

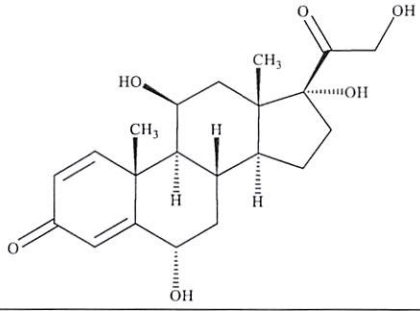
## Certificate of Analysis

Certificate No.: 20221216003



Date: December 16, 2022

Retest date: December 14, 2025

<b>Compound Name:</b> 6- <i>alpha</i> -Hydroxy Prednisolone	
<b>Synonyms:</b>	(6S,8S,9S,10R,11S,13S,14S,17R)-6,11,17-trihydroxy-17-(2-hydroxyacetyl)-10,13-dimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[ <i>a</i> ]phenanthren-3-one
<b>TLC Catalogue Number:</b>	P-11180
<b>CAS Number:</b>	95909-33-4
<b>Molecular Weight:</b>	376.45
<b>Molecular Formula:</b>	C <sub>21</sub> H <sub>28</sub> O <sub>6</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	3758-007A10
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO



Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>98.2%</b>
<b>Impurity (HPLC)</b>	RT 9.06, 1.72%	
<b>Water Content (KF)</b>	N/A	<b>1.5%</b>
<b>Optical Rotation</b>	[α] <sub>D</sub> <sup>25.0</sup> (c=N/A, CH <sub>3</sub> OH): +88.0°	[α] <sub>D</sub> <sup>20.0</sup> (c=0.37, CH <sub>3</sub> OH): <b>+93.2°</b>
<b>Residual Solvents (NMR)</b>	0.1% methanol and 0.5% ethyl acetate	
<b>Assay (%)</b>	Not less than 90.0%	<b>96.1%</b>
<b>Recommendation:</b>	<b>Release.</b> The compound contains 1.7% Hydrocortisone Impurity 63 (6α-Hydroxyhydrocortisone) (RT 9.06, TLC No. C-27152) according to its HPLC and LC-MS.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		12/19/2022
Approved by:	Quality Assurance		12/19/2022

**Attachments:** HPLC, IR, MS and NMR spectra.