



vetoquinol
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CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : ORIDERMYL POM AURIC NF 10G UA	Analytical code : 423621
Pharmaceutical form : Semi-Solided Otic Solutions	Manufacturing date : 25/10/2022
Batch number : 2C3463B	Expiration date : 24/10/2024

TESTS	SPECIFICATIONS	RESULTS
Characteristics of ointment	Pale yellow and fatty	Pass
Fill weight	≥ 10 g	10 g
Neomycin sulfate identity	Positive	Pass
Nystatin identity	Positive	Pass
Neomycin sulfate content	$\geq 322000 \leq 367500$ % IU/w	348134 % IU/w
Nystatin content	$\geq 9.2 \leq 10.5$ % MIU/w	10.1 % MIU/w
Triamcinolone and permethrin assay		
Triamcinolone acetonide identity	Positive	Pass
Triamcinolone acetonide content	$\geq 0.095 \leq 0.105$ % w/w	0.093 % w/w
Permethrin identity	Positive	Pass
Permethrin content	$\geq 0.950 \leq 1.050$ % w/w	0.975 % w/w
Cis/trans permethrin ratio	$\geq 0.299 \leq 0.370$	0.348
Permethrin impurities		
3-phenoxybenzyl alcohol	≤ 1.0 %w/w	< 0.2 % w/w
3-phenoxybenzoic acid	≤ 1.0 %w/w	< 0.2 % w/w
Each unknown impurity	≤ 1.0 %w/w	< 0.2 % w/w
Total impurities	≤ 3.0 %w/w	< 0.2 % w/w
Total viable aerobic count	≤ 100 cfu/g	< 10 cfu/g
Moulds and yeasts	≤ 10 cfu/g	< 10 cfu/g



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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

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TESTS	SPECIFICATIONS	RESULTS
Pseudomonas aeruginosa	Absence of growth	Pass
Staphylococcus aureus	Absence of growth	Pass



I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in the current European Union rules for Good Manufacturing Practice for medicinal products for veterinary use, and that the finished product in all aspects answers the requirements laid down in the marketing authorisation.

Released by Qualified Person :	Amelie LAVENS
Date :	16/02/2023 08:08:58
Decision :	FULL RELEASE

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