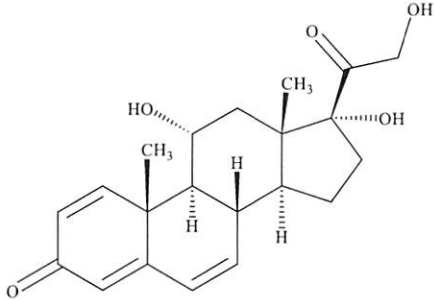


Certificate of Analysis



Certificate No.: **20240407010**

Date: April 7, 2024

Retest date: April 2, 2027

Compound Name:	Prednisolone Impurity 23	
Synonyms:	(8S,9S,10R,11R,13S,14S,17R)-11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13-dimethyl-8,9,10,11,12,13,14,15,16,17-decahydro-3H-cyclopenta[<i>a</i>]phenanthren-3-one	
TLC Catalogue Number:	P-111155	
CAS Number:	111186-94-8	
Molecular Weight:	358.43	
Molecular Formula:	C ₂₁ H ₂₆ O ₅	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	6072-057A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO	

Test Description	Specifications	Results
Visual Description	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%	98.4%
Impurity (HPLC)	RT 3.01, 0.13%; RT 11.67, 0.69%; RT 13.95, 0.15%	
Water Content (KF)	N/A	0.6%
Residual Solvents (NMR)	2.8% acetonitrile	
Assay (%)	Not less than 90.0%	95.1%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		04/10/2024
Approved by:	Quality Assurance		04/10/2024

Attachments: HPLC, IR, MS and NMR spectra.