

10110 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

USP	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Isobutyl Alcohol, NF, 54 gal (206.3 liters) Isopropyl Alcohol, NF, 5 gal (18.92 liters) Isopropyl Alcohol, NF, 1 qt (946 cc) Isopropyl Alcohol, NF, 1 qt (946 cc)	APIA Color	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.
Poliovirus Vaccine, Live, Oral, USP, Types 1, 2, and 3, 10 doses Poliovirus Vaccine, Live, Oral, USP, Types 1, 2 and 3, 100 doses	Classification of Defects	See Explanatory Notes
Prophylone Sodium Phosphate Injection, USP, Equivalent to 20 mg of Prophylone Phosphate per cc, 5 cc	Classification of Defects Color Limits	See Explanatory Notes See Explanatory Notes
Manitol Injection, USP, 15%, 150 cc, 5 cc	Classification of Defects	See Explanatory Notes
Histoplasmin, USP, 0.01 cc	Maximum unrefrigerated shipping times for items requiring refrigerated storage. Dye	See Explanatory Notes This is a skin test and the dye shows the placement of the material.
Protamine Sulfate Injection, USP, 10 mg per cc, Euc, 6s	Classification of Defects Color Limits Leakage Test for Ampuls Max Unrefrigerated Shipping times for items requiring refrigerated storage.	See Explanatory Notes See Explanatory Notes See Explanatory Notes See Explanatory Notes