Rituximab biosimilar, premium grade

Catalog # CD0-M36A2

Source

Rituximab biosimilar, premium grade (CD0-M36A2) is a chimeric monoclonal antibody recombinantly produced from human 293 cells (HEK293), which combines the variable region of a mouse monoclonal antibody with human IgG1 constant domain.
It is produced under our rigorous quality control system that incorporates a comprehensive set of tests including sterility and endotoxin tests. Product performance is carefully validated and tested for compatibility for cell culture use or any other applications in the early preclinical stage. When ready to transition into later clinical phases, we also offer a custom GMP protein service that tailors to your needs. We will work with you to customize and develop a GMP-grade product in accordance with your requests that also meets the requirements for raw and ancillary materials use in cell manufacturing of cell-based therapies.

Isotype

Human IgG1 | Human Kappa

Conjugate

Unconjugated

Specificity

This product is a genetically engineered chimeric murine/human monoclonal IgG1 kappa antibody directed against the CD20 antigen.

Endotoxin

Less than 0.01 EU per μg by the LAL method / rFC method.

Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-MALS.

Sterility

Negative

Mycoplasma

Negative.

Formulation

Supplied as 0.2 μm filtered solution in 25 mM Sodium citrate, 150 mM NaCl, pH6.5.

Contact us for customized product form or formulation.

Shipping

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

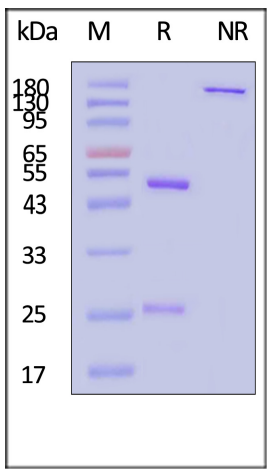
Storage

For long term storage, the product should be stored at liquid state at -70°C.

This product is stable after storage at:

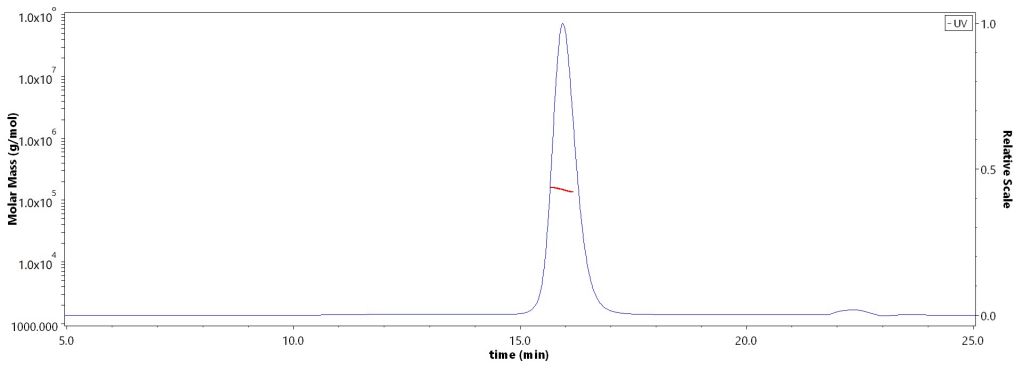
- 2-8°C for 12 months under sterile condition;
- -70°C for 24 months.

SDS-PAGE



Rituximab biosimilar, premium grade 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% (With Star Ribbon Pre-stained Protein Marker).

SEC-MALS



The purity of Rituximab biosimilar, premium grade (Cat. No. CD0-M36A2) is more than 95% and the molecular weight of this protein is around 135-160 kDa verified by SEC-MALS.
Report

