

Kalchem International

Chemicals & Compounding Supplies

檢驗報告書

CERTIFICATE OF ANALYSIS

表格一:

品名 Name of Product	Ketoprofen	包裝規格 packaging specification	25kg/drum
批號 Lot No.	KPG-1601001	批重 Batch Weight	500kg
檢驗單號 COA No.	KPG-1601001	報告日期 Report Date	2016.01.12
生產日期 MFG. Date	2016.01.06	復核日期 Re-test Date	2019.01.05

表格二:

KPG-1601001 173116116

分析項目 Analytical Contents	分析結果 Analytical Results	標準 Standard	
外觀 Appearance	White crystalline powder	白色或幾乎白色結晶或結晶性粉末 White or almost white, crystalline powder.	
溶解性 Solubility	Meets	不溶于水, 易溶于丙酮, 乙醇和氯仿。 practically insoluble in water, freely soluble in acetone, in ethanol(96 per cent) and in methylene chloride.	
鑑別 Identification		A. 供試品的紅外光譜與藥典USP標準品的圖譜一致。 IR spectrum of sample is the same with USP CRS spectrum. B. 供試品溶液的紫外光譜與藥典USP標準品溶液的圖譜一致, 且在最大吸收波長處的吸光系數的差異不超過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.	
A. 紅外吸收 IR Absorption	Meet		
B. 紫外吸收 UV Absorption	Meet		
熔點 Melting Range	95.0 - 95.4°C	92 - 97°C	
比旋度(20°C) Specific Rotation	0	-1 - 1°	
干燥失重 Loss on Drying	0.15%	0.5% Max	
灼殘餘量 Residue on Ignition	0.06%	0.2% Max	
重金屬 Heavy Metals	0.002% Max	0.002% Max	
色譜純度 Chromatographic Purity	0.11%	0.2% Max	
單雜質 Single Impurity	0.21%	1.0% Max	
總雜質 Total Impurities			
含量 Assay	99.5%	98.5 - 101.0%	
殘留溶劑 Residual solvents	乙醇 Ethanol	157ppm	2000 ppm Max
	氯仿 Chloroform	ND	60 ppm Max
	苯 Benzene		1 ppm Max
	甲苯 Toluene	2ppm	200 ppm Max

Packaging and storage: Preserve in tight containers

結論: 符合《美國藥典》38版

Conclusion: Complies with requirements of USP 38.

QA Dept. Minister: 吳俊

Reinspector: 吳俊

Tester: 黃德 蔣新賢

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