

CERTIFICATE OF ANALYSIS

Product: **IBRIN, soluție injectabilă**

Batch No.: **80 54 26 A**

Expiry: **08.04.2021**

Date of production: **09.04.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Milky-colored liquid with a hint of orange to pink. Becoming the divide the top orange to pink layer and bottom layer milky whitish. After shaking lightly mix the two layers. When shaken, both layers are easily mixed.		conforms
Content of original package	min. 100 ml +/- 2%		100.0 ml
Sterility	Vaccine must be sterile.		sterile
Efficacy	The vaccine is effective if the average antibody titre of 1:8 is proved in rabbits. If the test result is unsatisfactory, it is repeated with the double number of animals. Should be the result repeatedly unsatisfactory, the vaccine is considered as unsatisfactory.		conforms
pH	6.5 – 7.7		7.1
Formalin content	Max. 0.114 %		0.063 %
Thiomersal content	Max. 0.015 % (according to SOP D30)		0.009 %
Aluminium hydroxide content	0.8 – 1.2 %		0.90 %
Air tightness	The vials must be hermetically sealed.		conforms

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 247.



Hana
31/05/2019
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HEAD of QC, QP