



# Ophthalmic



A CLEAR  
VISION FOR  
EYE CARE





Nemera strives to improve the patient experience by providing safe and effective multidose eyedroppers for preservative-free solutions, used globally.

One of the main criticisms of self-administered eye care treatments today is poor patient adherence, especially with chronic diseases, such as Glaucoma and Dry Eye Disease (DED).

## GLAUCOMA

Glaucoma is a group of eye diseases which result in damage to the optic nerve and causes vision loss, being a leading cause of global irreversible blindness.

There are approximately **100 million people worldwide** with Glaucoma, around half of which is undiagnosed.

## DRY EYE DISEASE (DED)

### Global prevalence of DED

It is estimated that **1.4 billion people live with DED and that number is growing in both young and old adults.**

Dry Eye Disease (DED) is a common multifactorial disease of the ocular surface with loss of homeostasis of the tear film and ocular symptoms, such as irritation, redness, discharge, and easily fatigued eyes.

# Our ophthalmic products

COMMERCIALLY  
AVAILABLE



## Novelia®

Nemera has developed an innovative ophthalmic multidose device to avoid the need for preservatives in formulations. This device has been developed to prevent microbial growth over treatment duration\*.

Nemera has also designed and developed a Vented Cap version which removes and dries the remaining liquid on the dropper tip, and is silver-free

### Key features:

- Patented blue tip for better precision when targeting the eye
- 3 flow control options to accommodate highly liquid to highly viscous formulations
- 5 drop sizes (28µl to 46µl range)
- Large range of bottles (5ml to 15ml) and BFS (Blow-Fill-Seal) in white and transparent

\* Subject to microbiological testing conducted as part of stability studies

## A unique partner



**Highly visible solution  
with over 360 Rx and  
OTC products on  
market worldwide**



**Dedicated customer  
technical and  
regulatory support,  
highly experienced  
in the ophthalmic  
space**



**Reliable, on-time  
delivery with two  
manufacturing  
facilities in France  
and the US**

# Novelia®

## 0% preservatives, 100% eye protection!

The Novelia® platform includes a broad range of configurations to accommodate a wide panel of formulations



### Bottles (white and transparent)

- LDPE 5ml, 7.5ml, 11ml & 15ml (including soft versions)
- PP 11ml
- Novelia® BFS (Blow-Fill-Seal) allowing unique bottle shapes

### Caps

- 2 versions including vented option, depending on formulation and target market (available in White and Olive Green)

### Drop size

- Standard drop size: 40µl with water
- 5 additional drop sizes: (between 28µl and 46µl) to accommodate more formulations and attain target drop size

### Three patented PureFlow® Technology options

(PF10, PF200 & PF1500) for controlled flow\*\* for different viscosities, delivering one drop at a time

- **PureFlow 10**  
very liquid formulations
- **PureFlow 200**  
liquid formulations
- **PureFlow 1500**  
viscous formulations

\*\* Subject to performance testing to assess compatibility of the combination product

## HOW THE PUREFLOW® TECHNOLOGY WORKS:

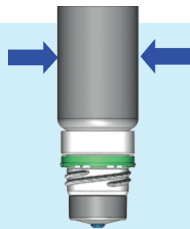
### PureFlow technology guarantees integrity of the system.

The Novelia® device features a one-way valve that ensures that liquid cannot be re-introduced into the container after a drop has been dispensed, completely removing the need to filter the liquid.

The intake of air into the dispenser takes place via a separate venting system with a silicone membrane referred to as PureFlow® technology. This is a continuous barrier of homogeneous material which guarantees the integrity of the system.

1

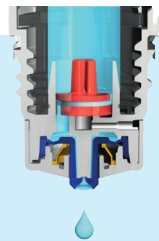
**Bottle squeezing**



2

**Valve opening**

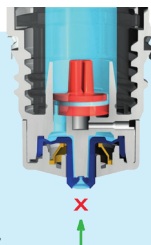
Drop delivery



3

**Valve reclosing**

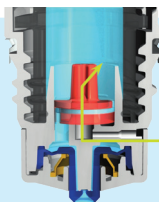
Valve recloses sealing the bottle tightly (no liquid back flow re-entering the bottle)



4

**Air compensation**

PureFlow® Technology allows air to diffuse into the bottle (no contaminated air can enter the bottle)



*Novelia® and PureFlow® are trademarks of Nemera La Verpillière SAS.*

*The shape and color of the nozzle of Novelia dispenser are protected by trademarks of Nemera La Verpillière SAS.*

# Our integrated combination product services

## ANALYTICAL SERVICES & DESIGN VERIFICATION

Our team of experts is dedicated to ensuring the safety, efficacy, and compliance of your combination product including:

- Comprehensive analytical services and design verification
- Advanced testing methods tailored to your formulation and active ingredients
- Testing method development, administration, and reporting
- Performance and integrity verification of your device and drug product
- Adherence to global standards throughout the process



## HUMAN FACTORS & USER EXPERIENCE MANAGEMENT

We provide exceptional support for combination products across diverse regulatory pathways, device types, and patient populations for global markets including:

- Human Factors program strategy and risk management
- Formative/summative testing (design validation) administration
- Human Factors Engineering documentation for regulatory submissions
- Enhances safety, usability, and overall satisfaction of your combination product.
- Aligns with FDA Human Factors Engineering guidelines and ISO 62366 standards
- Extends beyond the device to include instructions for use, packaging, and training programs to optimize user adherence and engagement



## REGULATORY STRATEGY & SUBMISSION AUTHORIZING

We provide tailored strategies and support for all stages of the regulatory process, including:

- Development of a comprehensive regulatory strategy including pre-market to post-market support
- Guidance on FDA regulations and international standards (ISO 14971, ISO 10993)
- Expert support in regional regulatory guidelines
- Assistance in authoring and compiling regulatory submissions, including: Premarket Approval (PMA), 510(k) submissions, CE marking documentation, and Notified body opinion support
- Accelerated submission processes, drawing from our experience in over 54 markets



# Our Ophthalmic featured services

## **CUSTOMIZED ANALYTICAL STUDIES (PERFORMANCE TESTING, MICROBIOLOGY, CHALLENGE TESTS...)**

Our laboratory has tailor made equipment for Novelia and a dedicated team with extensive expertise on the device. Nemera can conduct customized studies in standard and extreme conditions, as well as generate data to assess compatibility of the combination product, ready to use for registration. Data can also be generated to demonstrate the combination product's safety and compliance with the highest microbiological safety requirements.



## **INSTRUCTIONAL MATERIALS AND PACKAGING DEVELOPMENT**

We develop clear and concise instructions for use, in both paper and digital formats, tailored to the specifics of patient populations and drug products. Additionally, we develop user-friendly secondary packaging that is visually appealing while aligning with our customers' brand values. This comprehensive approach ensures a seamless and supportive experience with Novelia.



## **HUMAN FACTORS MANAGEMENT**

We develop customized human factors strategies and risk management plans. We then leverage our expertise in formative and summative usability testing to ensure customer applications meet user needs and comply with global regulatory standards. Furthermore, when required, we provide human factors engineering documentation for regulatory submissions, enhancing the safety, usability, and overall satisfaction of your product when utilizing Novelia.





 **Nemera**  
we put patients first

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