



Nanjing Hencen Pharmaceutical Co., Ltd.

Certificate of Analysis

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

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|---------------------------|---|---------------------------|-------------------------------|
| 批号 Batch No.: | 03A010 | 生产日期/Date of Manufacture: | 01/2022 |
| 报告日期 Date of Certificate: | 12.04.2022 | 有效期/Date of Expiration: | 01/2025 |
| 报告编号 Report No.: | S (C050) 220101 | 规格 Strength: | 5ml:100mg 铁 5ml:100mg Iron |
| 检验依据 Standard: | 蔗糖铁注射液质量标准 Iron Sucrose Injection In-house specification and USP specification | | |

| 检验项目 Test Item | 标准规定 Specification | 检验结果 Result |
|--|---|---|
| 性状 Description | 应为棕褐色胶体溶液 Brown-dark colloidal solution | 符合规定 Conforms |
| 鉴别 Identification | | |
| A: 铁 A: Iron | 应呈正反应 Positive | 呈正反应 Positive |
| B: 蔗糖 B: Sucrose | 应符合规定 Conforms | 符合规定 Conforms |
| C: 分子量 C: Molecular weight determination | M _w =34,000~60,000 Da M _n ≥24,000 Da M _w /M _n ≤1.7 | M _w :50894 M _n :33999 M _w /M _n :1.5 |
| 相对密度 Specific gravity | 1.135~1.165(20℃) | 1.152 |
| 浊点 Turbidity | 4.4~5.3 | 4.8 |
| 碱度 Alkalinity(mL 0.1 N hydrochloric acid VS/mL injection) | 0.5~0.8ml | 0.7 |
| pH | 10.5~11.1 (20℃) | 11.0 |
| 渗透压 Osmolarity | 1150~1350 mOsmol/L | 1200mOsmol/L |
| 低分子量二价铁和三价铁的复合物 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 In the polarograms obtained in the test for Limit of iron(II), no additional peaks are found | 未检出 Absent |
| 二价铁离子 Limit of iron (II) | ≤0.4% (W/V) | 0.2% |
| 氯化物 Content of Chloride (w/w) | 0.012%~0.025% | 0.016% |
| 细菌内毒素 Bacterial endotoxins | <0.5 EU/mg Iron | 符合规定 Conforms |
| 不溶性微粒 Particulate matter | 稀释注射液 (1/40), 所得溶液符合规定 Dilute injection(1/40), solution meets the requirements | 符合规定 Conforms |
| 无菌 Sterility | 符合规定 Conforms | 符合规定 Conforms |
| 装量 Volume | 装量不得少于标示量。 Not less than the labeled quantity | 符合规定 Conforms |
| 蔗糖 Assay for Sucrose | 260~340mg/ml | 280mg/ml |
| 铁含量 Assay for Iron | 95.0%~105.0% | 99.9% |

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: 王红 2022-04-12 复核/批准人 Check/Approve/Date:

王红

签发人 Supervisor/ Date:

王红 2022-04-12