

## TEST REPORT

Task Number #251126

Testing Date 26<sup>th</sup> Nov 2025

SAMPLE SOMATROPHIN 100 PEN

MANUFACTURER Body Pharm

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 98.80%

Dimer of related proteins N/A

### COMMENTS:

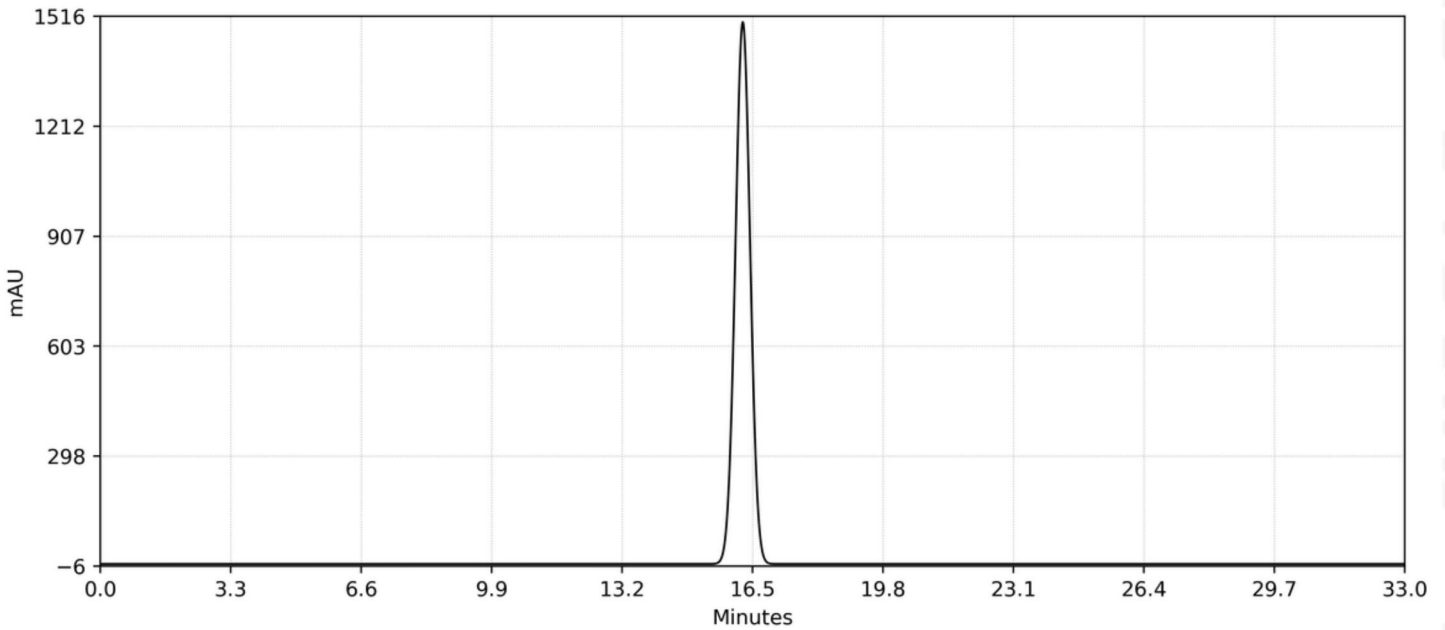
Analysis Conducted 26<sup>th</sup> Nov 2025

Signature

SAMPLE SOMATROPHIN 100 PEN

MANUFACTURER Body Pharm

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	98.8975	1.22	7100
3		32.678	0.02	0.015	0.0000	2.60	36248252
Σ			1533.11	41816.921	100.0000		

Analysis Conducted 26<sup>th</sup> Nov 2025

Signature

MANUFACTURER

Body Pharm

## Certificate of Analysis

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

Signature

