

# Nanjing Hencer Pharmaceutical Co., Ltd.

## Certificate of Analysis

蔗糖铁注射液 HIERRO SACARATO (IRON SUCROSE INJECTION)

|                           |   |                           |                               |
|---------------------------|---|---------------------------|-------------------------------|
| 批号 Batch No.:             | 03A008  | 生产日期 Date of Manufacture: | 01/2021                       |
| 报告日期 Date of Certificate: | 10.05.2021  | 有效期 Date of Expiration:   | 01/2024                       |
| 报告编号 Report No.:          | S (C050) 210101   | 规格 Strength:              | 5ml:100mg 铁<br>5ml:100mg Iron |
| 检验依据 Standard:            | 蔗糖铁注射液质量标准<br>Iron Sucrose Injection In-house specification and USP specification |                           |                               |

| 检验项目<br>Test Item   | 标准规定<br>Specification   | 检验结果<br>Result                              |
|---|---|---|
| 性状<br>Description   | 应为棕褐色胶体溶液<br>Brown-dark colloidal solution  | 符合规定<br>Conforms                            |
| 鉴别<br>Identification  |   |   |
| A: 铁<br>A: Iron   | 应呈正反应<br>Positive   | 呈正反应<br>Positive                            |
| B: 蔗糖<br>B: Sucrose   | 应符合规定<br>Conforms   | 符合规定<br>Conforms                            |
| C: 分子量<br>C: Molecular weight determination                                       | $M_w=34,000\sim60,000$ Da<br>$M_n \geq 24,000$ Da<br>$M_w/M_n \leq 1.7$   | $M_w:50845$<br>$M_n:35457$<br>$M_w/M_n:1.4$ |
| 相对密度<br>Specific gravity  | 1.135~1.165(20°C)   | 1.152                                       |
| 浊点<br>Turbidity   | 4.4~5.3   | 4.8   |
| 碱度<br>Alkalinity(mL 0.1 N hydrochloric acid VS/mL injection)                      | 0.5~0.8ml   | 0.6   |
| pH  | 10.5~11.1 (20°C)  | 10.9  |
| 渗透压<br>Osmolarity   | 1150~1350 mOsmol/L  | 1290mOsmol/L                                |
| 低分子量二价铁和三价铁的复合物<br>Absence of low molecular weight Fe (II) and Fe (III) complexes | 在二价铁检查极谱图上, 没有其他峰出现<br>In the polarograms obtained in the test for Limit of iron(II), no additional peaks are found | 未检出<br>Absent                               |
| 二价铁离子<br>Limit of iron (II)   | $\leq 0.4\%$ (W/V)  | 0.2%  |
| 氯化物<br>Content of Chloride (w/w)  | 0.012%~0.025%   | 0.016%                                      |
| 细菌内毒素<br>Bacterial endotoxins   | $< 0.5$ EU/mg Iron  | 符合规定<br>Conforms                            |
| 不溶性微粒<br>Particulate matter   | 稀释注射液 (1/40), 所得溶液符合规定<br>Dilute injection(1/40), solution meets the requirements                                   | 符合规定<br>Conforms                            |
| 无菌<br>Sterility   | 符合规定<br>Conforms  | 符合规定<br>Conforms                            |
| 装量<br>Volume  | 装量不得少于标示量。<br>Not less than the labeled quantity  | 符合规定<br>Conforms                            |
| 蔗糖 Assay for Sucrose  | 260~340mg/ml  | 292mg/ml                                    |
| 铁含量 Assay for Iron  | 95.0%~105.0%  | 100.9%                                      |

结论: 本品按蔗糖铁注射液质量标准检验, 结果符合规定

Conclusions: This product conforms to the above specifications.

报告人 Reporter/ Date: 王理红 2021-05-10 复核/批准人 Check/Approve/Date: 平冬梅 2021-05-10 签发人 Supervisor/ Date: 王理红 2021-05-10