

Certificate of Analysis

Product: SOMATROPIN
Batch No.: 20250614
Size: 12IU
Test Basis: EP 5.0

Report Date: 20250703
MFG Date: 20250620
Expire Date: 2027.05

Result

ITEMS	STANDARD	TEST RESULT
Charactors	a white freeze dried powder	COMFORMED

INDIFICATIONS

A(IEF)	CORRESPONDS TO REFERENCE	COMFORMED
B(HPLC/RP)	CORRESPONDS TO REFERENCE	COMFORMED
C(PEPTIDE MAPPING)	CORRESPONDS TO REFERENCE	COMFORMED
D(HPLC/SEC)	CORRESPONDS TO REFERENCE	COMFORMED

TESTS

PH	6.5-8.5	7.3
Related protein (HPLC/RP)	not greater than 13%	1.90%
Dimer and related substance of high molecular mass (HPLC/SEC)	not greater than 6%	0.10%
Isoform Distribution	not great than 6.25%	COMFORMED
Water	not great than 3%	1.50%
Bacterial endotoxins	not great than 5IU/mg hGH	<5IU/mg hGH
Host cell derived protein	not great than 20 ng/mg hGH	12 ng/mg hGH
Host-cell and vector-derived DN	not great than 20 pg/mg hGH	<10 pg/mg hGH
Test for sterility	COMFORMED	COMFORMED
Assay(HPLC/SEC)	90%-110% the amount of somatropin state on the label	100.20%

Conclusions: Fullfill with European Pharmaceutical 5.0 specifications

storage: In a sterile, airtight, at the temperature of 2-8 °C