

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 \pm 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	\leq 0.50 EU/ml	USP<85>
Sterility	Meets requirements of test	USP<71>
pH	6.4–7.4	USP<791>
Purity	\geq 99.0% (w/w)	Native PAGE
Polymer	\leq 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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