

Certificate of Analysis

LONG[®]R³IGF-I, Liquid Product (LP)

Repligen Sweden AB product name: LONG[®]R³IGF-I Liquid Product (LP)

Article number: 10-1011-125

Batch number:

Date of filling (MMM YYYY):

Re-test date (MMM YYYY):

Storage conditions: 2 – 8°C

Packaging: Nalgene PET-bottles, 125 mL

Quantity: 100 mL

This product is manufactured in accordance with the manufacturing formula for LONG[®]R³IGF-I (MF-0350) and Repligen Sweden AB Quality Policy (POL-0361).
Site of Manufacturing: Repligen Sweden AB, Box 965, SE-220 09 Lund, Sweden.

Aqueous solution of LONG[®]R³IGF-I and 0.1M acetic acid.

Category	Test Method	Limit	Result
Appearance	Visual inspection	Clear Liquid	
Identity (A)	Mass Spectrometry-Molecular weight	9108 – 9112 Da	
Identity (B)	RP-HPLC	Microheterogeneous mixture of LONG®R ³ IGF-I, typically 4 peaks with the major peak > 60% of total peak area	
Biological Activity	Stimulation of protein synthesis in the rat L6 myoblast cell line	ED ₅₀ < 10 ng/mL	
Bacterial endotoxins	LAL assay	< 0.10 EU/μg of protein	
Purity	SDS-PAGE	A single band ≥ 95% with the same electrophoretic mobility as the LONG®R ³ IGF-I reference standard	
		No additional individual band > 5%. Total of additional individual bands ≤ 5%.	
Concentration	RP-HPLC	0.9 – 1.1 mg/mL	
Bioburden	Bioburden Analysis	Total viable aerobic count ≤ 100 cfu/mL	
		Enterobacteriaceae and gram negatives absent in 1 mL	
		<i>Pseudomonas aeruginosa</i> , absent in 1 mL	
		<i>Staphylococcus aureus</i> , absent in 1 mL	

This batch fulfills the specification

 Place and date

 Name
 QC
 Repligen Sweden AB

 Place and date

 Name
 QA
 Repligen Sweden AB