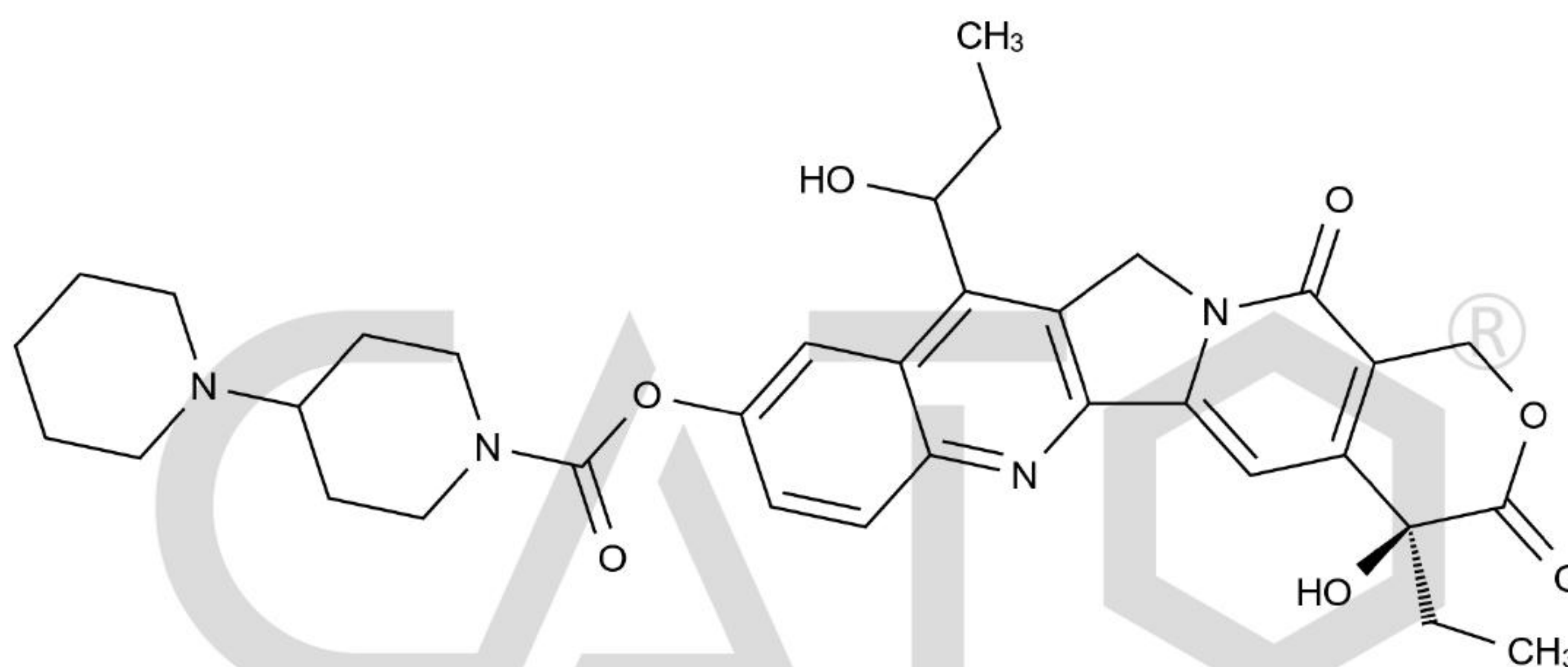


Certificate of Analysis

Reference Material & Standard

Product Name:	Irinotecan EP Impurity K	Catalogue Number:	C4X-166716
Synonyms:	N/A	Lot Number:	0522-RE-0015
CAS Number:	2508174-07-8	Expiry Date:	Nov 17, 2024
Molecular Formula:	C ₃₄ H ₄₀ N ₄ O ₇	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	616.70	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	95.1497%
Water Content	Karl Fischer	4.3%
Residual Solvents	NMR	Not detected in NMR
Assay		91.1%

Comment:

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

$$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$$

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Hin Lam

Reviewed by:

Yuki-i

Approved by General Manager:

David

Date: May 18, 2023

Date: May 24, 2023

Date: May 24, 2023



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