Wuhan HengHeDa Pharm Co., Ltd

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CERTIFICATE OF ANALYSIS

Product name	Lu	mbrokinase	Batch NO.	HHD20220604	
Quantity		50kg	CAS NO	556743-18-1	
Production date	20	022-06-04	Expiry Date	2024-06-03	
Test based on enterprise standard					
Test Item		Specification		Result	
Appearance		Slightly Yellow Powder, fishy smell, humidifying and slightly soluble in water.		complies	
Identification		Prepare a solution (0.5 mg/ml) and test according to spectrophotometry, at 278 nm has the largest absorption. Blood clot should be dissolved		complies	
Solution Clarity&Color		Should not be thicker than standards		complies	
Loss on drying		Not more than 6.0% (60℃, P2O5)		4.0%	
PH		6.0-8.0 (1mg/ml water solution)		7.0	
Heavy Metals		≤10ppm		complies	
Total plate count		≤10000cfu/g		< 750cfu/g	
Yeast and Moulds		≤500cfu/g		< 100cfu/g	
Coliform		≤100cfu/g		complies	
Partical Size		60-200mesh		complies	
Potency (On dried base)		Not less than 12000 unit in every 1 mg		15656unit/mg	
Enzymatic Specific Activity		Not less than 20000 unit in every 1 mg		25252 unit/mg	

Storage	Store in cool & dry place, keep away from strong light and heat.
5	

Shelf life

2 years when properly stored.

Conclusion: This product complies with above specification.

Inspector

Shen Wu

