Biopharma
Product specification

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Rethink Tomorrow

Recombumin® Alpha 20%

Recombinant human albumin USP-NF*

Definition

Recombumin Alpha 20% 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: 230-010
CAS number: 70024-90-7 (human serum albumin)
Presentation: 50 ml Type II glass vial containing 50 ml of a 20% (w/v) protein solution. Each vial contains 10 g rAlbumin protein.

Source

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

Application

Recombumin Alpha 20% 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 20% is stable for two years when stored under these conditions in the unopened container.

Formulation

Component	Function	Nominal concentration
Recombinant human albumin	"Active" ingredient	200 g/L
Sodium	Tonicity	145 mM
Octanoate	Stabilizing agent	16 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 20% 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 20% is not approved in its own right as a therapeutic agent for use in applications such as plasma expansion.

Specifications

Description	Limits	Analytical method
Mass analysis	Theoretical mass ± 20 Da (66418 to 66458)	Mass analysis
Peptide mapping	Chromatographic profiles of test solution are similar to those of the standard solution	Peptide mapping
Endotoxin	≤ 0.50 EU/ml	USP<85>
Sterility	Meets requirements of test	USP<71>
pH	6.4–7.4	USP<791>
Purity	≥ 99.0% (w/w)	Native PAGE
Polymer	≤ 1.0% (w/w) rHA	GP. HPLC
Protein	19.0 - 21.0 (% w/v)	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	150 ng/g rHA	ELISA
Octanoate	4–12mM	Gas Chromatography
Polysorbate 80	100mg/L (Provisional)	SEC-HPLC

Specification reference FP002.02.

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