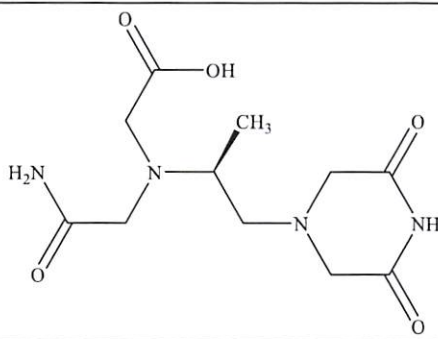


# Certificate of Analysis



 Certificate No.: **20251208015**

Date: December 8, 2025

Retest date: December 4, 2026

<b>Compound Name:</b> Dexrazoxane Impurity 1		
<b>Synonyms:</b>	(S)-N-(2-amino-2-oxoethyl)-N-(1-(3,5-dioxopiperazin-1-yl)propan-2-yl)glycine	
<b>TLC Catalogue Number:</b>	R-088007	
<b>CAS Number:</b>	120418-77-1	
<b>Alternate CAS Number:</b>	N/A	
<b>Molecular Weight:</b>	286.29	
<b>Molecular Formula:</b>	C <sub>11</sub> H <sub>18</sub> N <sub>4</sub> O <sub>5</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	5767-005A8	
<b>Storage Conditions:</b>	Store at -20 °C	
<b>Solubility:</b>	Methanol, DMSO, DMF, 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>
<b>Purity (HPLC)</b>	Not less than 85.0%	<b>91.7%</b>
<b>Impurity (HPLC)</b>	RT 3.77, 0.31%; RT 9.28, 0.58%; RT 16.32, 7.34%	
<b>Purity (Chiral HPLC)</b>	Not less than 98.0%	<b>100.0%</b>
<b>Residue (TGA at 900 °C)</b>	N/A	<b>0.1%</b>
<b>Optical Rotation</b>	N/A	[α] <sub>D</sub> <sup>25.0</sup> (c=0.30, DMF): <b>+14.3°</b>
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (qNMR)</b>	Not less than 55.0%	<b>57.1%</b>
<b>Recommendation:</b>	<b>Release.</b> The compound contains 7.3% Dexrazoxane Impurity 32 (RT 16.32, free form of TLC No. R-088005) according to its HPLC and LC-MS.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		12/08/2025
Approved by:	Quality Assurance		12/08/2025

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