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CERTIFICATE

FOR QUALITY CONTROL

Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 390 – 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	6.32
Sodium Chloride	0.65 – 1.15 %	0.89 %
Sterility	Sterile	Passes
Pyrogens	≤ 1.15 °C (if summed response of three rabbits does not exceed)	+ 0.3 °C

Date of manufacture: March 2016

Expiry date: February 2021


CONCLUSION:

Diluent (Saline) for BCG Vaccine Lot № 390-2 meets European Pharmacopoeia requirements.

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

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Head of Quality Control Department:


 J. Cenkova, MD