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

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

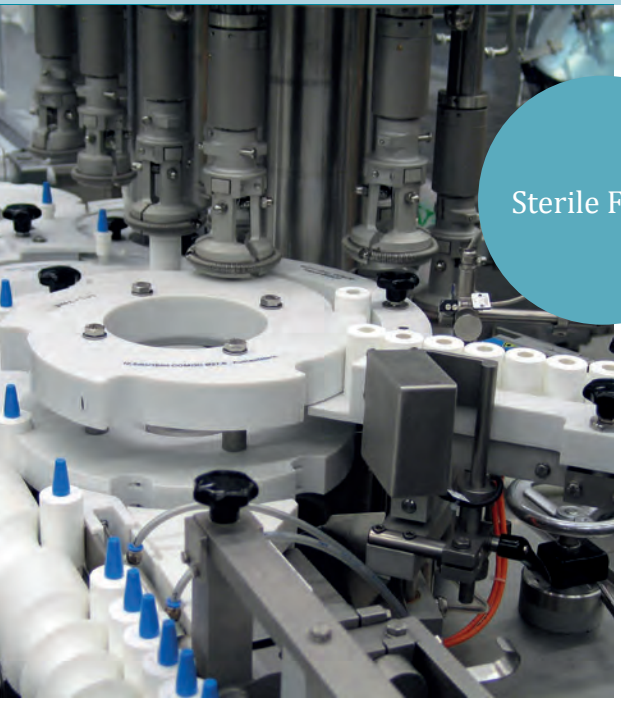
Raw material provision for primary packaging

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

Specifications

COMFORT®-System airless

COMFORT®-System Horizontal Spray

Dosage
45 mg
85 mg
140 mg

Plastic
5 ml
15 ml
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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Version January 2016