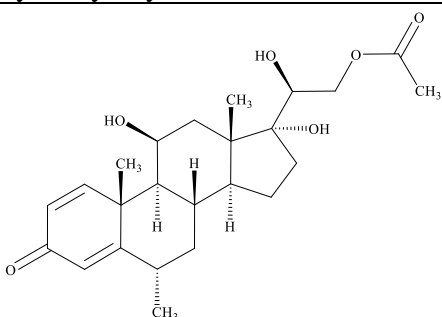


Certificate of Analysis

Certificate No.: 20201225003

Date: December 25, 2020

Retest date: December 22, 2023

Compound Name:	Methylprednisolone Acetate EP Impurity A (20S-Isomer)	
Synonyms:	(S)-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-hydroxyethyl acetate	
TLC Catalogue Number:	P-111166	
CAS Number:	N/A	
Molecular Weight:	418.53	
Molecular Formula:	C ₂₄ H ₃₄ O ₆	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4218-008A6	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF, 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
Purity (HPLC)	Not less than 95.0%	99.0%
Impurity (HPLC)	RT 6.84, 0.12%; RT 8.63, 0.74%	
Water Content (KF)	N/A	0.2%
Residual Solvents (NMR)	0.1% methanol and 0.7% ethyl acetate	
Assay (%)	Not less than 90.0%	98.0%
Recommendation:	Released.	

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

Attachments: HPLC, IR, MS and NMR spectra.