

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10097

NAME	ADDITIONAL REQUIREMENT	SIGNIFICANCE
Betamethasone Valerate Cream, NF, Equivalent to 0.1% of Betamethasone, 45 Grams Betamethasone Valerate Cream, NF, Equivalent to 0.1% of Betamethasone, 15 Grams	pH Microbial Limits Leakage Test	A pH range is not given in NF, thus a pH range is specified to assure greater stability over the shelf life of the item. Bacteria limits to control the amount of viable microorganisms and to prohibit those organisms that should not be present in the product. This assures that undesirable contamination is not present in the product. To assure that the tubes of cream do not leak.
Glucocoyl Suppositories, NF, 10 mg, 50s	Weight of Suppository Drip point and melting time for suppositories	To assure uniformity in weights of suppositories. Not included in NF monograph. To assure that the suppositories are made with a base which will melt within a specified time frame to release its medication. No such requirement exists in the compendia.
Glucethidone Sulfate Tablets, USP, 25 mg, 100s Glucethidone Sulfate Tablets, USP, 10 mg, 100s Glucethidone Sulfate Tablets, USP, 15 mg, 1000s	Hardness Limits Limit for Foreign Substance and Melting Range for Active Ingredient	To assure greater stability over the shelf life of the item. Not included in NF monograph.
Primidone Phosphate Tablets, USP, 25.5 mg, 150s	Classification of Defects	See Explanatory Notes. To assure that impurities are detected that may arise from production procedures, or from changes in sources of materials, or in processing of the item. The presence of these impurities is inconsistent with good manufacturing practices.
		See Explanatory Notes.