

Certificate of Analysis

No.: G05-20231001

Product Name: Recombinant Human Growth Hormone		Specification: 500mg/vial
Batch No: Y20231001		Mfg. Date: 2023.10.27
Expire Date: 2026.04.26		Storage: Protect from light, Sealed, 2~8℃
Quantity: 170 vials		Sample Date: 2023.10.30
Test standard: QS-C07		
Test Results		
Test Items	Specification	Results
《Appearance》	White lyophilized Powder	Conforms
《Identification》		
IEF	Main belt position of test sample solution should be consistent with the main belt position of reference substance solution	Conforms
Retention time upon the method of Related Protein test	The retention time of test sample major peak complies to reference standard	Conforms
《Inspection》		
Clarity and color of solution	Solution should be clear and colorless; Such as turbidity,compared with 2 turbidity standard solution,shall not be thicker	Conforms
Related protein	No more than 10.0%	2.51%
High-molecular protein	No more than 6.0%	0.05%
Water	No more than 3.0%	2.0%
Undue toxicity	Should comply with the rule	/
Visible particles	Should comply with the rule	Conforms
Insoluble particle	Should comply with the rule	Conforms
Bacterial endotoxin	No more than 5.0EU/mg	Less than 5.0EU/mg
Sterile	Should comply with the rule	Conforms
Content uniformity	Should comply with the rule	Conforms
Air tightness	Should comply with the rule	Conforms
Biological activity	No less than 3.0 units/mg （Test should be performed at least once a year）	/
Dissolution rate	Within 1 minute	Conforms
《Assay》	90.0%~110.0%	95.1%
Conclusion:	According to “rhGH quality standard” [QS-C07], the test results meet the standard	
Comments:	_____	