Quality specification of RUE "Belmedpreparaty" on API

Verapamil hydrochloride

Manufacturer:
Piramal Enterprises Limited, India

No.	Items	Requirements of in-house technical documentation of the Republic of Belarus
1.	Description	White or almost white crystalline powder. Soluble in water P, freely soluble in methanol P, moderately soluble in 96% ethanol P. Melts by temperature near 144 ^{o}C
2.	Identification	B. The IR spectrum should correspond to the IR spectrum of the verapamil hydrochloride standard (EP CRS). D. Characteristic reaction (b) for chlorides.
3.	Clarity of solution	Solution S should be clear
4.	Color of solution	Solution S should be colorless
5.	pH	4,5 – 6,0
6.	Specific optical rotation	From -0,10^{o} till +0,10^{o}
7.	Related substances: - any impurity - total impurities	 Not more than 0,1% Not more than 0,3%
8.	Heavy metals	Not more than 10 ppm
9.	Loss on drying	Not more than 0,5%
10.	Sulfated ash	Not more than 0,1%
11.	Residual solvents: - toluene - methanol - ethyl acetate - isopropyl alcohol - acetone	 Not more than 890 ppm Not more than 3000 ppm Not more than 5000 ppm Not more than 5000 ppm Not more than 5000 ppm
12.	Microbiological purity: *For manufacturing of non-sterile finished dosages* - Total count of aerobes in 1 gr - Total count of fungus in 1 gr - Escherichia coli in 1 gr *For manufacturing of sterile finished dosages* - Total count of aerobes and fungus in 1 gr - gram-negative bacteria tolerant to bile, or bacteria of the family Enterobacteriaceae in 1 gr - Pseudomonas aeruginosa in 1 gr - Staphylococcus aureus in	 10^3 CFU 10^2 CFU absence 10^2 CFU absence absence absence

	1 gr	
13.	Assay	Not less than 99,0% and not more than 101,0% (calculated on dry basis)
14.	Storage conditions	In the protected from light place
15.	Shelf life	5 years

*Tests are made in case API is used for the production of sterile finished dosages.