

10094 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Fluorouracil Injection, USP, 50 mg per cc, 10 cc, 10s	Classification of Defects Shall contain not more than 0.3 mg free fluoride per ml	See Explanatory Notes. To provide tighter limits in order to assure the best production procedures and controls are utilized consistent with good manufacturing practices.
Lactic Acid, USP	Injection shall be colorless to faint yellow Pyrogen Test Leakage Test for Ampuls Free from Sediment	See Explanatory Notes. To assure that pyrogens are not present. See Explanatory Notes. To assure best production procedures and controls are utilized consistent with good manufacturing practices.
Iophendylate Injection, USP, 3 cc, 3s	Classification of Defects Leakage Test for Ampuls	See Explanatory Notes. See Explanatory Notes.
Hydrocortisone Tablets, USP, 20 mg, 100s	Classification of Defects	See Explanatory Notes.
Griseofulvin Tablets, USP, 0.50 Gm, 500s		
Iodized Oil, NF, 20 cc	Classification of Defects	See Explanatory Notes.
Iron Dextran Injection, USP, 10 cc	Classification of Defects	See Explanatory Notes.
Iodochlorhydroxyquin, USP, 1/4 lb (13.4 Gm)	Color and Clarity of Solutions	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.