



Product Information Sheet (PIS)

Analytical Reference Material (ARM)

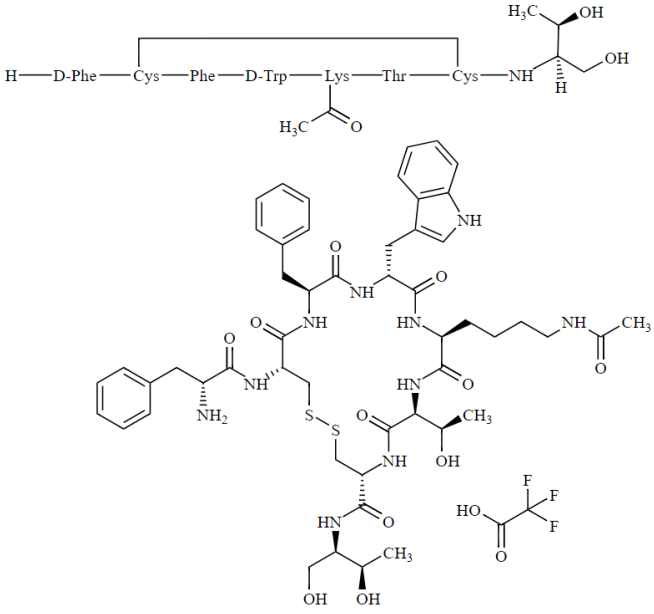
N-ACETYL-LYS-OCTREOTIDE TRIFLUOROACETATE

((4R,7S,10S,13R,16S,19R)-13-((1*H*-indol-3-yl)methyl)-10-(4-acetamidobutyl)-19-((R)-2-amino-3-phenylpropanamido)-16-benzyl-*N*-((2R,3R)-1,3-dihydroxybutan-2-yl)-7-((R)-1-hydroxyethyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentaazacycloicosane-4-carboxamide, 2,2,2-trifluoroacetic acid)

USP Catalog No.: 1477690

USP Lot No.: F214R0

Chemical Information

Chemical Structure: 	CAS Number:	173606-11-6 (free base)
	Molecular Formula:	C ₅₁ H ₆₈ N ₁₀ O ₁₁ S ₂ . C ₂ HF ₃ O ₂
	Molecular Weight:	1175.32

Label

Not for use as a drug. Not intended for administration to humans or animals. See SDS prior to use at www.usp.org/sds.



Lot: F214R0

ANALYTICAL REFERENCE MATERIAL

N-ACETYL-LYS-OCTREOTIDE TRIFLUOROACETATE 25 mg

((4R,7S,10S,13R,16S,19R)-13-((1*H*-indol-3-yl)methyl)-10-(4-acetamidobutyl)-19-((R)-2-amino-3-phenylpropanamido)-16-benzyl-*N*-((2R,3R)-1,3-dihydroxybutan-2-yl)-7-((R)-1-hydroxyethyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentaazacycloicosane-4-carboxamide, 2,2,2-trifluoroacetic acid)

Store in a refrigerator. Protect from light. Keep container tightly closed.

The material is for use in analytical laboratory applications.
See product information sheet for any additional information.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
Cat. No. 1477690 Material mfd. in China



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Re-Test Date

01-MAR-2026

Note: Use of the product after the retest date is done at customer discretion

Tests and Results

Test	Results
Appearance	Fine white powder
Identification by IR	Conforms to the Structure
Identification by Mass Spectrometry	Conforms to the Structure
Identification by ^1H NMR	Conforms to the Structure
Identification by ^{19}F NMR	Conforms to the Structure
Purity by HPLC	99.3%
Impurities by HPLC [#]	RT 10.14, 0.27%; RT 12.56, 0.35%
Residual Solvents by NMR	Not Detected
Assigned Value*	93.6 %

[#] Only the Impurity greater than 0.1% is reported.

