

Biopharma  
Product specification

Recombunin® Alpha 10%  
Recombinant human albumin USP-NF\*

### Definition

Recombunin 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: Recombunin 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

Recombunin 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.

Recombunin 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).

Recombunin 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](http://www.kaketsuken.or.jp/eng/index.html)) to cGMP, for research or further manufacturing use only. Recombunin 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 $\pm$ 20 Da (66418 to 66458)	Mass analysis
Endotoxin	$\leq$ 0.50 EU/ml	LAL
Sterility	Meets requirements of test	USP<71>
pH	6.4–7.4	Standard QC method
Purity	$\geq$ 99.0% (w/w)	Native PAGE
Polymer	$\leq$ 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 $\leq$ 15 ng/g rHA YA53H $\leq$ 150 ng/g rHA	ELISA
Octanoate	4–12mM	Gas chromatography
Polysorbate 80	50 mg/L (Provisional)	SEC-HPLC

Specification reference FP002.02.

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