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## Plasma Protein Fraction

» Plasma Protein Fraction conforms to the regulations of the federal Food and Drug Administration concerning biologics (640.90 to 640.96) (see [Biologics \(1041\)](#)). It is a sterile preparation of serum albumin and globulin obtained by fractionating material (source blood, plasma, or serum) 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 having protein components of approved composition and sedimentation coefficient content. Not less than 83 percent of its total protein is albumin and not more than 17 percent of its total protein consists of alpha and beta globulins. Not more than 1 percent of its total protein has the electrophoretic properties of gamma globulin. It is a solution containing, in each 100 mL, 5 g of protein, and it contains not less than 94 percent and not more than 106 percent of the labeled amount. It contains no added antimicrobial agent, but it contains sodium acetyltryptophanate with or without sodium caprylate as a stabilizing agent. It has a sodium content of not less than 130 mEq per L and not more than 160 mEq per L and a potassium content of not more than 2 mEq per L. It has a pH between 6.7 and 7.3, measured in a solution diluted to contain 1 percent of protein with 0.15 M sodium chloride. It meets the requirements of the test for heat stability.

**Packaging and storage**—Preserve at the temperature indicated on the label.

**Expiration date**—The minimum expiration date is not later than 5 years after issue from manufacturer's cold storage (5°, 1 year) if labeling recommends storage between 2° and 10°; not later than 3 years after issue from manufacturer's cold storage (5°, 1 year) if labeling recommends storage at temperatures not higher than 30°.

**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 hours after the container is entered. Label it also to state the osmotic equivalent in terms of plasma and the sodium content.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PLASMA PROTEIN FRACTION	<a href="#">Julie Zhang</a> Associate Science & Standards Liaison	BI02 Biologics Monographs 2 - Proteins
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	BI02 Biologics Monographs 2 - Proteins

**Chromatographic Database Information:** [Chromatographic Database](#)

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