GMP Human IL-1 beta Protein

Catalog # GMP-ILBH16



Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests
- No animal derived peptone and lactose used in production process

Source

GMP Human IL-1 beta Protein(GMP-ILBH16) is expressed from E. coli cells. It contains AA Ala 117 - Ser 269 (Accession # <u>P01584-1</u>). Predicted N-terminus: Met

Molecular Characterization

IL-1 beta(Ala 117 - Ser 269) P01584-1

This protein carries no "tag".

The protein has a calculated MW of 17.5 kDa. The protein migrates as 18 kDa±3 kDa when calibrated against <u>Star Ribbon Pre-stained Protein Marker</u> under reducing (R) condition (SDS-PAGE).

Endotoxin

Less than 10 EU/mg by the LAL method.

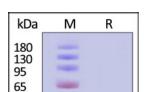
Host Cell Protein

<0.5 ng/µg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/µg of protein tested by qPCR.

SDS-PAGE



Sterility

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.

Mycoplasma

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 µm filtered solution in PBS, pH7.4 with protectants.

Contact us for customized product form or formulation.

Shipping

This product is supplied and shipped with blue ice, please inquire the shipping cost.

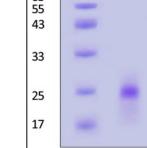
Storage

Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.





>>> www.acrobiosystems.com





GMP Human IL-1 beta Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With <u>Star Ribbon Pre-stained Protein Marker</u>).

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents:

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

Animal-Free materials

Materials purchased from the approved suppliers by QA

ISO 5 clean rooms and automatic filling equipment

Qualified personnel

Quality-related documents review and approve by QA

Fully batch production and control records

Equipment maintenance and calibration

Validation of analytical procedures

Stability studies conducted

Comprehensive regulatory support files

Request For Regulatory Support Files (RSF)

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

 SDS-PAGE

 Protein content

 Endotoxin level

 Residual Host Cell DNA content

 Residual Host Cell Protein content

 Biological activity analysis

Microbial testing

Mycoplasma testing

In vitro virus assay

Residual moisture

Batch-to-batch consistency



>>> www.acrobiosystems.com

9/18/2024

Catalog # GMP-ILBH16



Background

Interleukin-1 beta (IL-1 β) is a non-secreted proinflammatory cytokine produced mainly by activated macrophages, as well as neutrophils, epithelial cells, and endothelial cells. It possesses metabolic, physiological, haematopoietic activities, and plays one of the central roles in the regulation of the immune responses. Both IL-1 α and IL-1 β binds to the same receptor and has similar but not identical biological properties; The mature human IL1 β shares 96 % amino acid sequence identity with rhesus and 67 % -78 % with canine, mouse and rat IL-1 β .

Clinical and Translational Updates



>>> www.acrobiosystems.com

