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Add the following:

▲Plerixafor Injection

DEFINITION

Plerixafor Injection is a sterile isotonic solution of Plerixafor in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of plerixafor ($C_{28}H_{54}N_8$) with no preservatives.

IDENTIFICATION

- **A.** The UV spectrum of the plerixafor peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **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: Methanol and water (8.5: 91.5). To each liter of the solution, add 1 mL of trifluoroacetic acid.

Solution B: Methanol and water (50:50). To each liter of the solution, add 1 mL of trifluoroacetic acid.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
20	100	0
32	48	52
33	10	90
34	10	90

Diluent: 0.05 N hydrochloric acid

Standard solution: 2 mg/mL of USP Plerixafor RS in *Diluent*. Sonicate to dissolve.

Sample solution: Nominally 2 mg/mL of plerixafor from Injection prepared as follows. Empty and pool the contents of a suitable number of vials into a suitable glass container to obtain NLT 22 mL of the solution. Mix and transfer 5 mL of the pooled sample into a 50-mL volumetric flask and dilute with *Diluent* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 6.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of plerixafor ($C_{28}H_{54}N_8$) in the portion of Injection taken:

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

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

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

C_S = concentration of USP Plerixafor RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

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

System suitability solution: 2 mg/mL of USP Plerixafor System Suitability Mixture RS in *Diluent*. Sonicate to dissolve.

Standard solution: 0.004 mg/mL of USP Plerixafor RS in *Diluent*

Sensitivity solution: 0.002 mg/mL of USP Plerixafor RS in *Diluent* from the *Standard solution*

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

[Note—Plerixafor 4-benzyl analog and plerixafor 8-benzyl analog coelute under these chromatographic conditions. The relative retention times in *Table 2* are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Plerixafor benzyl alcohol[a]	0.9
Plerixafor	1.0
Plerixafor 4-benzyl analog[b] and plerixafor 8-benzyl analog[c]	2.5
Plerixafor 11-benzyl analog[d]	2.7

[a] {4-[(1,4,8,11-Tetraazacyclotetradecan-1-yl)methyl]phenyl}methanol.

[b] 1,4-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.

[c] 1,8-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.

[d] 1,11-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.

Suitability requirements

Resolution: NLT 1.0 between plerixafor and plerixafor benzyl alcohol, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any unspecified degradation product in the portion of Injection taken:

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

r_U = peak response of any unspecified degradation product from the *Sample solution*

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

C_S = concentration of USP Plerixafor RS in the *Standard solution* (mg/mL)

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

F = relative response factor (see *Table 3*)

Acceptance criteria: See *Table 3*. The reporting threshold is 0.1%.

Table 3

Name	Relative Response Factor	Acceptance Criteria, NMT (%)
Any unspecified degradation product	1.0	0.2
Total degradation products	—	1.5

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** Meets the requirements
- **Sterility Tests ⟨71⟩:** Meets the requirements
- **pH ⟨791⟩:** 6.0–7.5
- **Osmolality and Osmolarity ⟨785⟩:** 270–310 mOsm/kg
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **Other Requirements:** Meets the requirements under *Injections and Implanted Drug Products ⟨1⟩, Product Quality Tests Common to Parenteral Dosage Forms, Universal Tests, Container Content*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers, preferably of Type I glass. Store at controlled room temperature.
- **USP Reference Standards ⟨11⟩**

  USP Plerixafor RS

  USP Plerixafor System Suitability Mixture RS

  Contains a mixture of the following 5 compounds:

  Plerixafor.
  Plerixafor 4-benzyl analog: 1,4-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.
  Plerixafor 8-benzyl analog: 1,8-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.
  Plerixafor 11-benzyl analog: 1,11-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.
  Plerixafor benzyl alcohol: {4-[(1,4,8,11-Tetraazacyclotetradecan-1-yl)methyl]phenyl}methanol.

▲ (USP 1-Aug-2024)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PLERIXAFOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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