

Biopharma

Handling recommendations

Recombumin®

Recombinant human albumin USP-NF*

Definition

Recombumin® Prime and Recombumin® Alpha are recombinant human albumin (rAlbumin) products sold as a formulation excipients for protein drugs and for delivery of proteins and small molecules; they are 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 information

	Recombumin® Prime	Recombumin® Alpha
Product code	200-010	230-005 (10% w/v) or 230-010 (20% w/v)
CAS number	70024-90-7 (human serum albumin)100 g/L	
Presentation	50 ml Type II glass vial containing 50 ml of a 20% (w/v) protein solution; each vial contains 10 g rAlbumin protein.	50 ml Type II glass vial containing 50 ml of either a 10% (w/v) protein solution or 20% (w/v) protein solution; each vial contains 5 g or 10 g rAlbumin protein respectively.

Extraction for immediate use

1. Perform all activities in a controlled environment such as a laminar flow cabinet using aseptic techniques.
2. Procedure based on ISO 8362-2, Injection containers for injectables and accessories – Part 2: Closures for injection vials.
3. Use a 19-gauge needle attached to a hypodermic syringe.
4. Do not remove the aluminum overseal.
5. Do not remove the rubber stopper from the vial.
6. Remove the flip-off cap from the overseal.
7. Insert the hypodermic needle through the stopper.
8. Remove the desired quantity of product from the vial.
9. The stopper may be penetrated up to three times without compromising its integrity.
10. Store remaining solution in the original vial at 2–8°C (36–46°F). Do not freeze.

Extraction for storage in secondary containers

1. Perform all activities in a controlled environment such as a laminar flow cabinet using aseptic techniques.
2. Prepare the required quantity of clean and sterilized Type I or Type II secondary glass containers with butyl rubber stoppers according to the specific requirements of the application in question. Storage of rAlbumin in plastic containers may be acceptable, but Novozymes makes no recommendations on which plastics are suitable for this purpose.
3. Extract the required quantities of product as described above in steps 3–8.
4. Dispense the extracted volumes of Recombumin into the secondary containers and close immediately. Ideally the headspace in the container should represent less than 25% of the nominal volume of the container to reduce product oxidation if this is important for the individual application.
5. Store at 2–8°C (36–46°F). Do not freeze. rAlbumin prepared as above will be stable for extended periods, however there is no data to support a specific expiry. The user must determine the stability in the context of their specific application and use of the material.

*Meets National Formulary (NF) standards as published by the United States Pharmacopeia (USP).

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