§ 640.92 Tests on final product.

Tests shall be performed on the final product to determine that it meets the following standards:

(a) Protein concentration. The final product shall be a 5.0 ±0.30 percent solution of protein.

(b) Protein composition. The total protein in the final product shall consist of at least 83 percent albumin, and no more than 17 percent globulins. No more than 1 percent of the total protein shall be gamma globulin. The protein composition shall be determined by a method that has been approved for each manufacturer by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

(c) pH. The pH shall be 7.0 ±0.3 when measured in a solution of the final product diluted to a concentration of 1 percent protein with 0.15 molar sodium chloride.

(d) Sodium concentration. The sodium concentration of the final product shall be 130 to 160 milliequivalents per liter.

(e) Potassium concentration. The potassium concentration of the final product shall not exceed 2 milliequivalents per liter.

(f) Heat stability. A final container sample of Plasma Protein Fraction (Human) shall remain unchanged, as determined by visual inspection, after heating at 57 °C for 50 hours, when compared to its control consisting of a sample, from the same lot, which has not undergone this heating.


§ 640.93 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.


§ 640.94 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.”


Subpart J—Immune Globulin (Human)

§ 640.100 Immune Globulin (Human).

(a) Proper name and definition. The proper name of this product shall be Immune Globulin (Human). The product is defined as a sterile solution containing antibodies derived from human plasma.

(b) Source material. The source material of Immune Globulin (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.
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(c) **Additives in source material.** The source material shall contain no additives other than citrate or acid citrate dextrose anticoagulant solution, unless it is shown that the processing method yields a product free of the additive to such an extent that the safety, purity, and potency of the product will not be affected adversely.


§ 640.104 Potency.

(a) **Antibody levels and tests.** Each lot of final product shall contain at least the minimum levels of antibodies for diphtheria, measles, and for at least one type of poliomyelitis. In the event the final bulk solution is stored at a temperature of \(-10^\circ\)C or lower, Globulin as a solid free from alcohol and containing less than 5 percent moisture shall be stored at a temperature of \(0^\circ\)C or lower.