



Certificate of Analysis

Product Name	Irinotecan hydrochloride	Manufacture Date	Oct.25.2023
Batch Number	SW231025	Analysis Date	Oct.27.2023
Batch Quantity	100kg	Expiry Date	Oct.25.2025

ANALYSIS	SPECIFICATION	RESULT
Appearance	Yellow powder	Conform
Particle Size	100% through 80 mesh	Conform
Solubility	Soluble in DMSO or DMF at approximately 20mg/ml. Sparingly soluble in aqueous buffers. /n	Conform
	Soluble in DMSO at 100mg/ml. Soluble in water at 25mg/ml with warming	Conform
Melting point	250-256 °C (dec.)	255 °C
Heavy metals		
Pb	≤5 ppm	3ppm
Hg	≤5 ppm	Conform
As	≤5 ppm	N.D.
Cd	≤1 ppm	Conform
Cr	≤1 ppm	Conform
Ni	≤1 ppm	N.D.
Cu	≤10 ppm	6.32ppm
Zn	≤10 ppm	Conform
Fe	≤10 ppm	2.9ppm
Microbial limits	Total aerobic microbial count: not exceed 1000cfu/g	20cfu/g
	Total molds and yeasts count: not exceed 100cfu/g	20cfu/g
Assay	99%	99.4%

Packing description	Sealed export grade drum & double of sealed plastic bag
Storage	Store in a cool and dry place, stay away from strong light and heat
Shelf life	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 方臻

