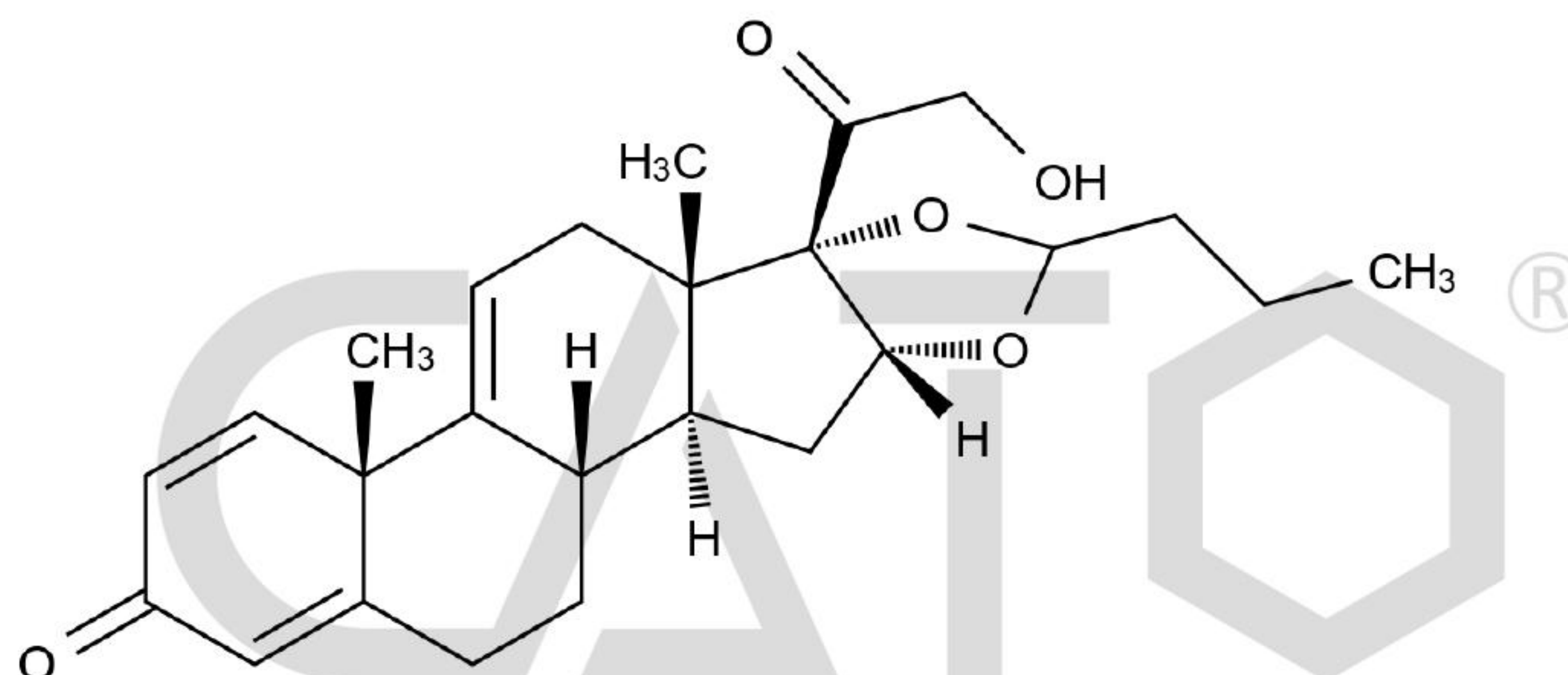


Certificate of Analysis

Reference Material & Standard

Product Name:	Budesonide EP Impurity H (Mixture of Epimer)	Catalogue Number:	C4X-13898
Synonyms:	N/A	Lot Number:	0429-RH-0103
CAS Number:	313474-58-7	Expiry Date:	May 06, 2030
Molecular Formula:	C ₂₅ H ₃₂ O ₅	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	412.52	Shipping Condition:	Shipping with Ice Packs
Solubility:	Acetonitrile		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&CNMR&HNMR	Confirmed
Purity	HPLC	99.050%
Loss on Drying	TGA	0.0543%
Assay		99.0%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Loss on Drying) * Purity HPLC (%) / 100%

Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Sep 04, 2026

Date: Sep 04, 2026

Date: Sep 04, 2026



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