



Sterisart® NF gamma Septum – 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. As a manufacturer of such products, you 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 microorganisms present are concentrated on the membrane filter surfaces in the sample containers, then nutrient media are added to these containers and the containers are incubated under the conditions specified.

The Sterisart® NF system with order number 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 along 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 pumped into these containers, and the containers are subsequently incubated for two weeks, then evaluated.

The new Sterisart® systems with a partitioned (i.e. septated) connector allow sterile sampling during incubation and guarantee a sterile barrier between the interior and exterior of the container during further incubation.

The Sterisart® NF 16475 type is available as a special isolator version with the model suffix "gamma Septum," which is indicated by the last letters of the order number: GSD.

Sterisart® NF systems can also be used with other manufacturers' pumps which have been specially designed for disposable closed sterility testing systems. This requires one of two adapters to ensure the correct seating of Sartorius NF units in the pumps of other manufacturers – adapter order number 16412V (for older pumps) or 1ZE---0014 (for the latest pump versions).

However, you will not need these adapters if you are using Sterisart® Universal pumps 16419 and 16420. Recently designed by Sartorius Stedim Biotech, these versatile and flexible pumps offer considerable benefits, and are ideal for use in clean rooms and clean benches as well as in isolators when installed in the working surface.

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 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 Millipore pumps. Please clarify pump type used	2	16412 V
Pump adapters	For use with Sterisart® systems in newer Millipore Equinox pumps. Please clarify pump type used.	1	1ZE---0014

Further Sterisart® units and accessories are available on request.

Comprehensive validation support literature is also available on request.
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