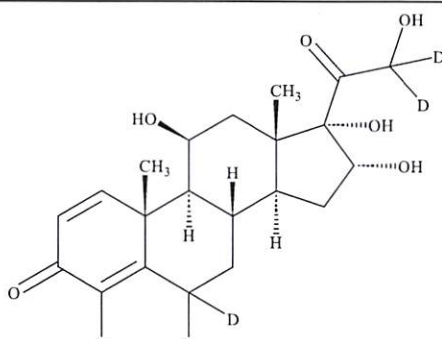


Certificate of Analysis



Certificate No.: **20250627020**

Date: June 27, 2025

Retest date: June 25, 2028

Compound Name:	Budesonide EP Impurity A-d₅ (16-<i>alpha</i>-Hydroxy-Prednisolone-d₅)	
Synonyms:	(8S,9S,10R,11S,13S,14S,16R,17S)-11,16,17-trihydroxy-17-(2-hydroxyacetyl-d ₂)-10,13-dimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[<i>a</i>]phenanthren-3-one-4,6,6-d ₃	
TLC Catalogue Number:	B-0352	
CAS Number:	N/A	
Alternate CAS Number:	13951-70-7 (non-labelled)	
Molecular Weight:	381.48	
Molecular Formula:	C ₂₁ H ₂₃ D ₅ O ₆	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	6953-005A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF	

Test Description	Specifications	Results
Visual Description	Pale yellow solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.8%
Impurity (HPLC)	RT 4.20, 0.12%; RT 13.23, 0.50%; RT 16.11, 0.17%	
Isotopic Enrichment	Not less than 95.0%	97.7%
Water Content (KF)	N/A	0.2%
Residual Solvents (NMR)	0.9% tetrahydrofuran and 0.1% acetonitrile	
Assay (%)	Not less than 90.0%	97.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/27/2025
Approved by:	Quality Assurance		06/27/2025

Attachments: Peak Attribution Table, HPLC, IR, MS and NMR spectra.