



URSATEC
WHEN PRESERVATIVE FREE MATTERS®

Dual safety without preservatives



... when preservative free matters®

... when preservative free matters®

The philosophy

Preservatives can cause various allergic reactions such as allergic rhinitis and rhinitis medicamentosa.

Ursatec Verpackung GmbH is dedicated to support the global health care industry in avoiding preservatives in any kind of medical device, pharmaceutical or cosmetic products. Health care administrations recommend the development of preservative-free pharmaceutical and cosmetic products worldwide.

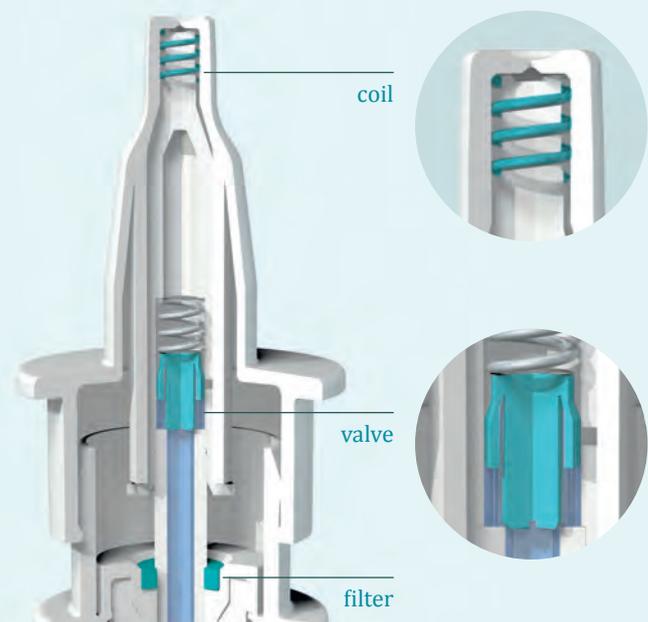
„The US Food and Drug Administration (FDA) has urged the pharma industry to develop preservative-free nasal sprays“

(In-Pharmatechnologist.com, 2006)

Dual microbiological protection

The safety of the patented preservative-free Ursatec dosage systems is based on a unique combination of two independent protection mechanisms:

- Microbiologically tight valves
- Protective surface areas



Preservative free products

Products & services

APPLICATIONS	
<input checked="" type="checkbox"/>	Nasal
<input checked="" type="checkbox"/>	Buccal/Sublingual
<input checked="" type="checkbox"/>	Otological
<input checked="" type="checkbox"/>	Topical
<input type="checkbox"/>	Inhalative



3K[®] system non airless

The 3K[®] system is a non-airless system. It can be used in combination with glass and plastic containers.

APPLICATIONS	
<input checked="" type="checkbox"/>	Nasal
<input checked="" type="checkbox"/>	Buccal/Sublingual
<input checked="" type="checkbox"/>	Otological
<input checked="" type="checkbox"/>	Topical
<input type="checkbox"/>	Inhalative



COMFORT[®] system airless

The COMFORT[®] system is an airless system. It allows the delivery of the product in any position and is therefore also suitable for upside down use.

APPLICATIONS	
<input type="checkbox"/>	Nasal
<input type="checkbox"/>	Buccal/Sublingual
<input type="checkbox"/>	Otological
<input type="checkbox"/>	Topical
<input checked="" type="checkbox"/>	Inhalative



SoftBreezer[®] liquid nebulizer

SoftBreezer[®] is the first preservative-free mobile nebulizer for consumer health products such as isotonic saline inhalation solutions. The new device is suitable for all kind of preventive products.

SERVICES	
<input type="checkbox"/>	Development
<input type="checkbox"/>	Project management
<input checked="" type="checkbox"/>	Contract filling
<input type="checkbox"/>	Quality control
<input type="checkbox"/>	Lab services



Contract filling

Our service includes complete coordination of the order, provision of the raw materials, sterilization of primary packaging, GMP-compliant filling under aseptic conditions in clean room class A as well as quality control and microbiological safety tests under validated conditions.

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URSATEC
WHEN PRESERVATIVE FREE MATTERS

Technical Information & Service



Ursatec dosage systems
for preservative free application

Value Added Supply Chain for your Product

Our philosophy:
Preservatives shall be avoided
wherever possible

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

(In-Pharmatechnologist.com, 2006)

Services



Safety & Quality

Technical Information

Services



Our Services

For your advanced preservative free products

Ursatec Verpackung GmbH is your partner for all challenges associated with the application of preservative free pharmaceuticals, medical devices and cosmetic products. Through our experienced project management and well-established supply chain, we are able to provide finished products ready to sell.

