

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10123

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Phenobarbital Tablets, USP, 0.4 Gram, 500s	Limits for Foreign Substances (chloride test, Residue on Ignition) 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.
Sodium Ethacrynic Acid for Injection, USP, Lycopodium Equivalent to 50 mg of Ethacrynic Acid	Accelerated Aging Test Classification of Defects	See Explanatory Notes See Explanatory Notes
Sodium Oxacillin Capsules, USP, Equivalent to 0.5 Gram of Oxacillin in each Capsule, 100s	Classification of Defects Solubility Time Limit	See Explanatory Notes See Explanatory Notes
Proparheline Bromide Tablets, USP, 15 mg, 100s Proparheline Bromide Tablets, USP, 15 mg, 1000s	Classification of Defects Accelerated Aging Test Limits for foreign impurities (Completeness of solution and Infrared spectrum) for active ingredient	See Explanatory Notes See Explanatory Notes 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.