

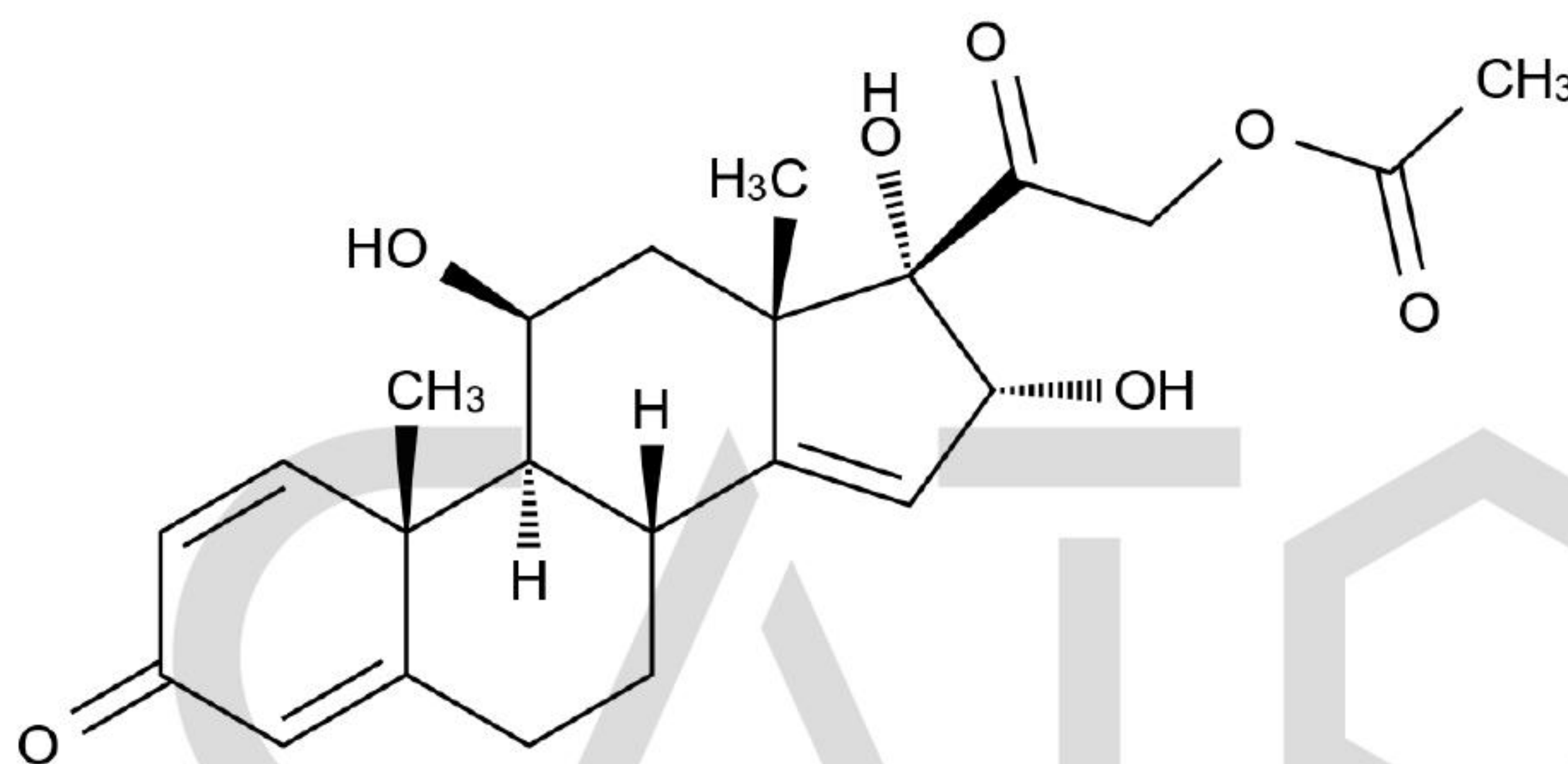
Certificate of Analysis

Reference Material & Standard

Product Name:	Budesonide 1,4,14-Triene Triol Impurity	Catalogue Number:	CP111778
Synonyms:	N/A	Lot Number:	0218-RG-0084
CAS Number:	131918-72-4	Expiry Date:	Feb 07, 2028
Molecular Formula:	C23H28O7	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	416.46	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.677%
Water Content	Karl Fischer	0.91%
Residual Solvents	NMR	0.14% methanol
Assay		97.6%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Feb 18, 2025

Date: Feb 18, 2025

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