



Nanjing Hencer Pharmaceutical Co., Ltd.

Certificate of Analysis

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

批号 Batch No.:	03A014	生产日期 Date of Manufacture:	11/2023
报告日期 Date of Certificate:	23/05/2024	有效期 Date of Expiration:	11/2026
报告编号 Report No.:	S(C050)231101	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	$M_w=34,000\sim60,000$ Da $M_n\geq24,000$ Da $M_w/M_n\leq1.7$	$M_w:55691$ $M_n:37113$ $M_w/M_n:1.5$
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℃)	10.9
渗透压 Osmolarity	1150~1350 mOsmol/L	1280mOsmol/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)	$\leq 0.4\%$ (W/V)	0.2%
氯化物 Content of Chloride (w/w)	0.012%~0.025%	0.018%
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	285mg/ml
铁含量 Assay for Iron	95.0%~105.0%	98.8%

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: 李正强 2024-05-23

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