

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10085

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Anisophthaline Injection, USP, 25 mg per cc, 10 cc	Color Limits Leakage Tests for Ampuls Classification of Defects	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes.
Benzalkonium Chloride Solution, USP, 10%, 4 fl oz (118 cc)	Benzalkonium Chloride, USP, is not available to manufacture this monographed item. Therefore Defense Medical Purchase Description delineates tests and requirements for a Benzalkonium Chloride concentrate for use in manufacture of 10% solution. The USP monograph for the solution requires limited tests since it is assumed USP Benzalkonium Chloride will be used.	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
Acetazolamide Tablets, USP, 250 mg, 100s	Classification of Defects	See Explanatory Notes.
Cortisone Acetate Suspension, Sterile, USP, 25 mg per cc, 20 cc	Classification of Defects Shall be isotonic	See Explanatory Notes. To assure less irritation upon instillation into the eye.
Collodion, Flexible, USP, 1 fl oz (29.5 cc)	Classification of Defects	See Explanatory Notes.
Atropine Sulfate Ophthalmic Solution, USP, 1%, 15 cc	Tighter pH Isotonic	A tighter pH range is specified in order to afford greater stability over the shelf life of the item. To assure less irritation upon instillation into the eye.
	Rabbit Eye Irritation Test	To reduce the potential for irritation to the eye.
Gals-proxamide Tablets, USP, 0.25 Gram, 250s	Classification of Defects	See Explanatory Notes.
Clofibrate Capsules, NF, 500 mg, 100s	Classification of Defects	See Explanatory Notes.