

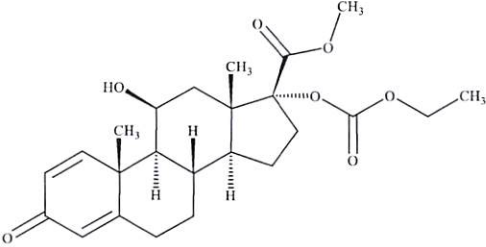
Certificate of Analysis

Certificate No.: 20250321018



Date: March 21, 2025

Retest date: March 20, 2028

Compound Name: Loteprednol Impurity 7	
Synonyms:	methyl (8S,9S,10R,11S,13S,14S,17R)-17-((ethoxycarbonyloxy)-11-hydroxy-10,13-dimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthrene-17-carboxylate
TLC Catalogue Number:	L-3911
CAS Number:	182068-96-8
Alternate CAS Number:	N/A
Molecular Weight:	432.51
Molecular Formula:	C ₂₄ H ₃₂ O ₇
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2751-071A2
Storage Conditions:	Store at 2-8 °C
Solubility:	Acetonitrile, Methanol



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%	100.0%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.1%
Optical Rotation	N/A	[α] _D ^{22.0} (c=0.61, CHCl ₃): +19.3°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.9%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03/21/2025
Approved by:	Quality Assurance		03/21/2025

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