



GMP/ISO Certificate

华阴市锦前程药业有限公司

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分析报告单

CERTIFICATE OF ANALYSIS

STP-QS-465-T1-03

1/1

产品名称 Product name	水杨酸 Salicylic acid	生产日期 Manufacturing Date	2024.09.16
批号 Batch No.	YC2409055	检验日期 Test Date	2024.09.17
批量 Batch quantity	1127kg	报告日期 Issued Date	2024.09.18
检验依据 Reference Spec.	BP2020/EP10.0/USPNF2024	有效期至 Expiry Date	2027.09.15
检查项目 Test items	规格 Specifications	检验结果 Test Results	
性状 Characters	白色或几乎白色，结晶性粉末或白色或无色针状晶体，微溶于水，易溶于乙醇（96%），微溶于二氯甲烷 A white, or almost white, crystalline powder or white or colourless, acicular crystals, slightly soluble in water, freely soluble in ethanol (96 per cent), sparingly soluble in methylene chloride.	符合规定 Complies	
鉴别 Identification	A. 熔点 158 °C -161 °C Melting point 158 °C to 161 °C	158.9-160.2°C	
	B. 红外吸收图谱应与标准品图谱一致 The IR spectrum of sample complies with Salicylic acid CRS	符合规定 Complies	
溶液外观 Appearance of solution	溶液应澄清 Solution is clear and colourless	澄清 Clear	
氯化物 Chlorides	≤100ppm NMT100ppm	< 100ppm	
硫酸盐 Sulfates	≤200ppm NMT200ppm	< 200ppm	
重金属 Heavy metals	≤20ppm NMT20ppm	< 20ppm	
干燥失重 Loss on drying	≤0.5% NMT0.5%	0.02%	
炽灼残渣 Residue on ignition	≤0.05% NMT 0.05%	0.02%	
相关物质 Related substances	4-羟基苯甲酸 4-hydroxybenzoic acid	≤0.1%	0.001%
	4-羟基间苯二甲酸 4-hydroxyisophthalic acid	≤0.05%	0.002%
	苯酚 Phenol	≤0.02%	N.D
	其它杂质 Any other impurities	≤0.05%	N.D
	总杂质 Total impurities	≤0.2%	0.003%
含量 (干品计) Assay (on dried basis)	含 C ₇ H ₆ O ₃ 为 99.0%-100.5% Contains C ₇ H ₆ O ₃ 99.0%-100.5%	99.5%	
【结论】 Conclusion	本品按 BP2020/EP10.0/USPNF2024 检验，结果[符]合规定。 The product comply with the requirements of BP2020/EP10.0/USPNF2024.		

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2024.09.18

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2024.09.18

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2024.09.18

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Reported by/Date:

2024.09.18