

# COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10093

| NAME                                                 | ADDITIONAL REQUIREMENTS                                                                  | SIGNIFICANCE                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diphenhydramine Tablets, USP, 0.0 mg, 100s           | Classification of Defects<br>Color                                                       | See Explanatory Notes.<br>The color pink for this dosage is important to differentiate it from another dosage size.                                                                                                                                                                                  |
| Haloperidol Tablets, NF, 2 mg, 1000s                 | Classification of Defects<br>Hardness<br>Thin Layer Chromatography for Active Ingredient | See Explanatory Notes.<br>See Explanatory Notes.<br>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. |
| Cyclopentolate Tablets, NF, 1 mg, 100s               | Classification of Defects<br>Hardness                                                    | See Explanatory Notes.<br>See Explanatory Notes.                                                                                                                                                                                                                                                     |
| Fluorouracil Ointment, NF, 0.05%, 15 Gram            | Classification of Defects                                                                | See Explanatory Notes.                                                                                                                                                                                                                                                                               |
| Cleavitamin A and B Capsules, NF, 100s               | Leakage Test<br>Upper assay limits<br>Classification of Defects                          | To assure that the tubes of ointment do not leak.<br>To preclude possibility of use of superpotent material.<br>See Explanatory Notes                                                                                                                                                                |
| Scalpa Benzene Hexachloride Cream, USP, 1%, 50 Grams | Leakage Test                                                                             | To assure that the tubes of cream do not leak.                                                                                                                                                                                                                                                       |