 3) | |
| | | | | :TS2 (Ammonia buffer) | |
| | | | | TS (/ 260~) 650 R 67.5 :Procedure | |
| | | | | . 1000 | |
| 100 | | | R | :TS (/ 100) Ammonium acetate | |
| | | | | . C ₂ H ₇ NO ₂ | |
| 38.5 | | | R | :TS (/ 40) Ammonium acetate | |
| | | | | .(/ 0.5) C ₂ H ₇ NO ₂ | |
| | | | | TS (/ 40) :Note | |
| 2 | | | R | :TS (/ 2) Ammonium acetate | |
| | | | | . C ₂ H ₇ NO ₂ | |
| | | | | TS (/ 2) :Note | |

| | | | | |
|-----|---------------|--|---|------------------|
| | :TS | 4.62 | (Ammonium acetate buffer) | |
| | 4.62 | TS (/ 100) | | :Procedure |
| | | | .TS (/ 60~) | |
| | : | TS (Ammonium mercurithiocyanate) | | |
| R | | 27 R | 30 | :procedure |
| | | | . | 1000 |
| | : | TS (Ammonium molybdate/sulfuric acid) | / | |
| | | R | 0.5 | :Procedure |
| | | | . | 10 TS (/ 1760~) |
| | : | TS (Ammonium molybdate/vanadate) | / | |
| R | | 0.1 R | 4 | :Procedure |
| 100 | TS (/ 1000~) | 20 | . | 70 |
| | | | | . |
| . | (37 | 1963 SRIP) (NH ₄) ₂ S ₂ O ₈ | :R (Ammonium persulfate) | |
| | : | TS (Ammonium persulfate/phosphate buffer) | / | |
| TS | 7.4 | R | 10 | :Procedure |
| | | | . | 100 |
| . | (39 | 1963 SRIP) NH ₄ [Cr(NH ₃) ₂ (SCN) ₄], H ₂ O | :R (Ammonium reineckate) | |
| 10 | R | : | TS (/ 10) Ammonium reineckate | |
| | | . | NH ₄ [Cr(NH ₃) ₂ (SCN) ₄] | |
| 50 | R | : | TS (/ 50) Ammonium sulfamate | |
| | | . | NH ₄ OSO ₂ NH ₂ | |
| | : | TS Ammonium sulfide | | |
| 25 | .TS (/ 100~) | R | | :Procedure |
| | | .TS (/ 100~) | 50 | |

• porous

100 R 5 :Procedure

:RS (Carbidopa)

.C₂₈H₃₈N₂O₄.2HCl.7H₂O :R (Cephaeline hydrochloride)

$$[\alpha]_D^{20^\circ\text{C}} = +25^\circ \quad / \quad 20 \quad \text{: Specific optical rotation}$$

| | | | | |
|----|----------------------|-------|---|------------|
| 28 | Ce(SO ₄) | 33.23 | R | :Procedure |
|----|----------------------|-------|---|------------|

/ 0.1 :Method of standardization

| | | | |
|-------------|-----|--------------|------|
| 80 | | 25 | : |
| R | 2.5 | TS (/ 105~) | 10 |
| VS (/ 0.1) | R | 1 | . 15 |
| | | | . TS |

:RS (Chloramphenicol palmitate)

.C₆H₆ClN -4 :R (4-Chloraniline)

:Description

. ° 70 :Melting temperature

.C₈H₈ClNO :R (4-Chloroacetanilide) **-4**

:Description

| | | | |
|--------|---|--|-------------------------------|
| .R | TS (/ 750~) | | :Solubility |
| | | . ° 180 | :Melting temperature |
| | | | :RS (Cimetidine) |
| . (69 | 1963 SRIP) | C ₁₉ H ₂₂ N ₂ O | :R (Cinchonine) |
| | R | | :PbR (Citric acid) |
| | | | :RS (Clofazimine) |
| | | | :RS (Clomifene citrate) |
| | :RS (Clomifene citrate Z-isomer) | | Z- |
| | | | .RS |
| . (70 | 1963 SRIP) | CoCl ₂ ·6H ₂ O | :R (Cobalt (II) chloride) II |
| | | .189 | |
| 30 | :TS (/ 30) | (Cobalt (II) chloride) II | |
| | | | . CoCl ₂ |
| 5 | :TS (/ 5) | (Cobalt (II) chloride) II | |
| | | | . CoCl ₂ |
| | | | :TS (Cobalt (II) chloride) II |
| 2.5 | R (II) | 6.5 | :Procedure |
| | . 100 | 97.5 | TS (/ 250~) |
| | .328 | 2 | |
| | .Co(NO ₃) ₂ ·6H ₂ O | | :R (Cobalt (II) nitrate) |
| | | | :Description |
| | | | :Solubility |
| R (II) | :TS (/ 100) | (Cobalt (II) nitrate) (II) | |
| | | . Co(NO ₃) ₂ | 100 |
| | :TS (/ 10) | (Cobalt (II) nitrate) (II) | |
| . 100 | R (II) | 1.6 | :Procedure |

