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CERTIFICATE OF ANALYSIS

Analysis Date: Nov 2025

Re-test Date: Oct 2028

Product Name: Budesonide EP Impurity D

Identification:

Chemical Name: 16 α ,17-[(1R)-Butylidenebis(oxy)]-11 β -hydroxy-3,20-dioxopregna-1,4-dien-21-al (as per EP & USP)

Synonyms : 21-dehydrobudesonide (USP) ;
Budesonide Aldehyde Impurity

CAS Number : 85234-63-5

CAT Number : CP-B19004

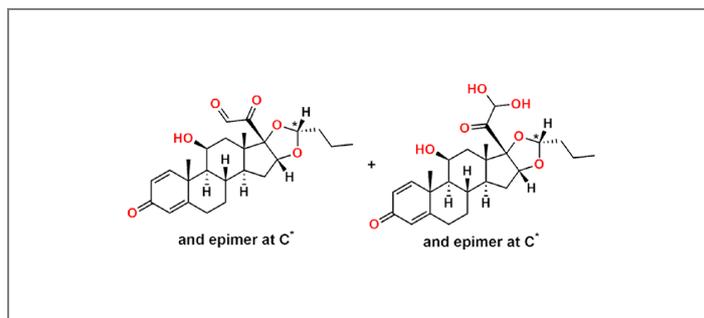
Molecular Formula : C₂₅H₃₂O₆

Molecular Weight : 428.52

Batch Number : CP-25-144-I

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	Off White Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to Structure By Mass
4)	Purity by HPLC	Peak 1(RT-9.620)-53.88% Peak 2(RT-10.749)-38.19% Total Purity-92.07%
5)	¹ H NMR	Confirm to Structure
6)	IR	Confirm to Structure
7)	Weight loss by TGA	2.449%
8)	Potency by TGA	89.81%



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.