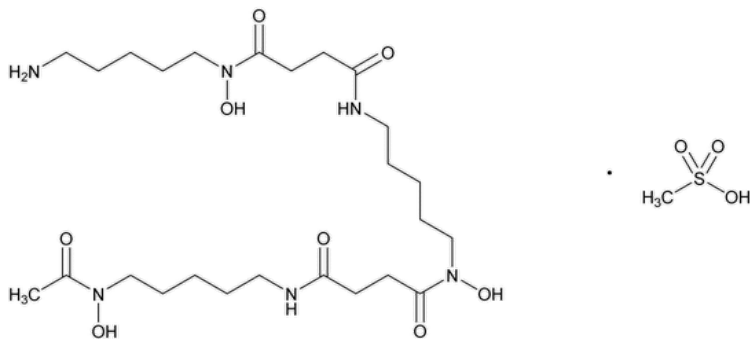


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Deferoxamine Mesylate



$C_{25}H_{48}N_6O_8 \cdot CH_3O_3S$ 656.79
Butanediamide, N'-[5-[[[5-(acetylhydroxyamino)pentyl] amino]-1,4-dioxobutyl]hydroxyamino]pentyl]-N-(5-aminopentyl)-N-hydroxy-, monomethanesulfonate;
N-[5-[3-[(5-Aminopentyl)hydroxycarbonyl]propionamido] pentyl]-3-[[5-(N-hydroxyacetamido)pentyl]carbonyl]propionohydroxamic acid monomethanesulfonate (salt) CAS RN®: 138-14-7; UNII: V9TKO7E06K.

DEFINITION
Deferoxamine Mesylate contains NLT 93.0% and NMT 102.0% of deferoxamine mesylate ($C_{25}H_{48}N_6O_8 \cdot CH_3O_3S$), calculated on the anhydrous basis.

IDENTIFICATION
Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**
Solution A: 1.32 g/L of dibasic ammonium phosphate in water. Adjust with phosphoric acid to a pH of 3.0.
Solution B: Acetonitrile and *Solution A* (1:1)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	88	12
20	80	20
35	57.5	42.5
35.1	88	12
40	88	

Diluent: Acetonitrile and water (6:94)

Standard solution: 1.0 mg/mL of [USP Deferoxamine Mesylate RS](#) in *Diluent*

Sample solution: 1.0 mg/mL of Deferoxamine Mesylate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 7.5-cm; 3.5-μm packing L1

Temperatures

Column: 32°

Autosampler: 5°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of deferoxamine mesylate ($C_{25}H_{48}N_6O_8 \cdot CH_4O_3S$) in the portion of Deferoxamine Mesylate taken:

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

r_U = peak response of deferoxamine from the *Sample solution*

r_S = peak response of deferoxamine from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–102.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%, 2.0 g being used
- [CHLORIDE AND SULFATE, Chloride \(221\)](#): NMT 0.012%; a 1.2-g portion shows no more chloride than corresponds to 0.20 mL of 0.020 N hydrochloric acid.
- [CHLORIDE AND SULFATE, Sulfate \(221\)](#): NMT 0.04%; a 0.5-g portion shows no more sulfate than corresponds to 0.20 mL of 0.020 N sulfuric acid.
- **ORGANIC IMPURITIES**

Solution A, Solution B, Diluent, Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard stock solution: Use the *Standard solution*, prepared as directed in the Assay. [NOTE—[USP Deferoxamine Mesylate RS](#) contains impurity A as a minor component.]

Standard solution: 0.01 mg/mL of [USP Deferoxamine Mesylate RS](#) in *Diluent* from the *Standard stock solution*

System suitability

Samples: *Standard stock solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between the impurity A and deferoxamine peaks, *Standard stock solution*

Relative standard deviation: NMT 5.0% for the deferoxamine peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Deferoxamine Mesylate taken:

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

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of deferoxamine from the *Standard solution*