Quality specification of RUE “Belmedpreparaty” on API

Ketotifen fumarate

Manufacturer:
Laboratori Alchemia S.r.l., Italy

No.	Items	Requirements of in-house technical documentation of the Republic of Belarus
1.	Description	Cryptocrystalline powder from white to brownish-yellow color. Moderately soluble in water P, lightly soluble in methanol P, very lightly soluble in heptane P.
2.	Identification	A. IR-spectrum of the tested API should comply with IR-spectrum of ketotifen hydrofumarate reference standard (EP CRS).
3.	Clarity of solution	Solution should be clear
4.	Color of solution	Color of solution should be not more intense than reference standards Y $(Ж)_4$, BY $(КЖ)_4$ or B $(К)_4$
5.	Loss on drying	Not more than 0,5%
6.	Sulfated ash	Not more than 0,1%
7.	pH	From 2,5 to 4,0
8.	Heavy metals	Not more than 10 ppm
9.	Related substances: - impurity A - impurity G - unspecified impurities - total impurities	 Not more than 0,2% Not more than 0,15% Not more than 0,10% Not more than 0,3%
10.	Residual solvents: - methanol	 Not more than 3000 ppm
11.	Microbiological purity: - Total count of aerobes - Total count of fungus - Escherichia coli in 1 gr	 10^3 CFU/g 10^2 CFU/g Absence (in 1g)
12.	Assay	Not less than 98,5% and not more than 101,0% (calculated on dry basis)
13.	Storage conditions	In the sealed container, in the protected from moisture and light place, under temperature not higher than 25 ^oC
14.	Shelf life	5 years