



Test item	specification	Results
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## Characters

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

Color reaction	It should respond positively	Positive	Complied
Color reaction	It should respond positively	Positive	Complied
Color reaction	It should respond positively	Positive	Complied

## Test

Sulfate	Calculated on dried basis, 20%	Compliance
	16.0% ~24.0%	d

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%	Compliance
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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
<b>Microbial limit</b>	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: