

Miedykol

A brand by IKEM

Mikem (Shandong) Biopharmaceutical Science and Technology Co., Ltd.

Certificate Of Analysis

PRODUCT:	Nicardipine Hydrochloride		
BATCH NO. :	202309001	MFG.DATE:	Sep.14,2023
QUANTITY:	5KG	EXP DATE:	Sep.13,2024

ITEM	STANDARD	RESULT
Appearance	A light yellow to off white crystalline powder	Yellow crystalline powder
Identification	1.The infrared absorption is same as reference	conform
	2.The retention time of the major of the sample solution corresponds to that of the standard silution,as obtained in the assay	conform
	3.Should be positive reaction	conform
Impurity B	NMT 0.1%	0.08%
Impurity C	NMT 0.5%	N.D.
Impurity D	NMT 0.5%	N.D.
Other individual impurity	NMT 0.1%	0.01%
Total impurity	NMT 1.0%	0.11%
Less on drying	NMT 0.5%	0.06%
Residue on ignition	NMT 0.1%	0.10%
Assay(on dried base)	98.0%-102.0%	101.8%

Conclusion:it conforms to the USP standard

QC Checker: 王健

Analysis: 刘艳