

陕西締都医药化工有限公司

Shaanxi Dideu Medichem Co. Ltd

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Certificate Of Analysis

Product Name	Yohimbine HCL	Batch No.	2502161154
Sample Qty Base	50.23KG	MFG. Date	2025.02.16
Report Date	2025.02.17	EXP. Date	2027.02.15
CAS NO	65-19-0	Packing	1KG/BAG
Item	Standard		Test Results
Appearance	White of Yellow powder		Complies
Identification	A.Infrared Absorption		Complies
	B.The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation obtained as directed in the Assay		Complies
Solubility	Soluble in Boiling Water ; slightly soluble in water and in alcohol		Confirm
Assay,% (On Dry Basis)	98		99.12
Melting Point	Melts at about 295°, With Decomposition		Confirm
Loss on drying,%	≤1.0		0.55
Specific optical Rotation,°	+100 to +105		+103.5
Single impurity,%	≤1.0		Complies
Total Impurities,%	≤2.0		Complies
Residual Solvents Total,PPM	≤ 3000		Complies
Methanol,PPM	≤ 1870		Complies
Ethylene Dichloride Chloroform,PPM	≤ 60		Complies
Chromatographic Purity ,%	≤1.0		Complies
Individual Sum of Impurity,%	≤2.0		Complies
Total Viable count,cfu /gm	≤1000		Complies
Bacteria count,cfu /gm	≤100		Complies
Fungal count	Should be absent		Complies
Escherichia coli Salmonella-	Should be absent		Complies
Pseudomonasaeruginosa	Should be absent		Complies
E.Coli	Should be absent		Complies
Storage	Protect from the light and Store in a dry place. (RT)		Complies
Conclusion	The batch conforms to the USP42 standard		

Reported By: 周文杰

Checked By:

张建蓉

QC Manager: 郭毅军

QA Manager:

郭建

