§ 640.10 Red Blood Cells

(a) One or more segments shall be provided with each unit of Whole Blood or Red Blood Cells when issued or re-issued.

(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

§ 640.11 General requirements.

(a) Storage. Immediately after processing, the Red Blood Cells shall be placed in storage and maintained at a temperature between 1 and 6 °C.

(b) Inspection. The product shall be inspected immediately after separation of the plasma, periodically during storage, and at the time of issue. The product shall not be issued if there is any abnormality in color or physical appearance or if there is any indication of microbial contamination.

§ 640.12 Suitability of donor.

The source blood for Red Blood Cells shall be obtained from a donor who meets the criteria for donor suitability prescribed in §640.3.

§ 640.13 Collection of the blood.

(a) The source blood shall be collected as prescribed in §640.4.

(b) Source blood may also be derived from Whole Blood manufactured in accordance with applicable provisions of this subchapter.

§ 640.14 Testing the blood.

Blood from which Red Blood Cells are prepared shall be tested as prescribed in §610.40 of this chapter and §640.5 (a), (b), and (c).

§ 640.15 Segments for testing.

Segments collected in integral tubing shall meet the following standards:

(a) Segments shall be provided with each unit of Whole Blood or Red Blood Cells when issued or re-issued.

(b) Before they are filled, segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

§ 640.16 Processing.

(a) Separation. Within the timeframe specified in the directions for use for the blood collecting, processing, and storage system used, Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. A portion of the plasma sufficient to insure optimal cell preservation shall be left with the red cells except when a cryoprotective substance or additive solution is added for prolonged storage.

(b) Sterile system. All surfaces that come in contact with the red cells shall be sterile and pyrogen-free.

(c) Final containers. Final containers used for Red Blood Cells shall be the original blood containers unless the method of processing requires a different container. The final container shall meet the requirements for blood containers prescribed in §640.2(c). At the time of filing, if a different container is used, it shall be marked or identified by number or other symbol so as to relate it to the donor of that unit of red cells.

§ 640.17 Modifications for specific products.

Red Blood Cells Frozen: A cryoprotective substance may be added to the Red Blood Cells for extended manufacturers’ storage at −65 °C or colder, provided the manufacturer submits data considered by the Director, Center for Biologics Evaluation and Research, as adequately demonstrating...
through in vivo cell survival and other appropriate tests that the addition of the substance, the materials used and the processing methods results in a final product that meets the required standards of safety, purity, and potency for Red Blood Cells, and that the frozen product will maintain those properties for the prescribed dating period. Section 640.11 (a) and (b) do not apply while a cryophylactic substance is present.

§ 640.24 Processing.

(a) Separation of plasma and platelets and resuspension of the platelets must be in a closed system. Platelets must not be pooled during processing unless the platelets are pooled 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 Evaluation and Research.

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 and 24 °C unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24 °C until it arrives at the processing laboratory where it shall be held between 20 and 24 °C until the platelets are separated.

§ 640.23 Testing the blood.

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

(b) The tests shall be performed on a sample of blood collected at the time of collecting the source blood, and such sample container shall be labeled with the donor’s number before the container is filled.

§ 640.21 Suitability of donors.

(a) Whole blood donors shall meet the criteria for suitability prescribed in §640.3.

(c) Platelethpheresis donors must meet the criteria for suitability as prescribed in §§640.3 and 640.6(c)(6) or as described in an approved biologics license application (BLA) or an approved supplement to a BLA. Informed consent must be obtained as prescribed in §640.61.

§ 640.22 Collection of source material.

(a) Whole blood used as the source of Platelets shall be collected as prescribed in §640.4.

(c) If platelethpheresis is used, the procedure for collection must be as prescribed in §§640.62, 640.64 (except paragraph (c)), and 640.65, or as described in an approved biologics license application (BLA) or an approved supplement to a BLA.

(d) The phlebotomy shall be performed by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor’s tissue.