

# COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10099

| NAME                                                                                                      | ADDITIONAL REQUIREMENTS                                                                                                                                                                                                                                                                        | SIGNIFICANCE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ascorbic Acid Tablets, USP, 0.5 Gram, Classification of Defects                                           | Classification of Defects                                                                                                                                                                                                                                                                      | See Explanatory Notes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Methycysteine Maleate Tablets, NF, 2 mg; 560s                                                             | Classification of Defects                                                                                                                                                                                                                                                                      | See Explanatory Notes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Globulin, Immune Serum, USP, (Human), 10 cc                                                               | Classification of Defects<br>Maximum unrefrigerated shipping times for items requiring refrigerated storage<br>No albumin or fibrinogen shall be permitted in the finished product.<br><br>Derived from Venous Blood Only<br><br>Clear and Free of Turbidity, Sediment, and Particulate Matter | See Explanatory Notes.<br>See Explanatory Notes.<br><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.<br>To avoid unwanted blood specific substances which are present in placental blood.<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.<br><br>See Explanatory Notes. |
| Dextrose and Sodium Chloride Injection, USP, 5% Dextrose in 0.9% Solution of Sodium Chloride, 1000 cc, 6s | Classification of Defects                                                                                                                                                                                                                                                                      | See Explanatory Notes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Sodium Chloride Injection, USP, 5 cc, 25s                                                                 | Classification of Defects<br>Leakage Test for Ampuls<br>Color Limits                                                                                                                                                                                                                           | See Explanatory Notes.<br>See Explanatory Notes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |