| NAME | ADDITIONAL REQUIREMENTS | SIGNIFICANCE |
|---|---|---|
| Phenylephrine Hydrochloride Solution, USP, 0.25%, 15 cc | Free from particulation and sediment | 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. See Explanatory Notes. |
| | Color Limits<br>Bulk Solution shall have an adjusted pH and finished solution shall fall within specific pH limits | The USP monograph does not specifically require compliance with pH for this item. Our P.D. specifies a pH range in order to afford greater patient acceptance in pediatric use (Professional requirement). |
| | Tighter Assay Limits | To assure a tighter manufacturing control. |
| | Minimum limit for the quantity of preservative at time of delivery. | To assure at least a minimum quantity of preservative will be present for stability of product. |
| Meglumine Iodipamide Injection, USP, 52%, 20 cc | Classification of Defects | See Explanatory Notes. |
| Nitrofurantoin Oral Suspension, USP, 5 mg per cc, 16 fl oz (473) | Classification of Defects | See Explanatory Notes. |
| Antigen, Lymphogranuloma Venereum, USP, 1 cc | Each lot must be checked against known cases of Lymphogranuloma Venereum, and yield a positive skin response. | To assure that the antigen is specific for its intended use. |
| | Maximum unrefrigerated shipping time for refrigerated items. | See Explanatory Notes. |