You can count on us for complete service packages or single components only.



Product Development

Solutions for pharmaceuticals, medical device and cosmetic products

Ursatec's partnerships with contract development organizations are the basis for offering professional expertise to our customers. Together with formulation specialists, Ursatec supports its clients in creating new application paths for innovative pharmaceutical and cosmetic products

Step by step, we lead you through the product development, starting with developing the formulation via small scale test fillings up to the final product ready to sell. All operations of course fulfill the requirements of the relevant international guidances such as e.g. the EMEA guideline.



Documentation

Get your analytical file ready for submittal

Even at the beginning of the formulation development, it is necessary to clarify the registration questions concerning the pharmaceutical quality of products such as inhalation or nasal sprays. The same considerations must be made when revising a formulation for a new registration. To file for registration, many documents are required by the authorities. The necessary quality documentation includes the following data:

- Composition and formulation development
- Manufacturing controls
- Quality control of the raw materials
- Finished product including stability tests

Services

Material Provision

Raw material provision for primary packaging

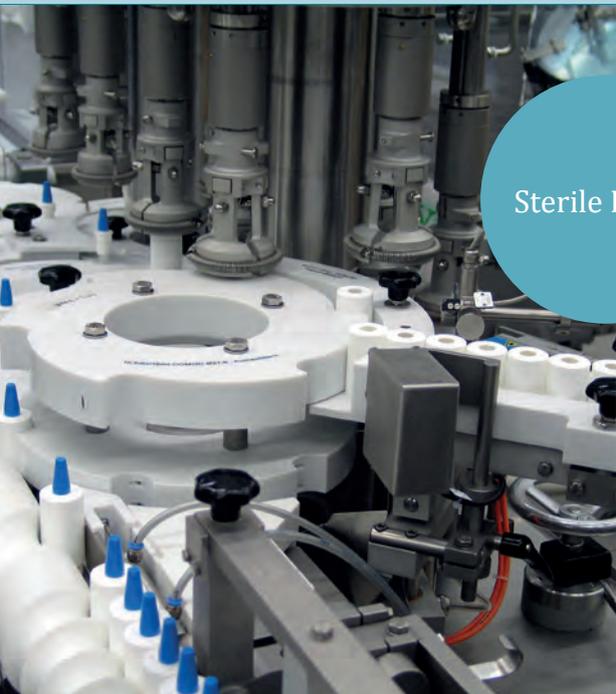
All raw materials are sourced in standard quantities from qualified suppliers. The material's quality, e.g. conformity with common requirements with respect to food-contact, pharmacopeial requirements, REACH, etc., as far as applicable, is defined by comprehensive specifications. The safety of all polymers and colouring materials used for the manufacture is assured by corresponding certificates of the suppliers. Prior to use for manufacture, each material batch is subjected to at least an identity test.



Sterilization

Proven, reliable and validated processes

The individual components of the Ursatec systems, pumps and bottles, are sterilized according to validated procedures in compliance with respective norms and standards. The ethylenoxide sterilization was shown to be a particularly suitable sterilization procedure for the systems, as this procedure is very safe, reliable and mild with respect to the materials. Upon completion of the sterilization cycle, the goods are subjected to desorption in specific desorption cells under validated conditions ensuring that the residual ethylene oxide (EO) and ethylene chlorhydrine (ECH) are below the tolerance limits of the respective norms and directives. The sterilization is exclusively carried out at qualified and certified partner companies, which are subjected to regular audits.



Sterile Filling

Best standards – clean room class A

For the production of today's most challenging preservative free products, Ursatec has qualified the best partners to meet the high quality standards these products create. The filling machinery of our partners operates in a clean room class A environment which is designed by a team of scientists and engineers in consultation with industrial and regulatory experts. They incorporate those special engineering design concepts and control systems for aseptic filling in order to guarantee full microbiological protection of the preservative free product.

Their facilities include:

- Experienced and well-trained dedicated staff
- Air handling system with HEPA- filtered air
- Raw materials sealed until arrival in filling suite

Together with its partners, Ursatec offers a full service concept delivering a completely finished product to the customer ready to sell.

