



Certificate of Analysis

Product name	Protamine sulfate			Product code	C01B3
Product batch	2003002H	Manufacturing date	2020.03.10	Product weight	9.95KG
Packaging specification	5KG/Barrel	Standard	EP 9.0		
Analysis date	2020.03.15	Report date	2020.04.14	Re- test date	2023.03.09

Test item specification Results

Conclusion

Characters

		White or off- white powder, slightly soluble in water, insoluble in ethanol or ether and ether	
Appearance	White or off- white powder, slightly soluble in water, insoluble in ethanol or ether	White or off- white powder, slightly soluble in water, insoluble in ethanol and ether	Complied

Specific rotation	- 65° to - 85°	- 77°	Complied
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Identification

Color reaction	It should respond positively	Positive	Complied
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Test

Nitrogen	Calculated on dried basis, 21.0% ~25.0%	24.9%	Complied
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Sulfate	Calculated on dried basis, 16.0% ~24.0%	20%	Complied
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Residual solvents	Ethanol: NMT 0.5%, Acetone: NMT 0.5%	Ethanol: 0.07%, Acetone: not detected	Complied
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Loss on drying	NMT 5%	2.7%	Complied
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Mercury	The consumed dithizone titration solution of the test solution shall not exceed the standard (0.001%)	Complied	Complied
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Heavy metals	NMT 20ppm	Complied	Complied
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Abnormal toxicity	Intravenous administration complied	Complied	Complied
Bacterial endotoxin	NMT 6EU/mg	Complied	Complied
Content	Each mg of Protamine Sulfate neutralizes NLT 100 Heparin Units on the dried basis.	Complied	Complied
Microbial limit	Total aerobic, mould and yeast: NMT 100cfu/g	<100cfu/g	Complied

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
Weiqing Liu

Reviewer: Dongxue Liu

Director:

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