

Version :03
Update : 05/15/2022

CERTIFICATE OF ANALYSIS

Product Information

Product Name:	Hirudin, Medicinal leech
Cat. No.:	Z02812
Lot No.:	M2207011
Size:	Specified on product label
Formulation:	Lyophilized from a 0.2 μ m filtered solution in 20 mM PBS, pH 7.0, 2% mannitol.
Reconstitution:	It is recommended that this vial be briefly centrifuged prior to opening to bring the contents to the bottom. Reconstitute the lyophilized powder in sterile distilled water or aqueous buffer containing 0.1% BSA to a concentration of 0.1-1.0 mg/ml.
Stability & Storage:	Upon receiving, this product remains stable for up to 6 months at -70°C or -20°C. Upon reconstitution, the product should be stable for up to 1 week at 4°C or up to 3 months at -20°C. Avoid repeated freeze-thaw cycles.

Quality Control

Test Items	Specifications	Results
Appearance	White Freeze-dried Powder	Pass
Purity	> 96% as analyzed by SDS-PAGE > 96% as analyzed by HPLC	Pass
Endotoxin Level	< 1 EU/ μ g of protein by LAL method	Pass
Biological Activity	The biological activity is determined by chromogenic assay, 1 unit is defined as the amount of Hirudin that neutralizes 1 unit of the WHO preparation 89/588 of thrombin. The specific activity is no less than 14,000 ATU/mg protein.	Pass

Date: 07/15/2022

Approved by:

Dandan Yao

Quality Department

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