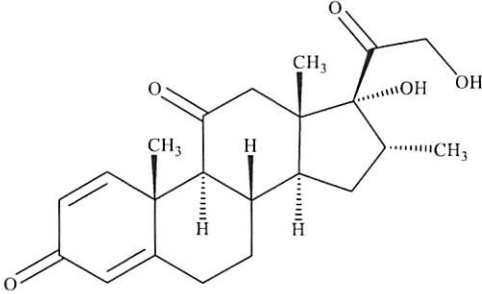


Certificate of Analysis



Certificate No.: **20241217008**

Date: December 17, 2024

Retest date: December 16, 2027

Compound Name:	Dexamethasone EP Impurity J	
Synonyms:	(8S,9S,10R,13S,14S,16R,17R)-17-hydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-7,8,9,10,12,13,14,15,16,17-decahydro-3H-cyclopenta[<i>a</i>]phenanthrene-3,11(6H)-dione	
TLC Catalogue Number:	D-3614	
CAS Number:	2036-77-3	
Molecular Weight:	372.46	
Molecular Formula:	C ₂₂ H ₂₈ O ₅	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3932-038A4	
Storage Conditions:	Hygroscopic, store at 2-8 °C	
Solubility:	DMSO, Acetonitrile, DMF, Methanol	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.3%
Impurity (HPLC)	RT 19.20, 0.31%; RT 19.39, 0.15%	
Water Content (KF)	N/A	2.9%
Optical Rotation	N/A	$[\alpha]_D^{25.0}$ (c=0.60, dioxane): +130.7°
Residual Solvents (NMR)	0.1% diethyl ether	
Assay (%)	Not less than 90.0%	96.3%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		12/19/2024
Approved by:	Quality Assurance		12/19/2024

Attachments: HPLC, IR, MS and NMR spectra.