

Analysis Date: 23-08-2025

Re-test Date: 23-08-2028

METHYLPREDNISOLONE HYDROGEN SUCCINATE EP IMPURITY F

Identification

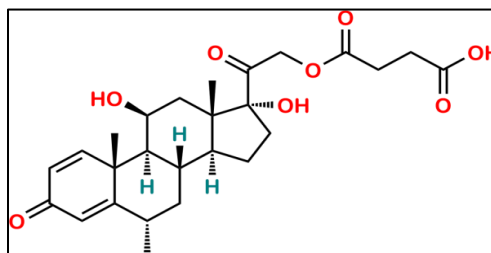
Chemical Name : 4-[(11b,17-dihydroxy-6b-methyl-3,2--dioxopregna-1,4-dien-21-yl)]-4-oxobutanoic acid

CAT No : ALL-METHYLPREDNISOLONEH-8

CAS No : 2376134-25-5

Molecular Formula : C₂₆H₃₄O₈

Molecular Weight : 476.6



Analytical Information

Batch Code	: ALL-METHYLPREDNISOLONEH-8	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 96.71%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.547%	¹H NMR	: Confirm
Residue Of Ignition	: 0.763%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.547+0.763) × 98.00]/100 = 96.71%

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