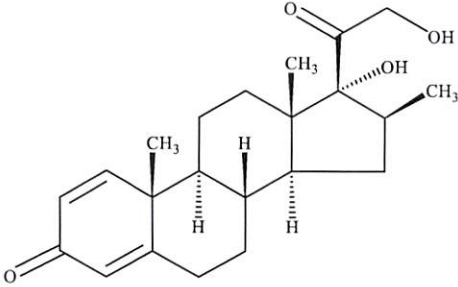


Certificate of Analysis



Certificate No.: **20260512502**

Date: May 12, 2026

Retest date: March 10, 2029

Compound Name:	Betamethasone EP Impurity J	
Synonyms:	(8R,9S,10R,13S,14S,16S,17R)-17-hydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[<i>a</i>]phenanthren-3-one	
TLC Catalogue Number:	B-065021	
CAS Number:	18383-24-9	
Alternate CAS Number:	N/A	
Molecular Weight:	358.48	
Molecular Formula:	C ₂₂ H ₃₀ O ₄	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4285-060A4	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF	

Test Description	Specifications	Results
Visual Description	White to off-white 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%	99.4%
Impurity (HPLC)	RT 10.34, 0.35%	
Water Content (KF)	N/A	0.1%
Residue (TGA at 900 °C)	N/A	0.5%
Residual Solvents (NMR)	0.2% methanol	
Assay (%)	Not less than 90.0%	98.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/12/2026
Approved by:	Quality Assurance		05/12/2026

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