Lab Services

Single components or full service

Laboratory services provided by Ursatec and its partners comply with strict international standards. This creates the essential basis for the successful approval and sale of your pharmaceutical product in national and international markets. Ursatec offers laboratory services through its partners that range from the preclinical phase all the way to the market approval of your pharmaceutical products. You can count on us for complete service packages or individual service components, including

- Development and validation of methods
- Stability testing and storage
- Testing of raw materials
- Complete service packages for batch release
- Analytical services upon request

Safety & Quality



Manufacturing Excellence

State-of-the-art production sites

Ursatec products are exclusively manufactured and processed by qualified and certified partners, with whom a longstanding and trustful cooperation is the aim. The construction of individual components as well as the assembly of the components to the full functional system is carried out according to established quality criteria, in accordance with the principles of GMP-rules of the WHO. For the reproducible maintenance of the defined high quality standard, all necessary technical, organizational and structural measures have been taken and are verified by regular audits. All facilities, production lines and testing installations are routinely cleaned, serviced and tested on their proper performance. All steps of manufacture and control relevant for quality assurance are carried out according to written operating procedures and are documented correspondingly.



Quality Control

Certified according to EN ISO 9001 and EN ISO 13485

The tests for the release control of pumps and bottles of the preservative free Ursatec systems are carried out according to established internal operating procedures and testing instructions on basis of data obtained by numerous in-process controls. All results are documented in the testing certificates, and a batch found in compliance with specifications is released.

As a result of the requirements with respect to the microbiological purity of the container content, the pump and the container must form a tightly sealed system. The microbiological safety of Ursatec's systems is therefore routinely controlled. Customers formulations can have an impact on the test parameters – therefore all relevant parameters, e.g. interaction product/container, efficiency of germ-reducing measures, preciseness of dosing, etc., must be additionally tested with the finished product, i.e. the sealed container filled with the respective formulation. These tests and further experiments, such as stability tests, in-use safety tests, in-use stability tests, etc. can be carried out at Ursatec's or at cooperating institutions.



Microbiological Safety

Double safety without preservatives

To ensure the microbiological safety of the non-preserved product, the Ursatec system is equipped with a patented double protection mechanism. Although the valve demonstrably provides effective protection of the container contents after the first opening, protective surface areas reduce the number of germs near the product outlet and the product channel. This activity is optimized by the low volume of the dead space and the maximum possible surface area, resulting in a significant germ reduction or prevention of microbial growth, respectively in the vicinity of the outlet opening. The combination of a highly efficient valve with oligodynamically active construction components in optimal position does not only ensure comprehensive protection of the container contents against contamination, but also minimises the bioburden of the next dose to be dispensed. Appropriate testing procedures demonstrating the microbiological safeguard of the Ursatec system have been published in the medical and pharmaceutical literature, and the safety of the materials used to produce the Ursatec system has been demonstrated by numerous investigations.

Technical Information

Specifications

3K®-System
non airless

3K®-System Nasal Spray



Dosage	Plastic	Glass
45 mg	5 ml	10 ml
70 mg	10 ml	15 ml
90 mg	20 ml	20 ml
100 mg	30 ml	
140 mg		

3K®-System Nasal Dropper



Dosage
30 mg
45 mg
85 mg

3K®-System Ear Spray



Dosage
65 mg
100 mg
150 mg

3K®-System Horizontal Spray

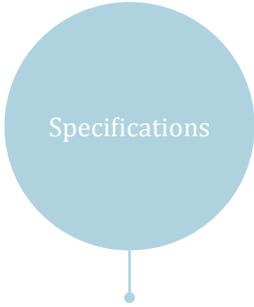


Dosage
45 mg
85 mg
140 mg

3K®-System Throat Spray



Dosage
65 mg
100 mg
150 mg



COMFORT®-System
airless

COMFORT®-System Horizontal Spray



Dosage	Plastic
45 mg	5 ml
85 mg	15 ml
140 mg	30 ml
	50 ml

COMOD®-Design Nasal Dropper/Spray



Dosage
30 mg
45 mg
70 mg
140 mg

COMFORT®-System Ear Spray



Dosage
65 mg
100 mg
150 mg

COMFORT®-System Nasal Dropper/Spray



Dosage
30 mg
45 mg
85 mg
100 mg
140 mg

COMFORT®-System Throat Spray



Dosage
65 mg
100 mg
150 mg

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URSATEC
WHEN PRESERVATIVE FREE MATTERS®

Packaging solutions for
advanced therapeutic compounds



Ursatec dosage systems for
preservative free dermal products

Innovative packaging solutions ...

