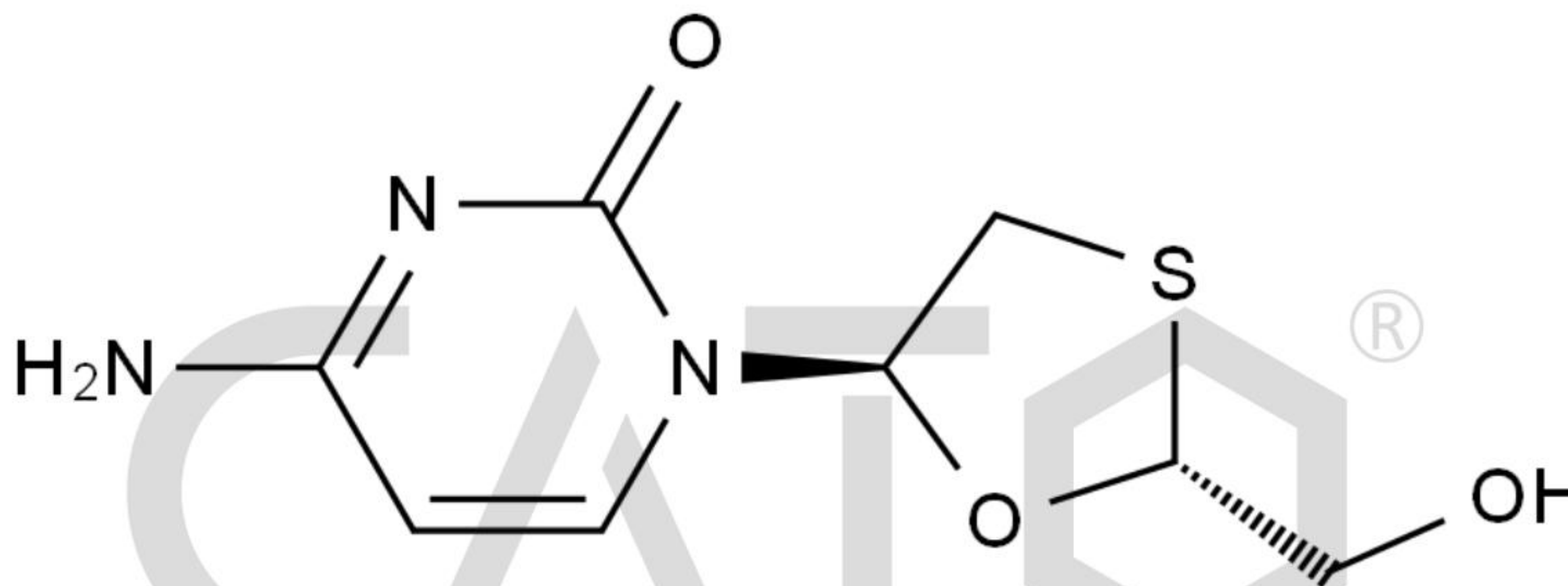


Certificate of Analysis

Reference Material & Standard

Product Name:	Lamivudine Impurity B((2R,5R)-Isomer)	Catalogue Number:	C4X-119412
Synonyms:	N/A	Lot Number:	0308-RD-0011
CAS Number:	139757-68-9	Expiry Date:	Feb 25, 2025
Molecular Formula:	C ₈ H ₁₁ N ₃ O ₃ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	229.26		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	98.5859%
Water Content	Karl Fischer	0.3%
Residual Solvents	NMR	0.2% ethanol
Specific Rotation		[α] _D 21.0(c=0.37,CH ₃ OH)/+161.5°
Assay		98.1%

Comment:

The calculation of the mass balance 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:

Hinlam

Reviewed by:

Cady

Approved by General Manager:

David

Date: Mar 08, 2022

Date: Mar 08, 2022

Date: Mar 08, 2022

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