Quality specification of RUE “Belmedpreparaty” on API

# Atorvastatim calcium

**Manufacturer:**
***Zhejiang Lepu Pharmaceutical Co. Ltd., China***

| No. | Items | Requirements of in-house technical documentation of the Republic of Belarus |
|---|---|---|
| 1. | Description | White or almost white powder. Very lightly soluble in water P, lightly soluble in 96% ethanol P, practically insoluble in methylene chloride P.<br>Polymorphic |
| 3. | Identification | A. IR- spectrum of the tested API should correspond to IR-spectrum of atorvastatin calcium standard sample (EP CRS)<br>B. Tested sample should meet the requirements on “Enantiomeric purity”<br>D. Typical reaction (b) on calcium |
| 4. | Enantiomeric purity<br>- impurity E | Not more than 0,15% |
| 5. | Related substances:<br>- impurity A<br>- impurity F<br>- impurity G<br>- impurity D<br>- any unspecified impurity<br>- total impurities | <br>Not more than 0,2%<br>Not more than 0,15%<br>Not more than 0,15%<br>Not more than 0,15%<br>Not more than 0,10%<br>Not more than 0,6% |
| 6. | Sodium | Not more than 0,4% (calculated on anhydrous basis) |
| 7. | Water | 3,5% - 5,5% |
| 8. | Residual solvents:<br>- ethanol<br>- toluene<br>- N-hexane | <br>Not more than 5000 ppm<br>Not more than 890 ppm<br>Not more than 290 ppm |
| 9. | Microbiological purity:<br>- Total count of aerobes in 1 gr<br>- Total count of fungus in 1 gr<br>- Escherichia coli in 1 gr | <br>$10^3$ CFU<br>$10^2$ CFU<br>absence |
| 10. | Assay | Not less than 98,0% and not more than 102,0% (calculated on anhydrous basis) |
| 11. | Storage conditions | In the sealed container, in the protected from light place, under temperature not higher than 25 $^oC$ |
| 12. | Shelf life | 2 years |