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CERTIFICATE OF ANALYSIS

Analysis Date: Dec 2025

Re-test Date: Nov 2027

Product Name: Budesonide EP Impurity L

Identification:

Chemical Name: 16 α ,17-[(1R)-Butylidenebis(oxy)]-21-hydroxypregna-1,4-diene-3,11,20-trione (as per EP)

Synonyms : Budesonide USP Related
Compound L ; 11-
ketobudesonide (USP)

CAS Number : 216453-74-6

CAT Number : CP-B19012

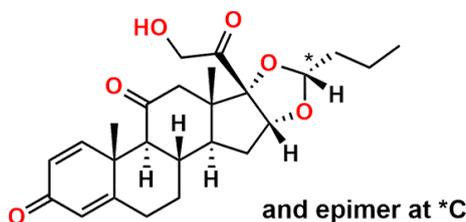
Molecular Formula : C₂₅H₃₂O₆

Molecular Weight : 428.52

Batch Number : CP-BUD-L-1225

Storage Condition : Tightly closed, Inert atmosphere at 2 to 8° C

Shipping condition : All Products are stable to be shipped at room temperature, if specific condition required it is mention in the COA



Analytical Information:

Sr. No.	Test	Result
1)	Description	White Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	94.41%
5)	¹ HNMR	Confirm to structure
6)	IR	Confirm to Structure
7)	Weight loss by TGA	0.104%
8)	Potency by TGA	94.31%



Prepared and Reviewed By

Ms Priyanka Salunkhe
(Quality Control)

Approved By

Ms Rohini Gagare
(Quality Assurance)

Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions.