

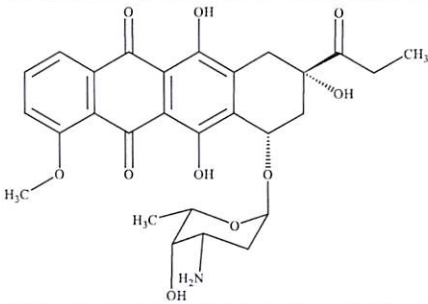
Certificate of Analysis

Certificate No.: 20240320014


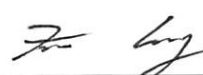
Date: March 20, 2024

Retest date: March 20, 2027

Compound Name: Daunorubicin EP Impurity F (8-Ethyl Daunorubicin)	
Synonyms:	(8S,10S)-10-(((2R,4S,5S,6S)-4-amino-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl)oxy)-6,8,11-trihydroxy-1-methoxy-8-propionyl-7,8,9,10-tetrahydrotetracene-5,12-dione
TLC Catalogue Number:	D-486
CAS Number:	771423-67-7
Molecular Weight:	541.55
Molecular Formula:	C ₂₈ H ₃₁ NO ₁₀
Source:	TLC Pharmaceutical Standards
Source Lot No.:	4363-042A9
Storage Conditions:	Hygroscopic, store at 2-8 °C
Solubility:	Methanol, DMSO



Test Description	Specifications	Results
Visual Description	Black solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	97.7%
Impurity (HPLC)	RT 14.56, 0.36%; RT 31.47, 0.62%; RT 35.34, 0.37%	
Water Content (KF)	N/A	4.9%
Residual Solvents (NMR)	0.1% methanol	
Assay (%)	Not less than 90.0%	92.8%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03/22/2024
Approved by:	Quality Assurance		03/22/2024

Attachments: HPLC, IR, MS and NMR spectra.