



# 华阴市锦前程药业有限公司

## JQC (Huayin) Pharmaceutical Co., Ltd

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### 分析报告单

### CERTIFICATE OF ANALYSIS

1/1

STP-QS-465-T1-02

|                                    |   |                            |            |
|------------------------------------|---|----------------------------|------------|
| 产品名称<br>Product name               | 水杨酸<br>Salicylic acid   | 生产日期<br>Manufacturing Date | 2023.05.01 |
| 批号<br>Batch No.                    | YC2305002   | 检验日期<br>Test Date          | 2023.05.02 |
|                                    |   | 报告日期<br>Issued Date        | 2023.05.04 |
| 检验依据<br>Reference Spec.            | BP2020/EP10.0/USPNF2023   | 有效期至<br>Expiry Date        | 2026.04.30 |
| 检查项目<br>Test items                 | 规格<br>Specifications  | 检验结果<br>Test Results       |            |
| 性状<br>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<br>易溶于乙醇 (96%), 微溶于二氯甲烷<br>A white, or almost white, crystalline powder or white<br>or colourless, acicular crystals, slightly soluble in water,<br>freely soluble in ethanol (96 per cent), sparingly soluble<br>in methylene chloride. | 符合规定<br>Complies           |            |
| 鉴别<br>Identification               | A. 熔点 158 °C -161 °C<br>Melting point 158 °C to 161 °C  | 158.6-160.2°C              |            |
|                                    | B. 红外吸收图谱应与标准品图谱一致<br>The IR spectrum of sample complies with Salicylic acid<br>CRS   | 符合规定<br>Complies           |            |
| 溶液外观<br>Appearance of<br>solution  | 溶液应澄清<br>Solution is clear and colourless   | 澄清<br>Clear                |            |
| 氯化物<br>Chlorides                   | ≤100ppm<br>NMT100ppm  | < 100ppm                   |            |
| 硫酸盐<br>Sulfates                    | ≤200ppm<br>NMT200ppm  | < 200ppm                   |            |
| 重金属<br>Heavy metals                | ≤20ppm<br>NMT20ppm  | < 20ppm                    |            |
| 干燥失重<br>Loss on drying             | ≤0.5%<br>NMT0.5%  | 0.02%                      |            |
| 炽灼残渣<br>Residue on ignition        | ≤0.05%<br>NMT 0.05%   | 0.03%                      |            |
| 相关物质<br>Related substances         | 4-羟基苯甲酸<br>4-hydroxybenzoic acid  | ≤0.1%                      | 0.001%     |
|                                    | 4-羟基间苯二甲酸<br>4-hydroxyisophthalic acid  | ≤0.05%                     | 0.002%     |
|                                    | 苯酚<br>Phenol  | ≤0.02%                     | N.D        |
|                                    | 其它杂质<br>Any other impurities  | ≤0.05%                     | N.D        |
|                                    | 总杂质<br>Total impurities   | ≤0.2%                      | 0.002%     |
| 含量 (干品计)<br>Assay (on dried basis) | 含 C <sub>7</sub> H <sub>6</sub> O <sub>3</sub> 为 99.0%-100.5%<br>Contains C <sub>7</sub> H <sub>6</sub> O <sub>3</sub> 99.0%-100.5%   | 99.6%                      |            |
| 【结论】<br>Conclusion                 | 本品按 BP2020/EP10.0/USPNF2023 检验, 结果[符]合规定。<br>The product comply with the requirements of BP2020/EP10.0/USPNF2023.   |                            |            |

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