| | | |
|---------------|---------------|---|
| TS (/ 150~) | TS (/ 710~) | 5 VS (/ 0.05) |
| | | . 250 |
| | | :(Culture medium Cm8) Cm8 |
| 10 R | 10 R | 10 <i>:Procedure</i> |
| . 1000 | R | 17 R 3.0 R |
| 121 | 7.1-6.9 | VS (/ 0.05) |
| | | . 20-18 ° |
| | | :(Culture medium Cm9) Cm9 |
| R 10 R | 10 R | 10 <i>:Procedure</i> |
| . 1000 | | R 3.0 |
| . 20-18 ° 121 | 7.1-6.9 | VS (/ 0.05) |
| | | :(Culture medium Cm10) Cm10 |
| R | 5 R | 1 <i>:Procedure</i> |
| R | 14 R | 5 R 5 |
| | | . 1000 |
| | | :(Culture medium Cm11) Cm11 |
| R 15 R | 6 R | 10 <i>:Procedure</i> |
| VS (/ 1) | | . 1000 |
| | .7.8 | |
| | . 20-18 ° 121 | |
| | | :RS (Cytarabine) |
| | | :RS (Dexamethasone sodium phosphate) |
| | | :RS (Dextromethorphan hydrobromide) |
| | | :R (Diatomaceous support) |
| | | <i>:Description</i> |
| | flux-calcined | |

.alkali-washed

.C₂₀H₁₀C₁₂O₅ :R (Dichlorofluorescein)

:Description

:Solubility

:TS (Dichlorofluorescein)

Procedure

:RS (Dicloxacillin sodium)

:R (Diethylaminoethylcellulose)

.C₁₂H₁₄O₄ :R (Diethyl phthalate)

$$\rho_{20} = 1.117 \text{ : Mass density}$$

. $n_D^{20} = 1.500 - 1.505$: *Refractive index*

:RS (Diloxanide furoate)

.C₄H₉NO :R (Dimethylacetamide)

Description

° 165 : *Boiling temperature*

$\rho_{20} = 0.94$: *Mass density*

:TS5 (4-Dimethylaminobenzaldehyde)

-4

Procedure

55

:TS6 (4-Dimethylaminobenzaldehyde)

-4

Procedure

TS (/ 750~)

.VS (/ 0.0001)

-4

| | | | | | |
|----------------|------|--------------|--|---|----------------|
| | | | | $\text{C}_8\text{H}_{11}\text{N}$:R (N,N-Dimethylaniline) | -N,N |
| | | | | :Description | |
| .R | R | TS (/ 750~) | | :Miscibility | |
| | | | | . ° 193 :Boiling temperature | |
| | | | | . / 0.96= ρ_{20} :Mass density | |
| | | | | $\text{C}_2\text{H}_6\text{OS}$:R (Dimethyl sulfoxide) | |
| | | | | :Description | |
| | | | | . / 1.10 = ρ_{20} :Mass density | |
| .(80 | 1963 | SRIP) | $\text{C}_6\text{H}_4\text{ClN}_2\text{O}_4$:R (2,4-Dinitrochlorobenzene) | -4,2 | |
| | | | :RS (Diphenoxylate hydrochloride) | | |
| | | | :TS (Diphenylamine/sulfuric acid) | / | |
| .TS (/ 1760~) | | 100 | R | 1.0 | :Procedure |
| | | TS | / | | :Storage |
| | | | | | |
| | | | $\text{C}_{13}\text{H}_{14}\text{N}_4\text{O}$:R (1.5-Diphenylcarbazine) | -5,1 | |
| | | | | :Description | |
| | | | | . ° 174 :Melting temperature | |
| | | | | :TS (Diphenylcarbazine) | |
| | 10 | | R | -5,1 | 0.2 :Procedure |
| | | | | .TS (/ 710~) | 90 R |
| | | 0.5 | | :Sensitivity test to chromate | |
| 0.2 | 50 | | 5 | . 1000 | VS (/ 0.0167) |
| | | TS | | 0.5 | VS (/ 2) |
| | | | | :TS (/ 20) (Disodium edetate) | |
| | R | | | $\text{C}_{10}\text{H}_{14}\text{N}_2\text{Na}_2\text{O}_8$ | 20 |
| | | | | :TS (/ 10) (Disodium edetate) | |
| | R | | | | |

