

Quality specification of RUE “Belmedpreparaty” on API Levofloxacin hemihydrate (tablet grade)

Manufacturer:

Zhejiang Starry Pharmaceutical Co. Ltd., China

No.	Items	Requirements of in-house technical documentation of the Republic of Belarus
1.	Description	Light yellow crystalline powder. Soluble in Dimethylsulfoxide P and acetic acid, moderately soluble in Water P, methanol P, acetone P, practically insoluble in glycerin P and n-octanol P.
2.	Identification	A. IR-spectrum of the test substance should correspond to the IR spectrum of the levofloxacin standard (USP RS) shown in pic.1 B. LC on the chromatogram of the test solution, the retention time of the main peak should correspond to the retention time of the main peak on the chromatogram of the reference solution
3.	Clarity of solution	Solution should be not more intense than standard I
4.	Color of solution	Optical density of solution by wavelength 450 nm should be not more than 0,25
5.	Water	2,0% – 3,0%
6.	Specific optical rotation	-92° – -106° (calculated on anhydrous basis)
7.	Sulfated ash	Not more than 0,2%
8.	Heavy metals	Not more than 10 ppm
9.	Related substances: - impurity A - impurity B - impurity C - impurity D - impurity E - any unspecified impurity - total impurities	Not more than 0,3% Not more than 0,3% Not more than 0,3% Not more than 0,3% Not more than 0,8% Not more than 0,1% Not more than 0,5%
10.	Residual solvents: - methanol - ethanol - chloroform	Not more than 1000 ppm Not more than 3000 ppm Not more than 60 ppm
11.	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
13.	Assay	Not less than 98,0% and not more than 102,0% (calculated on anhydrous basis)
14.	Storage conditions	In the protected from light and moisture place, under temperature not higher than 25 °C
15.	Shelf life	3 years