Product Information Sheet (PIS)

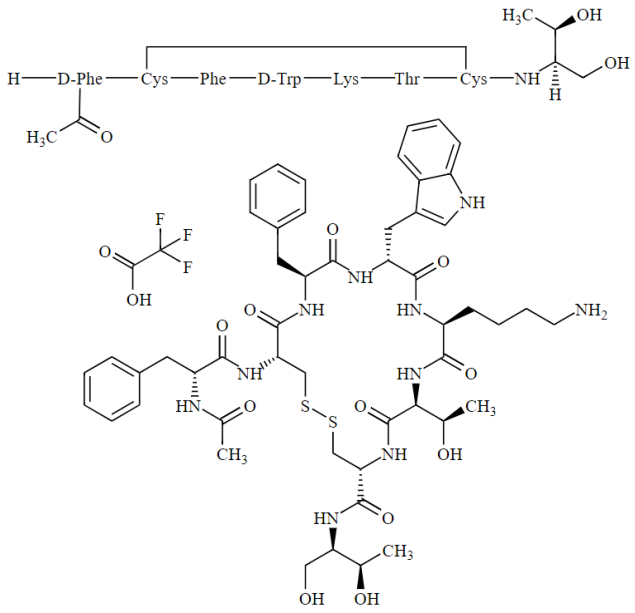
Analytical Reference Material (ARM)

N-ACETYL-PHE-OCTREOTIDE TRIFLUOROACETATE

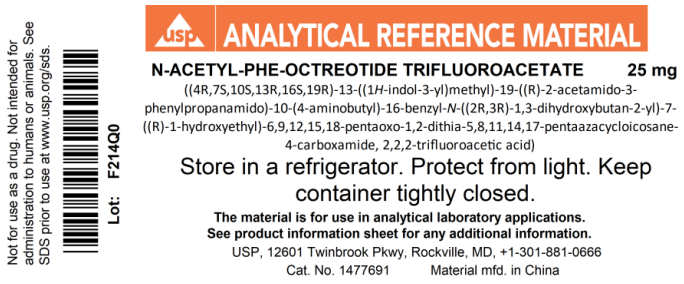
((4R,7S,10S,13R,16S,19R)-13-((1*H*-indol-3-yl)methyl)-19-((R)-2-acetamido-3-phenylpropanamido)-10-(4-aminobutyl)-16-benzyl-*N*-((2R,3R)-1,3-dihydroxybutan-2-yl)-7-((R)-1-hydroxyethyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentaazacycloicosane-4-carboxamide, 2,2,2-trifluoroacetic acid)

USP Catalog No.:	**1477691**
USP Lot No.:	**F214Q0**

Chemical Information

Chemical Structure: 	CAS Number: 83795-61-3 (free base)
	Molecular Formula: $C_{51}H_{68}N_{10}O_{11}S_2 . C_2HF_3O_2$
	Molecular Weight: 1175.32

Label



Re-Test Date

09-MAR-2026

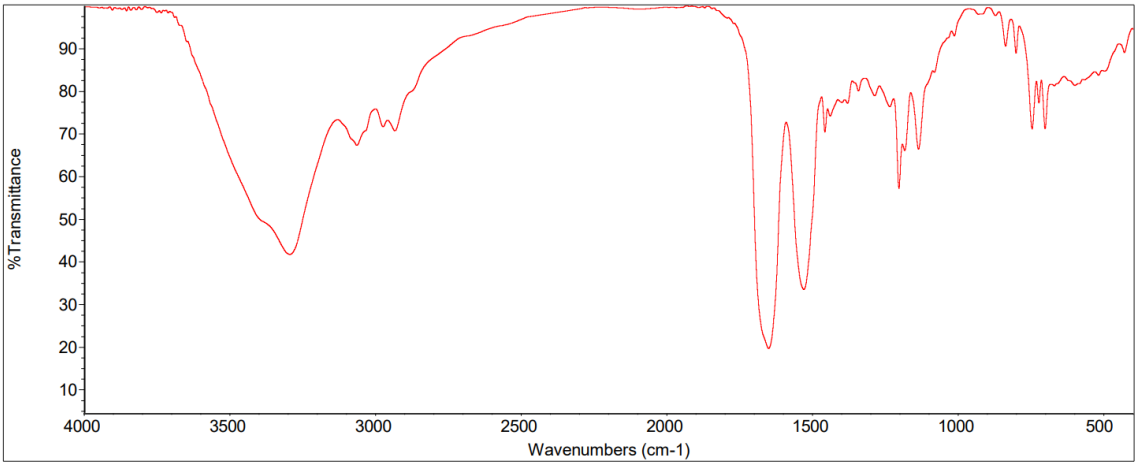
Note: Use of the product after the retest date is done at customer discretion

