

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10131

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Tetracycline Hydrochloride for Injection, USP, 0.1 Gram	Classification of Defects Solubility Time Limit Weight Variation	See Explanatory Notes. See Explanatory Notes. The USP monograph and CFR do not specifically require compliance with content uniformity for this item. Our requirement assures uniform quantity within limits and thus proper and uniform dosage.
Tetracycline Hydrochloride for Injection, USP, Intravenous, 0.50 Gram	Classification of Defects Solubility Time Limit Weight Variation	See Explanatory Notes. See Explanatory Notes. The USP monograph and CFR do not specifically require compliance with content uniformity for this item. Our requirement assures uniform quantity within limits and thus proper and uniform dosage.
Tobacurarine Chloride Injection, USP, 5 mg per cc, 10 cc, 6s	Classification of Defects Color Limits Tighter Lower pH Limit Shall be Isotonic Upper Assay Limit	See Explanatory Notes. See Explanatory Notes. To assure greater stability over the shelf life of the item. To prevent hemolysis of red blood cells at the site of the injection.
Vitamin A Capsules, USP, 50,000 USP Units, 100s	Classification of Defects Classification of Defects Classification of Defects Solubility Time Limit	To preclude possibility of use of super-potent material. No upper limit in USP. Fat soluble vitamins are stored in the body. See Explanatory Notes.
Perphenazine Tablets, NF, 5 mg, 500s Cyclophosphamide for Injection, USP, 100 mg, 12s	Classification of Defects Classification of Defects Classification of Defects Solubility Time Limit	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes. See Explanatory Notes.