

# Miedykol

A brand by MIKEM

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

## Certificate Of Analysis

PRODUCT:	LOTEPREDNOL ETABONATE		
BATCH NO.:	202103001	MFG.DATE	Mar.10,2021
QUANTITY:	3KG	EXP.DATE	Mar.09,2023

ITEM	STANDARD	RESULT
Appearance	a white to off-white powder	an off-white powder
Particle size	90%<10micron	Conform
Identification	1.The infrared absorption is same as reference	Conform
	2.Max.absorption is in the wavelength 245nm	Conform
Individual impurity	≤0.2%	0.07%
Total impurity	≤0.5%	0.11%
Methanol	≤0.3%	N.D.
Acetone	≤0.5%	0.07%
Loss on drying	≤0.5%	0.12%
Chlorides	≤0.01%	<0.01%
Heavy metals	≤0.001%	<0.001%
Residue on ignition	≤0.1%	0.08%
Sterility test	Should meets the requirements	Conform
Assay (on dried base)	98%~102%	99.5%
Solubility:Freely soluble in chloroform ,insoluble in water,sparingly soluble in acetone ,slightly soluble in methanol.		
Conclusion:it conforms to the factory's standard		

QC checker: 王建

Analysis: 刘超