

Certificate of Analysis

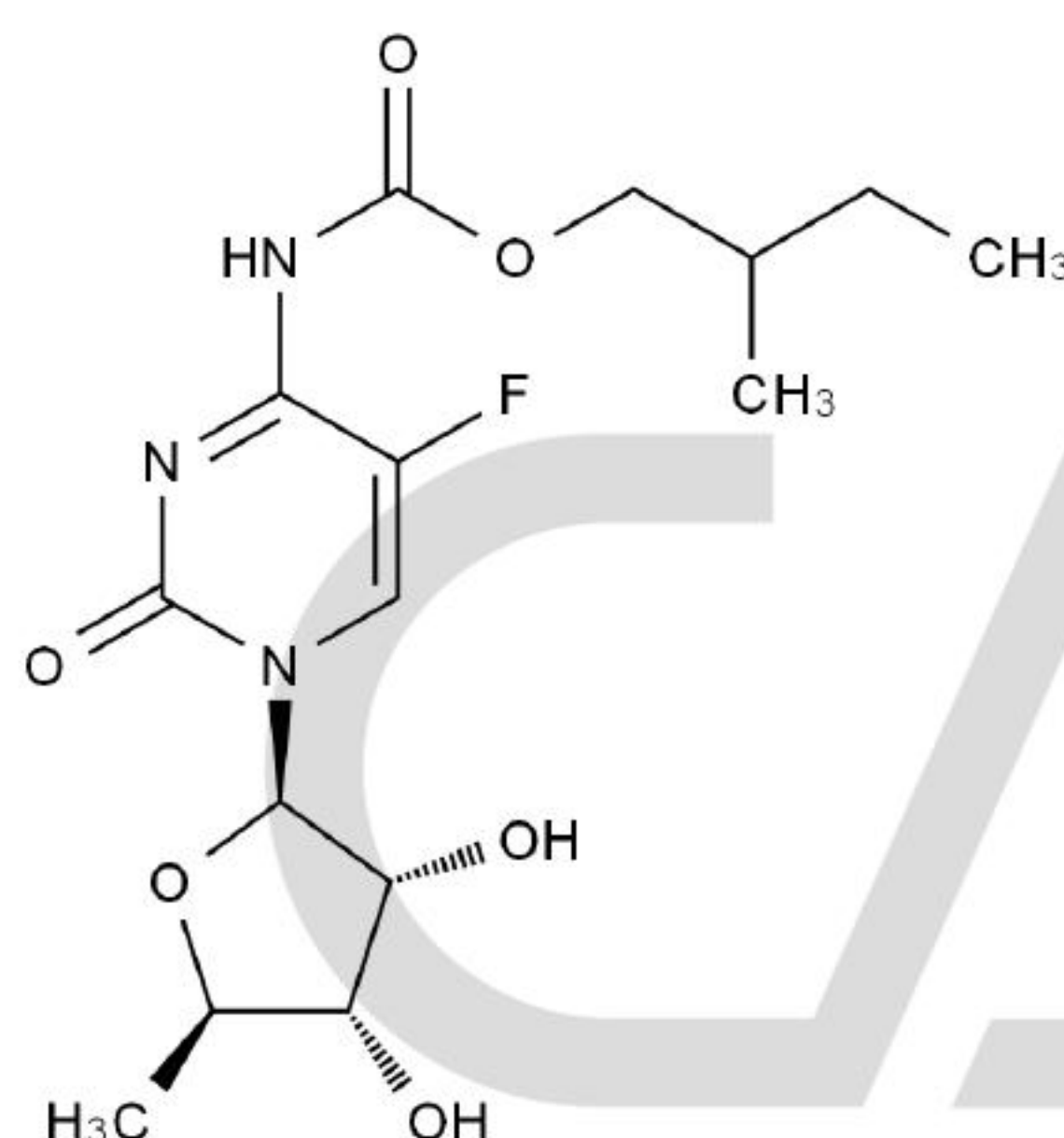
Reference Material & Standard

Product Name:	Capecitabine EP Impurity D (Mixture of Diastereomers)	Catalogue Number:	C4X-10246
Synonyms:	N/A	Lot Number:	1214-RE-0067
CAS Number:	910129-15-6	Expiry Date:	Dec 12, 2026
Molecular Formula:	C ₁₅ H ₂₂ FN ₃ O ₆	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	359.35		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.739%
Water Content	Karl Fischer	0.59%
Residual Solvents	NMR	Not detected in NMR
Assay		99.2%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Dec 19, 2023

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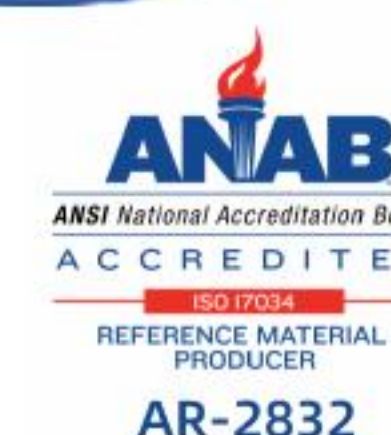
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