



Ophthalmic Squeeze Dispenser

Technology Platform



Aptar 
pharma

From formulation to patient.

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

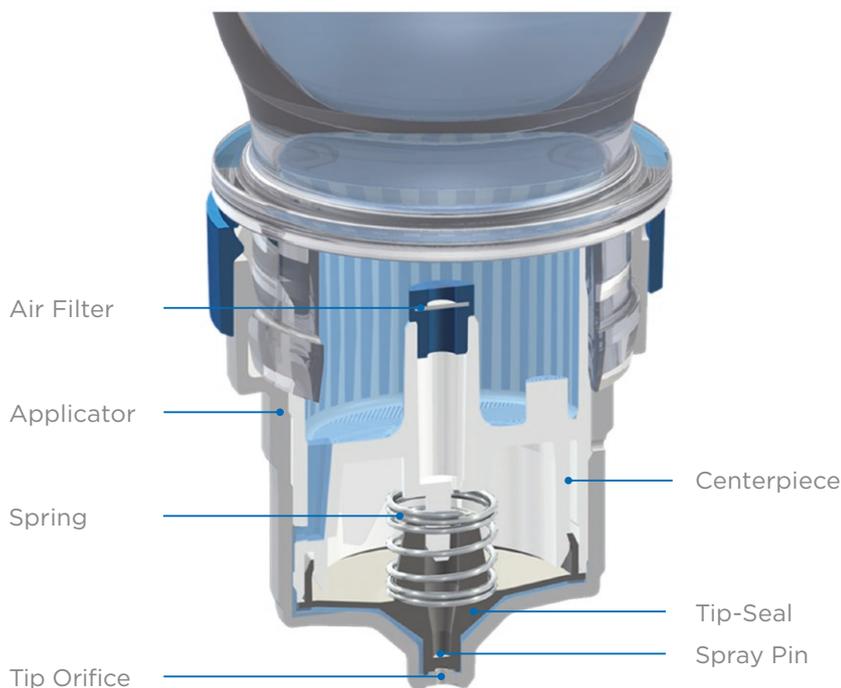
How the Ophthalmic Squeeze Dispenser works:



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 500 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 duckbill valve designed for media having chemical or physical properties impairing 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

Versatile Bottle Configurations

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



7ml



10ml

* Available from outside vendors

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

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