

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10083

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Quinidine Sulfate Tablets, USP, 0.2 Gm, 100s	Classification of Defects	See Explanatory Notes.
Castor Oil, USP, 1 qt	Free from sediment	To assure best production procedures and controls are utilized consistent with good manufacturing practices.
Gynocholamin Injection, USP, 1000 micrograms per cc, 10 cc	Classification of Defects pH Limits	See Explanatory Notes. To assure greater stability over the shelf life of the item. Not included in USP monograph.
Corticotropin Injection, Repository, USP, 40 units per cc, 5 cc	Classification of Defects Maximum unrefrigerated shipping times for items requiring refrigerated storage.	See Explanatory Notes. See Explanatory Notes.
Colchicine Tablets, USP, 0.65 mg, 100s	Classification of Defects	See Explanatory Notes.
Cephalexin Monohydrate for Oral Suspension	Weight Variation	CFR does not specifically require compliance with weight variation for this item. Our requirement assures uniform weight variation within limits and thus proper and uniform dosage.
Diazepam Injection, NF, 5 mg per cc, 2 cc, 10s	Classification of Defects Leakage Test for Ampuls	See Explanatory Notes. See Explanatory Notes.
Cephalexin Monohydrate Capsules, Equivalent to 0.25 Gram of Cephalexin, 100s	Classification of Defects	See Explanatory Notes.
Cascara Tablets, NF, 0.25 Gm, 100s	Classification of Defects	See Explanatory Notes.