



Sterisart® NF – 16475

System for Lyophilized or Soluble Powders in Unvented Vials



System for lyophilized or soluble powders in unvented vials (e.g. antibiotics)

International pharmacopeias require the complete sterility of pharmaceutical products that are injected into the bloodstream or that otherwise enter the body below the skin surface. Manufacturers of such products are required to supply proof of the sterility of the final product batch.

The preferred method for sterility testing is the membrane filter method – any microorganism present is concentrated on the membrane filter surfaces in the sample containers. In the final step nutrient media are added to these containers and the containers are incubated under the conditions specified.

The Sterisart® NF system 16475 has been specifically designed for sterility testing easy-to-dissolve powders (e.g. lyophilized antibiotics in powder form).

The dual-needle metal spike with a vent filter is used to remove dilution solution from closed vials, and is connected with a short metal dual-needle spike to a single tube.

The shorter dual-needle metal spike, which is additionally connected by the double tubing system to the Sterisart® containers, is used to fill dilution solution and, in conjunction with this, to dissolve the powder in the sample container (e.g., lyophilized antibiotic powder).

The dissolved powder is pumped through this double-needle spike into the two Sterisart® containers and filtered. The culture media described by the pharmacopeias are filled into these containers. The containers are subsequently incubated for two weeks, then evaluated.

The Sterisart® NF 16475 types are available as special isolator versions. The version with the suffix "gamma Septum" (or GSD) has a partitioned (i.e. septated) connector which allows sterile sampling during incubation avoiding a risk of contamination.

Ideally the systems are used in combination with the Sterisart® Universal pumps 16419 oder 16420. These can be used in clean rooms and clean benches or can be installed in isolators.

Sterisart® NF systems can also be used with other manufacturers' pumps which have been specially designed for disposable closed sterility testing systems. This requires an adapter to ensure the correct position of Sartorius NF units in the pumps of other manufacturers: 16412V (for older pumps) or 1ZG---0014 (for the latest pump versions).

Specifications

Pore size of the Sartochem® membrane filter	0.45 µm, tested with <i>Serratia marcescens</i>
Filter area	15.7 cm ² in each Sterisart® container
Flow rate (for water)	500 ml/min at 1 bar (approx. 15 psi)
Pore size of the air filters	0.2 µm PTFE, validated acc. to HIMA for the retention of <i>B. diminuta</i>
Sample container capacity	120 ml (graduation marks at 50, 75 and 100 ml)
Max. operating pressure	3 bar (approx. 44 psi) at 20 °C
Max. operating temperature	50 °C
Sterilization	gamma irradiation

Chemical compatibility of the components (24 hour contact at 20 °C)

	Sartochem® membrane	Tubing	Sterisart® container
Aqueous solutions	compatible	compatible	compatible
Alcohols	compatible	compatible	compatible
Aliphatic hydrocarbons	compatible	compatible	compatible
Oils	compatible	compatible	compatible
Salt solutions	compatible	compatible	compatible
Ether	compatible	compatible	compatible
Weak acids	compatible	compatible	limited compatibility
Weak bases	limited compatibility	compatible	limited compatibility
Aromatic hydrocarbons	compatible	not compatible	not compatible
Esters	compatible	not compatible	limited compatibility
Halogenated hydrocarbons	compatible	not compatible	not compatible

Ordering information

Name	Description	Quantity	Order number
Sterisart® NF gamma	System for lyophilized or soluble powders in unvented vials (gamma sterilized, double-packed, optimal for use in isolators)	Box of 10	16475 GBD
Sterisart® NF gamma Septum	System for lyophilized or soluble powders in unvented vials (gamma sterilized, double-packed, optimal for use in isolators)	Box of 10	16475 GSD
Sterisart® Universal pump	Basic version: Peristaltic pump for use with sample containers in sterility testing	1	16419
Sterisart® Universal pump	Upgraded version with display user software	1	16420
Pump adapters	For use with Sterisart® systems in older competitor pumps. Please clarify pump type used.	2	16412 V
Pump adapters	For use with Sterisart® systems in newer competitor pumps. Please clarify pump type used.	1	1ZG---0014

Further Sterisart® units and accessories are available on request.

Comprehensive validation support literature is available on request.
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