CERTIFICATE OF ANALYSIS

SOMATROPIN (rhGH) — 50 IU

Product / active ingredient	Recombinant human growth hormone (somatropin)
Manufacturer / brand reference	Pfizer / Genotropin (reference only)
Nominal content	50 IU (~16.67 mg), proposed presentation
Batch identifier	EDU-HGH-050-001
Sample type	Lyophilized powder for injection
Analytical record	Model batch record, 06 November 2026

Analytical Results and Specifications

Test / parameter	Acceptance criterion (model)	Result	Status
Appearance	White to off-white lyophilized cake	White intact cake	PASS
Identity (LC-MS / peptide map)	Conforms to somatropin reference	Conforms; expected mass observed	PASS
Protein content (RP-HPLC)	95.0–105.0% of label claim	99.2% (16.54 mg equivalent)	PASS
Monomer purity (SEC-HPLC)	≥ 98.0%	99.1%	PASS
High-molecular-weight species	≤ 2.0%	0.6%	PASS
Related proteins (RP-HPLC)	≤ 2.0% total	0.8%	PASS
Biological potency (bioassay)	90.0–110.0% nominal activity	101.3%	PASS
Bacterial endotoxins (USP <85>)	≤ 5 EU/mg (model limit)	0.12 EU/mg	PASS
Sterility (USP <71>)	No growth detected	No growth detected	PASS
Residual moisture (Karl Fischer)	≤ 3.0% w/w	1.2% w/w	PASS
Reconstitution / visual clarity	Clear, free of visible particles	Clear, no visible particles	PASS

Methods and Scientific Basis

Identity: LC-MS and peptide mapping; assay and related substances: RP-HPLC; aggregates: SEC-HPLC; potency: receptor-mediated cell assay; endotoxins: USP <85>; sterility: USP <71>; residual water: Karl Fischer titration. Specifications are model criteria, not verified Pfizer release specifications.

References

1. Pfizer. GENOTROPIN (somatropin) prescribing information. 2. United States Pharmacopeia, General Chapters <71> and <85>. 3. ICH Q6B: Specifications for Biotechnological/Biological Products.

SIMULATED TEST DATA • NOT ISSUED BY PFIZER • NOT VALID FOR PRODUCT RELEASE