Tests and Results

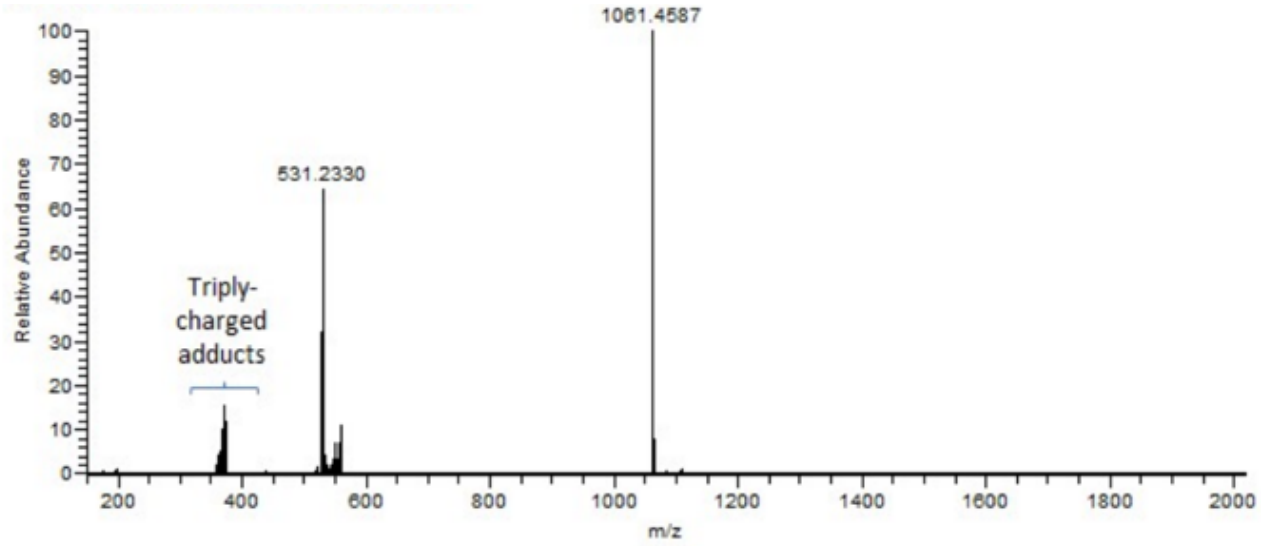
Test	Results
Appearance	Fine white powder
Identification by IR	Conforms to the Structure
Identification by Mass Spectrometry	Conforms to the Structure
Identification by ^{1}H NMR	Conforms to the Structure
Identification by ^{19}F NMR	Conforms to the Structure
Purity by HPLC	99.7%
Impurities by HPLC	RT 7.13, 0.13% #
Water Content by KF	3.5%
Residual Solvents by NMR (acetic acid)	0.1%
Assigned Value *	96.1%

Only the Impurity greater than 0.1% is reported.
* Assigned Value was calculated by taking into account the Purity by HPLC at 214nm, Water Content and Residual Solvents.

