

Certificate of Analysis

Product	Protamine sulfate			Product code	C01B3
name					
Product	2003002H	Manufacturing	2020.03.1	Product	9.95KG
batch		date	0	weight	
Packaging specification		5KG/Barrel	Standard	EP 9.0	
Analysis date	2020.03.15	Report date	2020.04.	Re- test date	2023.03.09
			14		

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Test item	specification				Results
Conclusion					
Characters					
Appearance	White or off- white powder, slightly soluble in water, insoluble in ethanol or ether	White powder soluble insolution and effects with the content of th	er, sli e in v ble in et	white ightly vater, hanol	Complie d
Specific rotation Identification	- 65 ° to - 85°	- 77°			Complie d
Color reaction	It should respond positively	Positi	/e		Complie d
Color reaction	It should respond positively	Positiv	ve .		Complie d
Color reaction	It should respond positively	Positi	/e		Complie d
Test					
Nitrogen	Calculated on dried basis, 21.0% ~25.0%	24.9%			Complie d
Sulfate	Calculated on dried basis, 16.0% ~24.0%	20%			Complie d
Residual solvents	Ethanol: NMT 0.5%, Acetone: NMT 0.5%	Ethan Aceto detec	ne:	.07%, not	Complie d
Loss on drying	NMT 5%	2.7%			Complie d
Mercury	The consumed dithizone titration solution of the test solution shall not exceed the standard (0.001%)	Comp	lied		Complie d
Heavy metals	NMT 20ppm	Comp	lied		Complie d

Abnormal toxicity	Intravenous administration complied	Complied	Complie d
Bacterial endotoxin	NMT 6EU/mg	Complied	Complie d
Content	Each mg of Protamine Sulfate neutralizes NLT 100 Heparin Units on the dried basis.	Complied	Complie d
Microbial limit	Total aerobic, mould and yeast: NMT 100cfu/g	<100cfu/g	Complie d

Test conclusion: According to < Protamine sulfate analysis operating procedures>(SOP-QC054)&< Protamine sulfate quality standard EP9.0>, this product is analyzed, and the results are complied.

Reporter: Miao Yang Reviewer: Dongxue Liu Director:

Weiqing Liu