

Short™ AE-IGF-1

Bioactive Grade, GMP-like, Animal Free
Human Insulin-like Growth Factor-1

Product Data Sheet

Synonyms

AE-IGF-1, RhShort AE-IGF-1, Short IGF
Insulin-like Growth Factor-I, Somatamedin C.

Introduction

Short™ AE-IGF-1 is a recombinant protein of human insulin-like growth factor-I (IGF-1) that has been engineered with an N-terminal Ala-Glu sequence for use specifically in Cell Culture. It is approximately 100-fold more biologically potent, *in-vitro*, than insulin and significantly increases recombinant protein production and reduces apoptosis. **Produced and tested according to GMP guidelines, this superior bioactive grade growth factor is certified 100% animal free** and ideally suited for both research and large-scale culture systems and bioreactors.

Application

For laboratory research and large-scale *in-vitro* biopharmaceutical manufacturing use only. Not for diagnostic or therapeutic use. Product use is for strictly *in-vitro* applications and prohibited for the use *in-vivo*.

Process Description

Short™ AE-IGF-1 is manufactured by CellRx according to GMP guidelines using a proprietary *Escherichia coli* based expression system that allows for hyperexpression of the molecule. The process utilizes **fully defined animal-free components**, proprietary feed and induction methods within a high cell density (HCD), fed-batch, bioreactor system. The recombinant IGF molecule accumulates as inclusion bodies which are subsequently recovered, solubilised and refolded into a stable tertiary structure and purified using various downstream unit operations, yielding $\geq 95\%$ RP-HPLC and $\geq 97\%$ SDS-PAGE **pure molecule that is highly bioactive**. Each batch is supplied with a detailed certificate of analysis.

Appearance/Formulation

Short™ AE-IGF-1 is available in sterile 0.2µm filtered 1mg/ml clear liquid formulation in 100mM acetic acid.

pH and Osmolality

Short™ AE-IGF-1 in sterile acetic acid at pH 2-4, is supplied as a **stable soluble product that can be added directly into cell culture media** without any further handling or risk of influence on cell culture pH and osmolality.

Purity, Endotoxin, Molecular Weight, Identity

Purity: $\geq 95\%$ as determined by RP-HPLC and $\geq 97\%$ by SDS-PAGE analysis, with a very low level of endotoxins making this product ideal for mammalian cell culture work.

Endotoxin Level: < 0.1 EU/µg

Molecular Weight: 7845-7850 Da

Identity: N-terminal analysis AEGPET

CAS RN: 2377686-75-2

Biological Activity

All cells that have a functional Type 1 IGF receptor will respond to Short™ AE-IGF-1. This includes commercially available cell lines such as CHO, PER.C6, BHK, HEK 293, Embryonic stem cells, mesenchymal stem cells, hematopoietic stem cells, fibroblasts and hybridomas.

Dosage

Initial seeding densities range at the time of inoculation from 2×10^5 viable cells/ml up to 1×10^6 viable cells/ml in a fed batch system with concentrations range from 25-200µg/L. For perfusion system, the optimum range has consistently been between 25-100µg/L (*note: these are guide ranges, optimum concentration has to be experimentally determined for each specific cell line*).

PACK SIZES

CAT#	PACK SIZE
8000	100µg
8005	1mg
8010	10mg
8011	100mg
8012	500mg
8013	1,000mg
8014	Bulk Custom*

*Contact us for bulk pricing options and evaluation samples

CONTACT SALES

sales@cellrxbio.com

Manufacturing Specifications

The entire manufacturing process is strictly controlled by a stringent Quality Management System that ensures full traceability with fully defined and approved chemicals that are 100% animal free.

The product is supplied as a liquid format that is stabilised with sterile acetic acid at pH 2-4, free of endotoxins, ready to use and stable for transportation at room temperature.

■ Animal-Free Manufacturing Conditions

The production facility is a controlled-access animal-free venue that ensures manufacturing and products are not exposed to potential contamination by animal components or byproducts. All process unit operation (PUO) and sub-unit operations (SUO) during the manufacturing process are conducted in accordance with defined and approved Standard Operating Procedures (SOPs).

■ Upstream Processing

Production is carried out using equipment and raw materials that are confirmed animal-free. Fermentation is carried out using dedicated manufacturing bioreactors.

Handling, Storage and Stability

NO reconstitution of the product is necessary.

Short™ AE-IGF-1 is supplied in a *Ready-To-Use* liquid format, in sterile 100 mM Acetic Acid for **shipping at ambient conditions**. Upon receipt, the product should be stored at 2-8°C under sterile conditions after repeated use. There is **NO need for adding carrier proteins or aliquoting** into smaller quantities for long-term storage at lower temperatures as required in other products. The advantages are not only in the ease of use, but also reduction in cold-chain shipping and storage costs. The product has a shelf-life of 4 years under the specified conditions above and as per the expiration date on the individual certificate of analysis.

PRODUCT SPECIFIC NOTICES

END USER TERMS OF USE

The following terms are offered to you upon your acceptance of these End User Terms of Use of the CellRx product. By using this product, you indicate your acknowledgment and agreement to these End User Terms of Use. If you do not agree to be bound by and comply with all of the provisions of these End User Terms of Use, you should contact your supplier of the product and make arrangements to return the product.

The End User is aware that CellRx sells products strictly for *in-vitro* application and is prohibited for the use *in-vivo*. THIS PRODUCT IS INTENDED FOR PURPOSES DESCRIBED ONLY AND IS NOT INTENDED FOR ANY HUMAN OR THERAPEUTIC USE.

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■ Downstream Processing

Cell disruption, inclusion body recovery and protein refolding are carried out using equipment and raw materials that are confirmed animal-free. Protein purification columns are animal-free and bulk filtration is carried out using animal-free filters. Purified proteins are stored in animal-free, microbial free and DNA free certified bottles and stored in access-controlled dedicated fridge/cold storage room.

■ Quality Systems and Assurance

The QMS system implemented for production includes:

- ✓ Training programs and Records.
- ✓ Raw material and vendor approval.
- ✓ Validated, testing and certification of equipment.
- ✓ Process, Equipment and Method SOPs.
- ✓ Equipment maintenance and calibration schedules.
- ✓ Facility maintenance, safety programs & pest control.
- ✓ Material review process for variance.

Product Support

This quality product is delivered for all types of mammalian cell culture and research projects. In order to increase the specific performance of each individual cell culture, CellRx supports the setup and optimization of your culture conditions. The support is customized for each individual program and is mediated through the advice of our specialists with more than 30 years of cell culture development expertise.

FOR MORE INFORMATION, PLEASE EMAIL
info@cellrxbio.com

TERMS AND CONDITIONS

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Short™ AE-IGF-1 is a registered trade-mark of CellRx Ltd. and covered by the following patents assigned to CellRx: US Patents 5,459,052, 5,691,168 and 5,708,134.

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