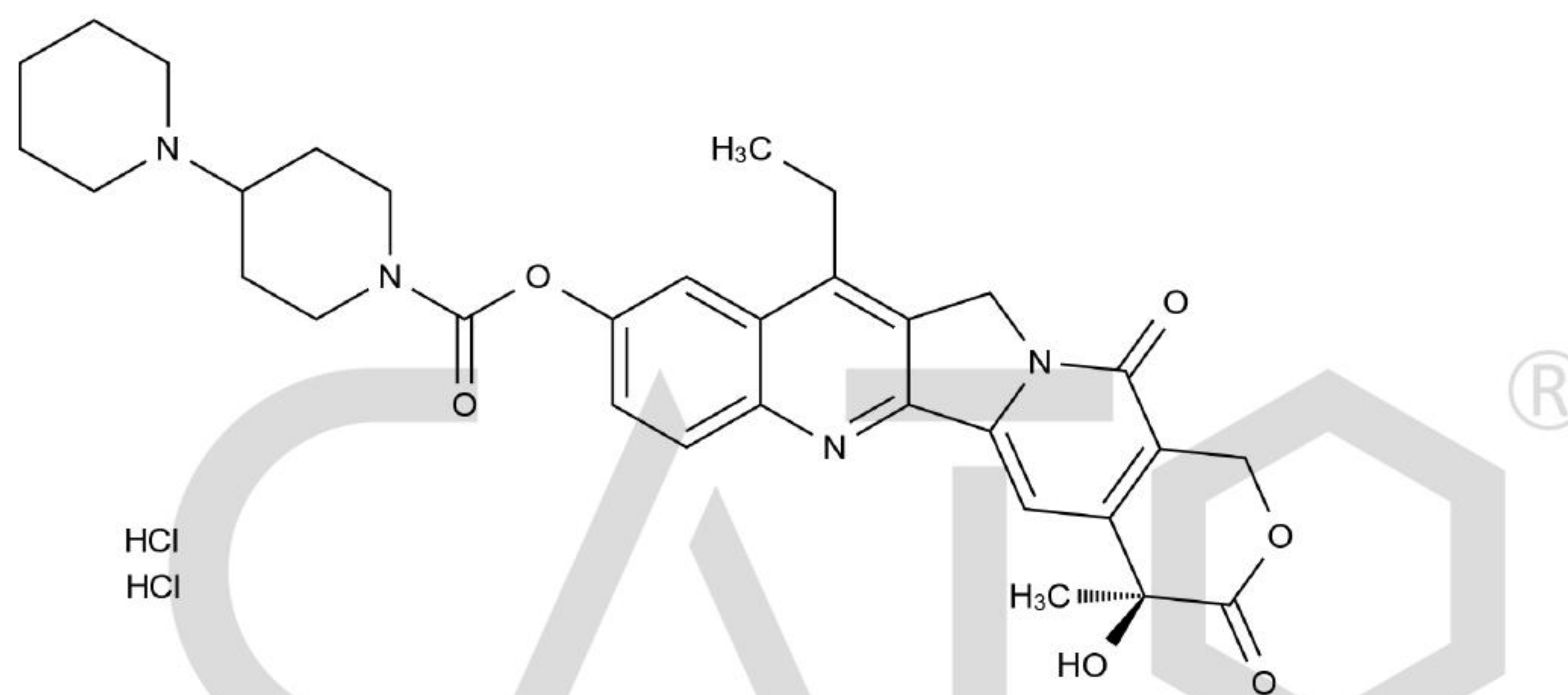


Certificate of Analysis

Reference Material & Standard

Product Name:	Irinotecan EP Impurity H DiHCl	Catalogue Number:	C4X-157113
Synonyms:	N/A	Lot Number:	0816-RH-0019
CAS Number:	1608617-71-5 (free base)	Expiry Date:	Aug 06, 2030
Molecular Formula:	C ₃₂ H ₃₆ N ₄ O ₆ 2*HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	572.65 2*36.46	Shipping Condition:	Shipping at Room Temperature

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.2407%
Water Content	Karl Fischer	2.40%
Residual Solvents	NMR	2.3% isopropanol
Specific Rotation		[α] _D 20.0(C=0.32, DMSO): +4.5°
Assay		94.6%

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:

Reviewed by:

Approved by General Manager:

Date: Aug 18, 2026

Date: Aug 18, 2026

Date: Aug 18, 2026



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