

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT	
Product name : OTIFREE 60ML RU	Manufacturing date : 30/01/2020
Batch number : 0E0342D	Expiration date : 29/01/2023

TESTS	SPECIFICATIONS	RESULTS
Appearance, color, odour	Pass	Pass
Content in unit container 60ml	Not less than declared	Pass
pH	$\geq 6 \leq 7$	7
Relative density	$\geq 1.010 \leq 1.080$ g/ml	1.032 g/ml
Total viable aerobic count cfu/ml	≤ 100 cfu/ml	20 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	Released by Qualified Person : Mariola KISZEWSKA
Date : 05/03/2020 10:48:01	Date : 14/05/2020 10:39:46
	Decision : FULL RELEASE

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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