| | | | | |
|---|-------------------------------|--------------|------------|------------|
| :TS (Ferric chloride/ferricyanide/arsenite) | | / | / | |
| | : | | :Procedure | |
| .TS (/ 70~) | 100 | R | 2.7 | (1) |
| . | 100 | R | 3.5 | (2) |
| .TS (/ 80~) | 25 | R | 3.8 | (3) |
| . | 100 | TS (/ 100~) | 50 | |
| .(3) | (2) | 5 (1) | 5 | |
| :TS (Ferric chloride/potassium ferricyanide) | | / | | |
| R | 0.10 | R | 2 | :Procedure |
| | | | 20 | |
| . | TS | / | : | |
| :TS (/ 50) (Ferricyanide standard) | | | | |
| K ₃ Fe(CN) ₆ | 7.8 | R | :Procedure | |
| . | 1000 | | 1.0 | . 100 |
| . | (/ 50) | | : | |
| :TS (/ 100) (Ferrocyanide standard) | | | | |
| K ₄ Fe(CN) ₆ ·3H ₂ O | 2.0 | R | :Procedure | |
| . | 100.0 | | 1.0 | . 100 |
| . | (/ 100) | | : | |
| . | :RS (Flucytosine) | | | |
| . | :RS (Fludrocortisone acetate) | | | |
| . | :RS (Fluorouracil) | | | |
| . | :SV RS (3-Formylrifamycin) | | | |
| . | :TS (Fuchsin,decolorized) | | | |
| | 600 | basic | 1 | :Procedure |
| | 100 | R | | 20 |

| | | | |
|---------------|---|--------------------|----|
| TS (/ 250~) | 1000 (0.3-0.2) R | TS (/ 250~) | 10 |
| | 3-2 | | |
| | TS | | |
| | :RS (Gallamine triethiodide) | | |
| | :RS (Gentamicin sulfate) | | |
| | :RS (Glibenclamide) | | |
| | :R (Glucose,anhydrous) | | |
| .150 | 2 | | |
| | (94 1963 SRIP) :R (Heptane) | | |
| | :R (Hexamethyldisilazane) | | |
| | <i>:Description</i> | | |
| | $\rho_{20} = / 0.77$ <i>:Mass density</i> | | |
| | :R (Hydrazine sulfate) | | |
| | <i>:Description</i> | | |
| .TS (/ 750~) | 40 | <i>:Solubility</i> | |
| " | 35 10 | <i>:Arsenic</i> | |
| . / 1 | (130 1) "Limit test for arsenic | | |
| | . / 1.0 <i>:Sulfated ash</i> | | |
| TS (/ 420~) | :TS (/ 330~) (Hydrochloric acid) | | |
| | (/ 9) $d \sim 1.15$ HCl 330 | | |
| TS (/ 250~) | :VS (/ 0.05) (Hydrochloric acid) | | |
| | . 1000 HCl 1.824 | | |
| | <i>:Method of standardization</i> | | |
| .200 | 1 VS (/ 1) | | |

TS (/ 250~) :VS (/ 0.005) (Hydrochloric acid)
. 1000 HCl 0.1824
:Method of standardization
.200 1 VS (/ 1)
(/ 250~) :VS (/ 0.0001) (Hydrochloric acid)
. 1000 HCl 3.647
:Method of standardization
.200 1 VS (/ 1)
:VS (/ 0.01) (Hydrochloric acid/methanol) /
. 1000 HCl 0.3647 TS (/ 250~)
:Method of standardization
.200 1 VS (/ 1)
:RS (Hydrocortisone sodium succinate)
.C₆H₄(OH)₂ :R (Hydroquinone)
:Description
.R TS (/ 750~) :Solubility
. ° 173 :Melting temperature
:
:TS (/ 200) (Hydroxylamine hydrochloride)
. NH₂OH,HCl 200 R
:RS -2- -2-(-3- -4)-3-(-)
:TS (-)-3-(4-Hydroxy-3-methoxyphenyl)-2-hydrazino-2-methylalanine
.10,11-Dihydro-5*H*-dibenz[*b,f*]azepine; C₁₄H₁₃N :R (Iminodibenzyl)
:Description
. ° 106 :Melting temperature
:R (pH-Indicator paper)

| | | | | | |
|----------------|----------------------|-------|--|--|--|
| .10-1 | | () | | | |
| | | | | :TS (Iodine/chloroform) / | |
| . 100 | | R | | 5.0 :Procedure | |
| I ₂ | 12.69 | R | | :VS (/ 0.05) (Iodine) | |
| | | | | . 1000 KI 18.0 | |
| | | | | :Method of standardization | |
| | | .202 | | 1 VS (/ 0.1) | |
| 1.8 | I ₂ 1.269 | R | | :VS (/ 0.005) (Iodine) | |
| | | | | . 1000 KI | |
| | | | | :Method of standardization | |
| | | .202 | | 1 VS (/ 0.1) | |
| I ₂ | 25.38 | R | | :VS (/ 0.0001) (Iodine) | |
| | | | | . 1000 KI 0.36 | |
| | | | | :Method of standardization | |
| | | .202 | | 1 VS (/ 0.1) | |
| | | | | :TS (Iron salicylate) | |
| 10 | | 250 R | | 0.5 :Procedure | |
| 100 | | . 500 | | TS (/ 100~) | |
| 80 | TS (/ 60~) | 20 | | TS (/ 11.5) | |
| | | . 500 | | TS (/ 150) | |
| | | | | :Storage | |
| | | | | : | |
| | | | | .C ₃ H ₉ N :R (Isopropylamine) | |
| | | | | :Description | |
| | | | | . ° 33 :Boiling point | |
| | | | | . ρ ₂₀ = / 0.69 :Mass density | |

