Subpart D—Plasma

§ 640.30 Plasma.

(a) *Proper name and definition.* The proper name of this component is Plasma. The component is defined as:

(1) The fluid portion of one unit of human blood intended for intravenous use which is collected in a closed system, stabilized against clotting, and separated from the red cells; or

(2) The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems.

(b) *Source.* (1) Plasma shall be obtained by separating plasma from blood collected from blood donors or by plasmapheresis.

(2) Plasma may be obtained from a unit of Whole Blood collected by another licensed establishment.

[42 FR 59878, Nov. 22, 1977; 48 FR 13026, Mar. 29, 1983, as amended at 50 FR 4139, Jan. 29, 1985; 72 FR 45888, Aug. 16, 2007]

§ 640.31 Eligibility of donors.

(a) Whole Blood donors must meet the criteria for donor eligibility prescribed in §§ 630.10 and 630.15 of this chapter.

(b) Collection establishments must determine the eligibility of plasmapheresis donors in accordance with §§ 630.10 and 630.15 of this chapter.

[80 FR 29904, May 22, 2015]

§ 640.32 Collection of source material.

(a) Whole Blood must be collected, transported, and stored as prescribed in § 640.4. When whole blood is intended for Plasma, Fresh Frozen Plasma, and Liquid Plasma, until the plasma is removed, the whole blood must be maintained at a temperature between 1 and 6 °C or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluations and Research. Whole blood intended for Platelet Rich Plasma must be maintained as prescribed in § 640.24 until the plasma is removed. The red blood cells must be placed in storage at a temperature between 1 and 6 °C immediately after the plasma is separated.

(b) Plasma obtained by plasmapheresis shall be collected as prescribed in § 640.64 (except that paragraph (c)(3) of § 640.64 shall not apply), and § 640.65.

[42 FR 59878, Nov. 22, 1977, as amended at 45 FR 27927, Apr. 25, 1980; 50 FR 4139, Jan. 29, 1985; 64 FR 45372, Aug. 19, 1999; 72 FR 45888, Aug. 16, 2007; 80 FR 29905, May 22, 2015]

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in § 610.40 of this chapter and § 640.5 (b) and (c).

(b) Manufacturers of Plasma collected by plasmapheresis shall have testing and recordkeeping responsibilities equivalent to those prescribed in §§ 640.71 and 640.72.

[42 FR 59878, Nov. 22, 1977, as amended at 44 FR 17658, Mar. 23, 1979; 50 FR 4139, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 66 FR 31165, June 11, 2001; 80 FR 29905, May 22, 2015]

§ 640.34 Processing.

(a) *Plasma.* Plasma shall be separated from the red blood cells and shall be stored at −18 °C or colder within 6 hours after transfer to the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system unless the product is to be stored as Liquid Plasma.

(b) *Fresh Frozen Plasma.* Fresh frozen plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma must be separated from the red blood cells or collected by an apheresis procedure, and placed in a freezer within 8 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system, and stored at −18 °C or colder.

(c) *Liquid Plasma.* Liquid Plasma shall be separated from the red blood cells and shall be stored at a temperature of 1 to 6 °C within 4 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.