

TEST REPORT

Task Number #251126

Testing Date 26th Nov 2025

SAMPLE SOMATROPHIN 100 PEN

MANUFACTURER www.bodypharm.me

BATCH SOM1012

SAMPLE DESCRIPTION See picture/s attached

TESTS REQUESTED Assessment of cartridge

RESULTS



Concentration of cartridge 3.08 x 33.5mg = 103.18IU per 3ml

Purity 98.89%

Dimer of related proteins N/A

COMMENTS:

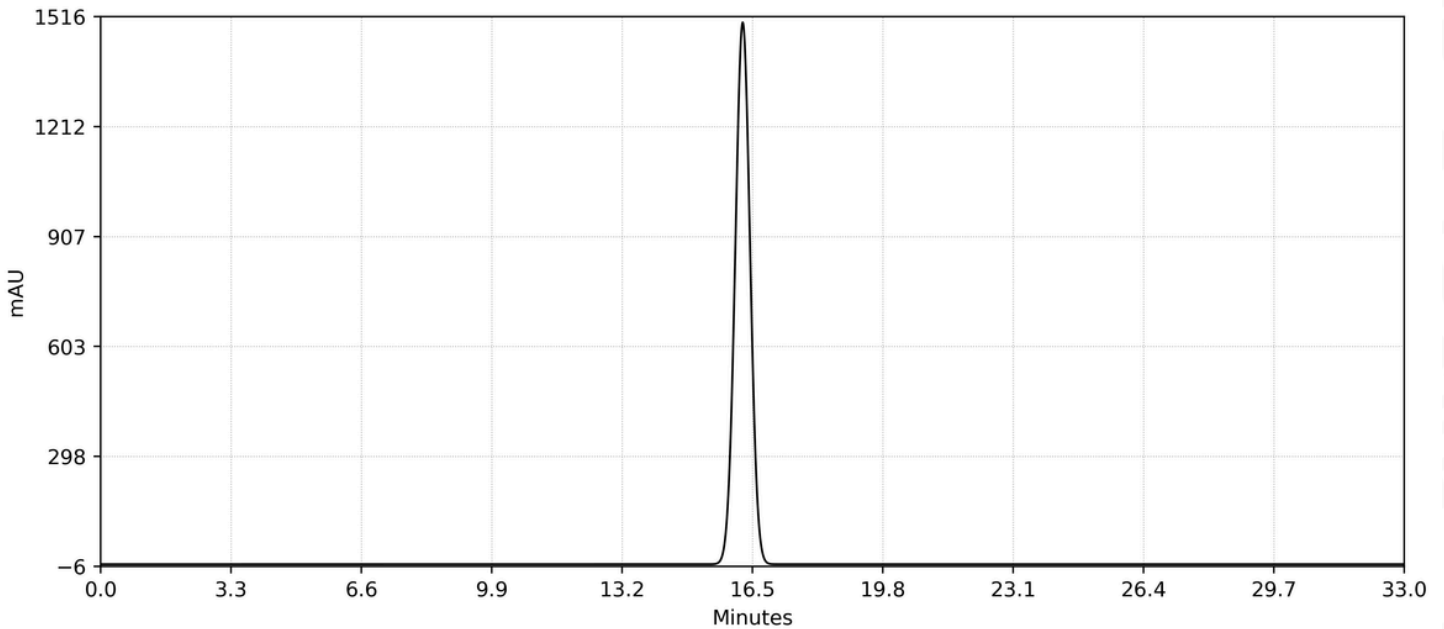
Analysis Conducted 26th Nov 2025

Signature

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ANALYSIS HPLC



ID	Component Name	Retention Time	Peak Height	Peak Area	Concentration	Tailing Factor	Theoretical Plates
1		14.353	14.22	461.000	1.1024	1.13	3907
2		16.251	1518.87	41355.906	98.89%	1.22	7100
3		32.678	0.02	0.015	0.0000	2.60	36248252
Σ			1533.11	41816.921	100.0000		

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Certificate of Analysis

Name	Recombinant Human Growth Hormone Injection	specs	100 IU / vial (33.3 mg / 3 ml)
Lot No.	RHGH-251126	Manufacture Date	2025-11-26
Storage	Store in a dark place and in a sealed container at 2-8°C. Do not freeze.		
Packaging	Neutral Borosilicate Glass Cartridge	Expiry Date	2027-11-25
Dosage Form	Injection (Cartridge)	Test Date	2025-11-26
Test Items	Acceptance Criteria	Test Results	
【Description】			
Appearance and Physical Inspection	Appearance Clear, colorless liquid, free from visible particles Clear	Conforms	
【Identification】			
HPLC Identification	Retention time of main peak consistent with reference standard	Conforms	
【Test】			
Fill Volume	Not less than 3.0 ml	3.2 ml / cartridge	
Seal Integrity	Shall be intact	Intact	
Peptide Mapping	Consistent with reference standard map	Consistent with reference standard	
pH Value	6.5 - 7.5	7.1	
Protein Concentration	33.3 mg/ml (95% - 105% of labeled amount)	33.5 mg/ml	
Related Proteins / Purity	≥ 98.0%	98.8%	
↳ Monomer			
↳ High Molecular Weight Proteins	≤ 1.5%	0.8%	
↳ Deamidated and Other Isomers	≤ 6.0%	3.2%	
Bacterial Endotoxins	< 5.0 EU/mg protein	0.5 EU/mg protein	
Sterility Test	Shall comply	No growth observed	
Phenol Content	2.50 - 3.50 mg/ml (For multi-dose products containing preservatives)	3.0mg/ml	
【Potency Assay】			
Content	90% - 110% of labeled potency (3.0 IU/mg protein)	102.5% (3.08 IU/mg)	
<p>Conclusion: This product has been tested according to the European Pharmacopoeia 12th Edition, Vol. III and the Enterprise Reference Standard. The results conform to the specifications and the batch is approved for release.</p>			

Signature

