

# Technical Bulletin

## LONG<sup>®</sup>R<sup>3</sup>IGF-I Storage, Stability and Specifications

### Format and Storage

LONG R<sup>3</sup>IGF-I is available as a lyophilized powder, Catalog No. 85580C, or a 1 mg/mL liquid formulation in 100 mM acetic acid, Catalog No. 91590C. Both formats are shipped at ambient temperature and stored at 2 to 8 °C.

Cat. No.	Format	Available Sizes	Storage
85580C	Lyophilized	5, 20 and 50 mg	2 to 8 °C
91590C	Liquid (1mg/mL)	5 mL, 100 mL	2 to 8 °C

After reconstituting a solution of lyophilized LONG R<sup>3</sup>IGF-I as prepared below, or after opening a vial of liquid LONG R<sup>3</sup>IGF-I, the product should be stored re-capped in the original vial at 2 to 8 °C. It is imperative that the vial is re-capped properly to form an airtight seal, as the volatile nature of the acetic acid solution can result in evaporation and consequentially a concentration of the LONG R<sup>3</sup>IGF-I in solution.

### Stability — Long-Term

Formal ICH Q7A compliant stability studies are used to assess the long-term stability of LONG R<sup>3</sup>IGF-I when stored at 2 to 8 °C. These studies are ongoing with the current shelf-life for each formulation indicated in the table below.

Cat. No.	Format	Shelf-life (2 to 8 °C storage)
85580C	Lyophilized	5 Years
91590C	Liquid (1mg/mL)	3 years

The following assays are performed to assess the stability of the liquid and lyophilized LONG R<sup>3</sup>IGF-I formulations throughout the formal stability studies.

Assay	
Protein Synthesis	Clarity of Solution
Endotoxin	Bioburden
Gel Electrophoresis	Mass Spectroscopy
Reverse Phase HPLC	N-Terminal Sequencing
Appearance	Particle Content

### Stability — Transport

The stability of LONG R<sup>3</sup>IGF-I during transport at ambient temperatures has been investigated for both formulations. Samples were sent from Novozymes Biopharma Australia to SAFC in Lenexa, Kansas, USA and returned to Novozymes Biopharma Australia with temperature loggers to record the temperature range during transit.

Cat. No.	Format	Range Recorded	Total Transit Time
85580C	Lyophilized	10 to 30 °C	9 days
91590C	Liquid (1mg/mL)	6 to 30 °C	20 days

The following assays were performed to assess the stability of LONG R<sup>3</sup>IGF-I following transport at uncontrolled ambient temperatures.

Assay	
Protein Synthesis	Clarity of Solution
Endotoxin	Bioburden
Gel Electrophoresis	Mass Spectroscopy
Reverse Phase HPLC	N-Terminal Sequencing
Appearance	

Specifications for all tests were within limits, demonstrating that both LONG R<sup>3</sup>IGF-I formulations remain stable during transport at uncontrolled ambient temperature.

### Final Product Specification

Catalog No. 85580C, Lyophilized LONG<sup>®</sup>R<sup>3</sup>IGF-I

Test	Specification
Appearance	White/creamy crystalline deposit
Biological Activity: by stimulation of protein synthesis	ED <sub>50</sub> < 10 ng/mL
Bacterial Endotoxin: by chromogenic LAL assay	< 0.10 EU/μg protein
Identity (A): by reverse phase HPLC	Conforms to reference standard by retention time and chromatographic profile
Identity (B): by N-terminal sequence analysis	MPFAMPLSSLFVNGPRTL
Molecular Weight: by mass spectrometry	9108 9112 daltons
Purity: by NuPage Bis-Tris gel electrophoresis	≥ 95% single band between 6000 and 14400 daltons

### Final Product Specification

Catalog No. 91590C, Lyophilized LONG R<sup>3</sup>IGF-I

Test	Specification
Appearance	Clear liquid
Biological Activity: by stimulation of protein synthesis	ED <sub>50</sub> < 10 ng/mL
Bacterial Endotoxin: by chromogenic LAL assay	< 0.10 EU/μg protein
Identity (A): by reverse phase HPLC	Microheterogeneous mixture of LONG R <sup>3</sup> IGF-I, typically 4 peaks with the major peak > 60% of total peak area
Identity (B): by amino acid sequence analysis of N-terminal 18 amino acids	MFPANPLSSLFVNGPRTL
Purity: by SDS-poly	9108 9112 daltons
Purity: by NuPage Bis-Tris gel electrophoresis	≥ 95% single band between 6000 and 14400 daltons

#### Warranty, Limitation of Remedies

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Issued March 2011 T097  
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