

10088 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	REMARKS
Chlorpheniramine Maleate Tablets, USP, 4 mg, 1000s	Classification of Defects	See Explanatory Notes.
Atropine Sulfate Injection, USP, 2 mg per cc, 25cc	pH Limits	A tighter pH range is specified in order to assure greater stability over the shelf life of the item.
	Tighter Assay Limits	To assure a tighter manufacturing control since this item contains 2 mg of Atropine Sulfate per cc.
	Color Limits	See Explanatory Notes.
	Classification of Defects	See Explanatory Notes.
Atropine Sulfate Injection, USP, 0.4 mg (1/150 gr) per cc, 20 cc	Color Limits	See Explanatory Notes.
	Classification of Defects	See Explanatory Notes.
Bethanechol Chloride Tablets, USP, 10 mg, 100s	Classification of Defects	See Explanatory Notes.
	Hardness Limits	See Explanatory Notes.
	Moisture Content	To assure the stability of the product, in that excessive moisture may cause deterioration.
	Limits for foreign substances (Heavy Metals), pH and clarity of solution for active ingredient	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.
Aspirin Tablets, USP, 75 mg, 36s	Palatability	See Explanatory Notes.
	Hardness	See Explanatory Notes.
	Classification of Defects	See Explanatory Notes.
Aspirin Split, Aromatic, NF, 1/4 pt	Removal torque for closure on immediate containers	To assure that the active ingredient is not readily lost from the containers.
Chloroquine Hydrochloride Injection, USP	Classification of Defects	See Explanatory Notes.