

Miedykol

A brand by IKEM

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

Certificate Of Analysis

PRODUCT:	CLOFARABINE		
BATCH NO. :	202111002	MFG.DATE:	Nov.20,2021
QUANTITY:	120g	EXP DATE:	Nov.19,2024

ITEM	STANDARD	RESULT
Appearance	a white to off-white crystalline powder, odorless ,nearly tasteless	A white crystalline powder
Specific rotation (C=0.5DMF)	+38~+42°	+40°
Identification	1.Max.absorption is in the wavelength 263nm	Conform
	2.The infrared absorption is same as reference	Conform
	3.Should show forward reaction	Conform
Melting point	225~230°C	226.0-227.0°C
Acidity or alkalinity	5.5~7.5	6.5
α -isomer	$\leq 0.15\%$	N.D.
Individual impurity	$\leq 0.1\%$	0.07%
Total impurity	$\leq 0.5\%$	0.17%
Methanol	$\leq 0.3\%$	0.05%
Acetonitrile	$\leq 0.041\%$	N.D.
Dichlormethane	$\leq 0.06\%$	N.D.
N-hexane	$\leq 0.029\%$	N.D.

Water content	≤0.5%	0.03%
Residue on ignition	≤0.1%	0.09%
Halide	≤0.0125%	<0.0125%
Sulfate	≤0.05%	<0.05%
Heavy metals	≤0.001%	<0.001%
Bacterlal Endotoxins	≤1.8EU/mg	<1.8EU/mg
Assay (on dried base)	99.0%~101.0%	99.5%
Solubility : Freely soluble in DMSO,slightly soluble in methanol,very slightly soluble in water, insoluble in ethyl acetate,soluble in saline is a concentration of 0.99 mg/ml.		
Conclusion:it : conforms to the factory's standard		

QC Checker: 王健

Analysis: 刘艳