The philosophy behind Ursatec Verpackung GmbH

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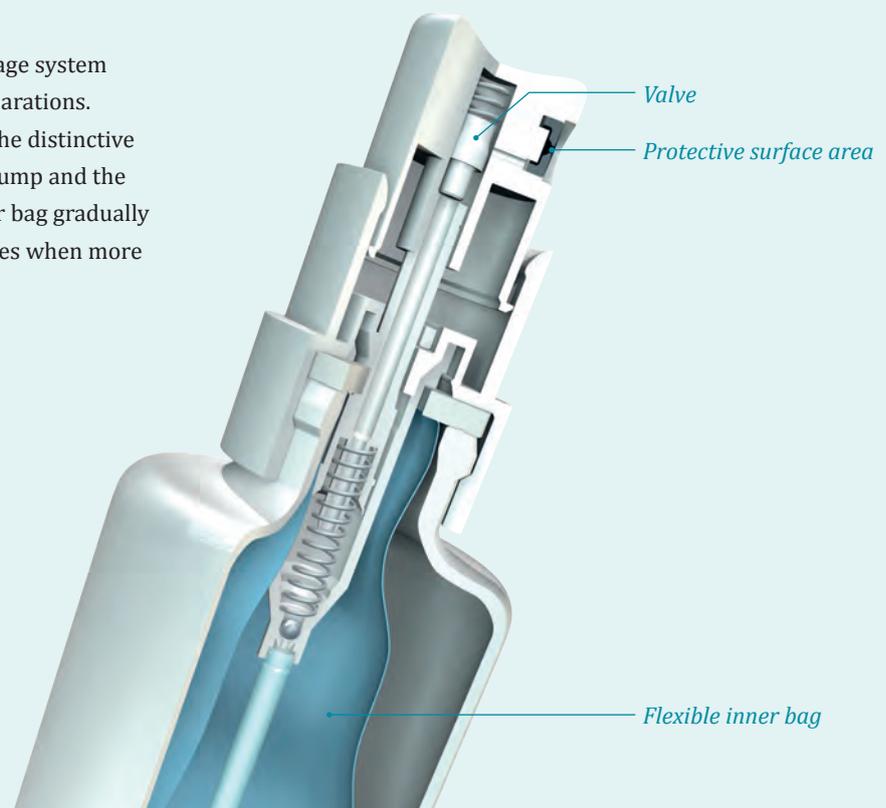
„The packaging should be designed to restrict the ingress of contaminants ...“

Cosmetics Europe: Guidelines on Microbial Quality Management, 1997

Dual microbiological protection

The COMFORT®-System is an airless dosage system for the delivery of preservative-free preparations. Microbiological safety is guaranteed by the distinctive construction of the unique COMFORT® pump and the special bag-in-bottle container. The inner bag gradually folds up as the negative pressure increases when more and more product is withdrawn.

- Safeguarded dosage system
- Aseptic filling process
- Oxygen protection



... for dermal application

For your demanding dermal product developments

The patented preservative-free Ursatec COMFORT®-System provides significant added value for advanced therapeutic compounds to the skin, buccal mucosa and ear. Depending on your specific requirements the COMFORT®-System allows the dispensation of a broad range of liquid preparations such as solutions, suspensions and lotions. Your product can be dispensed drop-wise, as a jet or as a spray and from any position (upright, upside down, horizontal).

As a response to the rising consumer demand for products that are free of harmful ingredients, the COMFORT®-System avoids the use of preservatives, which are suspected to cause allergic reactions and other side effects.

Benefits for your customers

Suitable for hydrophilic and lipophilic formulations such as solutions, suspensions and lotions.

- Preservative free
- 360° application
- Metered dose

Dosages and bottle sizes

Available dose sizes:

45 / 85 / 140 mg

Plastic bottle sizes:

15 / 30 / 50 ml



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Pure cosmetics for healthy beauty



Ursatec dosage systems
for preservative free cosmetics

Pure cosmetics ...

