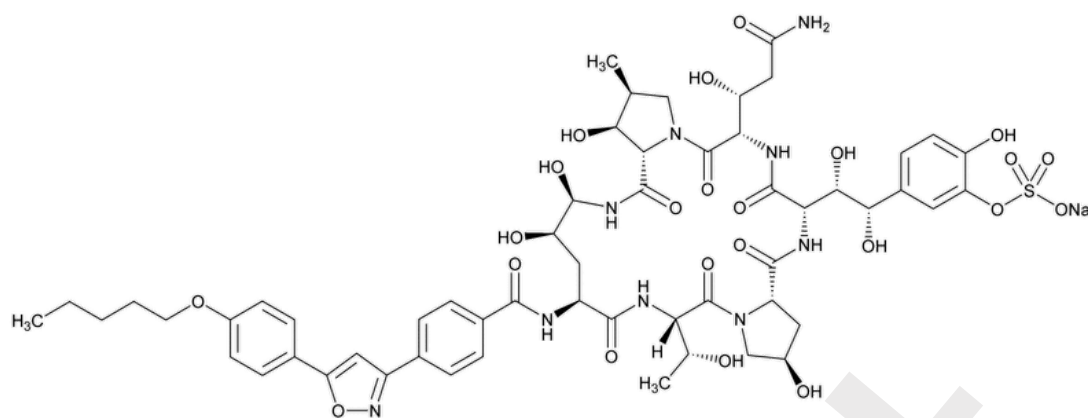


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Add the following:

▲Micafungin Sodium



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

Pneumocandin A0, 1-[(4*R*,5*R*)-4,5-dihydroxy-*N*²-[4-[5-[4-(pentyloxy)phenyl]-3-isoxazolyl]benzoyl]-l-ornithine]-4-[(4*S*)-4-hydroxy-4-[4-hydroxy-3-(sulfoxy)phenyl]-l-threonine]-, monosodium salt;
 Sodium 5-[(1*S*,2*S*)-2-[(2*R*,6*S*,9*S*,11*R*,12*R*,14*aS*,15*S*,16*S*,20*S*,23*S*,25*aS*)-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-hexaaxo-9-(4-[5-[4-(pentyloxy)phenyl]isoxazol-3-yl]benzamido)tetracosahydro-1*H*-dipyrrolo[2,1-*c*:2',1'-] [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