Status: Currently Official on 13-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-FC264F2B-D786-40D7-865D-D698D01C8D51_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1180_01_01
DOI Ref: tr6xy



# Albumin Human

**DEFINITION**

Albumin Human conforms to the regulations of the federal Food and Drug Administration concerning biologics (640.80 to 640.86) (see *Biologics* ⟨1041⟩). It is a sterile, nonpyrogenic preparation of serum albumin obtained by fractionating material (source blood, plasma, serum, or placentas) from healthy human donors, the source material being tested for the absence of hepatitis B surface antigen. It is made by a process that yields a product that is safe for intravenous use. NLT 96% of its total protein is albumin. It is a solution containing, in each 100 mL, either 25 g of serum albumin osmotically equivalent to 500 mL of normal human plasma, or 20 g equivalent to 400 mL, or 5 g equivalent to 100 mL, or 4 g equivalent to 80 mL, and contains NLT 93.75% and NMT 106.25% of the labeled amount in the case of the solution containing 4 g in each 100 mL, and NLT 94.0% and NMT 106.0% of the labeled amount in the other cases. It contains no added antimicrobial agent, but may contain sodium acetyltryptophanate with or without sodium caprylate as a stabilizing agent. It has a sodium content of NLT 130 mEq/L and NMT 160 mEq/L. It has a heme content such that the absorbance of a solution, diluted to contain 1% of protein, in a 1-cm holding cell, measured at a wavelength of 403 nm, is NMT 0.25. It meets the requirements of the test for heat stability and for pH.

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Preserve in tight containers, and store at the temperature recommended by the manufacturer or indicated on the label.

• **Expiration Date:** The expiration date is not later than 5 years after issue from manufacturer's cold storage (5°, 3 years) if labeling recommends storage between 2° and 10°; not later than 3 years after issue from manufacturer's cold storage (5°, 3 years) if labeling recommends storage at temperatures not higher than 37°; and not later than 10 years after date of manufacture if in a hermetically sealed metal container and labeling recommends storage between 2° and 10°.

• **Labeling:** Label it to state that it is not to be used if it is turbid and that it is to be used within 4 h after the container is entered. Label it also to state the osmotic equivalent in terms of plasma, the sodium content, and the type of source material (venous plasma, placental plasma, or both) from which it was prepared. Label it also to indicate that additional fluids are needed when the 20-g/100-mL or 25-g/100-mL product is administered to a markedly dehydrated patient.

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| ALBUMIN HUMAN | Jennifer Tong Sun<br>Senior Scientist II | BIO2 Biologics Monographs 2 - Proteins |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 41(6)

**Current DocID: GUID-FC264F2B-D786-40D7-865D-D698D01C8D51_1_en-US**
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