

CERTIFICATE OF ANALYSIS

Product Name	Protamine sulfate	Batch NO.	RY190111
Production date	2019.01.11	Expired Date	2022.01.10
CAS NO.	98001-69-5	Standard	Enterprise standard
Tests	Limits	Test results	
Appearance	White or almost white powder. slightly soluble in water, insoluble in ethanol or ether	Conforms	
Specific rotation	-65° ~ -85°	-77°	
Colour reaction	Identification of sulfate in aqueous solution: positive reaction	Positive	
Nitrogen	21.0%~25.0%	24.3%	
Sulfate	16%~24%	19.7%	
Loss on drying	≤5.0%	2.8%	
Mercury	According to the ultraviolet visible spectrophotometry, the volume of dithizone titrant consumed by the test solution shall not exceed the volume of single amount dithizone titrant sold by the standard mercury solution (0.001%)	Conforms	
Heavy metals	≤20ppm	Conforms	
Abnormal	Intravenous	Conforms	
Toxicity	Administration	N.D.	
Bacterial endotoxin	≤6.0EU/mg	Conforms	
Titer determination	Calculated on drying: anticoagulant unit of neutralizing heparin ≥100EU/mg	Conforms	
Microbial limit	Total aerobic,mould and yeast ≤100cfu/g	100cfu/g	
Conclusion: This batch meets enterprise standard.			

Tested by: Esther

Checked by: Alice

Approved by: Mich