

10096 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

SUBSTANCE	ADDITIONAL INFORMATION	EXPLANATORY NOTES
Estroval Tablets, USP 1 mg. Estradiol and 0.025 mg. Ethinyl Estradiol Tablets, USP, 100's	Classification of Defects Color of Tablets	See Explanatory Notes. In order to differentiate tablets taken in beginning of cycle with those to be taken toward end of dosage cycle.
Oral Tablets, USP, 1 mg. 1000's 0.025 mg. 100's	Classification of Defects Loss on Drying	See Explanatory Notes. To assure the stability of the product, in that excessive moisture may cause deterioration.
Hydrochloride Tablets, USP, 25 mg. 100's	Accelerated Aging Test (Stability)	See Explanatory Notes.
Hydrochloride Tablets, 25 mg. 100's	Weight Variation	As an added check to assure proper manufacture of this tablet which consists of a core which is then coated with dry ingredients and compressed.
Sodium Sulfosuccinate Solution, USP, 1%, 50 cc	Classification of Defects Limits for Foreign Substances (Arsenic) for Active Ingredient	See Explanatory Notes. To assure that impurities are detected that may arise from production procedures, or in from changes in sources of materials, or in the processing of the item. The presence of these impurities is inconsistent with good manufacturing practices.