

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10127

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Sulfadiazine tablets, USP, 0.5 Gram, 1000s	Classification of Defects Limits for foreign substances (color, chloride and sulfate) for active ingredient	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.
Triamcinolone Diacetate Suspension, Sterile, NF, 40 mg per cc, 5 cc	Classification of Defects Particle size of Triamcinolone Raw Material	See Explanatory Notes. This requirement was added to control the particle size of the active ingredient in the long acting parenteral suspension. Particle size is related to the release rate. This requirement is not covered by the NF monograph. To assure that pyrogens are not present.
Tolbutamide Tablets, USP, 0.5 Gram, 200s	Pyrogen test Classification of Defects	See Explanatory Notes.
Tolazamide Tablets, USP, 250 mg, 100 1000s	Classification of Defects Moisture	See Explanatory Notes. To assure the stability of the product, in that excessive moisture may cause deterioration.
Thimerosal Solution, NF, 1 pt (473 cc)	Color limits	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.