



西安康诺化工有限公司
Kono Chem Co., Ltd

CERTIFICATE OF ANALYSIS

检验报告单

产品名称 Product name	KETOCONAZOLE 酮康唑		
批 号 Batch No.	20021201	生产日期 MFG. DATE	2020.2.12
发放日期 Release Date	2020.2.13	有效期至 Exp. Date	2022.2.11
Quantity 数量	200 Kg	Quality standard 检验依据	Enterprise standard USP38
Tests 检验项目	Specifications 标准规定		Results 检验结果
Appearance 外观	Off-white to white powder 类白色至白色粉末		White powder 白色粉末
Identification 鉴别	1	Chemical identification 化学鉴别	Conforms 符合规定
	2	Infrared spectrometry 红外鉴别	Conforms 符合规定
Solubility 溶解度	Freely soluble in methylene chloride Soluble in methanol, Sparingly soluble in ethanol, Practically insoluble in water. 易溶于二氯甲烷, 溶于甲醇, 在乙醇中略溶, 难溶于水。		Conforms 符合规定
Melting Point(°C) 熔点	148~152		148~150
Specific rotation (°) 比旋度	-1~+1		-0.03
Loss on drying(% w/w) 干失	≤0.5		0.19
Residue on ignition(% w/w) 灼烧残渣	≤0.1		0.03
Heavy Metals(%)	≤0.002		Conforms 符合规定
Chromatographic purity by TLC 色谱纯度 (TLC)	The principal spot obtained from the Test solution has about the same size and RF value as that obtained from the standard solution, and the sum of the intensities of any secondary spots obtained from the Test solution does not exceed the intensity of the principal spot obtained from the Diluted standard solution. 应符合规定		Conforms 符合规定
Assay(%) 含量	It content not less than 98.0 and not more than 102.0 on dried basis. 98.0~102.0		99.87

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许珂



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Residual solvents 残留溶剂	Methanol $\leq 3000\text{ppm}$ 甲醇	Conforms 符合规定
	Acetone $\leq 5000\text{ppm}$ 丙酮	Conforms 符合规定
	Methyl Chloride $\leq 600\text{ppm}$ 氯甲烷	Conforms 符合规定
	Ethyl Acetate $\leq 5000\text{ppm}$ 醋酸	Conforms 符合规定
	Toluene $\leq 900\text{ppm}$ 甲苯	Conforms 符合规定
Conclusion 结论	The results conform to the USP38 standard. 本品结果符合 USP38 标准。	

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