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## 20 General References

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## 22 Date of Revision

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# Albumin

## 1 Nonproprietary Names

BP: Albumin Solution

PhEur: Human Albumin Solution

USP–NF: Albumin Human

## 2 Synonyms

*Alba*; *Albuconn*; *Albuminar*; albumin human solution; albumini humani solutio; *Albumisol*; *Albuspan*; *Albutein*; *Buminat*; human serum albumin; normal human serum albumin; *Octalbin*; *Plasbumin*; plasma albumin; *Pro-Bumin*; *Proserum*; *Zenalb*.

## 3 Chemical Name and CAS Registry Number

Serum albumin [70024-90-7]

## 4 Empirical Formula and Molecular Weight

Human serum albumin has a molecular weight of about 66 500 and is a single polypeptide chain consisting of 585 amino acids. Characteristic features are a single tryptophan residue, a relatively low content of methionine (6 residues), and a large number of cysteine (17) and of charged amino acid residues of aspartic acid (36), glutamic acid (61), lysine (59), and arginine (23).

## 5 Structural Formula

**Primary structure** Human albumin is a single polypeptide chain of 585 amino acids and contains seven disulfide bridges.

**Secondary structure** Human albumin is known to have a secondary structure that is about 55%  $\alpha$ -helix. The remaining 45% is believed to be divided among turns, disordered, and  $\beta$  structures.<sup>(1)</sup>

Albumin is the only major plasma protein that does not contain carbohydrate constituents. Assays of crystalline albumin show less than one sugar residue per molecule.

## 6 Functional Category

Adsorbent; cryoprotectant; dispersing agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Albumin is primarily used as an excipient in parenteral pharmaceutical formulations, where it is used as a stabilizing agent for

formulations containing proteins and enzymes.<sup>(2,3)</sup> Albumin has also been used to prepare microspheres, microcapsules and nanoparticles for experimental drug-delivery systems.<sup>(4–13)</sup>

As a stabilizing agent, albumin has been employed in protein formulations at concentrations as low as 0.003%, although concentrations of 1–5% are commonly used. Albumin has also been used as a cosolvent<sup>(14)</sup> for parenteral drugs, as a cryoprotectant during lyophilization,<sup>(15,16)</sup> and to prevent adsorption of other proteins to surfaces.

## 8 Description

The USP 40–NF 35 S1 describes albumin human as a sterile nonpyrogenic preparation of serum albumin obtained from healthy human donors; *see* Section 13. It is available as a solution containing 4, 5, 20, or 25 g of serum albumin in 100 mL of solution, with not less than 96% of the total protein content as albumin. The solution contains no added antimicrobial preservative but may contain sodium acetyltryptophanate with or without sodium caprylate as a stabilizing agent.

The PhEur 9.2 similarly describes albumin solution as an aqueous solution of protein obtained from human plasma; *see* Section 13. It is available as a concentrated solution containing 150–250 g/L of total protein or as an isotonic solution containing 35–50 g/L of total protein. Not less than 95% of the total protein content is albumin. A suitable stabilizer against the effects of heat, such as sodium caprylate (sodium octanoate) or *N*-acetyltryptophan or a combination of these two at a suitable concentration, may be added, but no antimicrobial preservative is added.

Aqueous albumin solutions are slightly viscous and range in color from almost colorless to amber depending upon the protein concentration. In the solid state, albumin appears as brownish amorphous lumps, scales, or powder.

## 9 Pharmacopeial Specifications

*See* Table I.

## 10 Typical Properties

**Acidity/alkalinity** pH = 6.7–7.3 for a 1% w/v solution, in 0.9% w/v sodium chloride solution, at 20°C.

**Osmolarity** A 4–5% w/v aqueous solution is isoosmotic with serum.