

10142 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Scopolamine Hydrobromide Injection, USP, 0.5 mg, 1 cc, 12s	Classification of Defects Leakage Test for Ampuls Color Limits Safety Test (mouse test)	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes. To assure the material is non-toxic.
Sulfisoxazole Tablets, USP, 0.5 Gram, 1000s	Classification of Defects IR identity of Active Ingredient in tablets- compared to USP standard Moisture X-Ray Diffraction Limits of foreign substances (Color of 10% solution, Chlorine NMT 100 PPM)	See Explanatory Notes. To assure that impurities are detected that may arise from production pro- cedures, or from changes in sources of materials, or in the processing of the item. The presence of these impur- ities is inconsistent with good manufacturing practices. To assure the stability of the product, in that excessive moisture may cause deterioration. Insures that the particle size of the active ingredient in the finished tablet is optimal. To assure that impurities are detected that may arise from production pro- cedures, or from changes in sources of materials, or in the processing of the item. The presence of these impur- ities is inconsistent with good manufacturing practices.
Soda Lime, USP, 2 1/2 lb (1.13 Kg)	Tighter Moisture Tighter Hardness	To assure optimum moisture at time of use. This item is in a canister for use in the field.
Soda Lime, USP, 5 lb (2.27 Kg)	Tighter Moisture	To assure optimum moisture at time of use.