

10134 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Water, Purified, USP, Distilled, 1500 cc, 6s	Color Limits Sterility and Pyrogenicity	See Explanatory Notes. To assure proper requirements for a solution used as irrigating fluid.
Phenylephrine Hydrochloride Solution, USP, 1%, 1 pt	Free from particulation and sediment	To assure that impurities are detected that may arise from production pro- cedures, 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.
	Color Limits Tighter assay limits	See Explanatory Notes. To assure a tighter manufacturing control.
	Minimum limit for the quantity of preser- vative at time of delivery	To assure at least a minimum quantity of preservative will be present for stability of product.
	Formula specified	Obtained from R & D study to prevent ready deterioration.
Cholera Vaccine, USP, 20 cc	Classification of Defects Limit on Blood Group A and B Substances. Maximum unrefrigerated shipment time for refrigerated item	See Explanatory Notes. To avoid unwanted blood specific substances. See Explanatory Notes.
Undecylenic Acid Ointment, Compound, NF, 28.35 Gram	Leakage for tubes Stability Iodine number	To assure that the tubes of ointments do not leak. To assure that the ointment will be usable after freezing and heating. To assure that the correct amount of double bonds are in the compound.