



CERTIFICATE OF ANALYSIS

Product: OTIBIOVIN

Batch No.: 756029A  
Expiry: 09/2024  
Date of production: 21.10.2022

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Colourless, faintly turbid solution, mildly opalescent. Slight turbidity or sediment may be formed during storage, which dissipates after shaking. The turbidity does not affect efficacy of the product.		conforms
Content of original package	min. 15 ml, 20 ml		20.5 ml
pH value (Concentration of hydrogen ions)	3 - 6		4
Microbiological safety	Must comply. TAMC (CFU/g): 10 <sup>2</sup> TYMC (CFU/g): 10 <sup>1</sup> Absence of Staphylococcus aureus (in 1 g or 1 ml) Absence of Pseudomonas aeruginosa (in 1 g or 1 ml)		complies 0 CFU/g 0 CFU/g absent absent
Triamcinolone content	0.475 - 0.525 mg/ml	0.450 - 0.525 mg/ml	0.484 mg/ml
Triamcinolone identity	It shall be proved.		conforms
Gentamycin content	1.8 - 2.2 mg/ml		1.9 mg/ml
Gentamycin identity	It shall be proved.		conforms
Salicylic acid content	4.75 - 5.25 mg/ml	4.50 - 5.25 mg/ml	5.108 mg/ml
Salicylic acid 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.



Mgr. Hana Nezvalová  
HEAD of QC, QP



CERTIFICATE OF ANALYSIS

Product: OTIBIOVIN

Batch No.: 745929A  
Expiry: 08/2024  
Date of production: 6.9.2022

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Colourless, faintly turbid solution, mildly opalescent. Slight turbidity or sediment may be formed during storage, which dissipates after shaking. The turbidity does not affect efficacy of the product.		conforms
Content of original package	min. 15 ml, 20 ml		20.0 ml
pH value (Concentration of hydrogen ions)	3 - 6		4
Microbiological safety	Must comply. TAMC (CFU/g): 10 <sup>2</sup> TYMC (CFU/g): 10 <sup>1</sup> Absence of Staphylococcus aureus (in 1 g or 1 ml) Absence of Pseudomonas aeruginosa (in 1 g or 1 ml)		complies 0 CFU/g 0 CFU/g absent absent
Triamcinolone content	0.475 - 0.525 mg/ml	0.450 - 0.525 mg/ml	0.494 mg/ml
Triamcinolone identity	It shall be proved.		conforms
Gentamycin content	1.8 - 2.2 mg/ml		1.9 mg/ml
Gentamycin identity	It shall be proved.		conforms
Salicylic acid content	4.75 - 5.25 mg/ml	4.50 - 5.25 mg/ml	5.072 mg/ml
Salicylic acid 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.V003.



Mgr. Hana Nezvalová  
HEAD of QC, QP