

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

Certificate Of Analysis

PRODUCT:	Prandprofen		
BATCH NO. :	202106001	MFG.DATE:	Jun.25,2021
QUANTITY:	10KG	EXP DATE:	Jun.24,2023

ITEM	STANDARD	RESULT
Appearance	White to light yellow crystalline powder	White crystalline powder
Identification	1.Max.absorption is in the wavelength 245nm,271nm,279nm,307nm 2.The infrared absorption is same as reference	Conform
Melting point	186-190°C	187.0-188.0°C
Individual impurity	≤0.5%	0.04%
Total impurity	≤1.0%	0.08%
Methanol	≤0.3%	N.D.
Dichloromethane	≤0.06%	N.D.
Dioxane	≤0.0038%	N.D.
Loss on drying	≤0.50%	0.16%
Chlorides	≤0.02%	<0.02%
Residue on ignition	≤0.10%	0.07%
Heavy metals	≤10ppm	<10ppm
Assay (on dried base)	≥98.5%	99.6%
Solubility: Freely soluble in DMF,soluble in aceticacid,sparingly soluble in methanol,slightly soluble in acetonitrile and ethanol and Acetic anhydride,very slightly soluble in ether,hardly insoluble in water.		
Conclusion:it conforms to the factory's standard		

QC Checker: 王建

Analysis: 刘超