

Ophthalmic Squeeze Dispenser

Technology Platform



From formulation to patient.

Aptar pharma

Ophthalmic Squeeze Dispenser

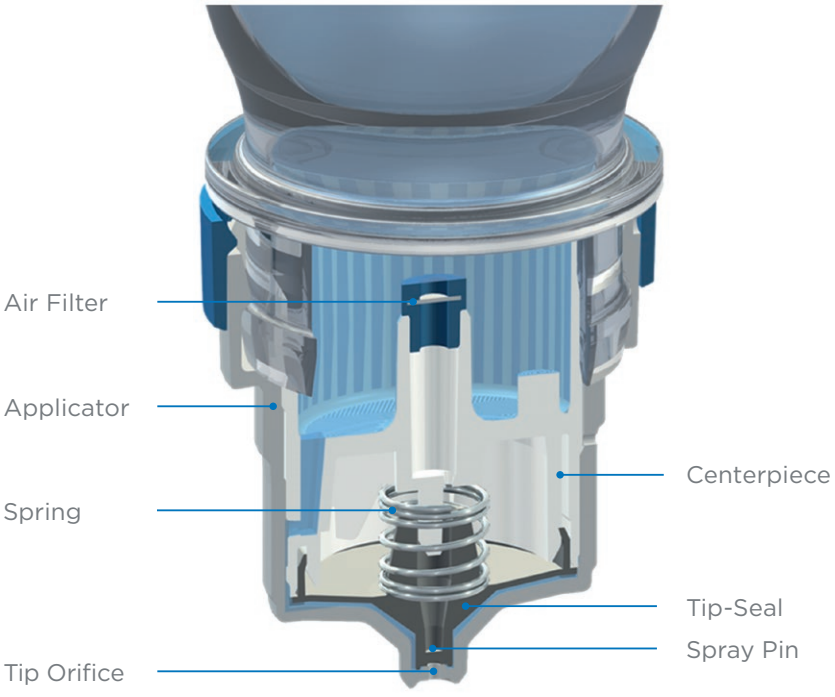
The versatile multidose technology platform for preservative-free ophthalmic formulations

Multidose Dispensing Developed for Preservative-Free Formulations

Preservatives in Eye Care formulations, such as Benzalkonium Chloride (BAC), can cause side effects with chronic use. The Ophthalmic Squeeze Dispenser represents a worldwide-accepted solution to address this challenge and support your development.

Key Benefits

- Purely mechanical Tip-Seal technology that has been developed for use without preservatives
- No additives, such as silver ions or surface coating in the dispenser‘s contact materials
- No filtering of formulation
- Metal-free fluid pathway



How the Ophthalmic Squeeze Dispenser works:



By squeezing the bottle ...



... the pressure inside the system rises until the Tip-Seal opens and releases the drop.

Tested for Microbiological Integrity that Protects Your Preservative-Free Eye Care Product

Aptar Pharma provides a set of data and test methods for the Ophthalmic Squeeze Dispenser which is designed to support pharmaceutical customers in preparing the dispensing part of their finished product dossier.

TSIT 2.0

(Tip-Seal Integrity Test)

Submersed actuation in challenge suspension containing *Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans*. Reflects most recently updated guidelines in highly regulated markets.



CCIT

The vacuum decay test method can be used as deterministic Container Closure Integrity Test (CCIT) for the filled OSD systems to meet the recommendations of the USP <1207> for sterile products.



Designed to Comply with Regulatory Standards Your Eye Care Product Has to Fulfill

- The Ophthalmic Squeeze Dispenser is designed to comply with regulatory requirements for dispenser tip, as defined in the FDA guidance: "Quality Considerations for Topical Ophthalmic Drug Products"*
- It is the only PFMD technology that is part of an approved system to deliver a prescription ophthalmic drug product in the US**



Aptar Pharma Service Packages Available to Support Development of Preservative-Free Eye Care Products

- Comprehensive data packages available
- Global CMO/CDMO network and excellent equipment vendor contacts
- Experienced Regulatory Affairs team to support registration processes worldwide
- Gold standard analytical lab services

Worldwide Accepted Technology Platform

- Leader in both consumer product and prescription Eye Care medications
- More than 650 references worldwide feature the Ophthalmic Squeeze Dispenser



*www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-considerations-topical-ophthalmic-drug-products
**https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/50790Orig1s025.pdf

Versatile Technology Platform Offers Easy Customization Solutions for the Ophthalmic Squeeze Dispenser

The technology platform allows for a wide range of customized configurations and applications for specific ophthalmic formulations.



Cap Options

- Standard Cap / Liner Cap / Pure Cap
- Caps available in various colors





Liner Cap



Pure Cap



Functional Options

Flow Control
Wide range of flow control settings for various formulation properties



Pure Pin
Ultra-clean COC material for sensitive formulations



* Illustrated in blue for visualization purposes only.

Filter Protection Valve
TPE one-way radial valve designed for media having chemical or physical properties imparing a proper filter function





Container Options*

Standard Bottle
Globally well-established container solution of the first generation

Soft Bottle
Notable squeeze force reduction for easy handling

Pure Bottle
Ultra-clean COC material assures high level of chemical inertness for sensitive formulations



Standard Soft Pure

* Available from outside vendors

Versatile Bottle Configurations

- Gamma- or ETO-sterilized
- White or translucent
- Variable container sizes



For more information, please visit www.aptar.com/pharma

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