



Ophthalmic Multidose System

Side Actuation Device® & ComfortGrip®

Preservative-free Solutions



Inside:

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- Application
- Service & Support

AP
AERO PUMP

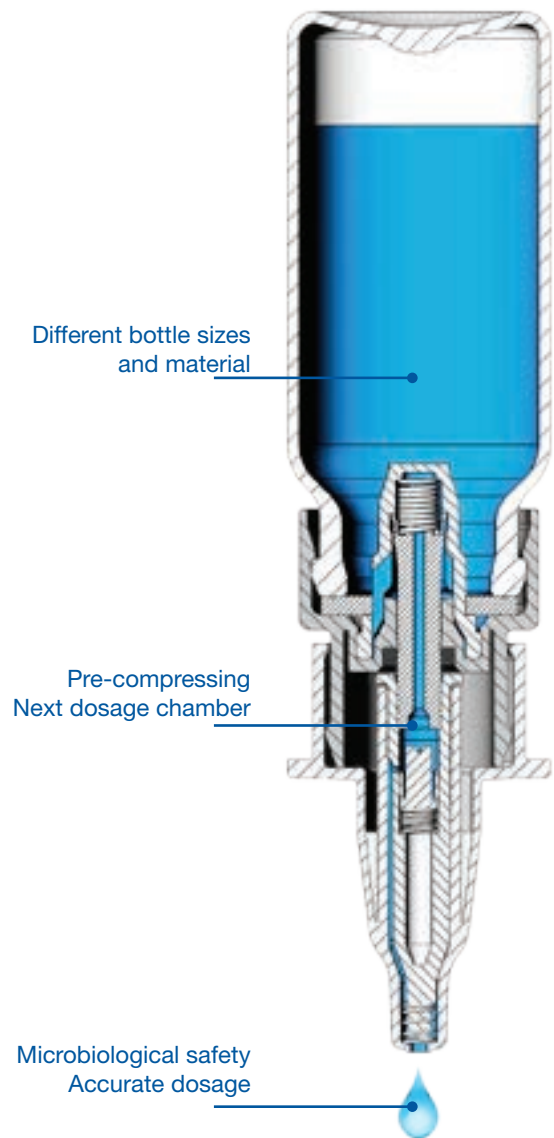
Functionality

When the pump is activated, the product contained in the dosing chamber of the pump is subjected to pressure, which opens the valve and releases an accurate drop. Upon completion of the dosing process the system is sealed by the microbiological leak proof valve.

This prevents the backflow of liquid. On release of the head base, the pump is reset to its initial position and a further aliquot of the product is drawn from the container into the dosing chamber.

The vacuum within the container is compensated by the subsequent inflow of air, which passes through a special filter matrix.

An oligodynamic effecting silver coil at the pump opening is a further microbiological safety component of the 3K-System.



Facts

- ✓ Removes need to use preservatives in your formulation
- ✓ Ensures the microbiological purity of the product against contamination
- ✓ Special germ reducing components
- ✓ Single dose delivery control for increased patient safety

Microbiology

Aero Pump Systems for the application of ophthalmic preparations

Regarding the microbiological safety of ophthalmic preparations, the European Pharmacopoeia sets high quality standards: preparations applied to the eye have to be sterile (Ph. Eur. 5.1.4).

In the last decades usually squeeze bottles were used as multidose systems for the storage and usage of ophthalmic preparations. Preservatives were added to these dosing systems to reduce microbial contamination and growth in the product during conventional use or storage. However, preservatives can cause side-effects like irritations of the conjunctiva.

Preservatives are dispensable if the multidose system offers specific safety features. The Aero Pump's 3K 180° dropper presents such kind of multidose systems for preservative-free ophthalmic preparations. Here, the preservative-free formulation inside the container is separated from the orifice by the means of

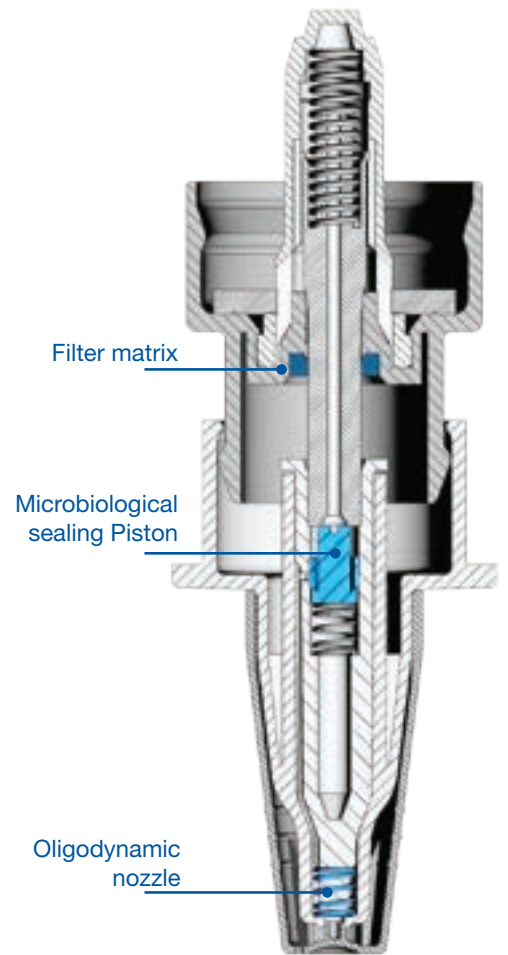
valves. During the actuation of the system negative pressure occurs inside the container.

