

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10139

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Chlordiazepoxide Hydrochloride Capsules, USP, 10 mg, 500s Chlordiazepoxide Hydrochloride Capsules, USP, 5 mg, 500s Chlordiazepoxide Hydrochloride Capsules, USP, 25 mg, 500s	Classification of Defects More Stringent limits of Impurities (Total lactam content)	See Explanatory Notes. To provide tighter limits in order to assure the best production procedures and controls are utilized consistent with good manufacturing practices.
Succinylcholine Chloride, Sterile, USP, 1 Gram Succinylcholine Chloride, Sterile, USP, 0.5 Gram	Classification of Defects Solubility time limit Nitrogen Content Acute Toxicity	See Explanatory Notes. See Explanatory Notes. An additional indirect assay and identity test. To assure the product is non-toxic.
Succinylcholine Chloride Injection, USP, 20 mg per cc, 10 cc, 6s	Classification of Defects Color Limits Shall be isotonic Nitrogen Content Acute toxicity Maximum unrefrigerated shipping time for item items requiring refrigerated storage. Additional tests for active ingredient (Nitrogen content, acute toxicity)	See Explanatory Notes. See Explanatory Notes. To prevent hemolysis of red blood cells at site of the injection. As an additional indirect test for identity and assay. To assure the product is non-toxic. See Explanatory Notes. An additional assay and to assure the active ingredient is non-toxic.
Chlordiazepoxide Hydrochloride, Sterile, USP, 100 mg, 10s	Classification of Defects Leakage tests for ampuls Color Limits Maximum unrefrigerated shipping times for items requiring refrigerated storage	See Explanatory Notes. See Explanatory Notes. See Explanatory Notes. See Explanatory Notes.