

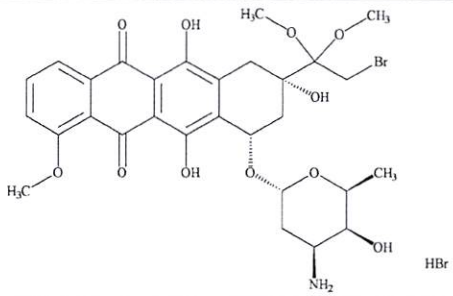


Certificate of Analysis



Certificate No.: 20240604003

Date: June 4, 2024

Retest date: June 3, 2027

Compound Name:	Doxorubicin EP Impurity B HBr	
Synonyms:	(8S,10S)-10-(((2R,4S,5S,6S)-4-amino-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl)oxy)-8-(2-bromo-1,1-dimethoxyethyl)-6,8,11-trihydroxy-1-methoxy-7,8,9,10-tetrahydrotetracene-5,12-dione, hydrobromide (1:1)	
TLC Catalogue Number:	D-349	
CAS Number:	148218-14-8	
Molecular Weight:	652.50 80.91	
Molecular Formula:	C ₂₉ H ₃₄ BrNO ₁₁ . HBr	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4657-051A9	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, Water	

Test Description	Specifications	Results
Visual Description	Red solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.8%
Impurity (HPLC)	RT 2.51, 0.41%; RT 2.67, 0.34%; RT 5.99, 0.15%	
Water Content (KF)	N/A	2.0%
Residual Solvents (NMR)	1.4% methanol	
Assay (%)	Not less than 90.0%	95.4%
Recommendation:	Release. The compound is unstable in acidic and basic solutions.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/05/2024
Approved by:	Quality Assurance		06/05/2024

Attachments: HPLC, IR, MS and NMR spectra.