

CERTIFICATE OF ANALYSIS

Report issued to	NEOLPHARMA Grupo Farmaceutico	Report No.	CMC/LAB/NPPHG2/2025
Sample Name	HGH 10IU (Somatropin)	ULR No.	NA
Manufacturer	NEOLPHARMA Grupo Farmaceutico (Mexico)	Reporting Date	07-09-2025
Active Ingredient	Somatropin (recombinant human growth hormone 191aa)	Sample Submitted By	Ing. Ricardo Alvarez Mendez, QA Manager (NEOLPHARMA)
Package	Lyophilized vial	Exp. Date	01-2028
Batch / Lot No.	NPPHG2	Sample Qty.	1 vial
Received Date	05-09-2025	Mfg. Lic. No.	COFEPRIS 153300201X0092
Sample Condition	Received in sealed intact condition	Ref. No.	NIL
Storage Condition	Store below 30C away from direct sunlight	Country of Origin	Mexico

Reference to Protocol / Method	USP 2024 . CMC-LAB/SOP/NPPHG2	Analysis Started on:	05-09-2025
Analysis Completed on:	07-09-2025	Review / Release Date:	08-09-2025

RESULT OF ANALYSIS


S.No	Test Parameter	Claim	Units	Results	Specifications	Test Method
1	Description	-	-	Complies	White to off-white lyophilized cake, reconstitutes to a clear solution, free from visible particulates.	Visual Evaluation.
2	Water Content (KF)	-	% w/w	1.8	Not more than 5.0 %	USP <921>
3	Identification	-	-	Complies	Positive for Somatropin (recombinant human growth hormone 191aa)	RP-HPLC / SDS-PAGE
4	Assay of Somatropin (recombinant human growth hormone 191aa)	10	IU/vial	10.08	9.00 - 11.00 IU/vial	RP-HPLC / SDS-PAGE
5	Sterility	-	-	Complies	No evidence of microbial growth	USP <71>
6	Bacterial Endotoxin	-	EU/ml	< 0.25	NMT 1.0 EU/ml	USP <85>

The sample submitted by NEOLPHARMA Grupo Farmaceutico **COMPLIES** with the declared specifications and is of standard pharmaceutical quality with respect to the parameters tested.

USP = United States Pharmacopela . HPLC = High Performance Liquid Chromatography . KF = Karl Fischer . NMT = Not More Than
 EU = Endotoxin Units . AV = Acceptance Value . COFEPRIS = Comision Pederal para la Proteccion contro Riesgos Sautarios


 QPB. Laura A. Martinez Rios
 Chief Analyst, Costamed Laboratory




 Dr. Arturo Gonzalez Pena
 Technical Director, Costamed Laboratory

**** End of Report ****

Terms and Conditions

1. This report is issued by Costamed Grupo Medico and refers only to the sample tested.
2. Sample will be destroyed one year from the date of issue unless otherwise specified.
3. Total liability of the laboratory is limited to the involved amount.
4. All disputes subject to Cosumel, Quintana Roo jurisdiction, Mexico.