

Certificate of Analysis

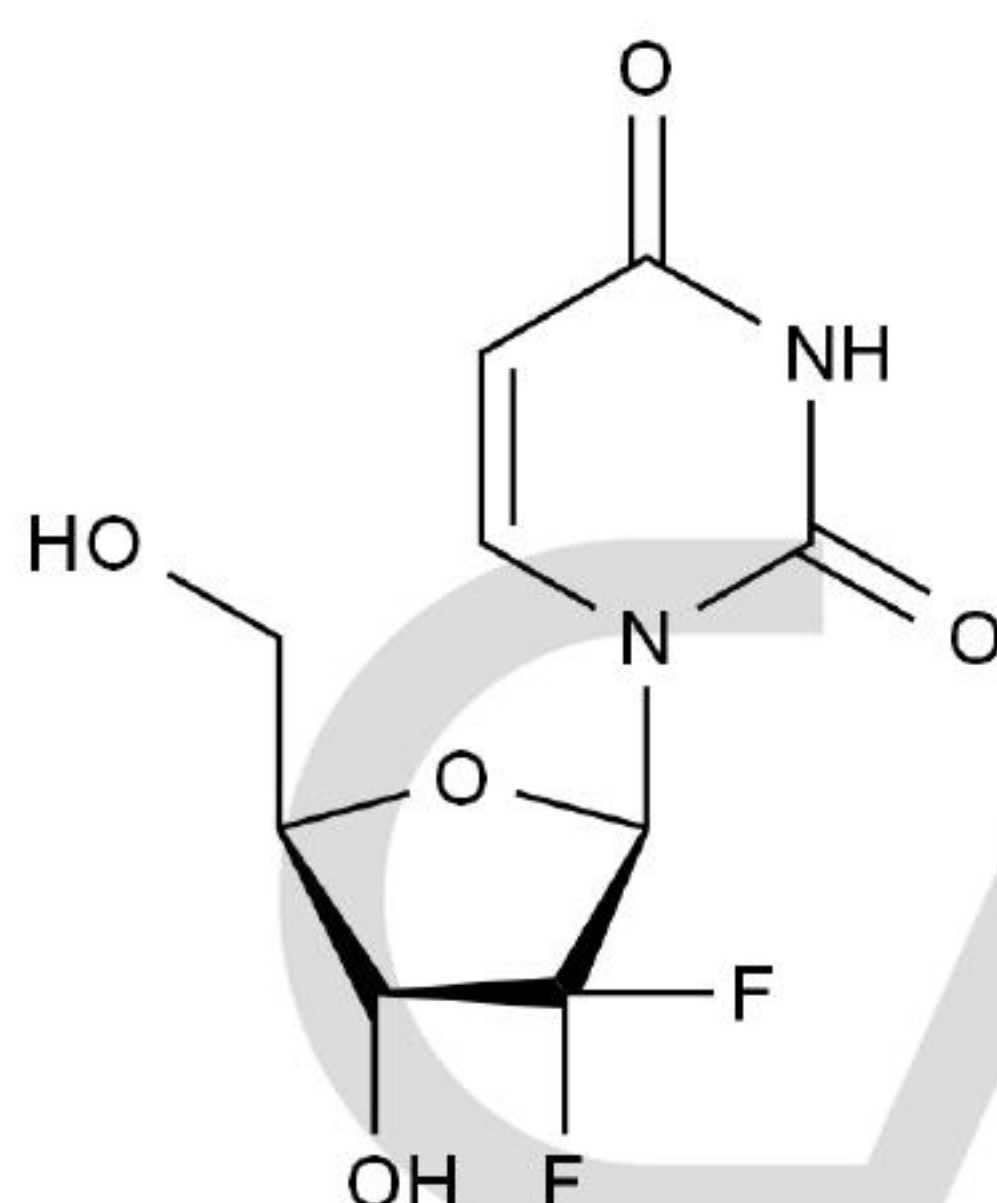
Reference Material & Standard

Product Name:	Gemcitabine EP Impurity C	Catalogue Number:	C4X-13727
Synonyms:	N/A	Lot Number:	0401-RG-0005
CAS Number:	114248-23-6	Expiry Date:	Oct 16, 2029
Molecular Formula:	C ₉ H ₁₀ F ₂ N ₂ O ₅	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	264.18		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.829%
Loss On Drying	TGA	0.0839%
Assay		99.7%

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: Oct 17, 2025

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