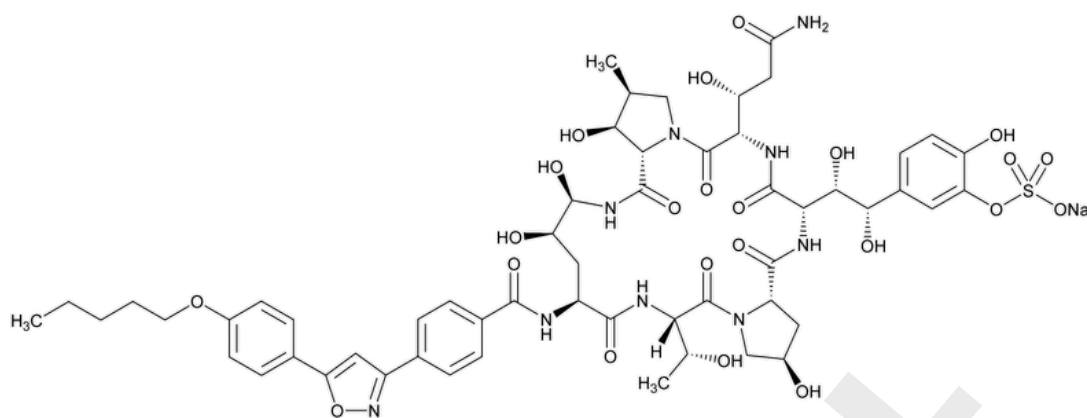


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Add the following:

▲Micafungin Sodium



$C_{56}H_{70}N_9NaO_{23}S$ 1292.27

Pneumocandin A0, 1-[(4R,5R)-4,5-dihydroxy-N²-[4-[5-[4-(pentyloxy)phenyl]-3-isoxazolyl]benzoyl]-L-ornithine]-4-[(4S)-4-hydroxy-4-[4-hydroxy-3-(sulfoxy)phenyl]-L-threonine]-, monosodium salt;
Sodium 5-[(1S,2S)-2-[(2R,6S,9S,11R,12R,14aS,15S,16S,20S,23S,25aS)-20-[(R)-3-amino-1-hydroxy-3-oxopropyl]-2,11,12,15-tetrahydro-6-[(R)-1-hydroxyethyl]-16-methyl-5,8,14,19,22,25-hexaoxa-9-(4-{5-[4-(pentyloxy)phenyl]isoxazol-3-yl}benzamido)tetracosahydro-1H-dipyrrolo[2,1-c:2',1'-l][1,4,7,10,13,16]hexaazacyclohenicosin-23-yl]-1,2-dihydroxyethyl]-2-hydroxyphenyl sulfate CAS RN[®]: 208538-73-2.

UNII: IS1UP79R56

DEFINITION

Micafungin Sodium contains NLT 95.0% and NMT 102.0% of micafungin sodium ($C_{56}H_{70}N_9NaO_{23}S$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sodium:** Meets the requirements

ASSAY

• PROCEDURE

Conduct the entire procedure, without exposure to direct sunlight, using a light-resistant vessel.

Buffer: 18.7 g/L of [sodium phosphate, monobasic, dihydrate](#) and 7.7 g/L of [sodium perchlorate](#) in [water](#). Adjust with [10% phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (450:700)

Diluent: [Acetonitrile](#) and [water](#) (3:7)

Standard solution: 0.5 mg/mL of [USP Micafungin Sodium RS](#) in *Diluent*

Sample solution: 0.5 mg/mL of Micafungin Sodium in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min**Injection volume:** 5 µL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 1.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of micafungin sodium ($C_{56}H_{70}N_9NaO_{23}S$) in the portion of Micafungin Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of micafungin from the *Sample solution* r_S = peak response of micafungin from the *Standard solution* C_S = concentration of [USP Micafungin Sodium RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Micafungin Sodium in the *Sample solution* (mg/mL)**Acceptance criteria:** 95.0%–102.0% on the anhydrous and solvent-free basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): 4.8%–5.8%• **ORGANIC IMPURITIES**

Conduct the entire procedure, without exposure to direct sunlight, using a light-resistant vessel.

Buffer and Mobile phase: Prepare as directed in the Assay.**Solution A:** 35.8 g/L of [sodium phosphate, dibasic, dodecahydrate](#)**Solution B:** 13.6 g/L of [potassium phosphate, monobasic](#)**Diluent:** *Solution A* and *Solution B* (2:1); pH 7.0**System suitability solution:** 4 mg/mL of [USP Micafungin Sodium RS](#) in *Diluent***Sensitivity solution:** 0.002 mg/mL of [USP Micafungin Sodium RS](#) in *Diluent***Standard solution:** 0.012 mg/mL of [USP Micafungin Sodium RS](#) in *Diluent***Sample solution:** 4 mg/mL of Micafungin Sodium in *Diluent***Chromatographic system:** Proceed as directed in the Assay, except for the *Injection volume*.**Injection volume:** 2 µL**System suitability****Samples:** *System suitability solution*, *Sensitivity solution*, and *Standard solution*[NOTE—See [Table 1](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 1.2 between micafungin and micafungin epimer, *System suitability solution***Tailing factor:** NMT 1.5, *Standard solution***Relative standard deviation:** NMT 5.0%, *Standard solution***Signal-to-noise ratio:** NLT 10, *Sensitivity solution***Analysis****Sample:** *Sample solution*

