## Description

**Human Serum Albumin (HSA) 25%** is a sterile aqueous solution for use in vaccine productions. It is currently used in very small quantities as stabilizers in vaccines. The HSA 25% solutions is a sterile, nonpyrogenic preparation of albumin serum protein. Each 100 mL contains 25 g of albumin and is prepared from human venous plasma using the Cohn cold ethanol fractionation process from sourced US Licensed manufacturer. The product is stabilized with 0.08 millimole sodium caprylate and 0.08 millimole sodium acetyltryptophanate per gram of protein.

A liter of Human Serum Albumin 25% solution contains 130 - 160 milli equivalents of sodium ion. The aluminum content of the solution is not more than 200 micrograms per liter during the shelf life of the product. The product contains no preservatives.

HSA25% is heated at 60 °C for ten hours. No positive assertion can be made, however, that this heat treatment completely destroys the causative agents of viral hepatitis.

HSA25%, solution is a transparent or slightly opalescent solution which may have a greenish tint or may vary from a pale straw to an amber color.

### Human albumin USP Chemical name:

### Serum albumin Molecular formula and molecular mass: 66,500 Da Structural formula:

Single polypeptide chain consisting of 585 amino acids and 7 disulfide bridges. Characteristic features are a single tryptophan residue, a relatively low content of methionine (6 residues), and a large number of cystein (17) and charged amino acid residues of aspartic acid (36), glutamic acid (61), lysine (59), and arginine (23). Human albumin has a secondary structure that is about 55% α-helix. The remaining 45% is believed to be divided among turns, disordered, and β structures.

Human albumin does not contain carbohydrate constituents. Physicochemical properties: Albumin is the most abundant plasma protein comprising about 50% of the total plasma protein in humans. Each albumin molecule can bind up to 10 molecules of free fatty acid, although the actual amount bound is usually far lower. Albumin has a pH of 6.7-7.3 for a 1% w/v solution, in 0.9% w/v NaCl solution at 20°C. A 4-5% w/v aqueous solution is iso-osmotic with serum. Albumin is freely soluble in dilute salt solutions and water. Aqueous solutions containing 40% w/v albumin can be readily prepared at pH 7.4. The high net charge of the peptide contributes to its solubility in aqueous media. The seven disulfide bridges contribute to its chemical and spatial conformation. At physiological pH, albumin has a net electrostatic charge of about -17.

## How Supplied

- 100 mL vial HSA25% frozen vials.

## Storage

HSA25% is stable for 60 months providing storage temperature -20 °C. Protect from repeated thawing and freezing cycles.

## TOXICOLOGY In animals:

The single dose toxicity testing is of little relevance and does not permit the evaluation of toxic or lethal doses or of a dose-effect relationship. Repeated dose toxicity testing is impracticable due to the development of antibodies to heterologous protein in animal models. To date, human albumin has not been reported to be associated with embryo-fetal toxicity, oncogenic or mutagenic potential. No signs of acute toxicity have been described in animal models

## References


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