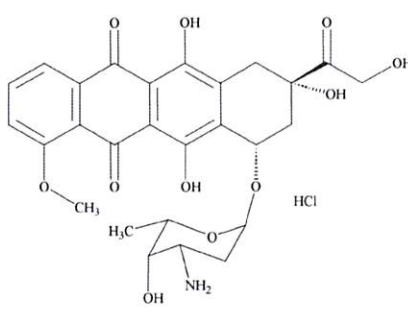


Certificate of Analysis



Certificate No.: 20240716010-2

Date: July 16, 2024

Retest date: July 16, 2027

Compound Name:	Doxorubicin HCl (Daunorubicin EP Impurity D HCl, Epirubicin EP Impurity C HCl)	
Synonyms:	(8S,10S)-10-(((2R,4S,5S,6S)-4-amino-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl)oxy)-6,8,11-trihydroxy-8-(2-hydroxyacetyl)-1-methoxy-7,8,9,10-tetrahydrotetracene-5,12-dione, hydrochloride (1:1)	
TLC Catalogue Number:	D-341	
CAS Number:	25316-40-9	
Alternate CAS Number:	23214-92-8 (free base)	
Molecular Weight:	543.53 36.46	
Molecular Formula:	C ₂₇ H ₂₉ NO ₁₁ · HCl	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	2161-025A4	
Storage Conditions:	Hygroscopic, store at 2-8 °C	
Solubility:	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
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.0%
Impurity (HPLC)	RT 14.27, 0.26%; RT 20.99, 0.70%; RT 25.46, 0.23%	
Water Content (KF)	N/A	9.8%
Residue (TGA at 800 °C)	N/A	0.4%
Optical Rotation	[α] _D ^{20.0} (c=0.10, CH ₃ OH): +248.0°	[α] _D ^{20.0} (c=0.10, CH ₃ OH): +255.7°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 85.0%	88.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		04/21/2025
Approved by:	Quality Assurance		04/21/2025

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