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## CERTIFICATE

### FOR QUALITY CONTROL

#### Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 406 – 1

<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	6.35
Sodium Chloride Ph. Eur. 2.2.20.	0.65 – 1.15 %	0.87 %
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 № 406-1 meets European Pharmacopoeia requirements.**

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

Date of issue: 27.09.2016

Head of Quality Control Department:

J. Cenkova, MD