

浙江金壳药业有限公司

ZHEJIANG GOLDEN-SHELL PHARMACEUTICAL CO., LTD

产品出厂检验报告单 (Certificate Of Analysis)

品名: D-氨基葡萄糖盐酸盐		Product Name: D-GLUCOSAMINE HYDROCHLORIDE	
生产批号: M-AT-1504012		报告日期: 2015.04.20	
Batch No.:		Report Date:	
生产日期: 2015.04.09		数量: 1000kg	
Manufacture Date:		Batch Size:	
有效期: 2018.04.08			
Expire Date:			
检验项目	Items	规格	Specification
鉴别	Identification	Infrared Absorption	Conformed
		Chloride	
		HPLC	
性状	Characteristics	A white crystalline powder	Conformed
比旋度	Specific rotation[α] _D ²⁰	+70.0° — +73.0°	+72.38°
含量	Content	98.0%—102.0%	99.5%
硫酸盐	Sulfates	≤0.24%	<0.24%
干燥失重	Loss on drying	≤1.0%	0.060%
炽灼残渣	Residue on ignition	≤0.1%	0.06%
酸碱度	pH	3.0 — 5.0	4.07
氯化物	Chloride	16.2% — 16.7%	16.4%
目数	Mesh Size	Meet the requirement	100%through 30mesh
砷	Arsenic	≤3ppm	<3ppm
铅	Lead	≤0.5ppm	<0.5ppm
汞	Mercury	≤0.5ppm	<0.5ppm
镉	Cd	≤0.5 ppm	<0.5ppm
铬	Cr	≤2.0 ppm	<2.0ppm
重金属	Heavy Metals	≤10ppm	<10ppm
总细菌数	Total plate count	≤1000cfu/g	110cfu/g
霉菌和酵母菌数	Yeast & Mold	≤100cfu/g	10cfu/g
大肠杆菌	E.COLI	Negative	Negative
沙门氏菌	Salmonella	Negative	Negative
金黄色葡萄球菌	Staphylococcus Aureus	Negative	Negative
储存条件	Storage Conditions	Preserve in tight, light-resistant containers.	
结论	Conclusion	Conforms to USP37	

报告人/Reporter:

王. 2015.04.20

复核人/Rechecked by:

王. 2015.04.20

质检中心专用章

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