

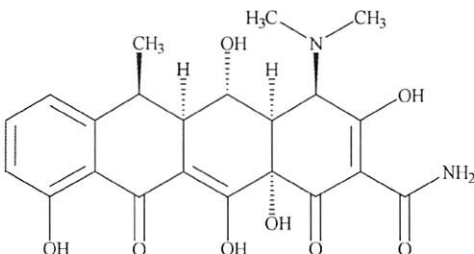
## Certificate of Analysis

Certificate No.: 20250318009-2



Date: March 18, 2025

Retest date: March 12, 2028

<b>Compound Name:</b> Doxycycline EP Impurity D (4- <i>epi</i> -6-Epidoxycycline)	
<b>Synonyms:</b>	(4R,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide
<b>TLC Catalogue Number:</b>	D-184
<b>CAS Number:</b>	97583-08-9
<b>Alternate CAS Number:</b>	N/A
<b>Molecular Weight:</b>	444.44
<b>Molecular Formula:</b>	C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	6687-037A5
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	DMSO, Water



Test Description	Specifications	Results
<b>Visual Description</b>	Pale yellow 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 90.0%	<b>93.1%</b>
<b>Impurity (HPLC)</b>	RT 14.33, 3.98%; RT 16.46, 0.55%; RT 26.97, 0.75%	
<b>Water Content (KF)</b>	N/A	<b>5.5%</b>
<b>Residual Solvents (NMR)</b>	1.9% formic acid and 2.3% dimethyl sulfoxide	
<b>Assay (%)</b>	Not less than 80.0%	<b>84.1%</b>
<b>Recommendation:</b>	<b>Release.</b> The compound contains 0.2% Doxycycline EP Impurity C (RT 14.08, TLC No. D-185) and 4.0% Doxycycline EP Impurity A (RT 14.33, TLC No. D-186) according to its HPLC.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/11/2025
Approved by:	Quality Assurance		07/11/2025

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