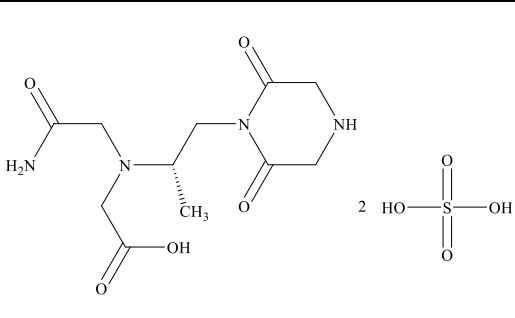


Certificate of Analysis

Certificate No.: 20210818025

Date: August 18, 2021

Retest date: July 15, 2024

Compound Name:	Dexrazoxane Impurity 3 Disulfate	
Synonyms:	(S)-N-(2-amino-2-oxoethyl)-N-(1-(2,6-dioxopiperazin-1-yl)propan-2-yl)glycine, sulfuric acid (1:2)	
TLC Catalogue Number:	R-088003	
CAS Number:	N/A	
Molecular Weight:	286.29 2*98.07	
Molecular Formula:	C ₁₁ H ₁₈ N ₄ O ₅ · 2 H ₂ O ₄ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4551-065A1	
Storage Conditions:	Hygroscopic, store at -20 °C	
Solubility:	Methanol, DMSO, Water, DMF	

Test Description	Specifications	Results
Visual Description	Pale gray solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.3%
Impurity (HPLC)	RT 5.71, 0.68%; RT 9.26, 0.25%; RT 13.31, 0.69%	
Water Content (KF)	N/A	3.4%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.33, DMF): +21.0°
Residual Solvents (NMR)	1.4% dichloromethane and 5.2% tetrahydrofuran	
Assay (S%)	13.3%	13.3%
Assay (%)	Not less than 85.0%	88.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.