Quality specification of RUE “Belmedpreparaty” on API

Rimantadine hydrochloride

Manufacturer:
Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd., China

No.	Items	Requirements of in-house technical documentation of the Republic of Belarus
1.	Description	White crystalline powder. Freely soluble in methanol P, soluble in 96% ethanol P and water P.
2.	Identification	A. IR-spectrum of the tested API should comply with IR-spectrum of rimantadine hydrochloride reference standard (Sigma) B. The principal spot on the chromatogram of the tested solution (b) should be similar on location, color and dimension with the spot on chromatogram of the standard sample solution (a) C. Typical reaction (a) on chlorides
3.	Clarity of solution	Solution should be clear
4.	Color of solution	Color of solution should be not more intense than reference standards Y (Ж)$_7$
5.	pH	4,5 – 6,5
6.	Sulfated ash	Not more than 0,1%
7.	Heavy metals	Not more than 10 ppm
8.	Sulfates	Not more than 0,05%
9.	Ammonium salt	Not more than 0,08%
10.	Loss on drying	Not more than 0,5%
11.	Related substances	Not more than 1,0%
12.	Residual solvents: - butyl acetate - ethanol - toluene	 Not more than 5000 ppm Not more than 5000 ppm Not more than 890 ppm
13.	Microbiological purity: - Total count of aerobes in 1 gr - Total count of fungus in 1 gr - Escherichia coli in 1 gr	 10^3 CFU 10^2 CFU absence
14.	Assay	Not less than 99,0% and not more than 101,0% (calculated on dry basis)
15.	Storage conditions	Under temperature not higher than 25 ^oC
16.	Shelf life	5 years