

Miedykol

A brand by IKEM

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

Certificate Of Analysis

PRODUCT:	Esmolol Hydrochloride		
BATCH NO. :	202110001	MFG.DATE:	Oct.25,2021
QUANTITY:	10KG	EXP DATE:	Oct.24,2023

ITEM	STANDARD	RESULT
Appearance	White or almost white crystalline powder	White crystalline powder
Identification	1.Should show forward reaction	Conform
	2.Should corresponds to the regulation	Conform
Melting point	85~92°C	89.5~91.5°C
Clarity	Should corresponds to the regulation	Conform
pH	2.5~4.5	3.6
Impurity I	≤0.2%	0.07%
Other individual impurity	≤0.3%	0.14%
Total impurity	≤1.0%	0.35%
Loss on drying	≤0.5%	0.22%
Residue on ignition	≤0.1%	0.07%
Heavy metals	≤0.002%	<0.002%
Sulfate	≤0.03%	<0.03%
Bacterial Endotoxin	≤0.1EU/mg	<0.1EU/mg
Sterility test	Should meets the requirements	Conform
Assay (on dried base)	≥98.5%	99.6%

Conclusion:it conforms to the factory's standard

QC Checker: 王建

Analysis: 刘超