

10144 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Dienestrol Cream, NF, 0.01%, 2 3/4 oz (78 Gram)	pH Rabbit vaginal irritation test and shall produce no Cornification in vaginal smears of rats (on the formulation)	A pH is specified in order to assure greater stability over the shelf life of the item. To assure that formulation does not cause irritation.
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, NF, Individually Sealed, 100s	Classification of Defects	See Explanatory Notes.
Pralidoxime Chloride, Sterile, USP, 5 Grams	Tighter Assay Limits Classification of Defects Stability test (Accelerated Aging Test) Color test, loss on drying, Elemental Analysis (C, H ₂ , N ₂ Cl ₂ O ₂), Bromide, Iodide, Sulfate, and Neutralization Equivalent. Solubility Time Limit Tighter Weight Variation	More stringent assay limits to assure the best production procedures and controls are utilized, consistent with good manufacturing practices. See Explanatory Notes. To provide tighter limits in order to assure the best production procedures and controls are utilized consistent with good manufacturing practices. See Explanatory Notes. Our requirements assure more uniform quantity within limits and thus proper and uniform dosage.
Sodium Sulfobromophthalein Injection, USP, 50 mg per cc, 3 cc, 10s Sodium Sulfobromophthalein Injection, USP, 50 mg per cc, 7.5 cc, 10s	Classification of Defects Toxicity test Double the current USP Pyrogen test dose Leakage test for ampuls	See Explanatory Notes. To assure that the injection which is given intravenously is non-toxic. Retained the pyrogen test dose of USPXX. See Explanatory Notes.
Methanamine Mandelate Tablets, USP, 0.5 Gram, 1000s	Classification of Defects Bioavailability Test	See Explanatory Notes. Product Suitability.