| | | | | | |
|-----------------------------------|---------------------------------------|------|-------|--|--------------------|
| | | | | :R (Lead acetate paper) | |
| TS (/ 80) | | 10 | | <i>:Procedure</i> | |
| . 40 × 15 | | | | . (/ 60~) | |
| | | | | <i>:Storage</i> | |
| Pb(NO ₃) ₂ | 100 | R | | :TS (/ 100) (Lead nitrate) | |
| | | | | | |
| | (105 | 1963 | SRIP) | PbO ₂ :R (Lead (IV) oxide) (IV) | |
| | | | | :RS (Levonorgestrel) | |
| | | | | :RS (Levothyroxine sodium) | |
| | | | | :RS (Liothyronine) | |
| | | | | .Li ₂ CO ₃ :R (Lithium carbonate) | |
| | | | | <i>:Description</i> | |
| .TS (/ 750~) | | | | <i>:Solubility</i> | |
| | | | | :TS (Lithium carbonate/trinitrophenol) | / |
| R | | 0.5 | R | 0.25 | <i>:Procedure</i> |
| | | | | . 100 | |
| | | | | .LiCl :R (Lithium chloride) | |
| | | | | <i>:Description</i> | |
| .R | TS (/ 750~) | | R | | <i>:Solubility</i> |
| | | | | | <i>:Storage</i> |
| LiCl | 10 | | | :TS (/ 10) (Lithium chloride) | |
| | | | | | |
| | | | | :RS (Loperamide hydrochloride) | |
| | | | | :R (Macrogol 1000) 1000 | |
| | | | | <i>:Description</i> | |
| | 17.3 m m ² s ⁻¹ | | ° 100 | | <i>:Viscosity</i> |

p-tert- C₃₄H₆₂O₁₁ :R (Macrogol *p*-isooctylphenyl ether) -P
 .octylphenoxy polyethoxy-ethanol
 . "Sterility testing of antibiotics"
 .C₄H₆MgO₄.4H₂O :R (Magnesium acetate)
 . :Description
 .TS (/ 750~) :Solubility
 .(110 1963 SRIP) MgCl₂.6H₂O :R (Magnesium chloride)
 :VS (/ 0.1) (Magnesium chloride)
 . 1000 R 20.5 :Procedure
 / 0.1 :Method of standardization
 . 25 (135 1)
 .MgCl₂.6H₂O 20.33 VS (/ 0.1)
 :TS (Mg / 0.1) (Magnesium)
 5 R 1.014 :Procedure
 . 1000 TS (/ 100~)
 :TS (Mg / 10) (Magnesium standard)
 . 100 TS (/ 0.1) 10
 :TS (Magnesium sulfate/sulfuric acid) /
 TS (/ 100~) R 25 :Procedure
 . 100
 . :RS (Mebendazole)
 .C₁₁H₈O₂ -4.1- -2 :R (Menadione)
 . :Description
 . ° 106 :Melting temperature
 :TS (Mercuric chloride/ethanol) /
 TS (/ 375~) R 2 :Procedure

. 100

:TS (Mercuric nitrate)

32 R 40 *:Procedure*
15 TS (/ 1000~)
:Storage

:VS (/ 0.02) (Mercuric nitrate)

10 R 6.85 *:Procedure*
1000 500 TS (/ 130~)
/ 0.02 *:Method of standardization*
.190 1 VS (/ 0.01)

:TS (Mercury/nitric acid) /

R 27 R 3 *:Procedure*
:Storage

:RS (Methotrexate)

:RS (Metoclopramide hydrochloride)

:RS (Miconazole nitrate)

. (120 1963 SRIP) MoO₃ **:R (Molybdenum trioxide)**

.C₂H₇NO **:R (Monoethanolamine)**

:Description

.R R *:Miscibility*

. ° 170 *:Boiling temperature*

.ρ₂₀= / 1.01 *:Mass density*

. n_D²⁰ = 1.453–1.455 *:Refractive index*

:RS (Naloxone hydrochloride)

:RS (Neamine)

| | | |
|-------------|--------------------------------|----------|
| :INN | RS (Framycetin sulfate) |) |
|-------------|--------------------------------|----------|

