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CERTIFICATE

FOR QUALITY CONTROL

Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 405 – 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	6.33
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: August 2016

Expiry date: July 2021


CONCLUSION:

Diluent (Saline) for BCG Vaccine Lot № 405-2 meets European Pharmacopoeia requirements.

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

Date of issue: 21.09.2016

Head of Quality Control Department:


 J. Cenkova, MD