

陕西締都医药化工有限公司

Shaanxi Dideu Medichem Co. Ltd

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No. 302 Jinggao South Rd, Jinghe Industrial Park, Gaoling County, Shaanxi Province, China 710200

Certificate Of Analysis

Product Name	Dihydroergotoxine mesylate	Batch No.	2405281556
Sample Qty Base	7.21 KGS	Date of Production	2024.05.28
Analysis Date	2024.05.29	Expiry Date	2027.05.27
CAS NO	8067-24-1	Packing	3.5 Kg/Drum
Item	Standard	Test Results	
Appearance	Ivory white powder	Complies	
Solubility	Slightly soluble In dichloromethane, moderately soluble in water and acetone, soluble in ethanol 96% and methanol.	Complies	
Identification	A.IR: Must match	Complies	
	B.TLC: Must match	Complies	
	C.HPLC: Must match	Complies	
pH of the solution	4.2~5.2	4.5	
Loss on drying,%	≤0.5	0.1	
Heavy metals, ppm	≤20	<20	
Assay USP,% HPLC	Dihydroergocornine MS	30.3~36.3	36.3
	Dihydroergocristine MS	30.0~35.0	31.65
	Alpha+Beta-Dihydroergocriptine MS	30.3~36.3	31.63
	Ratio Alpha/Beta Dihydrocriptine MS	1.5~2.5	2.2
Residual Solvents,ppm	Ethanol	≤1000	Not Detected
	Ethyl acetate	≤500	300
	Methylene Chloride	≤100	Not Detected
	Isopropanol	≤500	Not Detected
	Methanol	≤1000	Not Detected
	Dioxane	≤50	Not Detected
	Acetone	≤1500	Not Detected
	Palladium	≤5	<5
Storage	In a tightly closed container and protected from light		Complies
Conclusion	The batch conforms to the USP/EP standard		

Reported By: 李兵
2024.05.29

Checked By: 李兵
2024.05.29

QC Manager: 李兵
2024.05.29

QA Manager: 李兵
2024.05.29