Calculate the percentage of any individual impurity in the portion of Micafungin Sodium taken:

$$\text{Result} = (r_U/r_T) \times 100$$

 r_U = peak response of any individual impurity r_T = sum of all the peak responses**Acceptance criteria:** See [Table 1](#). The reporting threshold is 0.05%.**Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Micafungin open ring analog ^a	0.73	0.8
Desmethyl micafungin ^b	0.91	1.2
Micafungin serine analog ^c		
Micafungin	1.0	—
Micafungin epimer ^d	1.09	0.7
Deoxy micafungin ^e	1.12	0.5
Any individual unspecified impurity	—	0.3
Total impurities	—	3.5

^a Sodium 5-[(1S,2S,3S)-4-((2S,3R)-5-amino-1-[(2S,3S,4S)-2-carbamoyl-3-hydroxy-4-methylpyrrolidin-1-yl]-3-hydroxy-1,5-dioxopentan-2-yl)amino)-3-[(2S,4R)-1-[(2S,4R)-4,5-dihydroxy-1-(4-{5-[4-(pentyloxy)phenyl]isoxazol-3-yl}benzoyl)pyrrolidine-2-carbonyl]-L-threonyl)-4-hydroxypyrrolidine-2-carboxamido]-1,2-dihydroxy-4-oxobutyl]-2-hydroxyphenyl sulfate.

^b Sodium 5-[(1S,2S)-2-[(2R,6S,9S,11R,12R,14aS,15S,20S,23S,25aS)-20-[(R)-3-amino-1-hydroxy-3-oxopropyl]-2,11,12,15-tetrahydroxy-6-[(R)-1-hydroxyethyl]-5,8,14,19,22,25-hexaoxo-9-(4-{5-[4-(pentyloxy)phenyl]isoxazol-3-yl}benzamido)tetracosahydro-1H-dipyrrolo[2,1-c:2',1'-l][1,4,7,10,13,16]hexaazacyclohenicosin-23-yl)-1,2-dihydroxyethyl]-2-hydroxyphenyl sulfate.

^c Sodium 5-[(1S,2S)-2-[(2R,6S,9S,11R,12R,14aS,15S,16S,20S,23S,25aS)-20-[(R)-3-amino-1-hydroxy-3-oxopropyl]-2,11,12,15-tetrahydroxy-6-(hydroxymethyl)-16-methyl-5,8,14,19,22,25-hexaoxo-9-(4-{5-[4-(pentyloxy)phenyl]isoxazol-3-yl}benzamido)tetracosahydro-1H-dipyrrolo[2,1-c:2',1'-l][1,4,7,10,13,16]hexaazacyclohenicosin-23-yl)-1,2-dihydroxyethyl]-2-hydroxyphenyl sulfate.

^d Sodium 5-[(1S,2S)-2-[(2R,6S,9S,11R,12S,14aS,15S,16S,20S,23S,25aS)-20-[(R)-3-amino-1-hydroxy-3-oxopropyl]-2,11,12,15-tetrahydroxy-6-[(R)-1-hydroxyethyl]-16-methyl-5,8,14,19,22,25-hexaoxo-9-(4-{5-[4-(pentyloxy)phenyl]isoxazol-3-yl}benzamido)tetracosahydro-1H-dipyrrolo[2,1-c:2',1'-l][1,4,7,10,13,16]hexaazacyclohenicosin-23-yl)-1,2-dihydroxyethyl]-2-hydroxyphenyl sulfate.

^e Sodium 5-[(1S,2S)-2-[(2R,6S,9S,12R,14aS,15S,16S,20S,23S,25aS)-20-[(R)-3-amino-1-hydroxy-3-oxopropyl]-2,12,15-trihydroxy-6-[(R)-1-hydroxyethyl]-16-methyl-5,8,14,19,22,25-hexaoxo-9-(4-{5-[4-(pentyloxy)phenyl]isoxazol-3-yl}benzamido)tetracosahydro-1H-dipyrrolo[2,1-c:2',1'-l][1,4,7,10,13,16]hexaazacyclohenicosin-23-yl)-1,2-dihydroxyethyl]-2-hydroxyphenyl sulfate.

SPECIFIC TESTS

- **OPTICAL ROTATION** (781S), *Procedures, Specific Rotation*

Sample solution: 20 mg/mL in [water](#)

Acceptance criteria: –20° to –22°, on the anhydrous and solvent-free basis, measured at 20°

- **MICROBIAL ENUMERATION TESTS** (61), and **TESTS FOR SPECIFIED MICROORGANISMS** (62): The total aerobic microbial count does not exceed 10³ cfu/g. The total molds and yeasts count does not exceed 10² cfu/g.

- **BACTERIAL ENDOTOXINS TEST** (85): Meets the requirements

- **WATER DETERMINATION** (921), *Method I, Method Ia*

Sample: 0.5 g

Analysis: Use a mixture of [formamide](#) and [methanol](#) (2:1) as the solvent.

Acceptance criteria: NMT 8.0%

- **pH** (791)

Sample: 100 mg/mL

Acceptance criteria: 5.0–7.2

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store between 2° and 8°.

- **USP REFERENCE STANDARDS** (11).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MICAFUNGIN SODIUM	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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