

陕西缔都医药化工有限公司

Shaanxi Dideu Medichem Co. Ltd

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Certificate Of Analysis

Product Name		Mirogabalin Besylate	Batch No.	2407301305
Sample Qty Base		300.24KGS	MFG. Date	2024.07.30
Report Date		2024.07.30	EXP. Date	2026.07.29
CAS NO		1138245-21-2	Packing	1KGS / BAG
Item		Standard		Test Results
Appearance		White to light-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
Specific optical rotation,°		-70.0~-62.0		-66.2
Benzenesulfonic acid ,%		42~46		44.3
Related substances	Single impurity,%	≤0.2		0.053
	Total impurities,%	≤1.0		0.086
Stereoisomeric purity	Impurity A,%	≤0.15		0.068
	Impurity B,%	≤0.15		Not detected
	Impurity C,%	≤0.15		Not detected
Water,%		≤1.0		0.05
Residue on ignition,%		≤0.20		0.03
Assay,%		98-102		99.56
Storage		Preserve in a tightly closed container and protected from light		Complies
Conclusion		The batch conforms to the In House standard		

Reported By: 张丽川 Checked By: 程雪 QC Manager: 郭毅军 QA Manager: 李建国

