



Sterisart® NF – 16477

System for Liquids in Plastic Containers



Specifications

| | |
|---|---|
| Pore size of the Sartochem® membrane filter | 0.45µm, 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 |

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 16477 has been specifically designed for sterility testing of liquids in plastic containers. The unvented, non-coring needle with solid pointed tip and side opening minimizes clogging by particles when piercing the plastic container. The sample is pumped in equal volumes into the two Sterisart® containers and filtered. In the final step the culture media described by the pharmacopeias are pumped into these containers. The containers are subsequently incubated for two weeks and then evaluated. The enclosed venting needle guarantees venting of the container during sample transfer or the rinsing procedure as well as during media transfer.

The Sterisart® NF type 16477 is available as special isolator version with the model suffix "gamma," which is indicated by the last letters of the order number: GBD.

Ideally the systems are used in combination with the Sterisart® Universal pumps 16419 or 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 positioning of Sartorius NF units in the pumps of other manufacturers: 16412V (for older pumps) or 1ZG---0014 (for the latest pump versions).

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

| | Sartochem® membrane | Tubing | Sterisart® containers |
|--------------------------|--------------------------|----------------|--------------------------|
| 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 liquids in plastic containers (individually gamma sterilized, double-packed, optimal for use in isolators) | Box of 10 | 16477 GBD |
| 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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