.(124 1963 SRIP) $C_{15}H_{17}ClN_4$ C.I. C.I. 50040 :R (Neutral red)

| | | | | |
|-----|--------------|---|-----|------------|
| 100 | TS (/ 375~) | R | 0.1 | :Procedure |
|-----|--------------|---|-----|------------|

:RS (Niridazole-chlorethylcarboxamide) -

| .R | R | TS (/ 750~) | :Miscibility |
|----|---|--------------|--------------|
|----|---|--------------|--------------|

$$n_D^{20} = 1.380 : \text{Refractive index}$$

° 101 : (Boiling temperature)

:RS (Nystatin)

:Description

° 237 : (Boiling temperature)

$$/ \quad 0.92 = \rho_{20} : (\text{Mass density})$$

-4- -1 19 :R (Oracet blue B) B

| | | | | | | |
|--------------|------|---|--|--------------|-------|---|
| | | | $(C_{20}H_{14}N_2O_2)$ | -4- | -1 | $(C_{21}H_{16}N_2O_2)$ |
| | | | :TS (Oracet blue B/acetic acid) | | | /B |
| R1 | | | R B | 0.5 | | <i>:Procedure</i> |
| | | | | | | 100 |
| | | | $(131$ | 1963 | SRIP) | $C_2H_2O_4 \cdot 2H_2O$:R (Oxalic acid) |
| 0.05 | | R | | | | :TS (/ 0.05) (Oxalic acid) |
| | | | | | | 1000 $C_2H_2O_4$ |
| | 1000 | | R | 0.07 | | <i>:Procedure</i> |
| | | | | | | :RS (Oxamniquine) |
| | | | | | | :RS (Oxytetracycline dihydrate) |
| | | | :R (Paracetamol,4-aminophenol-free) | - | -4 | |
| : | | | | 237 | | |
| | 100 | | R | | | 5 |
| | 30 | | TS | 1.0 | | |
| | | | | | | |
| | | | $(CH_2O)_n$:R (Paraformaldehyde) | | | |
| | | | | | | <i>:Description</i> |
| evolution | | | | | | <i>:Solubility</i> |
| | | | .R | TS (/ 750~) | | |
| TS (/ 100~) | 10 | 1 | | | | <i>:Solubility in ammonia</i> |
| | | | | | | |
| | | | | / 1.0 | | <i>:Sulfated ash</i> |
| | 20 | 1 | | | | <i>:Acidity or alkalinity</i> |
| | | | | | | () |
| | | | | | | :RS (Paromomycin sulfate) |

| | | |
|--|---|---------------------------------------|
| $\text{C}_5\text{H}_{11}\text{NaO}_3\text{S}\cdot\text{H}_2\text{O}$:R (1-Pentanesulfonic acid sodium salt) | | -1 |
| | | :Description |
| | | :Solubility |
| 25 | 1 | :Clarity and colour of solution |
| | / 20 | :Water |
| | | :(1-Pentanesulfonic acid) |
| | | -1 |
| 1000 | R | -1 |
| 0.960 | | :Procedure |
| TS (/ 260~) | 4.3 | TS (/ 5.0) |
| | | : |
| | | :VS (/ 0.1) (Perchloric acid/dioxan) |
| R | TS (/ 1170~) | 8.5 :Procedure |
| | | 1000 |
| 0.7 | | :Method of standardization |
| A | 2 ° 120 | R |
| 1 (142 | 1) "Non-aqueous titration | " |
| | $\text{C}_8\text{H}_5\text{KO}_4$ 20.42 | VS (/ 0.1) / |
| | | :VS (/ 0.02) (Perchloric acid) |
| | VS (/ 0.1) | 20 :Procedure |
| | | 100 R1 |
| | | :Water and method of standardization |
| VS (/ 0.1) | | |
| | | .213 1 |
| $\text{C}_6\text{H}_8\text{N}_2\cdot 2\text{HCl}$:R (1,4-Phenylenediamine dihydrochloride) | | -4 1 |
| () tan | | :Description |
| | | : |
| R | TS (/ 750~) | :Solubility |
| | | :Storage |

