



**LOT RELEASE CERTIFICATE
OF VACCINE FOR HUMAN USE**

The following lot of : **BCG vaccine, freeze-dried (*Mycobacterium bovis* BCG)**,
Marketing Authorisation Number/ issued by: **20010843/Bulgarian Drug Agency, Bulgaria.**
Manufactured by **BB-NCIPD Ltd.**, 26 Y. Sakazov, 1504 Sofia, Bulgaria.

Meets all National requirements and Part A of the WHO Recommendations to assure the quality, safety and efficacy of freeze-dried BCG vaccines (WHO TRS No.979, 2013) and complies with Good Manufacturing Practices for Pharmaceutical Products: Main Principles (WHO TRS No. 908), Good Manufacturing Practices for Biological Products (WHO TRS No. 822.) and Guidelines for independent lot release of vaccines by regulatory authorities (WHO TRS No. 978, 2013.)


Lot Number	379
Type of container/ No. of doses per container	Ampoule /10 adult doses /20 infant doses
Total number of containers in this lot	15 100
Date of start of period of validity	12/01/2018
Expiry date	31/12/2020
Storage condition	+2° C ÷ +8° C/protected from light


This release certificate is based on the review and evaluation of the summary protocol of manufacturing and control.

The lot mentioned above complies with the relevant specification in the Marketing Authorisation and provisions for the release of biological products and has been approved for release.

This lot is intended for export only.

Certificate number: V/2018/WHO-0702
Date of issue: 11/04/2018

Name and function of signatory: 
Lusila Stefanova
Chief expert Department „Analyses of medicinal products“

Name and function of signatory: 
Pavlinka Stoyanova
Head of Division „Biological Analyses and Pharmacopoeia Activities“



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CERTIFICATE**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: | 379 |
| 3. Date of manufacture of the lot: | December 2017 |
| 4. Containers: | Vacuum ampoules containing
10 Doses / 20 Infant |
| 5. Identity test (stained smears,
growth on Lowenstein-Jensen): | Approved |
| 6. Test for absence of contaminating
microorganisms (WHO): | Approved |
| 7. Test for absence of virulent
Mycobacteria (WHO): | Approved |
| 8. Test for total bacterial content (Opacity): | 0.350 Approved |
| 9. Test for Number of Culturable Particles (NCP):
Method of determination: WHO/TB/Techn.Guide/77.9
Medium: Lowenstein-Jensen
No of container tested:
Date of the last satisfactory test:
NCP: | six
12.01.2018
4.2 x 10 ⁶ / ml |
| 10. Test for thermostability: | 23.81 % Approved |
| 11. Water /loss on drying/: | 0.010 % Approved |
| 12. Vacuum test: | Approved |
| 13. Expiry date: | December 2020 |

Date of issue: 22.02.2018

Head of Quality Control Department

P. Mitrenga, MSc



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CERTIFICATE FOR QUALITY CONTROL

Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 434-1-2

<i>Type of controls / Ph. Eur. Monograph</i>	<i>Standard</i>	<i>Results</i>
Appearance	Colourless transparent liquid	Passes
Extractable volume Ph. Eur. 2.9.17.	≥ 1.0 ml	Passes
pH Ph. Eur. 2.2.3.	5.00 – 7.00	6.06
Sodium Chloride Ph. Eur. 2.2.20.	0.65 – 1.15 %	0.90 %
Sterility Ph. Eur. 2.6.1.	Sterile	Passes
Pyrogens Ph. Eur. 2.6.8.	≤ 1.15 °C (if summed response of three rabbits does not exceed)	+ 0.4 °C

Date of manufacture: December 2017

Expiry date: November 2022

CONCLUSION:

Diluent (Saline) for BCG Vaccine Lot № 434-1-2 meets European Pharmacopoeia requirements.

The product has been produced in a firm with approved Quality Management System Standard: ISO 9001:2008

Date of issue: 11.01.2018

Head of Quality Control Department:


P. Mitrenga

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CERTIFICATE FOR QUALITY CONTROL

Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 434-1-3

<i>Type of controls / Ph. Eur. Monograph</i>	<i>Standard</i>	<i>Results</i>
Appearance	Colourless transparent liquid	Passes
Extractable volume Ph. Eur. 2.9.17.	≥ 1.0 ml	Passes
pH Ph. Eur. 2.2.3.	5.00 – 7.00	6.08
Sodium Chloride Ph. Eur. 2.2.20.	0.65 – 1.15 %	0.89 %
Sterility Ph. Eur. 2.6.1.	Sterile	Passes
Pyrogens Ph. Eur. 2.6.8.	≤ 1.15 °C (if summed response of three rabbits does not exceed)	+ 0.3 °C

Date of manufacture: December 2017

Expiry date: November 2022

CONCLUSION:

Diluent (Saline) for BCG Vaccine Lot № 434-1-3 meets European Pharmacopoeia requirements.

The product has been produced in a firm with approved Quality Management System Standard: ISO 9001:2008

Date of issue: 12.01.2018

Head of Quality Control Department:


P. Mitrenga