



Certificate of analysis

Product name: Irinotecan hydrochloride trihydrate

Cas number: 136572-09-3

Molecular Formula: C₃₃H₄₅ClN₄O₉

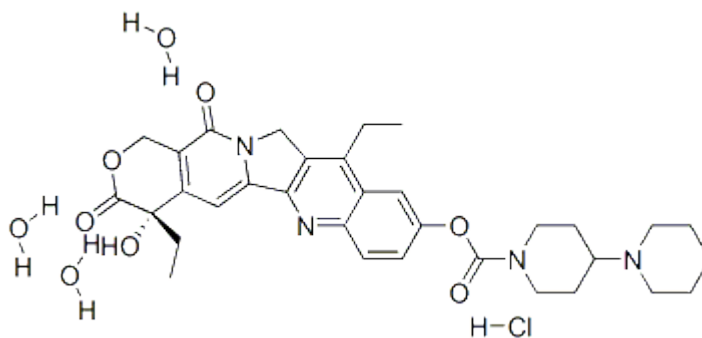
Molecular Weight: 677.18

Date of production: Mar. 11, 2020

Batch No: 20200311

Exp Date: Mar. 10, 2022

Chemical structure:



Items	Specifications	Results
Appearance	Pale yellow or yellow crystalline powder	Complies
Identification	HNMR HPLC MS	Complies
Organic Impurities	Limit of Irinotecan Hydrochloride Enantiomer $\leq$ 0.15%	0.08%
	7-Desethyl irinotecan $\leq$ 0.15%	0.04%
	Irinotecan $\leq$ 0.15%	0.03%
	Irinotecan related compound A $\leq$ 0.15%	0.04%
	11-Ethyl irinotecan $\leq$ 0.15%	0.03%
	Camptothecin $\leq$ 0.15%	N.D
	Irinotecan related compound B $\leq$ 0.15%	0.02%
	7-Ethylcamptothecin $\leq$ 0.15%	0.02%
	7,11-Diethyl-10-hydroxycamptothecin $\leq$ 0.10%	0.01%
	Any unspecified impurity $\leq$ 0.10%	$<$ 0.1%
	Total impurities $\leq$ 0.5%	0.19%
Residual solvents	Acetic acid $\leq$ 0.5%	N.D
	Acetone $\leq$ 0.5%	0.11%
	Chloroform $\leq$ 60 ppm	12PPM
	N,N-Dimethylformamide (DMF) $\leq$ 880 ppm	16PPM
	Dimethyl sulfoxide (DMSO) $\leq$ 0.5%	0.01%
	Ethanol $\leq$ 0.5%	0.03%
	Methanol $\leq$ 3000 ppm	69PPM
	Pyridine $\leq$ 200 ppm	6PPM
Residue on ignition	$\leq$ 0.1%	0.05%
Heavy metals	$\leq$ 10 PPM	$<$ 10 PPM
Assay	98.0% ~ 102.0% (calculated on the anhydrous basis)	99.8%

Conclusion: It complies with the usp42 Standard.