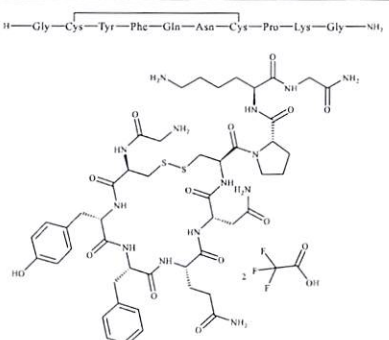


## Certificate of Analysis

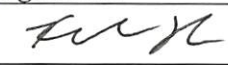

Certificate No.: 20250526515

Date: May 26, 2025

Retest date: May 22, 2026

<b>Compound Name:</b>	<b>Terlipressin EP Impurity B Ditrifluoroacetate (Des-1,2-Diglycine-Terlipressin Ditrifluoroacetate)</b>	
<b>Synonyms:</b>	(S)-N-((S)-6-amino-1-((2-amino-2-oxoethyl)amino)-1-oxohexan-2-yl)-1-((4R,7S,10S,13S,16S,19R)-7-(2-amino-2-oxoethyl)-10-(3-amino-3-oxopropyl)-19-(2-aminoacetamido)-13-benzyl-16-(4-hydroxybenzyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentazacycloicosane-4-carbonyl)pyrrolidine-2-carboxamide, 2,2,2-trifluoroacetic acid (1:2)	
<b>TLC Catalogue Number:</b>	PT-150004	
<b>CAS Number:</b>	N/A	
<b>Alternate CAS Number:</b>	4235-50-1 (free base)	
<b>Molecular Weight:</b>	1113.28 2*114.02	
<b>Molecular Formula:</b>	C <sub>48</sub> H <sub>68</sub> N <sub>14</sub> O <sub>13</sub> S <sub>2</sub> · 2 C <sub>2</sub> HF <sub>3</sub> O <sub>2</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	4956-033A8	
<b>Storage Conditions:</b>	Store at -20 °C	
<b>Solubility:</b>	Methanol, DMSO, solution of Acetonitrile and Water	

Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<sup>19</sup> F NMR	Conforms to structure	<b>Conforms</b>
<b>Elemental Analysis</b>	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>98.5%</b>
<b>Impurity (HPLC)</b>	RT 11.96, 0.23%; RT 14.17, 0.23%; RT 14.57, 0.48%	
<b>Water Content (KF)</b>	N/A	<b>7.0%</b>
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (%)</b>	Not less than 90.0%	<b>91.6%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/26/2025
Approved by:	Quality Assurance		05/26/2025

**Attachments:** Peak Attribution Table, HPLC, IR, MS and NMR spectra.