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GMP认证企业

华阴市锦前程药业有限公司

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分析报告单

CERTIFICATE OF ANALYSIS

产品名称 Product	水杨酸钠 Sodium salicylate	生产日期 Manufacturing Date	2020.03.31
批号 Batch No.	NC2003031	检验日期 Test Date	2020.04.05
数量 Quantity	5000kg	报告日期 Issued Date	2020.04.06
检验依据 Reference Spec.	《英国药典》2017 BP2017	有效期至 Expiry Date	2024.03.30
检查项目 Test items	规格 Specifications	结果 Results	
性状 Characters	应为白色结晶或鳞片状粉末,易溶于水,微溶于乙醇 A white, crystalline powder or small, colourless crystals or shiny flakes, freely soluble in water, sparingly soluble in alcohol	符合规定 Complies	
鉴别 A Identification A	样品红外吸收图谱与标准品图谱一致 Sample Infrared absorption spectrophoto-metry Complies with Sodium salicylate.CRS	符合规定 Complies	
鉴别 B Identification B	呈水杨酸盐反应 Gives the reactions of salicylates	呈正反应 Positive	
鉴别 C Identification C	呈钠盐反应 Gives reaction (b) of sodium	呈正反应 Positive	
外观 Appearance of solution	溶液清透且不深于 BY6 The solution is clear and not more intensely coloured than reference solution BY6	溶液清透且不深于 BY6 The solution is clear and <reference solution BY6	
酸度 Acidity	溶液变色消耗 0.01M NaOH≤2.0ml 0.01M NaOH not more than 2.0ml is required	0.88ml 0.01M NaOH	
氯化物 Chloride	≤200ppm NMT200ppm	<200ppm	
硫酸盐 Sulfate	≤600ppm NMT 600ppm	<600ppm	
重金属 Heavy metals	≤20ppm NMT ppm	<20ppm	
干燥失重 Loss on drying	≤0.5% NMT0.5%	0.04%	
含量(以干品计) Assay(dried substance)	含 C ₇ H ₅ NaO ₃ 为 99.0%-101.0% Contains C ₇ H ₅ NaO ₃ 99.0% to 101.0%	99.5%	
【结论】 Conclusion	本品按《英国药典》2017 检验。结果[符]合规定。 The product comply with the requirements of BP2017		

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2020.04.06

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Releaser:

2020.04.06

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2020.04.06

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Reported by:

2020.04.06