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CERTIFICATE

№ 166 / 12.12.2016
 For Quality Control of BCG Vaccine
 Freeze-dried

- | | |
|--|--|
| 1. Name and Address of manufacturer: | BB - NCIPD Ltd
26, Yanko Sakazov, 1504,
Sofia, Bulgaria |
| 2. Lot number and size of the Lot: | 255 15 060 amp |
| 3. Date of manufacture of the lot: | August 2016 |
| 4. Containers: | Vacuum ampoules containing
10 Doses / 20 Infant |
| 5. Appearance / color | |
| - freeze-dried vaccine | dry powder / whitish color |
| - reconstituted vaccine suspension | homogenous, slightly pale |
| 6. Identity test (stained smears, growth on Lowenstein-Jensen): | Approved |
| 7. Test for absence of contaminating microorganisms (WHO): | Approved |
| 8. Test for absence of virulent Mycobacteria (WHO): | Approved |
| 9. Test for total bacterial content (Opacity): | 0.375 Approved |
| 10. Test for Number of Culturable Particles (NCP): | |
| Method of determination: WHO/TB/Techn.Guide/77.9 | |
| Medium: Lowenstein-Jensen | |
| No of container tested: | six |
| Date of the last satisfactory test: | 12.09.2016 |
| NCP: | 4.5 x 10 ⁶ / ml |
| 11. Test for thermostability: | 24.44 % Approved |
| 12. Moisture content /Not more than 3,0 per cent/ | 0.013 % |
| /Loss on drying/ Date of performing the test | 19.08.2016 |
| 13. Vacuum test: | Approved |
| 14. Expiry date: | August 2019 |
| 15. Storage temperature | from +2 °C to +8 °C |

Head of Quality Control Department:

/J. Cenkova, MD/

Date of issue: 12.12.2016

Withdrawing October 2018