



# 湖北迅达药业股份有限公司

Hubei Xunda Pharmaceutical Co., Ltd.

## 检验报告书 CERTIFICATE OF ANALYSIS

品名 Name of Product	Ketoprofen	包装规格 Packaging Specification	25kg/drum×21 件 +8.6kg/drum×1 件
批号 Lot No.	KPO-2112002	批量 Batch Weight	533.6kg
检验单号 COA No.	KPO-21120201	报告日期 Report Date	2021.12.07
生产日期 MFG. Date	2021.11.30	复检期 Retest Date	2024.11.29

分析项目 Analytical Contents	标准 Standards	分析结果 Analytical Results
外观 Appearance	白色或类白色结晶或结晶性粉末。 White or almost white, crystalline powder.	White crystalline powder
溶解性 Solubility	不溶于水, 易溶于丙酮、乙醇和二氯甲烷。 practically insoluble in water, freely soluble in acetone, in ethanol(96 per cent) and in methylene chloride.	Meets
鉴别 Identification	A. 供试品的红外图谱与酮洛芬 USP 标准品的图谱一致。 IR spectrum of sample is the same with USP CRS spectrum. B. 供试品溶液的紫外图谱与酮洛芬 USP 标准品溶液的图谱一致。以干品计, 两者在 258nm 处吸收系数的差异不超过 3.0%。 Absorptivities at the wavelength of maximum absorbance at about 258nm do not differ by more than 3.0% calculated on the dried basis.	Meets  Meets
熔距 Melting Range	92.0°C~97.0°C	94.0°C~95.0°C
比旋度(以干品计) Specific Rotation	+1°~-1°	-0.1°
干燥失重 Loss on Drying	0.5% Max	0.12%
炽灼残渣 Residue on Ignition	0.2% Max	0.04%
色谱纯度 Chromatographic Purity		
最大已知杂质 Maximum Known Impurity	0.2% Max	0.11%
最大未知杂质 Maximum Unknown Impurity	0.10% Max	0.02%
总杂质 Total Impurities	1.0% Max	0.17%
含量 Assay	98.5%~101.0%	99.9%
残留溶剂 Residual solvents	甲醇 Methanol	3000 ppm Max ND
	乙醇 Ethanol	5000 ppm Max 100ppm
	苯 Benzene	2 ppm Max ND
	甲苯 Toluene	890 ppm Max 1ppm

Packaging and storage---Preserve in tight containers

结论: 符合《美国药典》43 版

Conclusion: Complies with USP 43

QA 批准人:  
QA Approver:

张子华  
2021.12.08

复核人:

Reviewer: 2021.12.08

报告人: 林煜 2021.12.07  
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