

# Miedykol

A brand by IKEM

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

## Certificate Of Analysis

PRODUCT:	Nepafenac		
BATCH NO.:	202401001	MFG.DATE	Jan.16,2024
QUANTITY	2kg	EXP.DATE	Jan.15,2027

ITEM	STANDARD	RESULT
Appearance	a yellow to light yellow crystalline powder	A yellow crystalline powder
Impurty A	≤0.1%	N.D.
Individual impurity	≤0.2%	0.04%
Total impurity	≤0.5%	0.07%
Acetonitrile	≤0.041%	N.D.
Isopropanol	≤0.5%	N.D.
Tetrahydrofuran	≤0.072%	N.D.
Dichloromethane	≤0.06%	N.D.
Loss on drying	≤0.5%	0.01%
Residue on ignition	≤0.1%	0.07%
Heavy metals	≤0.002%	<0.002%
Purity	98.5%~101.5%	99.85%

Conclusion:It conforms with factory's standard

Solubility:Freely soluble in Dimethyl sulfoxide ,insoluble in water ,sparingly soluble in tetrahydrofuran,slightly soluble in methanol and acetonitrile.

QC checker 王建

Analysis: 刘艳