§ 640.83 General requirements.

(a) Preservative. The final product shall not contain a preservative.

(b) Storage of bulk solution. After all processing steps have been completed, the sterile bulk solution shall be stored in a manner that will ensure the continued sterility of the product, and at a temperature that shall not exceed the recommended storage temperature of the final product prescribed in §610.53 of this chapter.

[42 FR 27582, May 31, 1977]

§ 640.84 Labeling.

In addition to the labeling requirements of §§610.60, 610.61, and 610.62 of this chapter, the container and package labels shall contain the following information:

(a) The osmotic equivalent in terms of plasma, and the sodium concentration in terms of a value or a range in milliequivalents per liter;

(b) The cautionary statement placed in a prominent position on the label, “Do Not Use if Turbid. Do Not Begin Administration More Than 4 Hours After the Container Has Been Entered.”;

(c) The need for additional fluids when 20 percent or 25 percent albumin is administered to a patient with marked dehydration;

(d) The protein concentration, expressed as a 4 percent, 5 percent, 20 percent, or 25 percent solution.


Subpart I—Plasma Protein Fraction (Human)

SOURCE: 42 FR 27583, May 31, 1977, unless otherwise noted.

§ 640.90 Plasma Protein Fraction (Human).

(a) Proper name and definition. The proper name of the product shall be Plasma Protein Fraction (Human). The product is defined as a sterile solution of protein composed of albumin and globulin, derived from human plasma.

(b) Source material. The source material of Plasma Protein Fraction (Human) shall be plasma recovered from Whole Blood prepared as prescribed in §§640.1 through 640.5, or Source Plasma prepared as prescribed in §§640.60 through 640.76.

(c) Additives in source material. Source material shall not contain an additive unless it is shown that the processing method yields a final product free of the additive to such extent that the continued safety, purity, potency, and effectiveness of the final product will not be adversely affected.


§ 640.91 Processing.

(a) Date of manufacture. The date of manufacture shall be the date of final sterile filtration of a uniform pool of bulk solution.

(b) Processing method. The processing method shall not affect the integrity of the product, and shall have been shown to yield consistently a product which:

(1) After the heating prescribed in paragraph (e) of this section does not show an increase in the components with electrophoretic mobility similar to that of alpha globulin that amounts to more than 5 percent of the total protein.

(2) Contains less than 5 percent protein with a sedimentation coefficient greater than 7.0 S.

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