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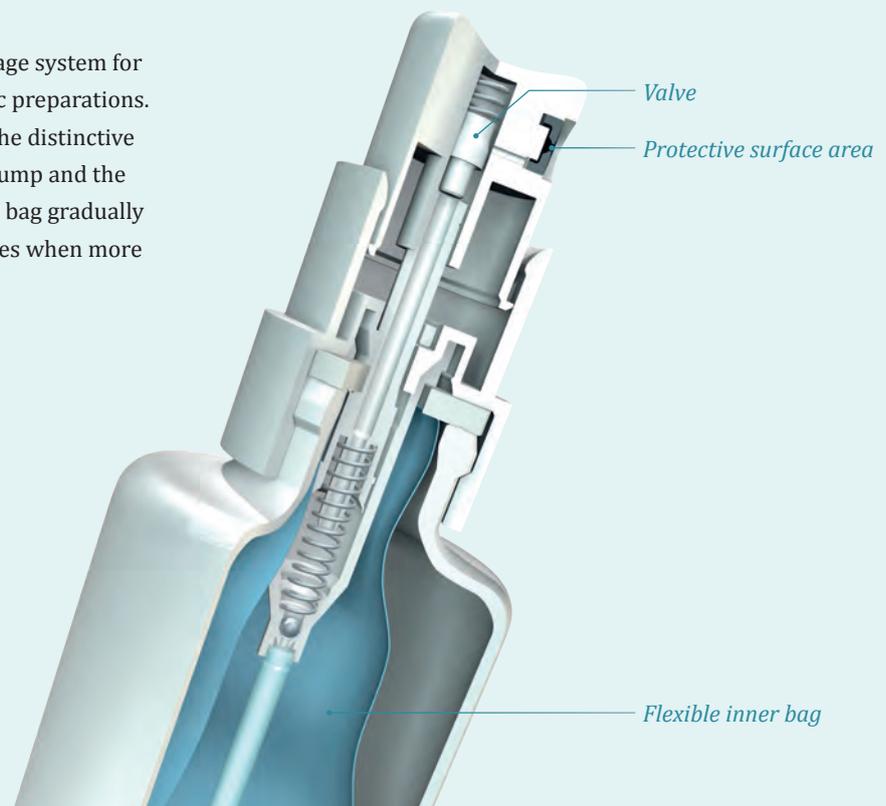
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Dual microbiological protection

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- Safeguarded dosage system
- Aseptic filling process
- Oxygen protection



... for healthy beauty

For your natural and organic cosmetics

A research with the title *Exploring the Territory of Natural & Organic Cosmetics* commissioned by NATRUE, an international non-profit association committed to protecting natural and organic cosmetics worldwide, was carried out in order to find out more about consumer expectations and understanding around these products.

In this study, 87 % of the respondents with allergies said that the potential harmfulness of ingredients is an important factor behind their purchasing decision.

The research also found out that 94 % of all women believed that organic cosmetics should not contain artificial or chemical ingredients!

- Preservative free
- Clean design
- 360° application



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URSATEC
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SoftBreezer®
gentle breathe



Ursatec dosage systems
for preservative free inhalation

Preservative free for a healthy life®

The philosophy behind Ursatec Verpackung GmbH

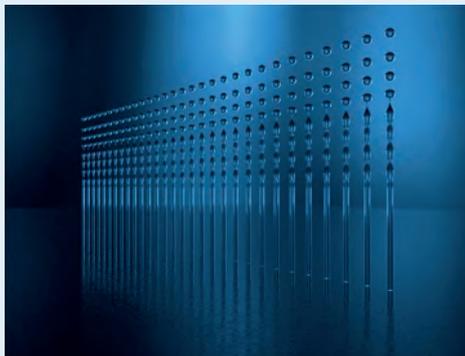
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„Devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons.“

Interinstitutional File: 2012/0266 (COD); Brussels, 27 June 2016 (OR. en); 10617/16
Council of the European Union

SoftBreezer® – innovative spray nozzle for gentle breathe

The SoftBreezer® spray nozzle unit developed by Medspray is based on highly precise orifices in a small surface.



Pressing water through the SoftBreezer® spray nozzle unit results in multiple jets which will automatically break up in small droplets (Rayleigh principle). The resulting spray mist is mono-disperse which means that all droplets have the same size for good lung deposition.

SoftBreezer[®] – refresh your life

Refresh your life

First preservative-free mobile nebulizer for consumer health products such as isotonic saline inhalation solutions. SoftBreezer[®] is a manually actuated, pocket size nebulizer device for aqueous solutions, releasing a mono-disperse aerosol, targeting the airways very efficiently.

The SoftBreezer[®] preservative-free spray pump is based on Ursatec's proven spray devices used for over 20 years.

Key Features

Suitable for all kind of preventive products.

- Gentle breathe
- Preservative free
- Propellant free
- Pocket size
- Proven 3K[®] technology
- Microbiologically safe

Data sheet

Pump delivery PD (water placebo)

25 mg

Airflow at 2 kPa

10 -20 lpm

Container fill

5 ml or 10 ml

Number of actuations/container

200 or 400

Microbial integrity of container in use

min. 90 days



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