

10098 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Bibacetylhydrazine Hydrochloride Injection, USP, 50 mg per cc, 10 cc Biphenhydramine Hydrochloride Injection, USP, 10 mg per cc, 10 cc	Color limits Classification of Defects	See Explanatory Notes. See Explanatory Notes.
Magnesium Sulfate Injection, USP, 50%, 2 cc, 12s	Classification of Defects Leakage Test for Ampuls Color limits	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes.
Scopolamine Tincture, USP, 1 pt (473 cc)	Free from sediment	To assure the best production procedures and controls are utilized consistent with good manufacturing practice.
Procaine Hydrochloride, Sterile, USP, 100 mg, 10s	Leakage Test for Ampuls	See Explanatory Notes.
	Classification of Defects Solubility Time Limit Autoclave Test	See Explanatory Notes. To assure the suitability of the product to withstand autoclaving.
Ephedrine Sulfate Injection, USP, 25 mg, 1 cc, 12s	Classification of Defects Leakage Test for Ampuls Color limits	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes.