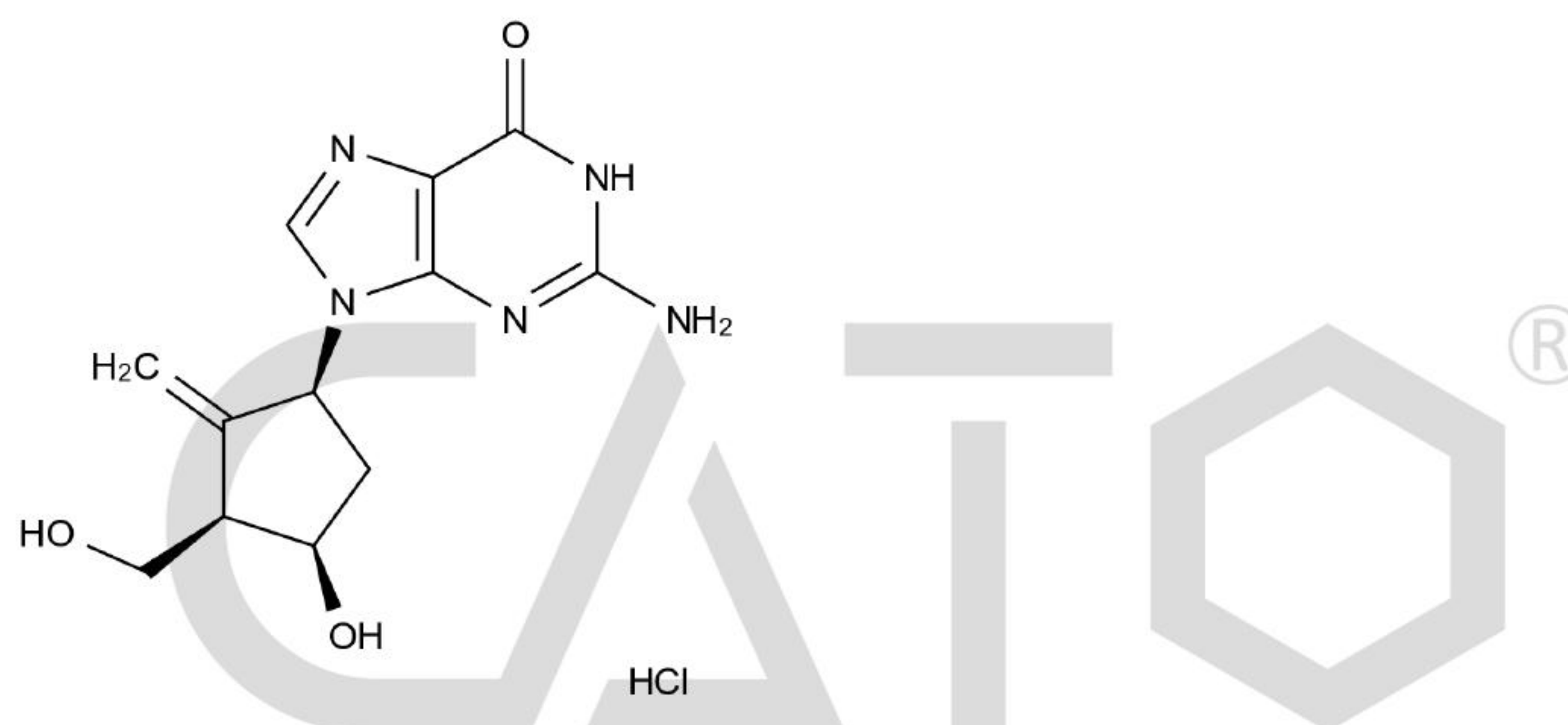


Certificate of Analysis

Reference Material & Standard

Product Name:	Entecavir EP Impurity D HCl	Catalogue Number:	C4X-107789
Synonyms:	N/A	Lot Number:	0831-RH-0166
CAS Number:	1367369-80-9(free base)	Expiry Date:	Nov 28, 2027
Molecular Formula:	C ₁₂ H ₁₅ N ₅ O ₃ HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	277.28 36.46	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	MS&HNMR	Confirmed
Purity	HPLC	97.44%
Loss on Drying	TGA	6.06%
Assay		91.5%

Comment:

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

$\text{Assay (\%)} = (100\% - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$

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

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date:

Date:

Date:

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