Catalog # GMP-CD5H24



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

Source

GMP Biotinylated Human CD5 Protein, His,Avitag(GMP-CD5H24) is expressed from human 293 cells (HEK293). It contains AA Arg 25 - Pro 372 (Accession # <u>P06127-1</u>).

Predicted N-terminus: Arg 25

Molecular Characterization

CD5(Arg 25 - Pro 372) Poly-his Avi P06127-1

This protein carries a polyhistidine tag at the C-terminus, followed by an Avi tag (Avitag[™]).

The protein has a calculated MW of 42.2 kDa. The protein migrates as 52 kDa±3 kDa when calibrated against <u>Star Ribbon Pre-stained Protein Marker</u> under reducing (R) condition (SDS-PAGE) due to glycosylation.

Labeling

Biotinylation of this product is performed using Avitag[™] technology. Briefly, the single lysine residue in the Avitag is enzymatically labeled with biotin.

Biotinylation

As determined by Quantitative ELISA binding assay against streptavidin.

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.

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 μ m 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:

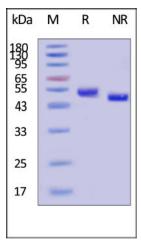
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.



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GMP Biotinylated Human CD5 Protein, His,Avitag on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

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

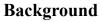


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Residual Host Cell Protein content Biological activity analysis Microbial testing Mycoplasma testing In vitro virus assay Residual moisture Batch-to-batch consistency



T-cell surface glycoprotein CD5 is also known as Lymphocyte antigen T1/Leu-1 and LEU1, which is phosphorylated on tyrosine residues by LYN, so CD5 can create binding sites for PTPN6/SHP-1.CD5 may act as a receptor in regulating T-cell proliferation. CD5 is expressed at various developmental and activation stages on human B cells.CD5 is a well established negative regulator of TCR and BCR signalling.CD5-positive cells may also prevent the emergence of autoimmunity by provision of cytokines such as IL-10. Development, selection and function of different B- and T-cell subsets or their preferential survival may be directly or indirectly dependent on different glycan structures associated with CD5 or CD5-like molecules.

Clinical and Translational Updates





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