# Quality specification of RUE "Belmedpreparaty" on API
# **Paclitaxel semi-synthetic**

**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.<br>Practically insoluble in water P, soluble in 96% ethanol P |
| 2. | Identification | A. IR-spectrum of the tested API should comply with IR-spectrum of Paclitaxel reference standard (EP CRS or USP RS)<br>B. Retention time of the principal spot on the chromatogram of the tested solution should comply with retention time of the principal spot on chromatogram of the standard sample solution |
| 3. | Specific optical rotation | From -49,0 till -55,0 (calculated on anhydrous basis) |
| 4. | Water | Not more than 3,0% |
| 5. | Sulfated ash | Not more than 0,2% |
| 6. | Heavy metals | Not more than 20 ppm |
| 7. | Related substances:<br>- impurity A<br>- impurity L<br>- impurities E, I<br>- sum of impurities H, J and M<br>- impurities G, K, N<br>- unspecified impurities<br>- sum of impurities | <br>Not more than 0,7%<br>Not more than 0,5%<br>Not more than 0,4%<br>Not more than 0,4%<br><br>Not more than 0,2%<br>Not more than 0,10%<br>Not more than 1,20% |
| 8. | Residual solvents:<br>- methanol<br>- ethanol<br>- acetone<br>- methylene chloride<br>- n-hexane<br>- ethyl acetate<br>- tetrahydrofuran<br>- pyridine<br>- toluene | <br>Not more than 3000 ppm<br>Not more than 5000 ppm<br>Not more than 5000 ppm<br>Not more than 600 ppm<br>Not more than 290 ppm<br>Not more than 5000 ppm<br>Not more than 720 ppm<br>Not more than 200 ppm<br>Not more than 890 ppm |
| 9. | Microbiological purity:<br>- Total count of aerobes and fungus in 1 gr<br>- Enterobacteriaceae in 1 gr<br>- Pseudomonas aeruginosa in 1 gr<br>- Staphylococcus aureus in 1 gr | <br>Not more than $10^2$ CFU<br><br>Absence<br>Absence<br><br>Absence |
| 10. | Bacterial endotoxins | Less than 0,4 EU/mg |
| 11. | Assay | Not less than 97,0% and not more than 102,0% (calculated |

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| | | on dry basis) |
| 12. | Storage conditions | In the protected from light place, under temperature not higher than 25 ºC |
| 13. | Shelf life | 3 years |