| | | | | | |
|--------------|--------------|---|---|--------------------------|------------|
| | | :TS (Phenylhydrazine/hydrochloric acid) | | / | |
| 2 | 50 | R | 0.75 | :Procedure | |
| . 200 | TS (/ 420~) | | 25 | R | |
| | | :TS (/ 10) (Phenylhydrazine hydrochloride) | | | |
| | | . 1000 | C ₆ H ₈ N ₂ ,HCl | 10 | R |
| | | :R (Phenyl/methylpolysiloxane) | | / | |
| . 100 | | | 95 | 5 | |
| | | : TS 7.4 | | Phosphate buffer | |
| 393.4 | 250 | | | 6.8 | :Procedure |
| | | | | .VS (/ 0.1) | |
| | | :TS 7.6 | | Phosphate buffer | |
| 200 | R | | | 1.36 | :Procedure |
| | | VS (/ 0.2) | | 42.4 | |
| | | : TS 8.0 | | Phosphate buffer | |
| 0.50 | R | | | 8.95 | :Procedure |
| | | . 1000 | R | | |
| | | :TS ، 7.8 باءء ، Phosphate buffer, sterile | | ءارئة الفوسفات العقيمة | |
| 45.2 | R | | | 6.8 | :Procedure |
| | | . 1000 | VS (/ 1) | | |
| TS (/ 110~) | | TS (/ 1440~) | | 7.8 | |
| | | | | .° 120 | 20 |
| | | :TS1 10.5 | | Phosphate buffer,sterile | |
| 20 | R | | | 35.0 | :Procedure |
| | | . 1000 | VS (/ 1) | | |
| 20 | TS (/ 110~) | | TS (/ 1440) | | 10.5 |
| | | | | .° 120 | |

| | | | | | | |
|-------------|-----|---------------|---------------|-----------------------------------|---------------------------|------|
| | | | :TS 6.0 | Phosphate/citrate buffer | / | |
| 35 | 60 | R | | 4.52 | :Procedure | |
| | | | .6.0 | TS (/ 20) | | |
| | | | :TS (/ | 5) Phosphate standard | | |
| | | R | | 0.716 | :Procedure | |
| | | | . | 100 | 1 | 1000 |
| | | | | :TS (/ 105~) | Phosphoric acid | |
| | 885 | TS (/ 1440~) | | 115 | :Procedure | |
| | | | | :TS Phosphotungstic acid | | |
| 18.75 | | 75 | R | 25 | :Procedure | |
| | | 6 | | .TS (/ 1440~) | | |
| | | | | . | 250 | |
| | | | . | ° 8 2 | :Storage | |
| | | | | .C ₅ H ₁₁ N | :R (Piperidine) | |
| | | | . | | :Description | |
| | | | .TS (/ 750~) | | :Miscibility | |
| | | | . | $\rho_{20} =$ / 0.86 | :Mass density | |
| | | | . | $n_D^{20} = 1.454$ | :Refractive index | |
| | | | . | ° 106 | :Boiling temperature | |
| | | | .° 15 12 | | :Congealing temperature | |
| .(145 | | 1963 | SRIP) | KSbO ₃ | :R (Potassium antimonate) | |
| | | | | :TS (Potassium antimonate) | | |
| | | 95 | R | 2 | :Procedure | |
| .VS (/ 1) | | 5 | VS (/ 1) | | | 50 |
| | | . | 150 | | 24 | |
| 10 (/ 0.1) | | 7 | | | :Sensitivity to sodium | |
| | | | . | 15 | | |

| | | | | | | |
|-----|-----------|-----|---------------------------------|--|------------------------------------|--------------|
| | | | | | TS | : |
| | R | | | :VS (/ 0.00833) | Potassium bromate | |
| | | | | | 1000 KBrO ₃ | 1.392 |
| | | | | .K ₂ CO ₃ ,1 _{1/2} H ₂ O | :R (Potassium carbonate) | |
| | | | | | | :Description |
| | | | | .TS (/ 750~) | | :Solubility |
| | | | | .K ₂ CO ₃ | :R (Potassium carbonate,anhydrous) | |
| | | | | | | :Description |
| | | | | .TS (/ 750~) | | :Solubility |
| 100 | | R | | :TS (/ 100) | (Potassium chloride) | |
| | | | | | | KCl |
| | | | | | :PbTS (Potassium cyanide) | |
| | 2 | | 90 | R | 10 | :Procedure |
| | | 100 | | 24 | TS (/ 60~) | |
| | | | | | :TS2 (Potassium dichromate) | |
| 7.5 | | 60 | R | | 1 | :Procedure |
| | | | | | .TS (/ 1760~) | |
| | | | | | :TS3 (Potassium dichromate) | |
| | | R | | | 0.5 | :Procedure |
| | | | | | . 100 | TS (/ 100~) |
| | | | | :TS (/ 100) | (Potassium dihydrogen phosphate) | |
| | | | | | KH ₂ PO ₄ | 100 R |
| | | | | :TS (/ 27.2) | (Potassium dihydrogen phosphate) | |
| | | | | .(/ 0.2) | KH ₂ PO ₄ | 27.2 R |
| | | | | :TS (/ 13.6) | (Potassium dihydrogen phosphate) | |
| | .(/ 0.1) | | KH ₂ PO ₄ | 13.6 | R | |