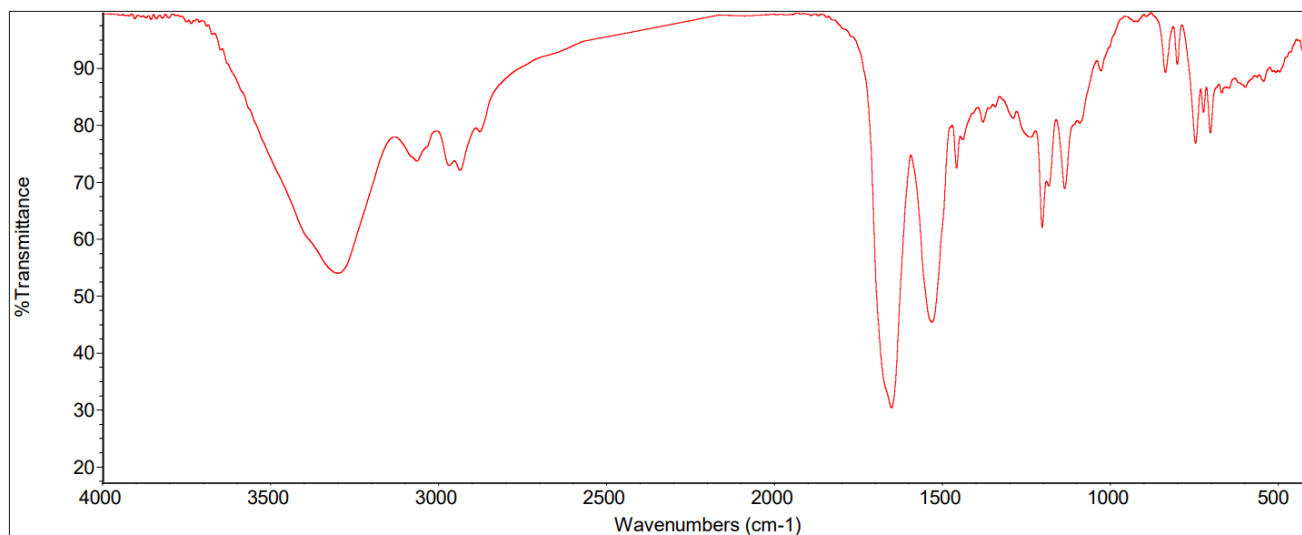
* Assigned Value was determined by Assay (qNMR).



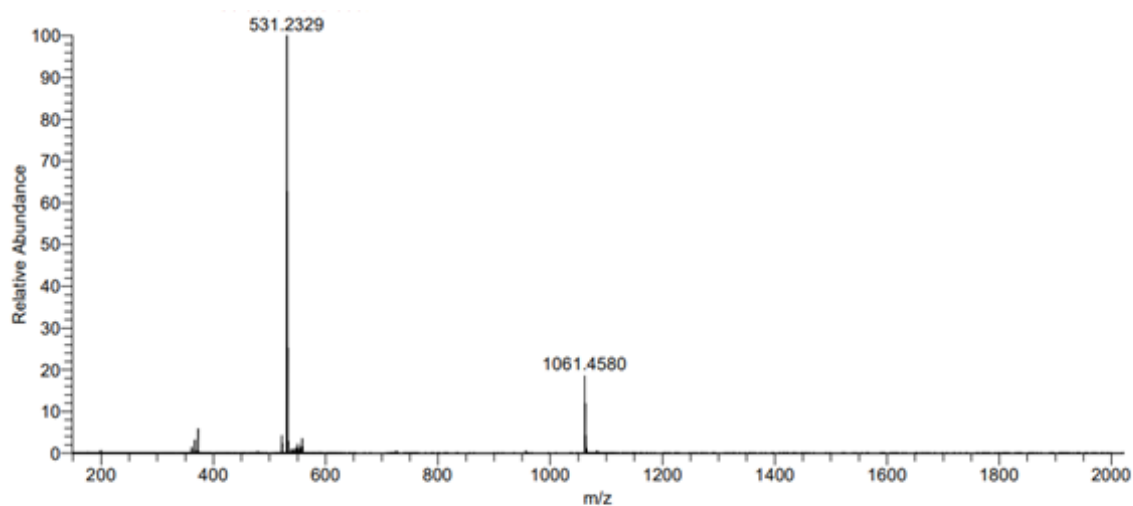
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IR Spectrum (KBr)



Mass Spectrum (High Throughput Molecular Weight Determination) of Parent Compound



