

Recombumin® Prime

Recombinant human albumin USP-NF*

Definition

Recombumin Prime is a recombinant human albumin (rAlbumin) manufactured to ICH Q7 standards, 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.

Product code: 200-010
 CAS number: 70024-90-7 (human serum albumin)
 Presentation: Recombumin Prime is sold in a 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 Prime has been successfully approved or evaluated in a wide range of customer-driven applications such as:

- Protein, peptide, or vaccine formulation
- Peptide conjugation for half-life extension
- Nanoparticle delivery of small-molecule drugs
- Medical device coating

Storage and stability

Store at 2–8°C (36–46°F). Do not freeze.

Recombumin Prime is stable for five 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	32 mM
Polysorbate 80	Stabilizing agent	15 mg/L
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 Prime is manufactured to ICH Q7 GMP at Novozymes' manufacturing facility in Nottingham, UK, and meets National Formulary (NF) standards as published by the United States Pharmacopeia (USP) for rAlbumin Human, for research or further manufacturing use only. Recombumin Prime is not approved in its own right as a therapeutic agent for use in applications such as plasma expansion.

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	6.7–7.3	Standard QC method
Purity	\geq 99.0% (w/w)	Native PAGE
Polymer	\leq 1.0% (w/w) rHA	GP. HPLC
Protein	19.0–21.0%	Kjeldahl
Sodium	130–160 mM	Atomic absorption spectroscopy
Appearance	A glass vial, free from defects, with a gray stopper retained by a metal and white plastic overseal, containing a slightly viscous, clear straw to amber colored solution practically free from visible contamination	Visual inspection
Host cell protein	\leq 0.15 μ g/g protein	ELISA
Con A-binding rHA	\leq 0.30% (w/w) protein	Con A Chromatography
Nickel	\leq 0.5 μ g/g protein	Atomic absorption spectroscopy
Potassium	\leq 0.01 mmol/g protein	Flame atomic absorption spectroscopy
DBA leachates: Dye Fragment (DAAS) Dye base Dye + spacer	\leq 0.1 μ g/g protein \leq 0.1 μ g/g protein \leq 0.4 μ g/g protein	RP-HPLC
PBA leachate	\leq 0.18 μ g/g protein	RP-HPLC
Octanoate	28.8–35.2 mM	Gas chromatography
Polysorbate 80	10–20 mg/L	SEC-HPLC

Specification reference FP002.02.

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