

CERTIFICATE OF ANALYSIS

Product: **OTIBIOVIN, soluție pentru aplicare topică**

Batch No.: **43 60 26 A**

Expiry: **17.10.2022**

Date of production: **18.10.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Colourless, faintly turbid solution, mildly opalescent. Faint turbidity can be observed, or sediment that disperses when being shaken can be formed, during storage. The turbidity mentioned does not affect efficacy of the preparation.		conforms
Content of original package	min. 15 ml, min. 20 ml		20 ml
pH value (Concentration of hydrogen ions)	3 - 6		4
Microbiological harmlessness	It shall comply with Ph. Eur., Article 5.1.4. - Category 2		conforms
Triamcinolone content	0.475 – 0.525 mg/ml	0.45 – 0.525 mg/ml	0.506 mg/ml
Triamcinolone identity	It shall be proved.		conforms
Gentamycin content	1.9 – 2.1 mg/ml	1.8 – 2.1 mg/ml	2.0 mg/ml
Gentamycin identity	It shall be proved.		conforms
Salicylic acid content	4.75 – 5.25 mg/ml	4.5 – 5.25 mg/ml	4.97 mg/ml
Salicylic acid identity	It shall be proved.		conforms
Carbethopendecinii bromidum content	(0.118 - 0.131) mg/ml	(0.112 - 0.131) mg/ml	0.1305 mg/ml
Carbethopendecinii bromidum identity	It shall be proved.		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. 340, spec.02.



19/11/2019
Mgr. Hana Nezvalová
HEAD of QC, QP