

Miedykol

A brand by IKEM

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

Certificate Of Analysis

PRODUCT:	Delafloxacin Meglumine		
BATCH NO. :	202203003	MFG.DATE:	Mar 30,2022
QUANTITY:	100G	EXP DATE:	Mar 29,2023

ITEM	STANDARD	RESULT
Appearance	White to pale yellow powder	Pale yellow powder
Identification	1.The infrared absorption is same as reference	Conform
	2.The retention time of the principal peak in chromatogram of sample must match with the retention time of the principal peak of standard	Conform
Individual impurity	≤0.1%	0.04%
Total impurity	≤1.0%	0.08%
Water	≤5.0%	4.2%
Acetonitrile	≤0.041%	N.D.
Isopropanol	≤0.5%	N.D.
N-methylpyrrolidone	≤0.053%	0.04%
N,N-dimethylformamide	≤0.088%	N.D.
Sulphated ash	≤0.2%	0.08%
Heavy metals	≤0.002%	≤0.002%
Assay(on the anhydrous basic)	98.0%-102.0%	100.4%
Solubility: Freely soluble in Dimethyl sulfoxide		
Conclusion:it conforms to the factory's standard		

QC Checker: 王津

Analysis: 刘艳