Bioactivity-ELISA

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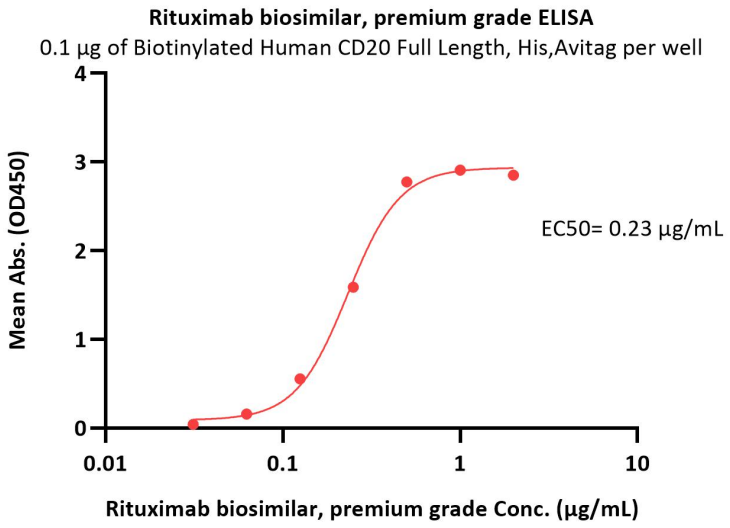
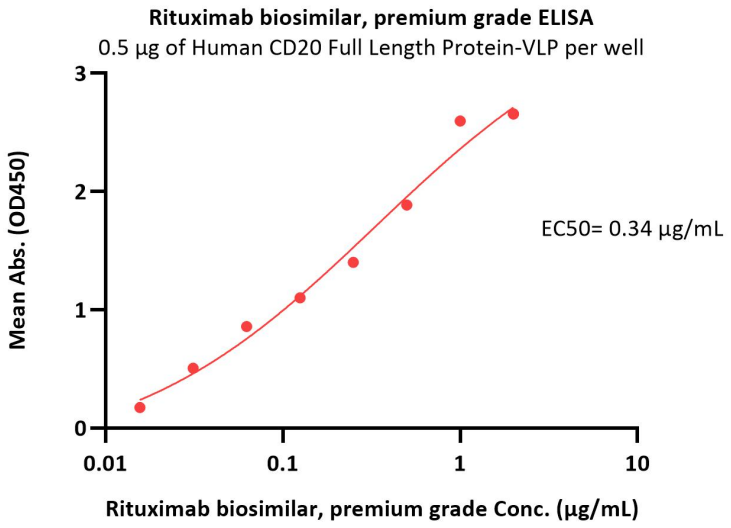


Immobilized Biotinylated Human CD20 Full Length, His,Avitag (Cat. No. CD0-H82E5) at 1 μg/mL (100 μL/well) on streptavidin (Cat. No. STN-N5116) precoated (0.5 μg/well) plate can bind Rituximab biosimilar, premium grade (Cat. No. CD0-M36A2) with a linear range of 0.031-1 μg/mL (QC tested).



Immobilized Human CD20 Full Length Protein-VLP (Cat. No. CDP-H52P6) at 5 μg/mL (100 μL/well) can bind Rituximab biosimilar, premium grade (Cat. No. CD0-M36A2) with a linear range of 0.016-1 μg/mL (Routinely tested).

Background

B-lymphocyte antigen CD20 is also known as B-lymphocyte surface antigen B1, Leukocyte surface antigen Leu-16, Membrane-spanning 4-domains subfamily A member 1 and MS4A1, is an activated-glycosylated phosphoprotein expressed on the surface of all B-cells beginning at the pro-B phase (CD45R+, CD117+) and progressively increasing in concentration until maturity. CD20 is expressed on all stages of B cell development except the first and last; it is present from late pro-B cells through memory cells, but not on either early pro-B cells or plasma blasts and plasma cells. It is found on B-cell lymphomas, hairy cell leukemia, B-cell chronic lymphocytic leukemia, and melanoma cancer stem cells. The protein has no known natural ligand and its function is to enable optimal B-cell immune response, specifically against T-independent antigens. It is suspected that it acts as a calcium channel in the cell membrane. CD20 / MS4A1 is the target of the monoclonal antibodies (mAb) rituximab, Ibritumomab tiuxetan, and tositumomab, which are all active agents in the treatment of all B cell lymphomas and leukemias. Defects in CD20 / MS4A1 are the cause of immunodeficiency common variable type 5 (CVID5); also called antibody deficiency due to CD20 defect. CVID5 is a primary immunodeficiency characterized by antibody deficiency, hypogammaglobulinemia, recurrent bacterial infections and an inability to mount an antibody response to antigen.

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