novozymes®
Rethink Tomorrow

Biopharma
Product specification

Recombumin® Alpha 10%

Recombinant human albumin USP-NF*

Definition

Recombumin Alpha 10% is a recombinant human albumin (rAlbumin) product sold as a formulation excipient for protein drugs and for delivery of proteins and small molecules; it is also used in the manufacture of a range of medical devices and in the preparation of media for specialized cell culture applications such as for stem cells or other cell therapies.

Product code: 230-005
CAS number: 70024-90-7 (human serum albumin)
Presentation: Recombumin Alpha 10% is sold in a 50 ml Type II glass vial containing 50 ml of a 10% (w/v) protein solution. Each vial contains 5 g rAlbumin protein.

Source

Recombinant *Saccharomyces cerevisiae* (baker's yeast) fermentation. Manufactured without the use of animal- or human-derived materials.

Application

Recombumin Alpha 10% has been successfully approved or evaluated in a wide range of customer-driven applications such as:

- Nanoparticle delivery of small-molecule drugs
- Medical device coating
- Albumin gel formation for products such as wound sealants
- IVF media
- Stem cell media

Storage and stability

Store at 2–8°C (36–46°F). Do not freeze.
Recombumin Alpha 10% is stable for five years when stored under these conditions in the unopened container.

Formulation

Component	Function	Nominal concentration
Recombinant human albumin	"Active" ingredient	100 g/L
Sodium	Tonicity	145 mM
Octanoate	Stabilizing agent	8 mM
Water for injection	Diluent/vehicle	To a volume of 1 L

* Meets National Formulary (NF) standards as published by the United States Pharmacopeia (USP).

Recombumin Alpha 10% is manufactured for Novozymes by our technology partner Kaketsuken (the Chemo-Sero Therapeutic Research Institute in Kumamoto, Japan; www.kaketsuken.or.jp/eng/index.html) to cGMP, for research or further manufacturing use only. Recombumin Alpha 10% is not approved in its own right as a therapeutic agent for use in applications such as plasma expansion.

Specifications

Description	Limits	Analytical method
Peptide mapping	Chromatographic profiles of test solution are similar to those of the standard solution	Peptide mapping
Mass analysis	Theoretical mass ± 20 Da (66418 to 66458)	Mass analysis
Endotoxin	≤ 0.50 EU/ml	LAL
Sterility	Meets requirements of test	USP<71>
pH	6.4–7.4	Standard QC method
Purity	≥ 99.0% (w/w)	Native PAGE
Polymer	≤ 1.0% (w/w) rHA	GP. HPLC
Protein	95–105 g/L	GP. HPLC
Sodium	120–160 mM	Atomic absorption spectroscopy
Appearance	A glass vial, free from defects, with a gray stopper retained by a metal and green plastic overseal, containing a slightly viscous, clear, straw to amber colored solution practically free from visible contamination	Visual inspection
Host cell protein	YA53M ≤ 15 ng/g rHA YA53H ≤ 150 ng/g rHA	ELISA
Octanoate	4–12mM	Gas chromatography
Polysorbate 80	50 mg/L (Provisional)	SEC-HPLC

Specification reference FP002.02.

Novozymes Biopharma US Inc.
(Reg. no: 01142208)
One Broadway · 14th Floor
Cambridge, MA 02142 · USA
Tel. +1 617 401 2500 · Fax +1 617 401 2501
biopharma@novozymes.com

Novozymes Biopharma DK A/S
(CVR no: 29603537)
Krogshoejvej 36
2880 Bagsvaerd · Denmark
Tel. +45 4446 2896 · Fax +45 4446 1080
www.biopharma.novozymes.com

Novozymes is the world leader in bioinnovation. Together with customers across a broad array of industries we create tomorrow's industrial biosolutions, improving our customers' business and the use of our planet's resources.