

## Certificate of Conformity

### 05502959 NASIVIN SENSITIVE 0,05% 10ML(RU)P&G-NEW

Customer material code: **81775842**

Marketing Auth. N°.: JIII-000511

Batch: **310850A**

Quantity released: 38.576 UN

Date of manufacture: 22.12.2023

Expiry Date: 12.2026

#### API Batches used

Code	Description	Batch Nr	Supplier Batch Nr
10501253	OXIMETAZOLINA CLORHIDRATO	2301269	23202115

## ANALYTICAL RESULTS

TEST	RELEASE SPECIFICATIONS	RESULTS
APPEARANCE OF SOLUTION	Not more colored than reference solution Y7	Conforms
APPEARANCE OF SOLUTION CLARITY	Solution should be transparent or not more opalescent than reference suspension	Conforms
RELATIVE DENSITY d 20/20	1.006-1,010	1,008
PH	5,6-6,1	5,9
AVERAGE MASS OF DELIVERED DOSE	38.25 mg - 51.75 mg	46,40
DELIVERED DOSE UNIFORMITY (WORT CASE) 25	0-2	0
DELIVERED DOSE UNIFORMITY (WORT CASE) 35	0-0	0
OSMOLALITY (mosm/kg)	270-330 mosmol/kg	295
FILLING VOLUME	>= 10 ml	11,7
OXYMETAZOLINE HYDROCHLORIDE IDENTITY	Must conforms	Conforms
OXYMETAZOLINE HYDROCHLORIDE ASSAY	475-525,0 µg/ml	507
HYDROLISIS PRODUCT	<=0.5% related to the content of Oxymethazolyne hydrochloride	0,00 %
ZP-1	<=0.5% related to the content of Oxymethazolyne hydrochloride	0,00 %
LARGEST UNIDENTIFIED DEGRADATION PRODUCT	<=0.1% related to the content of Oxymethazolyne hydrochloride	0,0 %
TOTAL DEGRADATION PRODUCTS	<=1,2%	0,0 %
PSEUDOMONA AERUGINOSA IN 1 ML	Absence/ml	Absence
STAPHYLOCOCCUS AUREUS IN 1ML	Absence/ml	Absence
Microbial Contamination FUNGI (TYMC)	<=10 <sup>1</sup> CFU/ml	< 1 cfu
Microbial Contamination BACTERIA (TAMC)	<=10 <sup>2</sup> CFU/ml	0 cfu
STERILITY TEST	Complies	Conforms

Deviations: NO  YES [ ] If significant deviations (which may have an impact on the quality of product).

Description of the event:

PNT:

This product has been analyzed by SOP: QAM\_01019 01039 SOP 0758 0657

Procter & Gamble  
DZ - ALTFELD

23. Jan. 2024

WARENEINGANG  
Michael Fuchs

## Certificate of Conformity

### 05502959 NASIVIN SENSITIVE 0,05% 10ML(RU)P&G-NEW

Customer material code: 81775842

Marketing Auth. N°.: JIII-000511

Batch: 310850A

Quantity released: 38.576 UN

Date of manufacture: 22.12.2023

Expiry Date: 12.2026

#### API Batches used

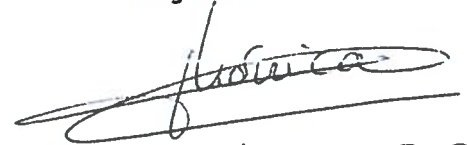
<u>Code</u>	<u>Description</u>	<u>Batch Nr</u>	<u>Supplier Batch Nr</u>
10501253	OXIMETAZOLINA CLORHIDRATO	2301269	23202115

#### Compliance statement:

I hereby certify that the above information is authentic and accurate according to MSM product data sheet 81775842. This batch of product has been manufactured, including packaging and quality control in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Released by: *Manica Sánchez*  
(Qualified person)

Signature:



19 JAN 2021