

Subpart F—Anti-Human Globulin**§ 660.50 Anti-Human Globulin.**

(a) *Proper name and definition.* The proper name of this product shall be Anti-Human Globulin which shall consist of one or more antiglobulin antibodies identified in §660.55(d) and be prepared by a method demonstrated to yield consistently a sterile product.

(b) *Source.* The source of this product shall be either serum from animals immunized with one or more human serum globulins or protein-rich fluids derived from stable immunoglobulin-secreting cell lines maintained either in tissue cultures or in secondary hosts.

[50 FR 5579, Feb. 11, 1985]

EFFECTIVE DATE NOTE: At 65 FR 77499, Dec. 12, 2000, §660.50(a) was amended by removing the words “and be prepared by a method demonstrated to yield consistently a sterile product”, effective June 11, 2001.

§ 660.51 Processing.

(a) *Processing method.* (1) The processing method shall be one that has been shown to yield consistently a specific, potent final product, free of properties that would adversely affect the product for its intended use throughout its dating period.

(2) Anti-IgG, -C3d (polyspecific) reagents and anti-IgG products may be colored green.

(3) Only that material which has been fully processed, thoroughly mixed in a single vessel, and sterile filtered shall constitute a lot. Each lot shall be identified by a lot number.

(4) A lot may be subdivided into clean, sterile vessels. Each subdivision shall constitute a subplot which shall be identified by the lot number to which has been added a distinctive prefix or suffix. If lots are to be subdivided, the manufacturer shall include this information in the license application and on the protocol. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

(b) *Final containers and dropper assemblies.* (1) Final containers and dropper assemblies shall be clean.

(2) Final containers and dropper pipettes shall be colorless and suffi-

ciently transparent to permit observation of the contents for presence of particulate matter or increased turbidity.

(c) *Date of manufacture.* The date of manufacture shall be the date the manufacturer begins the last entire group of potency tests.

(Approved by the Office of Management and Budget under control number 0910-0208)

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985]

EFFECTIVE DATE NOTE: At 65 FR 77499, Dec. 12, 2000, §660.51(a)(3) was amended by removing the word “sterile”; and in paragraph (a)(4) by removing the words “clean, sterile vessels. Each subdivision shall constitute a subplot” and adding in its place the word “sublots”, and in the third sentence by removing the words “and on the protocol”, effective June 11, 2001.

§ 660.52 Reference preparations.

Reference Anti-Human Globulin preparations shall be obtained from the Center for Biologics Evaluation and Research (HFB-221), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, and shall be used as described in the accompanying package insert for determining the potency of Anti-Human Globulin.

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[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11015, Mar. 26, 1990]

§ 660.53 Controls for serological procedures.

Red blood cells sensitized with complement shall be tested with appropriate positive and negative control antisera. All tests shall be performed in accordance with serological testing procedures approved by the Director, Center for Biologics Evaluation and Research (HFB-1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

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