

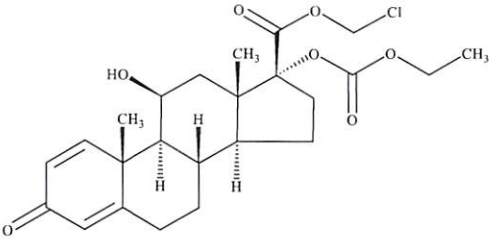
Certificate of Analysis

Certificate No.: **20250305002**



Date: March 5, 2025

Retest date: February 28, 2028

Compound Name: Loteprednol Etabonate	
Synonyms:	chloromethyl (8S,9S,10R,11S,13S,14S,17R)-17-((ethoxycarbonyl)oxy)-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-392
CAS Number:	82034-46-6
Alternate CAS Number:	2058252-98-3 (Monohydrate)
Molecular Weight:	466.96
Molecular Formula:	C ₂₄ H ₃₁ ClO ₇
Source:	TLC Pharmaceutical Standards
Source Lot No.:	6750-003A1
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Acetonitrile



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%	99.7%
Impurity (HPLC)	RT 8.46, 0.12%	
Water Content (KF)	N/A	0.1%
Residue (TGA at 900 °C)	N/A	0.0%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03/05/2025
Approved by:	Quality Assurance		03/05/2025

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