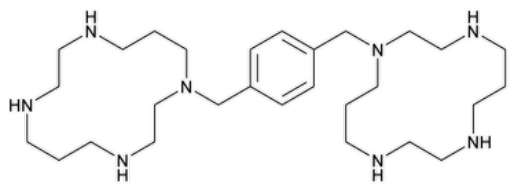


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Add the following:

▲Plerixafor



$C_{28}H_{54}N_8$ 502.80
1,4,8,11-Tetraazacyclotetradecane, 1,1'-[1,4-phenylenebis(methylene)]bis-;
1,4-Bis[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzene CAS RN®: 110078-46-1; UNII: S915P5499N.

DEFINITION
Plerixafor contains NLT 97.0% and NMT 103.0% of plerixafor ($C_{28}H_{54}N_8$), calculated on the anhydrous 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.

- ASSAY**
- **PROCEDURE**
Solution A: 0.1% (v/v) [trifluoroacetic acid](#) in [water](#)
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 (%)	Flow Rate (mL/min)
0	80	20	0.8
15	80	20	0.8
41	47	53	0.8
43	47	53	0.8
44	10	90	0.8
45	10	90	1.0
46	80	20	1.0
50	80	20	0.8

Diluent: 0.05 N [hydrochloric acid](#)
Standard solution: 1 mg/mL of [USP Plerixafor RS](#) in *Diluent*. Sonicate to dissolve.

Sample solution: 1 mg/mL of Plerixafor in *Diluent*. Sonicate to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Columns

Guard: 4.6-mm × 12.5-mm; 5-μm packing [L7](#)

Analytical: 4.6-mm × 15-cm; 3.5-μm packing [L7](#)

Column temperature: 40°

Flow rate: See [Table 1](#).

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 5.0

Relative standard deviation: NMT 1.10%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of plerixafor ($C_{28}H_{54}N_8$) in the portion of Plerixafor 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 = concentration of Plerixafor in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

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

System suitability solution: 1 mg/mL of [USP Plerixafor System Suitability Mixture RS](#) in *Diluent*. Sonicate to dissolve.

Sensitivity solution: 0.0005 mg/mL of [USP Plerixafor RS](#) in *Diluent* from the *Standard solution*

System suitability

[NOTE—Column conditioning may be performed as needed to meet the system suitability requirements using 1.6 mg/mL of [USP Plerixafor System Suitability Mixture RS](#) in [water](#) as a column conditioning solution. Flush the column with 0.1% v/v [trifluoroacetic acid](#) in [methanol](#) for 1 h. Equilibrate the column with the starting *Mobile phase* gradient for 30 min. Carry out multiple injections of the column conditioning solution until the resolution criterion of NLT 1.0 between plerixafor 4-benzyl analog and plerixafor 8-benzyl analog is met.]

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

[NOTE—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	0.85
Plerixafor	1.00



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