IR Spectrum (KBr)

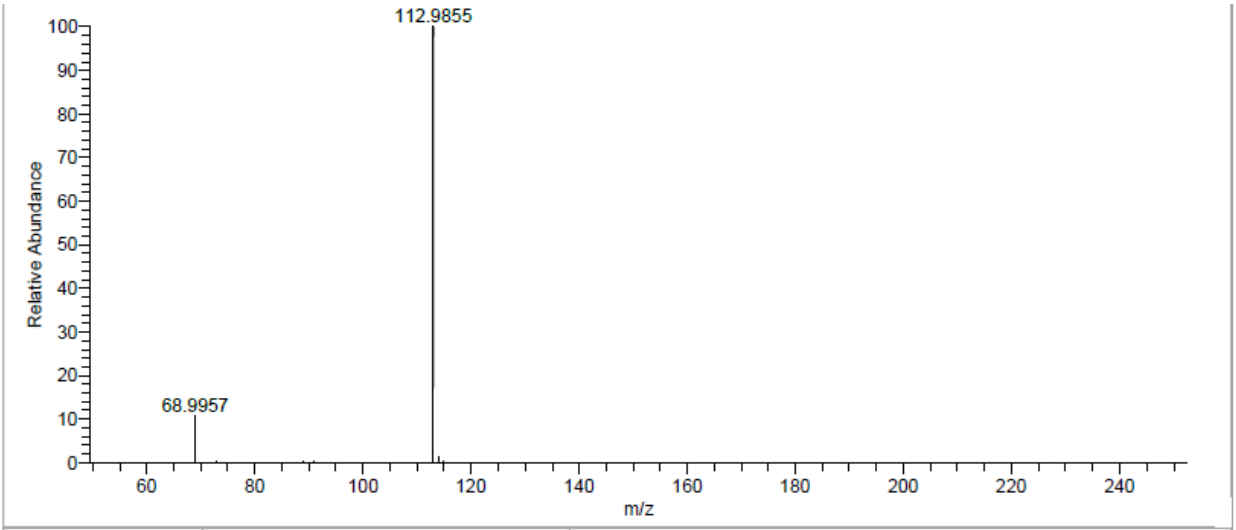


Mass Spectrum (High Throughput Molecular Weight Determination) of Parent Compound



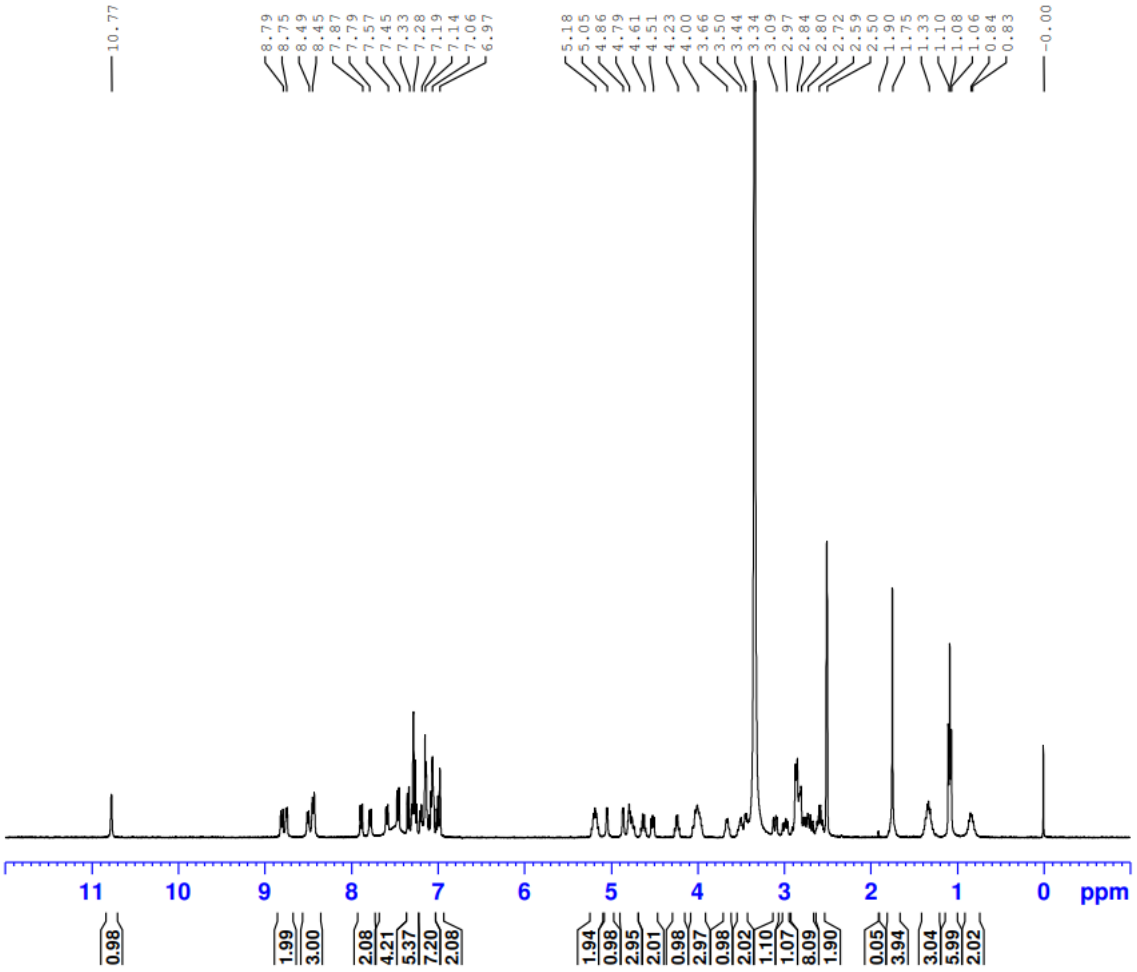
m/z	Assignment	Comment
531.2330	$[M+2H]^{2+}$	N/A
1061.4587	$[M+H]^{+}$	N/A

