

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10095

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Kaolin Mixture with Pectin, NF, 1 gal (3.78 liters)	Kaolin Sieve Size	Aids in maintaining suspension and ease of resuspension.
Lidocaine Ointment, USP, 5%, 35 Gram	Color Limits pH Limits	See Explanatory Notes. To assure greater stability over the shelf life of the item. Not included in USP monograph.
	Classification of Defects Leakage Test	See Explanatory Notes. To assure that the tubes of ointment do not leak.
Racitracin Ointment, USP, 500 Units per Gram, 1/2 oz (14.2 Grams) 12s	Upper Assay Limit	To preclude possibility of use of super-potent material. No upper assay limit given in regulations.
	Leakage Test	To assure that tubes of ointment do not leak.
Furosemide Tablets, USP, 40 mg, 100s	Disintegration	To allow less time to assure the tablets are disintegrated faster and thus release the active ingredient sooner. See Explanatory Notes.
	Classification of Defects Hardness Limits Color of solution, limits for chloride and sulfate, and Percent of Furosemide breakdown for active ingredient	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.