

CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT		
Product name : OTIFREE 60ML RU Batch number : 9E3296F		Manufacturing date : 21/11/2019 Expiration date : 20/11/2022
TESTS	SPECIFICATIONS	RESULTS
Appearance, color, odour	Pass	Pass
Content in unit container 60ml	Not less than declared	Pass
pH	$\geq 6 \leq 7$	6
Relative density	$\geq 1.010 \leq 1.080$ g/ml	1.033 g/ml
Total viable aerobic count cfu/ml	≤ 100 cfu/ml	<10 cfu/ml
Staphylococcus aureus in 1ml	Absence	Pass
Pseudomonas aeruginosa in 1ml	Absence	Pass

The batch meets requirements release specification

Approved by QC : Przemysław KOWALSKI Date : 17/12/2019 15:21:42	Released by Qualified Person : Mariola KISZEWSKA Date : 04/03/2020 09:44:36 Decision : FULL RELEASE
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Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely.
 Interpretation of the results of microbiological examination of non sterile products according to suitable Pharmacopoeia.
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