

Analysis Date: 26-04-2022

Re-test Date: 26-04-2025

HYDROCORTISONE EP IMPURITY J

Identification

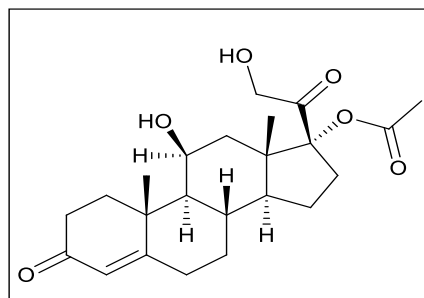
Chemical Name : 11 β ,21-dihydroxy-3,20-dioxopregn-4-en-17-yl acetate

CAT No : ALL-H03048

CAS No : 16463-74-4

Molecular Formula : C₂₃H₃₂O₆

Molecular Weight : 404.50



Analytical Information

Batch Code	: ALL-H03048	HPLC Purity	: 96.90 %
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.89 %
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.328 %	¹ H NMR	: Confirm
Residue Of Ignition	: 0.708 %		

Additional Information

%Potency = [100 -(Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 – (0.328 + 0.708) × 96.90]/100= 95.89 %

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