



# Nanjing Hencer Pharmaceutical Factory Certificate of Analysis

蔗糖铁注射液 Iron Sucrose Injection

批号 Batch No.:	W170201	生产日期 Date of Manufacture:	02/2017
报告日期 Date of Certificate:	2017/03/17	有效期 Date of Expiration:	02/2020
报告编号 Report No.:	S(C050)170201	规格 Strength:	5ml:100mg 铁 5ml:100mg Iron
检验依据 Standard:	蔗糖铁注射液厂检标准 Iron Sucrose Injection In-house specification		
信用证编号 Documentary Credit Number:	0100OCI704722	签发日期 Date of Issue:	170316

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 $M_n \geq 24,000$ Da $M_w/M_n \leq 1.7$	$M_w:43108$ $M_n:29918$ $M_w/M_n:1.4$
相对密度 Specific gravity	1.135~1.165(20℃)	1.154
浊点 Turbidity	4.4~5.3	4.7
碱度 Alkalinity(mL 0.1 N hydrochloric acid VS/mL injection)	0.5~0.8ml	0.7 ml
pH	10.5~11.1 (20℃)	11.0
渗透压 Osmolarity	1150~1350 mOsmol/L	1330 mOsmol/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%	0.017%
细菌内毒素 Bacterial endotoxins	$< 3.7$ 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 volume	符合规定 Conforms
蔗糖 Assay for Sucrose	260~340mg/ml	290 mg/ml
铁含量 Assay for Iron	95.0%~105.0%	102.2%

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.

检验人 Analyst / Date:  2017-03-17 复核人 Check/ Date:  2017-03-17 签发人 Supervisor/ Date:  2017-03-17

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