

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10091

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Erythromycin Tablets, 0.25 Gram, 100s	Classification of Defects	See Explanatory Notes.
Diphenylhydantoin Tablets, USP, 50-mg, 100s	Classification of Defects: Tighter Assay Limits Tighter Assay and Melting Range for Active Ingredient	See Explanatory Notes. To assure a tighter manufacturing control. 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.
Cortisone Acetate Tablets, USP, 25 mg, 40s	Classification of Defects	See Explanatory Notes.
Ethchlorvynol Capsules, NF, 500 mg, 100s	Classification of Defects	See Explanatory Notes.
Emetine Hydrochloride Injection, USP, 65 mg, 1 cc, 6s	Classification of Defects: Leakage Tests for Ampuls	See Explanatory Notes. See Explanatory Notes.
Ethyl Chloride, NF, 100 Grams	Free from Sediment	To assure best production procedures and controls are utilized consistent with good manufacturing practices.
Formaldehyde Solution, USP, 1 qt (946 cc)	Free from Sediment	To assure best production procedures and controls are utilized consistent with good manufacturing practices.
	APHA Color	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.
	Assay Requirement for Methanol	To assure proper quantity of this stabilizer to prevent polymerization.