

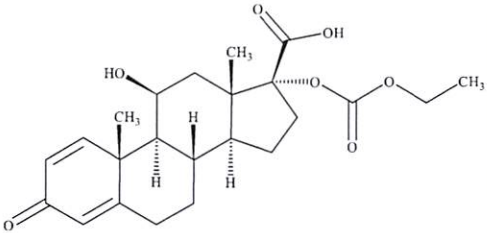
Certificate of Analysis

Certificate No.: **20221019502**

Date: October 19, 2022

Retest date: October 4, 2025

Compound Name: Loteprednol Impurity 1	
Synonyms:	(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-carboxylic acid
TLC Catalogue Number:	L-395
CAS Number:	133991-63-6
Molecular Weight:	418.49
Molecular Formula:	C ₂₃ H ₃₀ O ₇
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2751-070A2
Storage Conditions:	Hygroscopic, store at 2-8 °C
Solubility:	Methanol, Acetonitrile, 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%	98.6%
Impurity (HPLC)	RT 2.74, 1.16%; RT 3.71, 0.10%; RT 4.82, 0.14%	
Water Content (KF)	N/A	4.8%
Optical Rotation	N/A	$[\alpha]_D^{22.0}(c=0.59, \text{DMSO}): +5.6^\circ$
Residual Solvents (NMR)	0.1% ethanol and 4.3% acetonitrile	
Assay (%)	Not less than 85.0%	89.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control	<i>Kevin Zhu</i>	10/20/2022
Approved by:	Quality Assurance	<i>Kati</i>	10/20/2022

Attachments: HPLC, IR, MS and NMR spectra.