

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10119

NAME	ADDITIONAL REQUIREMENTS	SYNOPSIS
Potassium Phenoxymethyl Penicillin Tablets, USP, 400,000 Units, Individually Sealed, 100s Potassium Phenoxymethyl Penicillin Tablets, USP, 800,000 Units, Individually Sealed, 100s	Classification of Defects Accelerated Aging Test Tighter lower limit for assay and an upper assay limit	See Explanatory Notes. The tighter lower limit for assay assures the best production procedures and controls are utilized and the restricted upper limit will preclude possibility of use of superpotent material. No upper assay limit given in regulations.
Propunethine Bromide, Sterile, USP, 30 mg, 25s	Classification of Defects Solubility Time Limit Ultraviolet and infrared identity active ingredient	See Explanatory Notes. See Explanatory Notes. A more definitive identification for the active ingredient.
Propoxyphene Hydrochloride Capsules, USP, 65 mg, 500s Propoxyphene Hydrochloride Capsules, USP, 65 mg, Individually Sealed, 100s Venbol, USP, 1 oz (28.35 Gram)	Classification of Defects Levorotatory	See Explanatory Notes. The Synthetic levorotatory form is subjected to more purification to eliminate stereoisomers which may possibly differ in pharmacological action.
Vysstatin Ointment, USP, 30 Grams	Leakage Test	To assure that the tubes of ointment do not leak.
Sodium Pentobarbital Capsules, USP, 100 mg, Individually Sealed, 25s Sodium Lactate Injection, USP, 1/6 molar, 1000 cc, 6s	Classification of Defects Classification of Defects	See Explanatory Notes. See Explanatory Notes.
Nocetyl Calcium Sulfosuccinate Capsules, USP, 100 mg, Individually Sealed, 100s	Classification of Defects Leakage Test	See Explanatory Notes. To assure that the liquid fill does not leak