





**Batch Release Certificate n° 20/2024**

Name of product: OPHTHALMIC SOLUTION WITH LIPOSOMES  
 Trade name: NAVI LIPO, eye drops, 10 ml  
 Medical device certificate number: 1869/MDD  
 Issued on: 19/04/2016  
 Expiration date: 26/05/2024  
 Notified Body: IMQ  
 Destination Country: SLOVAKIA PO N24-07 PART 1 & PART 2

REF: D10NL278


batch number		Quantity / Batch Size	
BF02212		28 620	
Date of manufacture		Expiry date	
Year	Month	Year	Month
2023	12	2025	12

**Results of the tests made throughout production:**

pH	Osmolality	Test Result
(7,05 - 7,35)	(280 – 320 mOsm/kg)	X Conforming <input type="checkbox"/> Non conforming
7,33	313	
Result of the final microbiological tests		X Conforming <input type="checkbox"/> Non conforming
Verifying Compliance Labeling		X Conforming <input type="checkbox"/> Non conforming
Verifying Compliance transportation documents		X Conforming <input type="checkbox"/> Non conforming
<u>Presence of deviation during production process</u>		<u>X no deviation</u> <input type="checkbox"/> <u>One or more deviations</u> <u>If a deviation is present:</u> <input type="checkbox"/> <u>controlled</u> <input type="checkbox"/> <u>non controlled</u> <u>N° deviation:</u>

Remarks: Store between 5 and 35°C and protect from a direct source of light.

Monaco, 15/01/2024

Control of data performed by REGS QAI/RQS/RQA: 

Declaration of Conformity and Batch Release

The product NAVI LIPO batch n° BF02212 is a Medical Device class IIb (rule 15 annex IX point 2.1 Directive 93/42/EEC and following modifications) meets the requirements of annex I Directive 93/42/EEC and following modifications and the specifications related in the Technical File as provided according to annex II, excluding section 4, of the same directive.

Date: 15/01/2024

**NOVAX PHARMA S.A.M**  
 LE CORONADO  
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