



URSATEC
WHEN PRESERVATIVE FREE MATTERS®

**WHEN
PRESERVATIVE-FREE
MATTERS®**

Dosage Systems



Why is preservative-free important to your customers?

There is scientific evidence showing that preservatives can harm human physiology and cause various allergic reactions such as allergic rhinitis and atopic or contact dermatitis. They are known to have negative effects on the microbiome and can damage human epithelial cells.

To give an example in the area of nasal spray products: Some preservatives can have a repressive influence on the sensitive ciliated epithelium of the nasal mucosa (warning BFARM, 2003). However, an intact ciliated epithelium is necessary, for example, to transport pollen away or to be able to act against infectious particles (viruses, bacteria).

This philosophy can also be reconciled with current trends in both the pharmaceutical and cosmetics industries. Even though being highly regulated and rather conservative in implementing new ideas, the pharmaceutical industry has been calling for preservative-free formulations for years.

„The US Food and Drug Administration (FDA) has urged the pharma industry to develop preservative-free nasal sprays“

In-Pharmatechnologist.com, 2006

„Pharmaceutical companies are encouraged to consider novel strategies that allow the preservative-free formulation of paediatric medicines.“

EMA, ema.europa.eu, 2013

„Inclusion of antimicrobial preservatives or antioxidants in a finished product needs special justification. The use of these substances should be avoided in general, especially when considering the suitability of related formulations to the paediatric population.“

EMA, ema.europa.eu, 2010





Why URSATEC?

- ✓ We are the inventor and market leader in dosage systems for preservative-free applications and have sold almost two billion units within the last 25 years.
- ✓ Our technologically sophisticated dosage systems offer maximum protection against microbial contamination for a long period of time. They provide dispensing without any preservatives and thus guarantee a safe and very well tolerated use of the product.
- ✓ URSATEC "ONE Source" – We can do more than just packaging materials:



Idea



Dosage Systems



Product Development



Regulatory Affairs



Sterile Manufacturing



Supply Chain Management



URSATEC ONE Source

Delivering more than just dosage systems

Providing ready-to-market products including design, development, and registration

- ✓ We are your reliable and competent partner to guide you through the entire value chain of your product. Starting from the idea and passing through all steps, we provide support till your brand reaches your customer.
- ✓ Our ONE Source concept offers the advantage of having a single contract partner, instead of coordinating multiple suppliers and contract development and manufacturing organizations.
- ✓ We provide you with the perfect fit when it comes to pumps and bottles that are a validated and proven system. This minimizes the risk of product failures due to the usage of unvalidated compounds. In addition, we use experienced and verified filling partners, decreasing the risk even more.



Idea



Dosage Systems



Product Development



Regulatory Affairs



Sterile Filling

URSATEC ONE Source



The Dosage Systems

3K[®] and COMFORT[®] stand for safety and quality – without preservatives

Our patented 3K[®] and COMFORT[®] systems offer maximum protection against microbiological contamination, even after opening the product for the first time. They provide dispensing without any preservatives and thus guarantee safe and very well-tolerated use of the product. Both systems are characterized by the **unique URSATEC protection principle**: Microbiologically tight-closing valves in combination with oligodynamically acting components.

Thanks to the **multiple-safety technology**, our systems offer maximum protection against microbial contamination, even for long-term use:

- ✓ **Bacteriostatic surfaces** reduce the germ load at the opening of the nozzle and the entry of germs into the product channel.
- ✓ **Microbiologically tight-closing valves** secure the system against contamination.
- ✓ An **air-purifying filter** or an **airless inner bag** is used additionally, depending on the dosage system.
- ✓ A **controlled air intake** is guaranteed.
- ✓ **Secure sealing between pump and bottle** thanks to the harmonized design as an additional feature.
- ✓ **Locked connections** within the pump.

3K[®] System non-airless



For dispensing liquid pharmaceutical or cosmetic formulations.

COMFORT[®] System airless



For dispensing very sensitive liquid or semi-solid pharmaceutical as well as cosmetic formulations.



How does the 3K[®] system work, and what are the benefits?

Both a microbiologically tightly closing valve and the bacteriostatic effect of the surfaces used in the nozzle guarantee perfectly protected contents. In addition, the backflowing air is filtered after the pump has been actuated. Thus, the 3K[®] system guarantees perfect protection of the contents against microbiological contamination and in the meantime, provides all the advantages of a multi-dosing system for nasal, mouth & throat, dermal, and ear applications.



