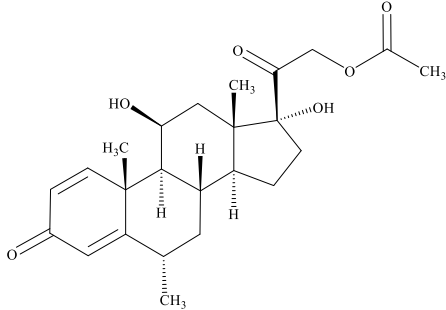


Certificate of Analysis

Certificate No.: 20220104013

Date: January 4, 2022

Retest date: December 30, 2024

Compound Name:	Methylprednisolone EP Impurity J (Methylprednisolone Acetate, Methylprednisolone Hydrogen Succinate EP Impurity C)	
Synonyms:	2-((6S,8S,9S,10R,11S,13S,14S,17R)-11,17-dihydroxy-6,10,13-trimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[<i>a</i>]phenanthren-17-yl)-2-oxoethyl acetate	
TLC Catalogue Number:	P-11191	
CAS Number:	53-36-1	
Molecular Weight:	416.51	
Molecular Formula:	C ₂₄ H ₃₂ O ₆	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	2691-088A1	
Storage Conditions:	Store at 2-8 °C	
Solubility:	DMSO, solution of Methanol and Acetonitrile	

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
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.7%
Impurity (HPLC)	RT 11.97, 0.11%	
Water Content (KF)	N/A	0.1%
Optical Rotation	[α] _D ^{20.0} (c=N/A, dioxane): +101.0°	[α] _D ^{20.5} (c=0.50, dioxane): +96.0°
Residual Solvents (NMR)	0.6% ethyl acetate and 2.6% methanol	
Assay (%)	Not less than 90.0%	96.4%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.