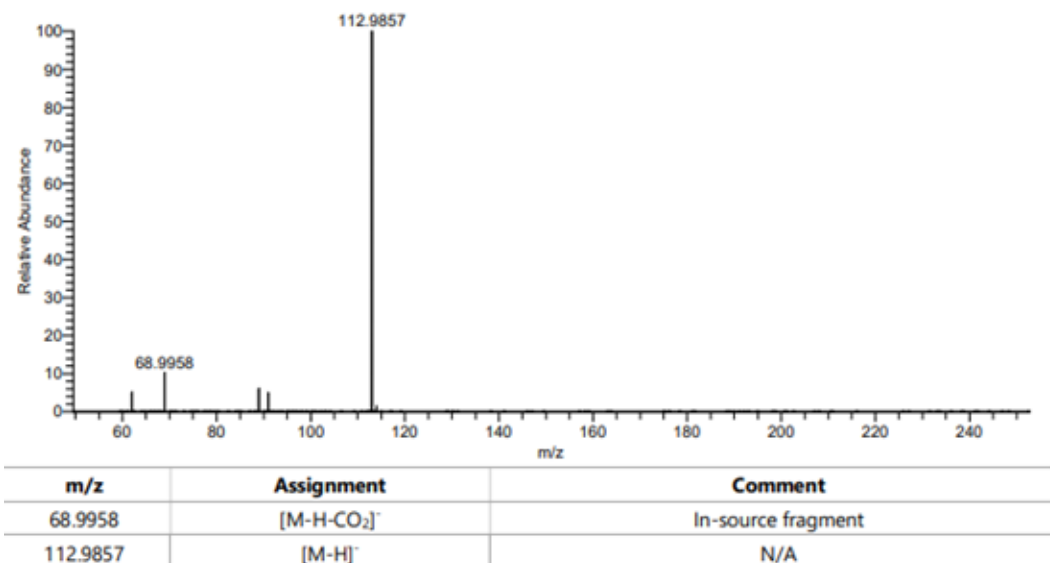
m/z	Assignment	Comment
531.2329	$[M+2H]^{2+}$	N/A
1061.4580	$[M+H]^+$	N/A



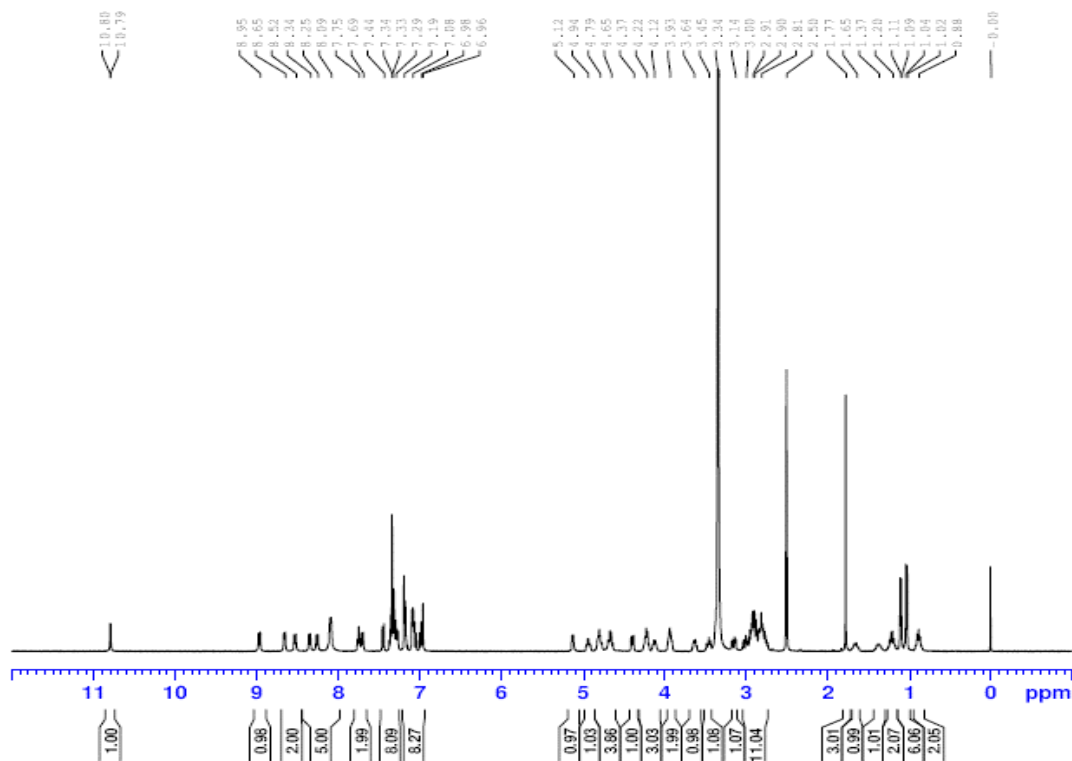
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Mass Spectrum (High Throughput Molecular Weight Determination) of Counterion



