



URSATEC  
WHEN PRESERVATIVE FREE MATTERS®



URSATEC dosage systems  
for preservative-free application

# ... when preservative-free matters®

## The philosophy

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

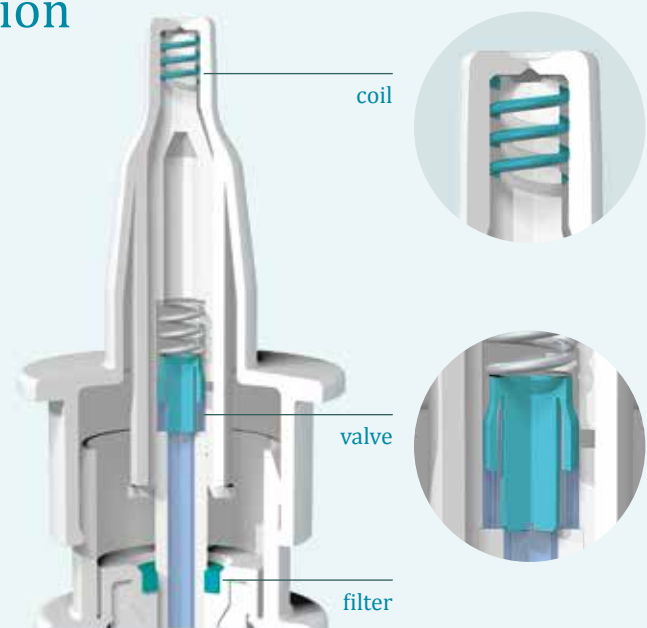
*“The US Food and Drug Administration (FDA) has urged the pharma industry to develop preservative-free nasal sprays.”*

(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





## Made in Germany

URSATEC is located in Tholey / Germany.  
And from here, we remain in close contact to customers and partners  
all over the world.

Our team consists of individuals with wide-ranging experience in the diverse areas of the pharmaceutical industry. We give advice to our customers when changing products, we handle the order processing as well as the production and inspection processes right up to the delivery of the finished goods. Our customers' individual requests are always taken into account, if necessary up to a detailed development of customized solutions.

The secret behind the achievements of URSATEC also lies in its future-oriented structure with an international network of highly qualified partners covering the full range of services, from consulting through development and pharmaceutical filling to sales support.

QUALITY STANDARDS: ISO 9001, ISO 13485, ISO 15378

# Our Services

## For your advanced preservative-free products

URSATEC 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.**



## Ursatec ONE Source

Finished products  
including aseptic filling



## Product Development

### Solutions for pharmaceuticals, medical devices 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 guidelines.



## 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

# Our Services

## Material Provision

### Raw material provision for primary packaging

All raw materials are sourced in standard quantities from qualified suppliers. Material quality requirements, e. g. food-contact regulations, pharmacopeial prerequisites, REACH, etc., are as far as applicable defined by comprehensive specifications. The safety of all polymers and coloring 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 ethylene oxide 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.



## Aseptic 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 require.

The filling machinery of our partners operate 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 site

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
- GMP conform testing of Droplet Size Distribution, Spray Pattern, Plume Geometry
- Testing of raw materials
- Complete service packages for batch release
- Analytical services upon request

# Our Partners

Manufacturing  
Excellence made  
in Germany

## 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 the defined high quality standard.



## Aero Pump is the URSATEC partner for the production of the microbiological protected pumps for preservative-free application

Aero Pump specializes in the production of application systems for the pharmaceutical industry. Aero Pump is one of the world's leading manufacturers of pharmaceutical application systems. The company has continued to grow since its foundation in 1976, and today sells over 300 million units around the world annually.

QUALITY STANDARDS: ISO 9001, ISO 15378





## Gaplast is the URSATEC partner for the production of innovative packaging solutions

Gaplast has been the preferred supplier of URSATEC producing plastic containers for preservative-free dosage systems such as 3K®, COMOD® or COMFORT® for many years. The production conditions guarantee compliance with national and international guidelines in all plants of Gaplast.

Gaplast offers a broad variety of novel plastic packaging solutions for pharmaceuticals and cosmetics.

QUALITY STANDARDS: ISO 9001, ISO 15378



## Ursapharm is the URSATEC partner for aseptic filling

Ursapharm is the solid partner for highly efficient contract filling of URSATEC's dosage systems for preservative-free application.

Ursapharm's modern production facilities are operated in full compliance with the national and international quality requirements of authorities and notified bodies.

QUALITY STANDARDS:  
GMP | ISO 13485 COMPLIANT

# 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 Throat/Ear Spray



#### Dosage

65 mg

100 mg

150 mg

### 3K®-System Dermal Spray



#### Dosage

45 mg

85 mg

140 mg

### SoftBreezer® Liquid Nebulizer



#### Dosage

25 mg



Specifications

COMFORT®-System  
airless

### COMFORT®-System Dermal Spray



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

### COMFORT®-System Nasal Spray



Dosage
45 mg
70 mg
90 mg
100 mg
140 mg

### COMFORT®-System Nasal Dropper



Dosage
30 mg
45 mg

### COMFORT®-System Throat Spray



Dosage
65 mg
100 mg
150 mg

### COMFORT®-System Ear Spray



Dosage
65 mg
100 mg
150 mg

URSATEC GmbH  
Marpinger Weg 4  
66636 Tholey  
Germany

Phone: +49 (0)6853 96199-0  
Fax: +49 (0)6853 96199-14

E-Mail: [m-contact@ursatec.com](mailto:m-contact@ursatec.com)  
Internet: [www.ursatec.com](http://www.ursatec.com)