

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10031

Thioridazine Hydrochloride Tablets USP, 10 mg, 1000's	Disintegration	Allow less time to assure the tablets will disintegrate faster & thus release the active ingredient sooner.
Thioridazine Hydrochloride Tablets, USP, 50 mg, 1000's	Limits for foreign substances (arsenic and heavy metals)	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.
Thioridazine Hydrochloride Tablets, USP, 100 mg, 1000's	Additional Assay	A more specific assay in as much as it is being compared to a reference standard. See Explanatory Notes.
Thioridazine Hydrochloride Tablets, USP, 25 mg, 1000s	Classification of defects	See Explanatory Notes.
Isoproterenol Hydrochloride Inhalation, USP, 1:200 Solution, 10 cc	Color Limits	See Explanatory Notes.
Potassium Permanganate Tablets for Solution, USP, 0.30 Gram, 100s	Accelerated Aging Test (Stability Test)	See Explanatory Notes.
Nitroglycerin Tablets, USP, 0.6 mg, 100s.	Additional assay	This additional assay method was necessary since the fluorometric procedure is more specific for the isoproterenol molecule in that a trihydroxyacrole derivative is formed with intact isoproterenol.
Nitroglycerin Tablets, USP, 0.3 mg, 100s	Solubility Time Limit (Tablets)	To assure that the tablets will dissolve within a reasonable time so that the solution can be used by the patient for external use. See Explanatory Notes.
	Classification of Defects	Specify a tighter time limit of 30 seconds in lieu of 2 minutes.
	Solubility Time Limit (Tablets)	Complaints on regular U.S.P. tablets were received including one from the physician to the Congress of the United States.
	Accelerated Aging Tests	See Explanatory Notes.
	Classification of Defects	See Explanatory Notes.