¹H NMR Spectrum recorded in [DMSO-d₆]

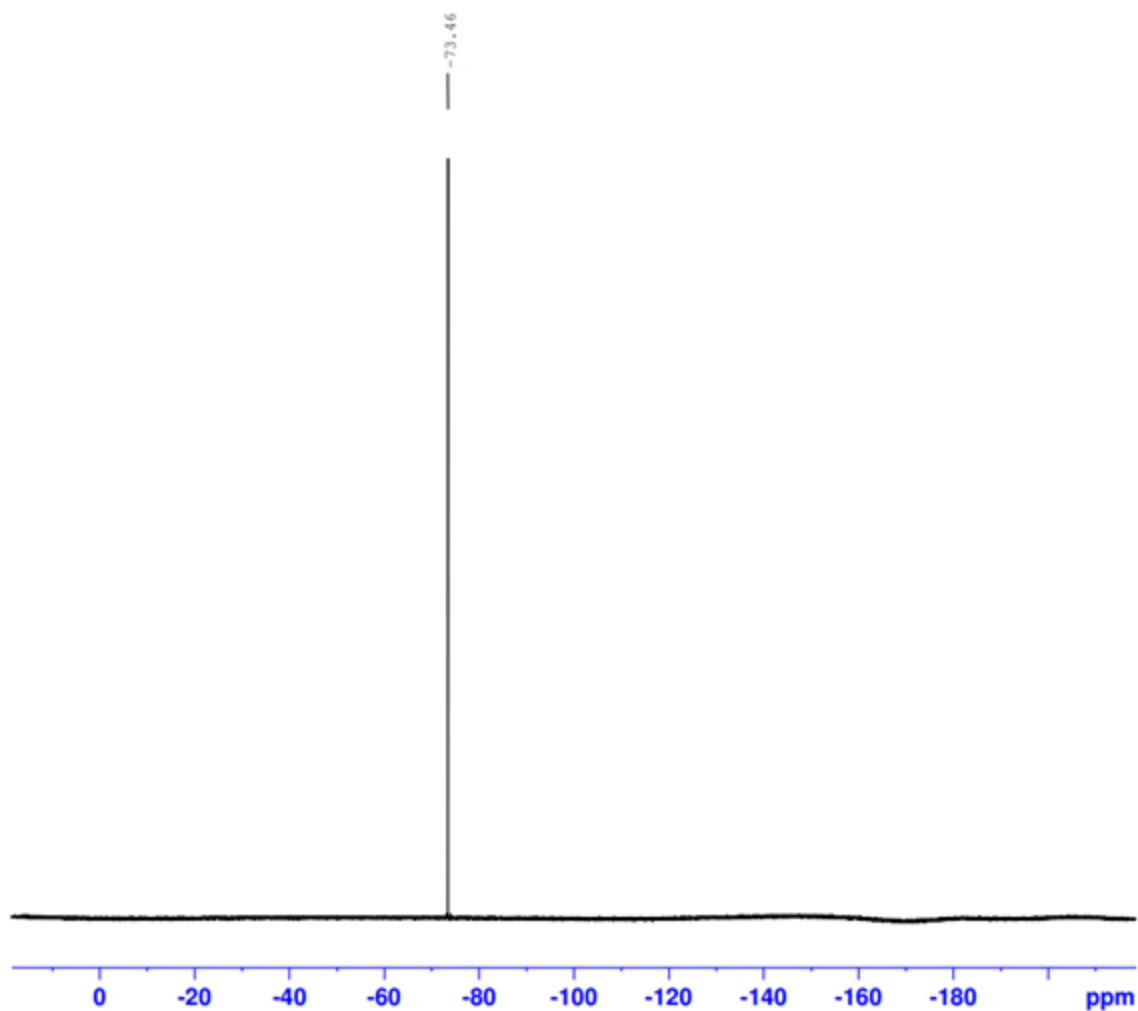




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^{19}F NMR Spectrum recorded in [DMSO-d₆]



