



Certificate of Analysis

Product Name	Docetaxel	Manufacture Date	May.23.2023
Batch Number	SW230523	Analysis Date	May.24.2023
Batch Quantity	10kg	Expiry Date	May.23.2025

ANALYSIS	SPECIFICATION	RESULT
Appearance	White or almost white crystals or crystalline powder	White powder
Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol, soluble in methylene chloride.	Conform
Identification	Specific optical rotation	Conform
	By IR	Conform
	It gives reaction of bromides	Conform
Particle Size	100% through 80 mesh	Conform
Appearance of Solution	Solution S is clear and not more intensely coloured than reference solution BY7	Conform
Water Content	≤ 4.0%	1.30%
Sulfated Ash	≤ 0.10%	0.046%
Melting Point	186-192 °C (dec.)	187 °C
Loss on drying	NMT 0.5%	0.02
Related Substances	Impurity A: ≤0.25%	ND
	Impurity C: ≤0.25%	0.04%
	Impurity D: ≤0.25%	0.018%
	Impurity E: ≤0.25%	ND
	Impurity B(TLC): ≤0.25%	ND
	Any other unspecified impurity: ≤0.10%	0.03%
	Total inpurities: ≤0.70%	0.16%
Bacterial Assay	Not more than 10EU/mg of Vecurium Bromide	Conform
Assay	99.0%~101.0%	99.88%

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: 方源

