Quality specification of RUE "Belmedpreparaty" for the **Atorvastatin Calcium (Atorvastatin Calcium Trihydrate)** API

Manufacturer:
Alcon Biosciences Private Limited, India

No.	Items	Requirements of in-house technical documentation of the Republic of Belarus
1.	Description	White or almost white powder. Very slightly soluble in water P, slightly soluble in 96% ethanol P, practically insoluble in methylene chloride P. Polymorphic
2.	Identification	A. IR-spectrum of the tested API should correspond to IR-spectrum of the Atorvastatin Calcium Trihydrate standard sample (EP CRS) B. Tested sample should meet the requirements for "Enantiomeric purity" test C. Tested sample should meet the requirements for "Water" test D. Typical reaction (b) to Calcium E. Possesses polymorphism (Form I) The X-ray diffraction pattern of the test sample should correspond to a typical X-ray pattern of Atorvastatin Calcium Trihydrate (Form I) is presented in fig.2
3.	Enantiomeric purity - impurity E	 NMT 0.3%
4.	Related substances: - Impurity A - Impurity B - Impurity C - Impurity D - Unspecified impurities - Total impurities	 NMT 0.3% NMT 0.3% NMT 0.15% NMT 0.15% NMT 0.10% NMT 1.5%
5.	Sodium	NMT 0.4% (calculated on anhydrous basis)
6.	Water	3.5% - 5.5%
7.	Residual solvents: - Methanol - Tret-butyl methyl ether - Tetrahydrofuran - Methylene chloride - Acetone	 NMT 3000 ppm NMT 1200 ppm NMT 720 ppm NMT 600 ppm NMT 5000 ppm
8.	Microbiological purity: - Total count of aerobes, TAMC per 1 g - Total combined yeasts and moulds count, TYMC per 1 g - Escherichia coli per 1 g	 10^3 CFU 10^2 CFU Absence
9.	Assay	NLT 97.0% and NMT 102.0% (calculated on anhydrous basis)
10.	Storage conditions	In air-tight container protected from light at a temperature below 25°C
11.	Shelf life	4 years