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CERTIFICATE FOR QUALITY CONTROL

Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 382 – 2

<i>Type of controls</i>	<i>Standard</i>	<i>Results</i>
Appearance	Colourless transparent liquid	Passes
Extractable volume	≥ 1.0 ml	Passes
pH	5.00 – 7.00	6.30
Sodium chloride	0.65 – 1.15 %	0.90 %
Sterility	Sterile	Passes
Pyrogens	≤ 1.15 °C (if summed response of three rabbits does not exceed)	+0.2 °C

Date of manufacture: January 2016
Expiry date : December 2020

CONCLUSION:

Diluent (Saline) for BCG Vaccine Lot № 382 – 2 meets European Pharmacopoeia requirements.

The Product has been produced in a firm with approved Quality Management System Standards: ISO 9001:2008.

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Head of Quality Control Department:


 J. Cenkova, MD