Quality specification of RUE "Belmedpreparaty" on API
Docetaxel

Manufacturer:
Shanghai Jinhe Bio-Pharmaceutical Co. Ltd., China

No.	Items	Requirements of in-house technical documentation of the Republic of Belarus
1.	Description	White or almost white crystalline powder Practically insoluble in water P, freely soluble in ethanol P, soluble in methylene chloride P
2.	Identification	A. Tested API should comply with requirements on the test "Specific optical rotation" B. IR- spectrum of the tested API should correspond to IR-spectrum of docetaxel trihydrate standard sample (EP CRS)
3.	Clarity of solution	Solution of 1,0 gr of the tested API shouldn't be more intense than reference sample II
4.	Color of solution	Color of solution S shouldn't be more intense than color of reference sample $B(K)_5$
5.	Specific optical rotation	From -41,5 till -38,5 ^{o} (calculated on anhydrous basis)
6.	Related substances: - impurity B - impurity A - impurity C - impurity E - unspecified impurities - total impurities	 Not more than 0,3% Not more than 0,2% Not more than 0,15% Not more than 0,15% Not more than 0,10% Not more than 0,8%
7.	Water	Not more than 1,5%
8.	Residual solvents: - methylene chloride - acetone - ethyl acetate - cyclohexane - methanol - pyridine - toluene - petroleum ether	 Not more than 200 ppm Not more than 5000 ppm Not more than 800 ppm Not more than 3880 ppm Not more than 500 ppm Not more than 200 ppm Not more than 200 ppm Not more than 500 ppm
9.	Heavy metals	Not more than 20 ppm
10.	Sulfated ash	Not more than 0,1%
11.	Bacterial endotoxins	Less than 0,3 EU/mg
12.	Microbiological purity: - Total count of aerobes and fungus in 1 gr - Enterobacteriaceae in 1 gr - Pseudomonas aeruginosa in 1 gr - Staphylococcus aureus in 1 gr	 Not more than 10^2 CFU absence absence absence
13.	Assay	Not less than 97,5% 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 ^{o}C
15.	Shelf life	2 years