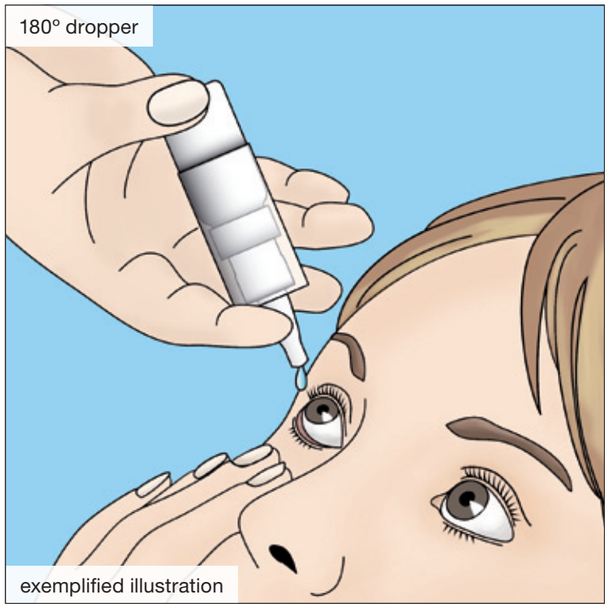
Application

- **For different target groups**
- **Convenient application**
- **Low actuation force**
- **Suitable for existing glass and plastic containers**
- **Filling on standard pump processing equipment possible**



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AERO PUMP
Pharmazeutische Applikationssysteme

Rev04/0112

Ophthalmic Multidose Systems

Preservative-Free Solutions

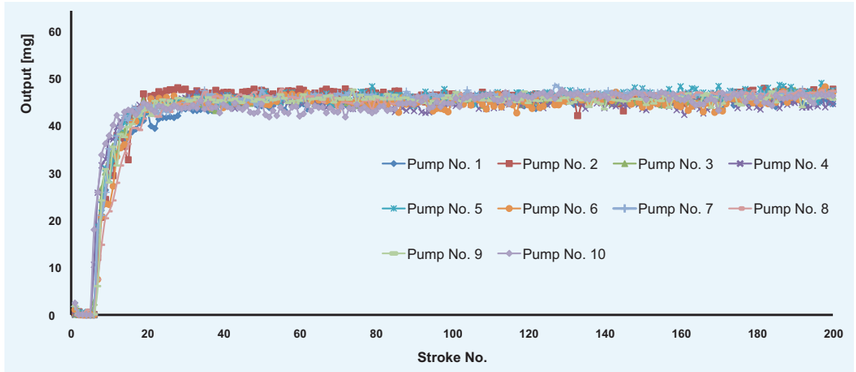
Inside

AERO PUMP

Performance

- **Reproducible droplet size**
- **Three way protection**
- **Snap-on closure for fast and safe processing in clean rooms**
- **Patented**
- **Fast priming**
- **Sterilizable by ETO**

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



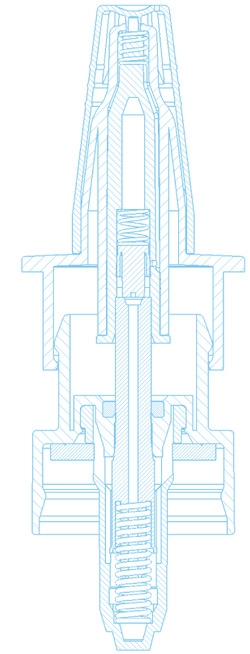
Availability

- **Standard dose size 28 mg / 45 mg**
- **Customization possible**

Aero Pump | Ophthalmic Multidose Systems

Microbiology

- **Microbiological studies available upon request**
- **Preservative free system is approved since almost two decades**
- **The current design was launched in 2006**



Microbiological quality after pre-test and dynamic integrity test 3K-dropper (exemplified illustration) (one test run out of several wider scaled testings)

Test	Pre-test	Dynamic Integrity	Dynamic Integrity
Number of Samples	cfu in the doses 1-3[1)]	cfu in the 1st dose 3 days after the last contamination[2)]	cfu in the content 3 days after the last contamination [3)]
20	< l.o.d.	< l.o.d.	< l.o.d.

1) Detection limit 15.15 cfu/ml (Volume of three doses 90 µl)
2) Detection limit 45.45 cfu/ml (Volume of one dose 30 µl)
3) Detection limit 0.2 cfu/ml (Volume being tested 1 ml)

< l.o.d. below limit of detection

This report focuses on the microbiological safety of Saline Solution in the dropper 3K. In order to test the safety of these products an extreme in-vivo-use was simulated as part of the experiments:

The testing condition of the dynamic integrity test contained a maximum of critical parameters such as an extreme high viable count (10^6 cfu/ml), a test organism well known as a successful contaminant (P.aeruginosa), and frequent, sequential contaminators.

Despite the extreme challenging parameters of the tests, which exceeded the usual real case conditions, no impairements of the microbiological quality of the product were seen. The repeated dipping into the bacterial suspension did not affect the quality of the first dose or the content.