| | | | | | | |
|----|-----|-----|---|--|-------------------|-------------------|
| | | | | :TS (/ 3.6) (Potassium iodate) | | |
| | | | | | KIO ₃ | 3.6 |
| KI | 100 | | | :TS (/ 100) (Potassium iodide) | | |
| | | | | | | |
| | | | | :TS2 (Potassium iodoplatinate) | | |
| | 45 | 2.5 | R | | 0.25 | <i>:Procedure</i> |
| | | 100 | R | | | TS (/ 100) |
| | | | | :TS (/ 25) Potassium permanganate) | | |
| | | | | | KMnO ₄ | 25 |
| R | | | | :TS (/ 200) (Potassium thiocyanate) | | |
| | | | | | KCNS | 200 |
| | | | | :RS (Praziquantel) | | |
| | | | | :RS (Prednisolone acetate) | | |
| | | | | :RS (Prednisolone sodium phosphate) | | |
| | | | | :RS (Probenecid) | | |
| | | | | :RS (Procarbazine hydrochloride) | | |
| | | | | :RS (Protionamide) | | |
| | | | | :RS (Pyrantel embonate) | | |
| | | | | :RS (Pyrazinamide) | | |
| | | | | :RS (Pyrimethamine) | | |
| | | | | :RS (Rifampicin quinone | | |
| | | | | :RS (Rifampicin) | | |
| | | | | :RS (Salbutamol) | | |
| | | | | :RS (Salbutamol sulfate) | | |
| | | | | .C₇H₆O₂ :R (Salicylaldehyde) | | |

| | | | | |
|--------------|--------|------|-------------------|---|
| | | | | :TS (/ 10) (Sodium alizarinsulfonate) |
| | | | $C_{14}H_7NaO_7S$ | 10 |
| | | | | :TS (/ 400) Sodium choride |
| | | | NaCl | 400 |
| | | | | :TS (/ 10) Sodium choride |
| | | | NaCl | 10 |
| | | | | :RS (Sodium cromoglicate) |
| | | | | :TS (/ 275) (Sodium dihydrogen phosphate) |
| | | | NaH_2PO_4 | 275 |
| | | | | $CHNaO_2$:R (Sodium formate) |
| | | | | <i>:Description</i> |
| | | | | $^{\circ} 253$ <i>:Melting temperature</i> |
| | | | | :TS(Sodium hydroxide/ethanol) / |
| TS (/ 750~) | | | R | 50 <i>:Procedure</i> |
| | | | | 1000 |
| | | | | :TS (/ 50) Sodium hydroxide |
| | | | NaOH | 50 |
| | | | | :TS (/ 35) Sodium nitrite |
| | (0.5) | | $NaNO_2$ | 35 R |
| R | | | | :TS (/ 8.5) Sodium Nitroprusside |
| | | | | $Na_2Fe(NO)(CN)_5$ 8.5 |
| | | | | :TS (Sodium Nitroprusside, alkaline) |
| R | | 1 | R | 1 <i>:Procedure</i> |
| | | | | 100 |
| | (191 | 1963 | SRIP) | Na_2O_2 :Sodium peroxide |
| | | | | $C_7H_5NaO_3$:R (Sodium salicylate) |

| | | | | |
|---|--|---|---|--|
| | .TS (/ 50) | 1 | 10 | TS |
| | | | | :RS (Sulfasalazine) |
| | | | | :TS (Sulfuric acid/methanol) / |
| .R | 90 TS (/ 1760~) | | 10 | <i>:Procedure</i> |
| | | | | |
| | TS (/ 1760~) | | | :VS (/ 0.125) (Sulfuric acid) |
| | | | 1000 H ₂ SO ₄ | 12.52 |
| | | | | <i>:Method of standardization</i> |
| | .209 | 1 | VS (/ 0.5) | |
| | .(205 | 1963 SRIP) | C ₇₆ H ₂₅ O ₄₆ | :R (Tannic acid) |
| C ₇₆ H ₂₅ O ₄₆ | 50 | R | | :TS (/ 50) (Tannic acid) |
| | | | | |
| 200 | | | | :TS (/ 200) (Tartaric acid) |
| | | | | C ₄ H ₆ O ₆ |
| | | | | :RS (Testosterone enantate) |
| | :(Tetrabutylammonium hydroxide/methanol) TS | | | / |
| | TS | | | <i>:Procedure</i> |
| | | | C ₁₆ H ₃₇ NO | 0.25 |
| | .C ₁₆ H ₃₇ NO | :TS (Tetrabutylammonium hydroxide) | | |
| | .(/ 1.5~) | | C ₁₆ H ₃₇ NO | 400 |
| | | | | .C₄H₈O :R (Tetrahydrofuran) |
| | | | | <i>:Description</i> |
| | | | | ° 66 <i>:Boiling point</i> |
| | | | ρ ₂₀ = / | 0.886-0.884 <i>:Mass density</i> |
| | | | | <i>:Storage</i> |
| | | | | <i>:Labelling</i> |
| | %0.1 | | | |

