

# 10090 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

| NAME                                                                                                                                                                                                    | ADDITIONAL REQUIREMENTS                                                                         | SIGNIFICANCE                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Histamine Phosphate Injection, USP,<br>1 mg, 1 cc, 6s                                                                                                                                                   | Classification of Defects<br>Leakage Test for Ampuls<br>Color Limits                            | See Explanatory Notes.<br>See Explanatory Notes.<br>See Explanatory Notes.                                                                                                                                                                                                                  |
| Flurandrenolide Cream, NF, 0.05%,<br>225 Grams<br>Flurandrenolide Cream, NF, 0.05%,<br>15 Grams<br>Flurandrenolide Cream, NF, 0.025%,<br>50 Grams                                                       | Classification of Defects<br>Leakage Test                                                       | See Explanatory Notes.<br>To assure that the containers of cream<br>do not leak.                                                                                                                                                                                                            |
| Dioctyl Calcium Sulfosuccinate<br>Capsules, NF, 0.24 Gram, 100s<br>Dioctyl Calcium Sulfosuccinate<br>Capsules, NF, 0.24 Gram, 1000s<br>Dioctyl Calcium Sulfosuccinate<br>Capsules, NF, 0.24 Gram, 5000s | Classification of Defects<br>Leakage Test                                                       | See Explanatory Notes.<br>To assure that the liquid fill does not<br>leak.                                                                                                                                                                                                                  |
| Dioctyl Sodium Sulfosuccinate<br>Capsules, USP, 100 mg, 1000s                                                                                                                                           | Classification of Defects<br>Limits for foreign substance (arsenic) in the<br>active ingredient | See Explanatory Notes.<br>To assure that impurities are detected that<br>may arise from production procedures, or<br>from changes in sources of materials, or<br>in the processing of the item. The<br>presence of these impurities is inconsis-<br>tent with good manufacturing practices. |
| Doxapram Hydrochloride Injection,<br>NF, 20 mg per cc, 20 cc                                                                                                                                            | Classification of Defects                                                                       | See Explanatory Notes.                                                                                                                                                                                                                                                                      |
| Digoxin Elixir, USP, 0.05 mg/cc, 60 cc                                                                                                                                                                  | Free from sediment                                                                              | To assure the best production procedures<br>and controls are utilized consistent with<br>good manufacturing practices.                                                                                                                                                                      |