

Sample Name	Human Growth Hormone	CAS	12629-01-5
Batch No.	G0120260201	Batch Size	1669.00g
Specification	0.5g/bag	MFG Date	2026.02.05
Storage	Sealed, 2-8°C	Retest Date	2028.02.04
Grade	Pharmaceutical for Human Use		
Test standard	USP Current Version		
Test items	Specifications	Results	
【Description】			
Appearance	This product is a white lyophilized powder.		Conformed
Solubility	Freely soluble in water		Conformed
【Identification】			
Reverse-phase chromatography	The retention time of the main peak in the test solution should be corresponds to that of the main peak in the reference solution.		Conformed
Peptide mapping	The peptide map of the test solution should be corresponds to the peptide map of the reference solution.		Conformed
Retention Time of High Molecular Weight Proteins	In the chromatogram recorded under the Assay item, the retention time of the main peak in the test solution should be corresponds to that of the main peak in the reference solution.		Conformed
【Test】			
Water content	The water content not more than 10.0%.		1.4%
Bacterial Endotoxins Test	The amount of bacterial endotoxins per 1 mg of Somatropin should be not more than 5.0 EU.		Conformed
Related proteins	The total related proteins should be not more than 6.0%.		3.1%
High molecular weight proteins	The sum of the peak areas of all the peaks with retention times less than that of the main peak of Somatropin should not more than 4.0%.		0.2%
Residual host-cell DNA	The host cell DNA residue per 1 mg of Somatropin should not exceed 1.5 ng.		Conformed
Residual host-ccll proteins	The residual host cell protein content per 1 mg of Somatropin should not exceed 10 ng.		Conformed
Biological activity	The biological activity per 1 mg of anhydrous Somatropin should be not less than 3.0 IU/mg.		3.3IU/mg

Certificate of Analysis

Total protein	The total protein content should be 0.12-0.17 mg per mg.	0.15mg/mg
Microbial limit	The total aerobic microbial count per 1 g of the test sample should not more than 3×10^2 cfu. The total number of molds and yeasts shall not more than 1×10^2 cfu.	Conformed
【Assay】		
Somatropin Content	The content of Somatropin ($C_{990}H_{1528}N_{262}O_{300}S_7$) per 1 mg of protein should be not less than 0.91 mg.	1.03mg/mg
【Conclusion】		
The product complies with the quality requirements for Human Growth Hormone (USP current version)		



ASTRAL SCIENTIFIC PTY LTD | T: (02) 9540 2055
W: www.compoundingchemicals.com.au | E: sales@compoundingchemicals.com.au