

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10143

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Pilocarpine Hydrochloride Ophthalmic Solution, USP, 1%, 15 cc	Shall contain suitable thickening agents - Viscosity limits specified	To assure contact of the active ingredient with the eye for maintenance of effect.
Pilocarpine Hydrochloride Ophthalmic Solution, USP, 2%, 15 cc	Rabbit eye irritation test	Reduce potential for irritation to the eye.
Pilocarpine Hydrochloride Ophthalmic Solution, USP, 4%, 15 cc	Chlorobutanol shall not be used in the solution	Chlorobutanol tends to break down and make the solution more acidic.
Ampicillin Capsules, USP, 0.25 Gram, 1000s	Classification of Defects	See Explanatory Notes.
Ampicillin Capsules, USP, 0.25 Gram, 100s		
Ampicillin Capsules, USP, 0.50 Gram, 100s		
Ampicillin for Oral Suspension, USP, Equivalent to 5.0 Grams of Ampicillin	Weight Variation	The USP monograph and CFR do not require compliance with content uniformity for this item. Our requirement assures uniform quantity within limits and thus proper and uniform dosage.
Ampicillin for Oral Suspension, USP, Equivalent to 3.75 Grams of Ampicillin		
Ampicillin for Oral Suspension, USP, Equivalent to 7.5 Grams of Ampicillin		
Aspirin Tablets, USP, 0.324 Gram, Individually Sealed, 100s	Classification of Defects Accelerated Aging Test Hardness Moisture content	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes. To assure the stability of the product, in that excessive moisture may cause deterioration.
Codeine Sulfate Tablets, NF, 30 mg, 100s	Classification of Defects	See Explanatory Notes.