. **:RS (Thioacetazone)**

. **:RS (Tiabendazol)**

%15 **:R (Titanium trichloride)**
 .(208 1963 SRIP) TiCl_3
 $\rho_{20} = / 1.2 \sim$:Mass density

100 **:VS (/ 0.1) (Titanium trichloride)**
 TS (/ 250~) 200 R
 . 1000 R
 . :Method of standardization

TS (/ 100~) VS (/ 0.1) 25
 . TS (/ 75) R
 . TiCl_3 15.43 VS (/ 0.1) 1
 .(208 1963 SRIP) $\text{C}_{28}\text{H}_{19}\text{N}_5\text{Na}_2\text{O}_6\text{S}_4$ **:R (Titan yellow)**
:TS (Titan yellow)
 . 100 R 0.05 :Procedure

. **:RS (Trihexyphenidyl hydrochloride)**
:TS (Triketohydrindene/butanol) /
 -1 R 0.1 :Procedure
 . 100

:TS (/ 1) (Triketohydrindene hydrate)
 . $\text{C}_9\text{H}_4\text{O}_3$ 1 R
:TS (Triketohydrindene/methanol) /
 R R 1.0 :Procedure
 . 100
 . / :

:TS (Triketohydrindene/pyridine/acetone) / /

| | | | | | |
|--------|---|--------------------------------------|---------------------------------|--|-------------------------------|
| | 100 | | 0.25 | :Procedure | |
| | | | | .R | R |
| | :TS (Triketohydrindene/pyridine/acetone) | | / | / | |
| | R | 1 | 1 | :Procedure | |
| | | | | . 100 | R -1 |
| | | | | . | : |
| | :TS (Triketohydrindene/stannous chloride) | | / | | |
| | 100 | R | 4 | :Procedure | |
| cation | | 1 | | .R (ethylene glycol monomethyl ether) | |
| R | 0.16 | (A) | (840- 300) | exchange resin | |
| | | (B) | TS 5.5 | | 100 |
| | | | | . | |
| (129 | 1963 | SRIP) C ₈ H ₁₈ | iso-Octane | :R (2.2.4-Trimethylpentane) | -4.2.2 |
| | | | | .C ₁₈ H ₁₅ Sb | :R (Triphenylantimony) |
| | | | | . ° 55 | :Melting temperature |
| | | | | .Na ₃ PO ₄ ·12H ₂ O | :R (Trisodium orthophosphate) |
| | | | | . | :Description |
| | TS (/ 750~) | | | | :Solubility |
| | | | | | .R |
| | TS : (/ 2) | | (Trisodium orthophosphate) | | |
| | | | Na ₃ PO ₄ | 2 | |
| | | | .1-β-D-Ribofuranosyluracil | C ₉ H ₁₂ N ₂ O ₆ | :R (Uridine) |
| | | | | | :Solubility |
| | | | | ° 165 | :Melting temperature |
| | | | | | :Storage |
| | | | | | :RS (Valproic acid) |

| | | | | | |
|-----------------|-----|---|------------------------|---|--|
| | | | V_2O_5 | :R (Vanadium pentoxide) | |
| | | | | | <i>:Description</i> |
| | | | | | <i>:Solubility</i> |
| | | | | | .TS (/ 750~) |
| | | | | :TS (Vanadium/sulfuric acid) | / |
| | 4 | R | | 0.20 | <i>:Procedure</i> |
| | | | . 100 | | TS (/ 1760~) |
| | | | | :TS (Vanillin/hydrochloric acid) | / |
| TS (/ 250~) | | | R | 1.0 | <i>:Procedure</i> |
| | | | | | . 100 |
| | | | . TS | / | : |
| | | | | :RS (Verapamil hydrochloride) | |
| | | | | :RS (Vincristine sulfate) | |
| | | | | :RS (Warfarin) | |
| | | | . (210 1963 SRIP) | $\text{C}_{13}\text{H}_{10}\text{O}_2$ | :R (Xanthidrol) |
| | | | | | :TS (Xanthidrol) |
| 99 TS (/ 420~) | | | 1 | 20 | <i>:Procedure</i> |
| | | | | | .TS (/ 300~) |
| | | | | $\text{Zn}(\text{C}_5\text{H}_{10}\text{NS}_2)_2$ | :R [Zinc bis (dibenzylthiocarbamate)] (|
| | | | | |) |
| | | | | | <i>:Description</i> |
| | | | .R | | <i>:Solubility</i> |
| | | | .° 180-178 | | <i>:Melting range</i> |
| | | | | :TS [Zinc bis (dibenzylthiocarbamate)] (|) |
| | R (| |) | 10.0 | <i>:Procedure</i> |
| | | | . 100 | R | |
| | | | :RS (| Z- |) (Zuclofifine) |

