

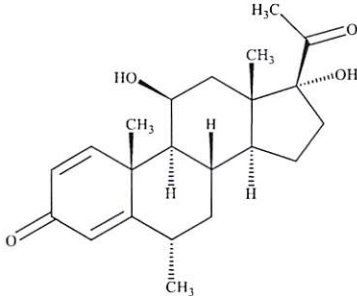
Certificate of Analysis

Certificate No.: **20240509505**



Date: May 9, 2024

Retest date: May 7, 2027

Compound Name: Methylprednisolone EP Impurity L (Fluorometholone USP Related Compound A)	
Synonyms:	(6S,8S,9S,10R,11S,13S,14S,17R)-17-acetyl-11,17-dihydroxy-6,10,13-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:	P-11148
CAS Number:	6870-94-6
Molecular Weight:	358.48
Molecular Formula:	C ₂₂ H ₃₀ O ₄
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2423-039A3
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%	98.2%
Impurity (HPLC)	RT 12.99, 0.20%; RT 14.71, 0.28%; RT 16.17, 0.94%	
Water Content (KF)	N/A	0.2%
Optical Rotation	N/A	[α] _D ^{20.0} (c=0.56, dioxane): +65.3°
Residual Solvents (NMR)	0.3% methanol and 0.1% dichloromethane	
Assay (%)	Not less than 90.0%	97.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/10/2024
Approved by:	Quality Assurance		05/10/2024

Attachments: HPLC, IR, MS and NMR spectra.