

Certificate of Analysis

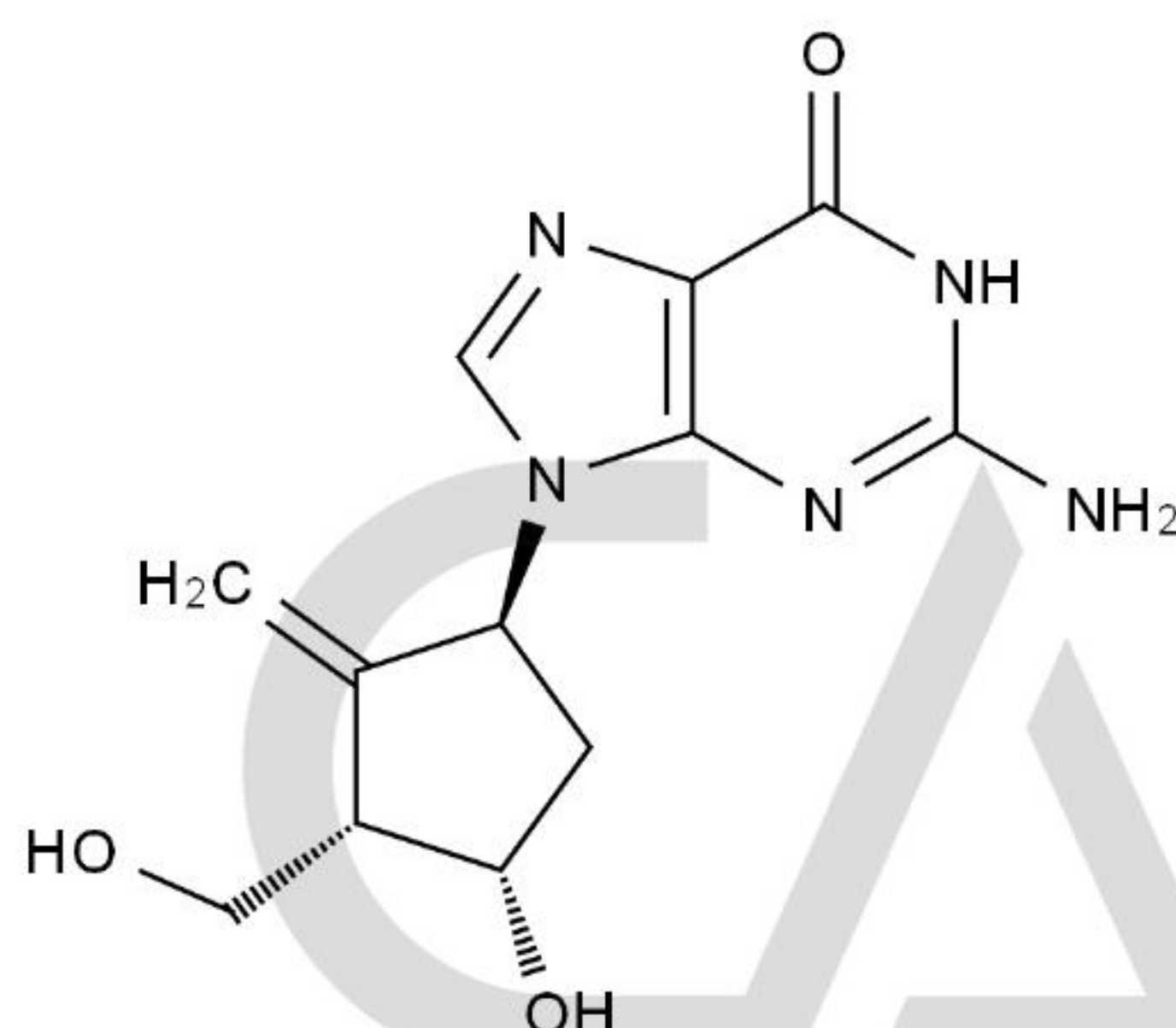
Reference Material & Standard

Product Name:	Entecavir EP Impurity B	Catalogue Number:	C4X-10776
Synonyms:	Entecavir 3-epimer	Lot Number:	0521-RH-0044
CAS Number:	1367369-77-4	Expiry Date:	May 24, 2030
Molecular Formula:	C ₁₂ H ₁₅ N ₅ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	277.28	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.897%
Loss on Drying	TGA	0.4940%
Assay		99.4%

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: May 25, 2026

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Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

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