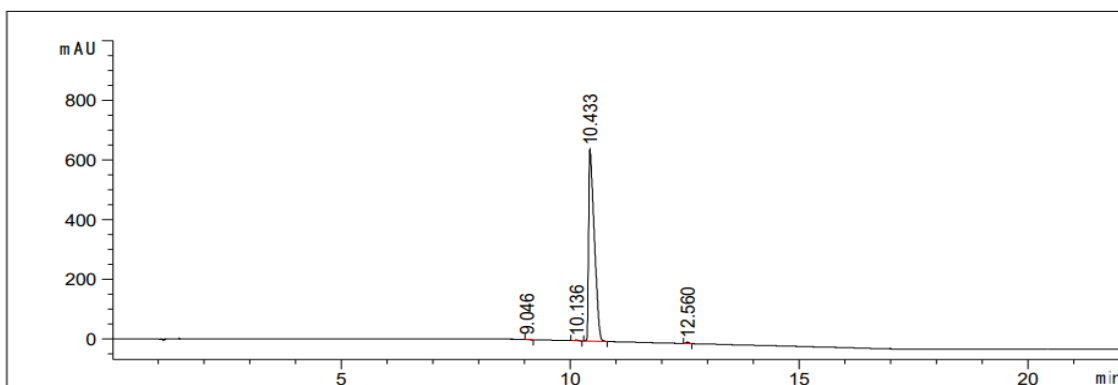


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Purity/Impurities by HPLC Conditions and Chromatogram

Column:	Poroshell 120 SB-C18 (100 × 4.6 mm, 2.7 µm)		
Column Temperature:	30°		
Mobile Phase A:	Acetonitrile		
Mobile Phase B:	0.05% TFA in water		
Gradient programme	Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
	0.0	25	75
	6.0	25	75
	15.0	40	60
	30.0	40	60
Flow rate:	1.0 mL/min		
Diluent:	Acetonitrile and water (1:1, %v/v)		
Injection volume:	1.5 µL , 1.8 mg/mL in diluent		
Detector:	UV, 210 nm		



Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	9.046	BBA	0.1309	1.86458	1.76989e-1	0.0336
2	10.136	BBA	0.1006	14.92025	2.33232	0.2691
3	10.433	BBA	0.1302	5507.54199	641.19067	99.3453
4	12.560	BBA	0.0628	19.50901	4.86487	0.3519
Totals :				5543.83584	648.56486	



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Use

Analytical Reference Materials are for use in analytical or laboratory applications. The material is intended for research and development use. It is the responsibility of the user to determine the suitability of the Analytical Reference Material for its use. Analytical Reference Materials are different from official USP Reference Standards. Analytical Reference Materials are not required for compendial compliance.

Storage Conditions

Storage conditions are lot-specific and may change from one lot to another. If no specific directions or limitations are provided on the USP Analytical Reference Materials label, the conditions of storage shall include storage at room temperature and protection from moisture, light, freezing, and excessive heat.

Instructions for Use

When refrigerator (2 to 8 °C) or freezer (at or below -10 °C) storage condition is stated on the label, allow the unopened container to reach ambient temperature in a desiccator prior to opening. After opening, any remaining portion should be stored and handled as described in the user's site policy.

Lot Validity

If a current lot of a USP Analytical Reference Material does not contain a retest date as indicated in this document, these materials do not have a valid use date (expiration date). USP recommends users check the status of such a lot. If a lot is listed as a "Current Lot," it is valid and suitable for use. Once a current lot is depleted, it becomes the "Previous Lot." At this time a valid use date is assigned, which is typically 3-12 months from the date of depletion."

If a current lot of a USP Analytical Reference Material contains a retest date as indicated in this document, such a lot is valid until the retest date listed on this document, or as indicated in any updates to the latest version of the Product Information Sheet.

It is the responsibility of the user to ascertain that a particular lot of a USP Analytical Reference Material has official status either as a "Current Lot" or as a "Previous Lot" within the assigned valid use date. The USP Catalog and the online USP Store at www.usp.org are updated daily. USP recommends referring to one of these sources prior to using the USP Analytical Reference Material to make sure the lot is valid for use.

Miscellaneous Information

See USP online store for availability, country of origin and material origin information, safety data sheet (SDS) etc.

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History

Date	Version	Details
25-JAN-2024	00 (Current)	First version

Danielle A. Vattimo

Quality Assurance