

CERTIFICATE OF ANALYSIS

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产品名称 Product Name	水杨酸 Salicylic acid	生产日期 Manufacturing Date	2018.10.15
批号 Batch No.	Y1810035	日期 Test Date	2018.10.16
数量 Quantity	1250kg	报告日期 Issued Date	2018.10.18
检验依据 Reference Spec.	《欧洲药典》9.0 Eur.Ph.9.0	有效期至 Expiry Date	2021.10.14
检查项目 Test items	规格 Specifications	结果 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%），微溶于氯仿 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	158.7-160.5 °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	
	C. 呈正反应 Positive	呈正反应 Positive	
溶液外观 Appearance of solution	溶液应澄清 Solution is clear and colourless	溶液澄清 Solution is clear and colourless	
相关物质 Related substances	Impurity A: 4-羟基苯甲酸 4-hydroxybenzoic acid	≤0.1%	0.002%
	Impurity B: 4-羟基间苯二甲酸 4-hydroxyisophthalic acid	≤0.05%	N.D
	Impurity C: 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%	0.002%
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%	0.03%	
硫酸盐灰分 Sulfated ash	≤0.1% NMT0.1%	0.03%	
含量（以干品计） Assay (dried substance)	含 C ₇ H ₆ O ₃ 为 99.0%-100.5% Contains C ₇ H ₆ O ₃ 99.0%-100.5%	99.6%	
【结论】 Conclusion	本品按《欧洲药典》9.0 检验，结果[符]合规定 The product comply with the requirements of Eur.Ph.9.0		

负责人/日期
Q M/Date:

李毅

2018.10.18

放行人/日期
Releaser/Date:

侯艳

2018.10.18

复核者/日期
Reviewer/Date:

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2018.10.18

报告者/日期
Reported by /Date:

李毅

2018.10.18