Benefits for your business / brand

- ✓ 100 % preservative-free formulations
- ✓ For liquid and slightly viscous suspensions
- ✓ Protection against chemical, physical and microbiological contamination
- ✓ Wide range of applications (nasal, oral, pharyngeal, otological, dermal)
- ✓ Different dosages (from 45mg to 150mg) and dispensation options (droplet, spray jet or spray)
- ✓ Bottles from 5 ml to 50 ml capacity (HDPE and Glass)
- ✓ Suitable for OTC products and prescription drugs

Benefits for your customer

- ✓ Safe & very well tolerated formulations
- ✓ Microbiome-friendly
- ✓ Easy to use and anatomical design / Fast priming and re-priming
- ✓ Suitable for multiple applications (nose, mouth & throat, ear, skin, and lung)
- ✓ Consistently accurate dosing
- ✓ 100% Made in Germany



Technical Facts and Figures

The 3K[®] system is a perfect fit.

3K[®] pumps + 3K[®] bottles = validated & proven system

Minimize the risk of product failures due to the usage of unvalidated compounds!

If you need other dosages than our standard ones, please just let us know. We also do customized developments!

3K[®] Bottles

HDPE	Glass
5 ml	10 ml
10 ml	15 ml
20 ml	20 ml
30 ml	
50 ml	

3K[®] Pumps



The world's only metered dose dropper for preservative-free applications



3K[®] UltraSoft Nasal Spray

A new tool for delivering drugs to the olfactory region

The advantages of the **nose-to-brain route** and **soft mist nasal sprays** for drug administration have been discussed in a recent publication. The possibility of bypassing the **blood-brain barrier (BBB)** opens up a noteworthy research area for the treatment of neurodegenerative diseases for which promising data already exist, e. g. on Parkinson's disease or intranasally administered insulin for memory loss. Another advantage of the intranasal route consists in overcoming the hepatic first-pass effect that results in **higher bioavailability** of the drug, **lower dosing**, and, consequently, **fewer side effects**. Established nasal spray pumps are limited in their ability to fulfill the described drug delivery needs. Using a pump that **unites the short actuation time** and **easy handling** of a standard spray pump, and a **distribution pattern that resembles a nebulizing system applied over several minutes**, for **reaching the olfactory region**, is a winning alternative.

3K[®] UltraSoft:

- ✓ Bypassing the BBB
- ✓ Higher bioavailability of drugs
- ✓ Lower dosing
- ✓ Fewer side effects
- ✓ Short actuation time
- ✓ Easy handling
- ✓ Reaching the olfactory region

UltraSoft Nasal Spray

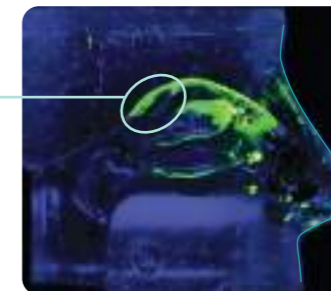


Dosage

45 mg

70 mg

3K[®] UltraSoft

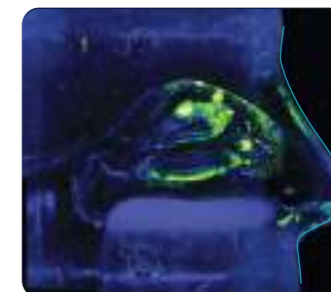


Target region

3K[®] Standard Pump



Aptar CPS pump



Silgan PFP NTM pump

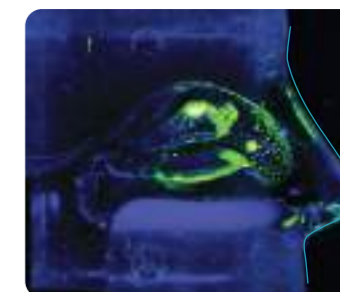


Figure: Comparison of different pumps concerning their distribution pattern of an aqueous solution in a Koken[®] nasal cast under continuous air flow of 15 L/min.



Inhalers | non-airless

Ecomyst90 & SoftBreezer®

Unique inhalation technology for liquid medications

- ✓ Preservative-free & Propellant-free
- ✓ Pocket size & Easy to use
- ✓ No batteries are needed
- ✓ Extremely fine nebulization
- ✓ Exact dosage: 25 mg
- ✓ Activation time: 1–3 seconds
- ✓ Respiratory resistance at 2 kPa: 15 LPM
- ✓ Compatible with 5 ml and 10 ml HDPE & Glass bottles
- ✓ Number of doses: 200 (5 ml) or 400 (10 ml)



OTC

SoftBreezer®

The world's only preservative-free pump-based liquid nebulizer with ultra-fine and dosed spray for gentle application of substance-based medical devices in the throat and bronchial area.



RX

Ecomyst90

A unique liquid inhaler that delivers an ultra-fine and dosed spray for prescription products aimed for use in the lungs, e.g. for the treatment of COPD and asthma.



How does the COMFORT® system work, and what are the benefits?

“Airless” literally means “without air” and indicates that the COMFORT® system does not require pressure compensation during actuation. The vacuum that emerges, when the pump is actuated successively, folds the flexible inner bag, which also allows semi-solid, less fluid formulations to be dispensed. In order to ensure the protection against the entry of microbiological contaminants, the COMFORT® system uses in addition to the tight-closing valve the oligodynamic effect of the surfaces at the outlet opening. This leads to provable perfect protection of the preservative-free contents.



