

Analysis Date: 25-01-2025

Re-test Date: 25-01-2028

HYDROCORTISONE EP IMPURITY B

Identification

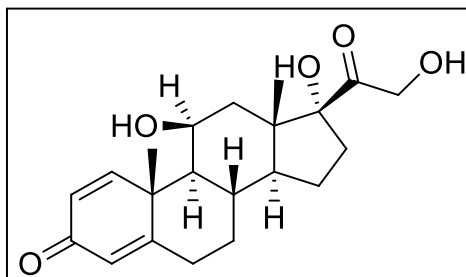
Chemical Name : 17,21-Dihydroxy-pregn-4-ene-3,11,20-trione

CAT No : ALL-HYD-1588

CAS No : 53-06-5

Molecular Formula : C₂₁H₂₈O₅

Molecular Weight : 360.44



Analytical Information

Batch Code	: ALL-HYD-1588	HPLC Purity	: 99.61%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.58 %
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.460%	¹H NMR	: Confirm
Residue Of Ignition	: 3.585%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.460+3.585) × 99.61]/100 = 95.58 %

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadase Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

Attachment : HPLC, Mass, ¹H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office