

10140 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NAME	ADDITIONAL REQUIREMENTS	SIGNIFICANCE
Xylometazoline Hydrochloride Solution, NF, 0.1%, 15 cc	Isotonic	To prevent irritation to the nasal membranes. See Explanatory Notes. A pH range is not given in NF, thus a pH range is specified to assure greater stability over the shelf life of the item. Bacteria limits to control the amount of viable microorganisms and to prohibit those organisms that should not be present in the product: This assures that undesirable contamination is not present in the product. To provide tighter limits in order to assure the best production procedures and controls are utilized consistent with good manufacturing practices.
	Color limit pH	
	Bacterial count	
	Additional requirements of active ingredient more stringent limits of impurities (arsenic)	
Xylometazoline Hydrochloride Solution, NF, 0.1%, 1 pt (473 cc)	Isotonic	To prevent irritation to the nasal membranes. See Explanatory Notes. A pH range is not given in NF, thus a pH range is specified to assure greater solubility over the shelf life of this item. Bacteria limits to control the amount of viable microorganisms and to prohibit those organisms that should not be present in the product: This assures that undesirable contamination is not present in the product. To provide tighter limits in order to assure the best production procedures and controls are utilized consistent with good manufacturing practices.
	Color limit pH	
	Bacterial Count	
	Additional requirements of active ingredient more stringent limits of impurities (arsenic)	