

Recombinant anti-Human CD3 mAb

Cat. No.: GMP-A018

GMP Grade

Animal-free, Ampicillin-free

01/ Description

Recombinant Anti-Human CD3 mAb is a T cell-activated antibody produced based on OKT3 through humanization modification and genetic engineering. On the premise of maintaining the activation ability of OKT3 monoclonal antibody on T cells, the product can eliminate the immunogenicity of murine antibodies to the greatest extent. The product recognizes the human TCR ϵ chain to activate the T cell activation signaling pathway, thus stimulating T cell activation and proliferation.

Recombinant Anti-Human CD3 mAb is expressed by mammalian cells, and is produced with raw materials of pharmaceutical applicable level. The host protein residue, nucleic acid residue and common pathogens are strictly controlled, and the production and quality management procedures of the product comply with GMP regulations to ensure the traceability of the production process and all raw materials.

02/Quality Elements

Item	Standard
Description	Transparent liquid
Visible particle	Conform to ChP
pH value	6.5–7.5
Purity	$\geq 95\%$
Bioactivity	1-10 ng/mL
Endotoxin	< 10 EU/mg
Host protein	$\leq 0.005\%$
Exogenous DNA residue	≤ 100 pg/mg
Mycoplasma test	Negative
Sterility test	Conform to ChP

Annotation: ChP refers to the Pharmacopoeia of the People's Republic of China.

03/ Complying to following regulations

- (1) 《Good Manufacturing Practice of Medical Products (2010 version, NMPA)》.
- (2) 《GMP Appendix – Cellular therapeutic product》 National Medical Products Administration.
- (3) 《Pharmacopoeia of the People's Republic of China》 2020 version, National Pharmacopoeia Commission.
- (4) USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered 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 Medicinal Products

04/ Application

In-vitro cultivation of various types of cell.

Recombinant Anti-Human CD3 mAb can satisfy most T cell expansion requirements and exhibit the same effects as OKT3. For difficult-to-expand cells, the product can be used in combination with Recombinant Anti-Human CD28 mAb (Cat. No: GMP-A063) or NovoNectin® GMP Grade (Cat. No.: GMP-CH38).

05/ Transport & Storage

This product is a liquid formulation and should be preserved in dry ice during shipment.

Storage at $-20 \pm 5^{\circ}\text{C}$, expiration date labeled on bottle.

06/ Precaution

- (1) Make sure the product properly stored and none expired before using.
- (2) Sterile condition without pyrogen is required for reconstitution, re-aliquoting, dilution.
- (3) After reconstitution, aliquoted solution vials should be stored at -70°C and minimize freeze-thaw cycles preventing denaturation of protein.

Applications in T cell activation and expansion:

General applications: The recommended concentration is 5–10 $\mu\text{g/mL}$; if necessary, the optimal concentration for specific cells can be selected at 5–20 $\mu\text{g/mL}$. Coating of culture flask:

- a. Calculate the volume on the basis of 150 $\mu\text{L/cm}^2$, dilute the Recombinant Anti-Human CD3 mAb, recombinant anti-CD28 mAb, and NovoNectin® GMP Grade with normal saline to 5–10 $\mu\text{g/mL}$, 5–10 $\mu\text{g/mL}$, and 25–50 $\mu\text{g/mL}$, respectively, and mix them to a coating solution;
- b. Add the diluted coating solution to a culture flask or bag and cover the bottom with the solution;
- c. Place the solution in a 37 $^{\circ}\text{C}$ incubator for 5–8 h, or at 2–5 $^{\circ}\text{C}$ overnight;
- d. Remove the liquid and wash the flask or bag 3 times with normal saline;
- e. The well-coated culture vessel shall be used immediately; if the vessel is to be used after more than 30 minutes, store it in normal saline.

07/Related Products

Cat. No.	Product Name
GMP-C070	Recombinant Human IL-1 alpha
GMP-CG93	Recombinant Human IL-1 beta
GMP-C013	Recombinant Human IL-2
GMP-CD03	Recombinant Human IL-4
GMP-C009	Recombinant Human IL-6
GMP-CD47	Recombinant Human IL-7
GMP-CI58	Recombinant Human IL-12
GMP-C016	Recombinant Human IL-15
GMP-CD72	Recombinant Human IL-18
GMP-CC45	Recombinant Human IL-21

Cat. No.	Product Name
GMP-CC79	Recombinant Human GM-CSF
GMP-CI57	Recombinant Human IFN-gamma
GMP-C008	Recombinant Human TNF-alpha
GMP-CH38	NovoNectin® GMP Grade
GMP-1647	Tscm Expander®
GMP-A037	Recombinant anti-Human 4-1BB mAb
GMP-A091	Recombinant anti-Human CD16 mAb
GMP-A063	Recombinant anti-Human CD28 mAb
GMP-A052	Recombinant anti-Human CD52 mAb
GMP-A065	Recombinant anti-Human CD56 mAb
GMP-A075	Recombinant anti-Human NKG2D mAb
GMP-B038	Anti-Human CD3/CD28 beads
CT19	CARTEST® CD19 Detection kit