

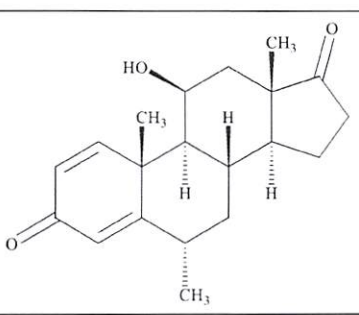
Certificate of Analysis

Certificate No.: **20231219020**


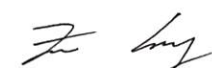
Date: December 19, 2023

Retest date: December 18, 2026

Compound Name: Methylprednisolone EP Impurity C (Methylprednisolone USP Related Compound C)	
Synonyms:	(6S,8S,9S,10R,11S,13S,14S)-11-hydroxy-6,10,13-trimethyl-7,8,9,10,11,12,13,14,15,16-decahydro-3H-cyclopenta[a]phenanthrene-3,17(6H)-dione
TLC Catalogue Number:	P-111112
CAS Number:	61919-52-6
Molecular Weight:	314.43
Molecular Formula:	C ₂₀ H ₂₆ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3224-014A11
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO



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%	99.8%
Impurity (HPLC)	RT 9.69, 0.12%	
Water Content (KF)	N/A	0.1%
Optical Rotation	[α] _D ^{20.0} (c=N/A, dioxane): +102.0°	[α] _D ^{20.0} (c=0.51, dioxane): +108.1°
Residual Solvents (NMR)	0.1% dichloromethane	
Assay (%)	Not less than 90.0%	99.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		12 / 20 / 2023
Approved by:	Quality Assurance		12 / 20 / 2023

Attachments: HPLC, IR, MS and NMR spectra.