

PRODUCT: OTIBLOCK SPRAY 45 ML
CODE: MIT-202-CL1
FORM: Finished Product
BATCH NUMBER: X027
MANUFACTURING DATE: 15/SEP/2025
CoA NUMBER: OT-X027-251008CL1
AMOUNT: 19.841 units
CLIENT: Farmacoquímica del Pacífico SPA

Parameter	Specification	Method	Result
Appearance	Liquid colourless and clear according to the standard	Ph.Eur. 2.2.2 Ph. Eur. 2.2.1	Conforms
Chemical parameters			
pH	4,5±0.4	Ph. Eur. 2.2.3	4,5
% of H ₂ O ₂	2,2-3,2% (W/W)	Monograph 01/2013: 0395. Ph. Eur.	3,1%
Microbiology			
TAMC	<10 ¹ cfu/ml or cfu/g	Ph. Eur, 2.6.12	<10 cfu/ g
TYMC	<10 ¹ cfu/ml or cfu/g	Ph. Eur, 2.6.12	<10 cfu/ g
S aureus	Absence in 1 ml or 1 g	Ph. Eur, 2.6.13	Absence
P aeruginosa	Absence in 1 ml or 1 g	Ph. Eur, 2.6.13	Absence

Storage: Store in dry place below 30 °C
 Shelf life: Three years when properly store: 2028/09

Conclusion: This product conforms to the above-mentioned specifications

Date: 08/Oct/2025

Authorized Person:

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