Biopharma
*Product specification*

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# 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 ± 20 Da (66418 to 66458) | Mass analysis |
| Endotoxin | ≤ 0.50 EU/ml | LAL |
| Sterility | Meets requirements of test | USP<71> |
| pH | 6.7–7.3 | Standard QC method |
| Purity | ≥ 99.0% (w/w) | Native PAGE |
| Polymer | ≤ 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 | ≤ 0.15 µg/g protein | ELISA |
| Con A-binding rHA | ≤ 0.30% (w/w) protein | Con A Chromatography |
| Nickel | ≤ 0.5 µg/g protein | Atomic absorption spectroscopy |
| Potassium | ≤ 0.01 mmol/g protein | Flame atomic absorption spectroscopy |
| DBA leachates:<br>Dye Fragment (DAAS)<br>Dye base<br>Dye + spacer | <br>≤ 0.1 µg/g protein<br>≤ 0.1 µg/g protein<br>≤ 0.4 µg/g protein | RP-HPLC |
| PBA leachate | ≤ 0.18 µg/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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