If the system is released, ambient air is filtered by sterile filters, whereby microbial contamination of the preparation is prevented. Moreover, a silvercoil with an antimicrobial effect, located at the orifice, prevents microbial growth in that semi-open area.

We have investigated the microbiological safety of the Aero Pump systems during storage and a simulated patients' use at our laboratory with a standard integrity test. It could be shown that preservative-free preparations

filled into the application systems described above were not contaminated with microorganisms and therefore, fulfil the requirement, that are comparable to those for preserved ophthalmic preparations of the European Pharmacopoeia.“

**Official statement made by
Antiinfectives Intelligence**



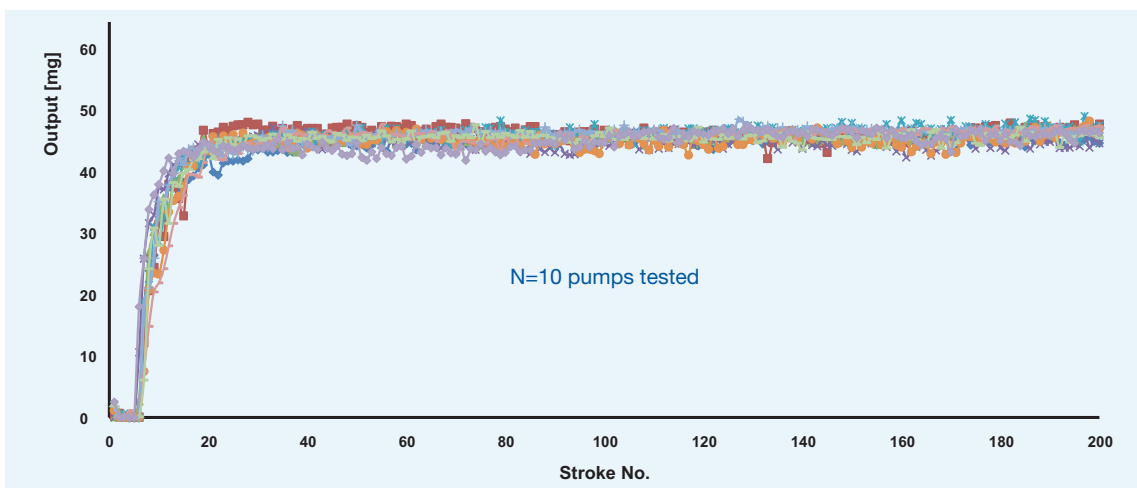
Facts

- ✓ Microbiological studies available upon request
- ✓ Preservative-free system has been approved for almost two decades
- ✓ Zero customer complaints since market launch in 2006

Performance

- ✓ Reproducible droplet size
- ✓ Three way microbiologic protection
- ✓ Snap-on closure for fast and safe processing in clean rooms
- ✓ Patented 3K®-technology
- ✓ Convenient handling
- ✓ Sterilized by ETO with our validated process according ISO Standards

Dose consistency for 3K-dropper 45mg (exemplified illustration)



