



华阴市锦前程药业有限公司

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分析报告单

CERTIFICATE OF ANALYSIS

R-43-004-01-06

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产品名称 Product name	阿司匹林 Aspirin	生产日期 Manufacturing Date	2022.09.19
批 号 Batch No.	CA2209027	检 验 日期 Test Date	2022.09.23
批 量 Batch quantity	5001kg	报 告 日期 Issued Date	2022.09.24
检 验 依据 Reference Spec.	BP2020/EP10.0/USPNF 2022	有 效 期 至 Expiry Date	2025.09.18
检查项目 Test items	规格 Specifications		检验结果 Test Results
性状 Characters	白色晶体, 通常是表状或针状, 或白色结晶性粉末。易溶于酒精; 溶于氯仿和乙醚; 少量溶于无水乙醚; 略溶于水; 约 143℃ 熔融 White crystals, commonly tabular or needle-like, or white, crystalline powder. freely soluble in alcohol; soluble in chloroform and in ether; sparingly soluble in absolute ether; slightly soluble in water; at about 143℃		符合规定 Complies
鉴别 Identification	A. 样品红外吸收图谱与标准品图谱一致 Sample infrared absorption spectrophotometry Complies with Aspirin CRS		符合规定 Complies
	B. 有沉淀生成, 熔点: 156-161℃ A crystalline precipitate is formed ,Melting point is 156-161℃		156.6-160.4℃
	C.显紫红色 A violet-red color is produce		呈正反应 Positive
溶液外观 Appearance of solution	溶液应澄清 Solution is clear and colourless		澄清 Clear
碳酸钠试液不溶物 Substances insoluble in sodium carbonate TS	溶液应澄清 The solution is clear .		澄清 Clear
易炭化物 Readily carbonizable substance	与对照液 Q 比较不得更深 No more color than M.F.Q		不深于对照液 Q No more color than M.F.Q
游离水杨酸 Free salicylic acid	≤0.1% NMT 0.1%		<0.1%
氯化物 Chloride	≤0.014% NMT 0.014%		<0.014%
硫酸盐 Sulfate	≤0.04% NMT 0.04%		<0.04%
干燥失重 Loss on drying	≤0.5% NMT0.5%		0.02%
重金属 (%) Heavy metals (%)	≤10ppm NMT10ppm		<10ppm
炽灼残渣 Residue on ignition	≤0.05% NMT0.05%		0.04%
残留溶剂 Residual solvents	醋酸 LOD≤0.5% Acetic acid: LOD≤0.5%		0.02%
相关物质 Related substances	杂质 Impurity A.	≤0.15%	N.D
	杂质 Impurity B.	≤0.15%	N.D
	杂质 Impurity C.	≤0.15%	0.02%
	杂质 Impurity D.	≤0.15%	0.01%
	杂质 Impurity E.	≤0.15%	N.D
	杂质 Impurity F.	≤0.15%	N.D
	未指明的单个杂质不超过 0.05% Unspecified Impurities:≤0.05%		0.004%
含量 (干品计) Assay (on dried basis)	杂质总和不超过 0.25% The sum of impurities:≤0.25%		0.03%
	含 C ₉ H ₈ O ₄ 为 99.5%-100.5% Contains C ₉ H ₈ O ₄ 99.5%-100.5%		99.8%
【结论】 Conclusion	本品按 BP2020/EP10.0/USPNF 2022 检验, 结果[符]合规定。 The product comply with the requirements of BP2020/EP10.0/USPNF 2022.		

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