Tinzyme Co., Limited

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Recombinant Human IL-15

Product Number: GMP-C016

Shipping and Storage

This product is a freeze-dried powder, transported at 2-8℃.

Freeze dried products are stored at -20 ℃, with an expiration date visible on the bottle body.

Description

Interleukin-15 (IL-15) is a member of the IL-2 cytokine family that exerts biological functions through the γ c (gamma c) receptor subunit. Both IL-2 and IL-15 are involved in early T cell proliferation and activation, and the anti-tumor activity of IL-15 also comes from directly activating CD8+effector T cells through non antigen-specific means. IL-15 can counteract IL-2 induced cell apoptosis and maintain CD8+memory T cells, which is crucial for maintaining long-term anti-tumor activity.

The recombinant human IL-15 protein is expressed in Escherichia coli and produced using non animal derived materials and pharmaceutical excipients. Implement the Good Manufacturing Practice for Drugs (revised in 2010), strictly control bacterial endotoxin residues, host protein residues, exogenous DNA residues, etc., to ensure product quality, safety, and effectiveness.

Element	Standard
Appearance	White loose body
Redissolution	Compliant with regulations
Visible foreign objects	Compliant with regulations
PH	6.5-7.5
Purity	≥ 95%
Activity	≥ 1.0×10^7 IU/mg
Bacterial endotoxin content	<10 EU/mg
Host protein residue	≤ 0.005%
Exogenous DNA residues	≤ 10 ng/mg
Mycoplasma detection	Negative
Sterility inspection	Compliant with regulations

Complying to Following Regulations

1. Good Manufacturing Practice for Drugs (Revised in 2010).
2. GMP Appendix - Cell Therapy Products - National Medical Products Administration.
3. The 2020 edition of the Chinese Pharmacopoeia is published by the National Pharmacopoeia Commission.
4. USP Chapter<1043>, Ancillary Materials for Cell, Gene, and Tissue Engineering Products are excipients used in cell therapy, gene therapy, and tissue engineering products.
5. USP Chapter<92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.
6. Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell based and Gene Therapy Medical Products.

Application

Can be used for various in vitro cell cultures.

Note

1. Before use, check that the storage conditions and product expiration date meet the regulations.
2. Dissolve with water for injection, protein concentration>100μg/ml.
3. Product re dissolution and packaging are strictly controlled for sterility and pyrogen free.

For Research Use Only

4. After the product is re dissolved and packaged, it can be stored at -70℃ to avoid repeated freeze-thaw cycles that may cause protein denaturation and other possible contamination risks.