Availability

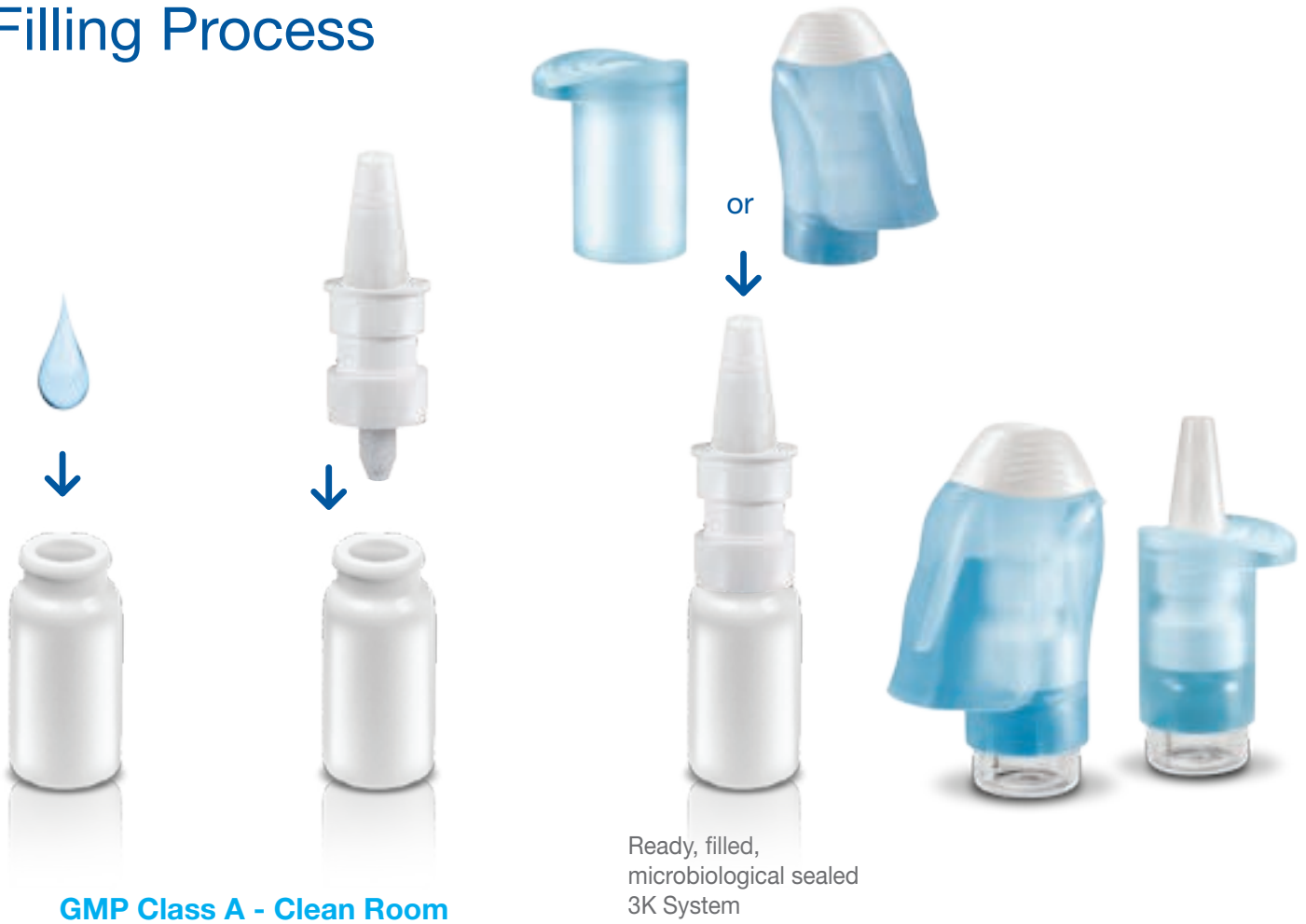
- ✓ Standard dose sizes: 28mg / 45mg
- ✓ System customization possible
- ✓ Clean room manufacturing ISO Class 7
- ✓ DMF available

Suitable container	Capacities
HDPE*	5ml, 10ml
Glass Type-I	5ml, 10ml

15ml by request



Filling Process



GMP Class A - Clean Room

Step 1
Aseptic
Filling

Step 2
Aseptic
Pump assembling

Step 3
Non-aseptic actuation
Sleeve assembling

Ready to use
3K Ophthalmic
Multidose System

Facts

- ✓ Filling and closing on standard pump processing equipment possible
- ✓ No necessity to assemble the finger sleeve under clean room conditions

Application

- ✓ For different target groups Rx and OTC products
- ✓ Convenient and Comfortable application
- ✓ Low actuation force
- ✓ Accurate dosage independent of priming force
- ✓ Suitable for existing glass and plastic containers
- ✓ Different container sizes available



Service / Support

Product consulting

- ✓ Pharmaceutical product portfolio
- ✓ Individual product development
- ✓ Product accessories
- ✓ Sampling

Technical Support

- ✓ Dosage determination
- ✓ Dosage adaption
- ✓ Extractables
- ✓ Microbiological analyzes

Certificated quality standards

- ✓ DIN EN ISO 9001
- ✓ DIN EN ISO 14001
- ✓ DIN EN ISO 15378
- ✓ DIN EN ISO 50001

Documentation

- ✓ Letter of conformity
- ✓ Product drawing
- ✓ Raw material data sheet
- ✓ Drug Master File (DMF)
- ✓ Applied Integrated Management System (IMS)





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Pharmazeutische
Applikationssysteme