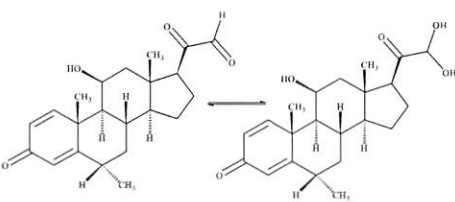


Certificate of Analysis


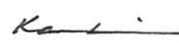
Certificate No.: 20250917017-2

Date: September 17, 2025

Retest date: September 16, 2026

Compound Name:	Methylprednisolone Acetate EP Impurity D	
Synonyms:	2-((6S,8S,9S,10R,11S,13S,14S,17S)-11-hydroxy-6,10,13-trimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthren-17-yl)-2-oxoacetaldehyde and (6S,8S,9S,10R,11S,13S,14S,17S)-17-(2,2-dihydroxyacetyl)-11-hydroxy-6,10,13-trimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthren-3-one	
TLC Catalogue Number:	P-111109	
CAS Number:	N/A	
Alternate CAS Number:	150899-33-5 (aldehyde form); 1338549-01-1 (diol form)	
Molecular Weight:	356.46 374.48	
Molecular Formula:	C ₂₂ H ₂₈ O ₄ C ₂₂ H ₃₀ O ₅	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4378-087A2	
Storage Conditions:	Protect from air, store at -20 °C	
Solubility:	DMF, DMSO, Acetonitrile	

Test Description	Specifications	Results
Visual Description	Pale yellow 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 90.0%	94.6%
Impurity (HPLC)	RT 12.66, 0.72%; RT 13.40, 1.49%; RT 20.42, 1.10%	
Residual Solvents (NMR)	2.1% diethyl ether and 0.6% tetrahydrofuran	
Assay (qNMR)	Not less than 75.0%	80.3%
Recommendation:	Release. The compound is unstable in methanol.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		10/21/2025
Approved by:	Quality Assurance		10/21/2025

Attachments: Peak Attribution Table, HPLC, IR, MS and NMR spectra.