

# Miedykol

A brand of Mikem

Mikem (Shandong) Biopharmaceutical Science and Technology Co., Ltd.  
**Certificate Of Analysis**

PRODUCT:	Nifedipine		
BATCH NO. :	202305003	MFG.DATE:	Jul.04,2023
QUANTITY:	100G	EXP DATE:	Jul.03,2025

ITEM	STANDARD	RESULT
Appearance	Yellow crystalline powder;Odorless;affected by light	Yellow crystalline powder;Odorless;affected by light.
Melting point	171-175°C	171.9-173.4°C
Identification	1.Should show forward reaction	Conform
	2.The infrared absorption is same as reference	Conform
	3.Max.Absorption is in the wavelength 237nm,There is a large wide absorption at the wavelength of320nm~355nm.	Conform
Individual impurity	≤0.2%	0.14%
Impurity I	≤0.1%	0.02%
Impurity II	≤0.1%	0.01%
Total impurity	≤0.5%	0.22%
Loss on drying	≤0.5%	0.2%
Residue on ignition	≤0.1%	0.05%
Heavy metals	≤0.001%	<0.001%
Assay(on dried basic)	98.0-102.0%	100.2%
Solubility:Soluble in acetone and trichloromethane,slightly soluble in ethanol,almost insoluble in water		
Conclusion:it conforms to the factory's standard		

QC Checker: 王建

Analysis: 刘艳