**COMFORT®
Nasal Dropper**



**COMFORT®
Ear Spray**



**COMFORT®
Mouth & Throat
Spray**



**COMFORT®
Dermal Spray**

Benefits for your business / brand

19

- ✓ 100 % preservative-free formulations
- ✓ For viscous solutions and semi-solid forms (lotions & suspensions)
- ✓ 360° application: use of the product is possible from any angle, even overhead
- ✓ Protection against chemical, physical and microbiological contamination
- ✓ Wide range of applications (nasal, oral, pharyngeal, otological, dermal)
- ✓ Suitable for very light-and oxygen sensitive ingredients
- ✓ Bottles from 5 ml to 100 ml capacity (PE)
- ✓ Different dosages (from 45 mg to 150 mg)
- ✓ Suitable for OTC products and prescription drugs

Benefits for your customer

- ✓ Safe & very well tolerated formulations
- ✓ Microbiome-friendly
- ✓ 360° application (use is possible from any angle)
- ✓ Easy to use and anatomical design / Fast priming and re-priming
- ✓ Suitable for multiple applications (nose, mouth & throat, ear, skin, and lung)
- ✓ Consistently accurate dosing
- ✓ 100% Made in Germany



Technical Facts & Figures

The COMFORT® system is a perfect fit.

Pumps + Bottles = validated & proven system

Minimize the risk of product failures due to the usage of unvalidated compounds!

If you need other dosages than our standard ones, please just let us know. We also do customized developments!

Bottles

PE
5 ml
15 ml
30 ml
50 ml
100 ml

Pumps



Sustainability

The three pillars of sustainability at URSATEC

1 Compensating our carbon footprint

Together with **ClimatePartner**, we accessed the Product Carbon Footprint (PCF) of our primary packaging materials, and you can choose a carbon-neutral version of our products. We offer the option “**carbon-neutral**” for your orders by selecting and supporting a carbon offset project. In doing so, you will offset the unavoidable emissions that occur in the manufacturing of your chosen products. You can then use the **unique ClimatePartner label “carbon-neutral product”** which provides transparency in climate action and is TÜV Austria certified. The ID and tracking URL on the label allows your customers to view the emissions, the offset amount and the carbon offset project itself. This offers maximum transparency of your carbon neutrality.



2 Reducing our emissions

We continuously work on avoidance and reduction of our emissions.

We not only reduce resources, such as electricity and water at our office site, we also use **green electricity** to power our offices. Along with **reforestation projects**, both locally and worldwide social-based projects, as well as **green education**, we have a broad variety of **compensation measures** and positive environmental impacts.

Within our reforestation project, we have created a 6.000sqm “company forest”. An area was selected that had to be cleared due to heavy bark beetle infestation and wind damage. Thanks to our support, 500 sycamores, 500 bird cherries and 100 wild service trees have now been planted.



3 Recyclability of our products

RecycleMe tested our packaging materials for their recyclability and scored A+++ with 96% recyclability in our 3K® system.

In this way, we avoid a cradle-to-grave life cycle for our products and close the loop by enabling cradle-to-cradle reuse of our plastics.

Recycle Me



Sustainability

Our sustainability network



- ✓ Three pillars of sustainability as highlighted on the previous page
- ✓ Cooperation with all suppliers & service providers on sustainability related topics



- ✓ TÜV-certified Sustainability Manager
- ✓ Goal: To reach EMAS certification within short-term
- ✓ Very active in fields of CRS (Corporate Social Responsibility), e. g.:
 - Supporting diverse sports activities
 - Social-medical aftercare
 - Bee projects



- ✓ Active in diverse CSR projects
- ✓ Optimization of production process with focus on reduction of emission



- ✓ Winner in Gold 2021 of the German Packaging Award for sustainability
- ✓ Pay attention to the recyclability of their products, use materials made from renewable raw materials, and use secondary raw materials from post-consumer recycling wherever possible
- ✓ Installed a photovoltaic system on their production buildings, which supplies electricity for their production and e-vehicles

Our mission to support our health and environment

Starting on the worldwide day of oceans, the 8th of June 2022, we initiated a virtual fundraiser challenge supporting the “Institute for Ocean Plastic Recycling”. Connecting our company with our three main suppliers across Germany with almost 180 participants and a course of over 1,200 km in length, we were running, cycling, trekking and swimming for 114 days for a good cause. With this virtual mission, we not only support the cleaning of the ocean from plastics, but also work on our personal fitness and activity. All four company sites were digitally connected, and all involved companies donated to the “Institute for Ocean Plastic Recycling” after finalizing the challenge end of September 2022.





www.ursatec.com