

# Miedykol

A brand by IKEM

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

## Certificate Of Analysis

PRODUCT:	Besifloxacin Hydrochloride		
BATCH NO. :	202401001	MFG.DATE:	Jan.04.2024
QUANTITY:	3KG	EXP DATE:	Jan.03,2026

ITEM	STANDARD	RESULT
Appearance	Off-White or light yellow powder	Light yellow powder
Solubility	Slightly soluble in methanol	Conform
Identification	1.The retention time of the principal peak obtained with the test solution is identical with the reference solution	Conform
	2.The infrared spectrogram obtained with the test solution is identical with the reference solution	Conform
Particle size	90% particles not more than 15u m	Conform
Impurity A	≤0.15%	N.D
Impurity B	≤0.15%	N.D
Other individual impurity	≤0.10%	N.D
Total impurity	≤0.5%	N.D
N,N-Dimethylformamide	≤0.088%	N.D
Ethanol	≤0.5%	0.0029%
Tetrahydrofuran	≤0.072%	N.D
Acetonitrile	≤0.041%	0.0039%



Methanol	$\leq 0.3\%$	0.0076%
Triethylamine	$\leq 0.016\%$	N.D
Toluene	$\leq 0.089\%$	N.D
Loss on drying	$\leq 0.5\%$	0.07%
Residue on ignition	$\leq 0.2\%$	0.05%
Heavy metals	$\leq 0.002\%$	<0.002%
Sterility test	Should meet the requirements	Conform
Assay (on dried base)	$\geq 98.5\%$	99.6%
Conclusion: it conform to the factory's standard		

QC Checker: 王建

Analysis: 刘艳

