

10138 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Blood Grouping Serum, Anti B, USP, Dried, Equivalent to 5 ml Blood Grouping Serum, Anti A, USP, Dried, Equivalent to 5 ml Blood Grouping Serum, Anti A, B, USP, Dried, Equivalent to 5 ml	Clear, free from particulate matter and sediment Absence of false agglutinins or other reactions Higher Avidity Requirements Tighter Titer requirements Certification by Blood Bank Center, Ft. Knox of final filled container Maximum unrefrigerated shipping time for refrigerated material	To assure that impurities are detected that may arise from production procedures, or from changes in sources of materials, or in the processing of the item. The presence of these impurities is inconsistent with good manufacturing practices. To assure against false positive reactions. To assure a more potent reagent to reduce the possibility of error. Requirement of military medical services which assures that each filling is tested and approved by their professional laboratory. FDA releases bulk lots; not necessarily filling lots. See Explanatory Notes.
Blood Grouping Serum, Anti RH, USP, Equivalent to 5 cc	Clear, free from particulate matter and sediment Absence of false agglutinins or other reactions Higher Avidity Requirements Tighter Titer requirements Certification by Blood Bank Center, Ft. Knox of final filled container Maximum unrefrigerated shipping time for refrigerated material	To assure that impurities are detected that may arise from production procedures, or from changes in sources of materials, or in the processing of the item. The presence of these impurities is inconsistent with good manufacturing practices. To assure against false positive reactions. To assure a more potent reagent to reduce the possibility of error. Requirement of military medical services which assures that each filling is tested and approved by their professional laboratory. FDA releases bulk lots; not necessarily filling lots. See Explanatory Notes.