Mass Spectrum (High Throughput Molecular Weight Determination) of Counterion

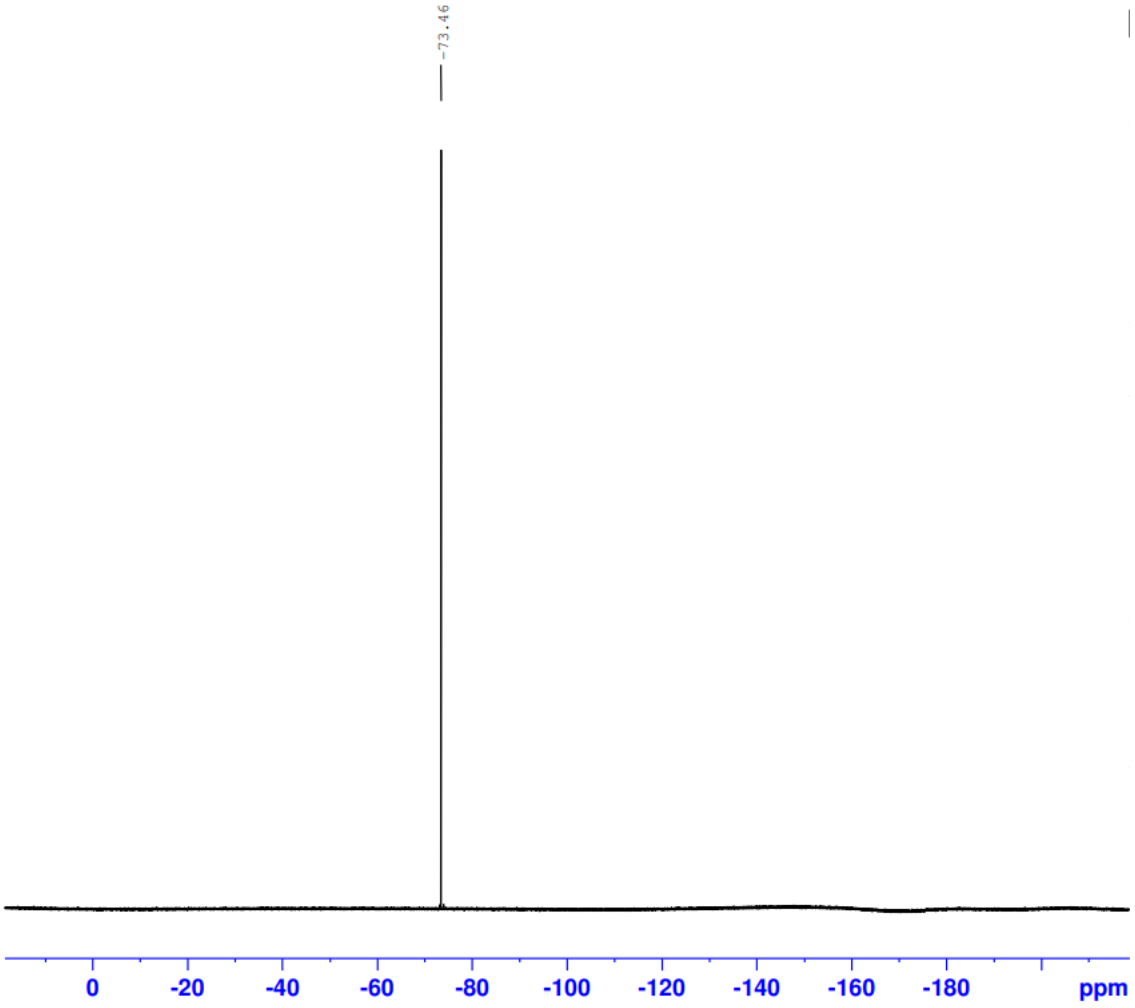


m/z	Assignment	Comment
68.9957	$[M-H-CO_2]^-$	In-source fragment
112.9855	$[M-H]^-$	N/A

^{1}H NMR Spectrum recorded in [DMSO-d6]

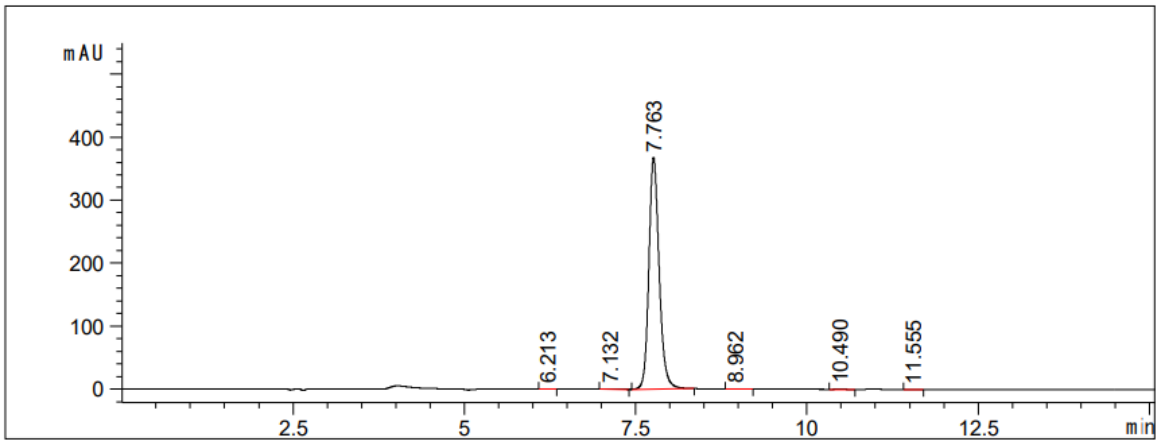


^{19}F NMR Spectrum recorded in [DMSO-d6]



Purity/Impurity by HPLC Conditions and Chromatogram

Column:	AdvanceBio Peptide Plus (250 × 2.1) mm, 2.7 µm
Column Temperature:	30°
Mobile Phase	Methanol and 0.1% Trifluoroacetic acid in water (55:45, %v/v)
Flow rate:	0.2 mL/min
Diluent:	Acetonitrile and water (1:1, %v/v)
Sample Concentration:	1.0 mg/mL in diluent
Injection volume:	0.300 µL
Detector:	UV, 214 nm



Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	6.213	BBA	0.1079	2.15519	2.99756e-1	0.0560
2	7.132	BB	0.1517	5.07357	4.94327e-1	0.1319
3	7.763	BBA	0.1621	3836.29785	366.62955	99.7033
4	8.962	BB	0.1694	1.97048	1.58087e-1	0.0512
5	10.490	BB	0.1373	1.42475	1.36992e-1	0.0370
6	11.555	BBA	0.1293	7.93210e-1	8.46966e-2	0.0206
Totals :				3847.71505	367.80341	

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.

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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.

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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.

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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
07-MAR-2024	00 (Current)	First version

Danielle A. Vattimo

Quality Assurance