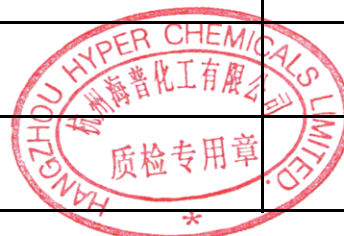


CERTIFICATE OF ANALYSIS

Product Name:	Irinotecan Hydrochloride		
Batch No.	SIRH202307006	COA No.	2300079
Manufacturing Date	July 3, 2023	Expiry Date TO	July 2, 2025
Quantity	10273g	Date of Issue	August 7, 2023
Packing	g/bag	Reference Standard	QS-01017
Storage	Preserve in tight,light-resistant containers and store at controlled room temperature.		
Analytical results			
Items	Specifications		Results
Appearance	Pale yellow to yellow crystalline powder.		Pale yellow crystalline powder
Identification	Infrared absorption spectrum of the substance being examined corresponds to that of Irinotecan Hydrochloride RS.		Complies
	The retention time of the major peak of the Sample solution corresponds to the irinotecan(S-enantiomer)peak in the Identification solutionas obtained in the test for Limit of Irinotecan Hydrochloride Enantiomer.		Complies
	Sample solution yields the characteristic reaction of chlorides.		Complies
Assay (as anhydrous substance)	98.2%~102.0%		99.90%
Residue on ignition	≤0.1%		0.05%
Heavy Metals	≤10 ppm		<10ppm
Water	7.0%~ 9.0%		7.20%



Bacterial Endotoxins	≤0.25 EU/mg	<0.25 EU/mg
Limit of Irinotecan Hydrochloride Enantiomer	R-enantiomer ≤0.15%	ND
Organic impurities Procedure 2	7-Desethylirinotecan(RRT0.82)≤0.15%	<0.03%
	Irinotecan related compound A(RRT1.15) ≤0.15%	<0.03%
	11-Ethyl irinotecan(RRT1.27)≤0.15%	ND
	Camptothecin(RRT1.35)≤0.15%	ND
	Irinotecan related compound B(RRT1.50)≤0.15%	<0.03%
	7-Ethylcamptothecin(RRT1.76)≤0.15%	<0.03%
	7,11-Diethyl-10-hydroxycamptothecin(RRT2.05)≤0.15%	ND
	Any unspecified impurity≤0.10%	<0.05%
	Total impurities≤0.50%	<0.13%
Microbial Limit	Total Aerobic Microbial Count(TAMC)≤800cfu/g	<10cfu/g
	Total Yeasts and Moulds Count(TYMC)≤80cfu/g	<1cfu/g
Residual solvents	Methanol≤2500 ppm	17ppm
	Acetone≤4500 ppm	265ppm
	Methylene chloride≤600 ppm	ND
	Pyridine≤200 ppm	ND
Conclusion	The above test results comply with USP 2023 and in-house specifications.	

Inspector: Carlifor Wu

Verifier: Jack He

