ITEM	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Epinephrine Suspension, Sterile, USP, 1:500, 1 cc, 12s	Classification of Defects	See Explanatory Notes.
	Leakage Test for Ampuls	See Explanatory Notes.
Epinephrine Injection, USP, 1:1000, 1 cc, 25s	Classification of Defects	See Explanatory Notes.
	Color Limits	See Explanatory Notes.
	Clarity of Solution	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.
	Leakage Tests for Ampuls	See Explanatory Notes.
Ergotamine Tartrate and Caffeine Tablets, USP, 100s	Classification of Defects	See Explanatory Notes.
	Tighter Assay Limits	To provide tighter limits in order to assure the best production procedures and controls are utilized consistent with good manufacturing practices.
	Limit for Alkaloid Isomer	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.
	Tighter Disintegration	To allow less time to assure the tablets are disintegrated faster and thus release the active ingredient sooner.
	Accelerated Aging Test	See Explanatory Notes.
	One-Year Storage Test	To assure that tablets conform to all the requirements for one year after the date of delivery to the Government.
	Dissolution Test	To assure the proper release of the active ingredient. Complaint history.