



Sterisart® NF – 16470

System for Difficult-to-Dissolve Powders in Unvented Vials



Tubing system for solution and dilution of difficult-to-dissolve powders (e.g., antibiotics) in unvented vials.

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. Nutrient media are added to these containers and the containers are incubated under the conditions specified.

The Sterisart® NF system 16470 has been specifically designed for dissolving and diluting powders with exceptionally low solubility. When used in combination with Sterisart® systems 16466 and 16467, Sterisart® NF allows sterility testing of these difficult-to-dissolve powders in closed, unvented vials.

The tubing system consists of a 3.6 cm dual-needle metal spike (yellow color-code) and a 2.3 cm metal dual needle spike, which are connected with each other by double tubing.

Half the length of this double tubing is separated into single tubes, and one of these is identified by the plastic ring sheaths.

Solvents and the powder to be dissolved are recirculated through this tubing system until the powder has been completely dissolved.

This solution is pumped in equal amounts through the Sterisart® NF systems, either 16466 or 16467, into the two Sterisart® containers and filtered. The culture media described by the pharmacopeias are pumped into these containers. The containers are subsequently incubated for two weeks, then evaluated.

The Sterisart® NF type 16470 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 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

| | |
|----------------------------|---------------------------------|
| 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 |
|--------------------------|-----------------------|
| Aqueous solutions | compatible |
| Alcohols | compatible |
| Aliphatic hydrocarbons | compatible |
| Oils | compatible |
| Salt solutions | compatible |
| Ether | compatible |
| Weak acids | compatible |
| Weak bases | limited compatibility |
| Aromatic hydrocarbons | compatible |
| Esters | compatible |
| Halogenated hydrocarbons | compatible |

Ordering information

| Name | Description | Quantity | Order number |
|----------------------------|--|-----------|--------------|
| Sterisart® NF gamma | System for difficult-to-dissolve powders in unvented vials (gamma sterilized, single-packed) | Box of 10 | 16470 GBD |
| Sterisart® NF alpha | Dual-needle metal spike for closed containers (sterilized with ETO; single-packed) | Box of 10 | 16466 ACD |
| Sterisart® NF alpha | 6 cm metal needle for open containers (sterilized with ETO; single-packed) | Box of 10 | 16467 ACD |
| Sterisart® NF gamma | Dual-needle metal spike for closed containers (gamma sterilized, double-packed) | Box of 10 | 16466 GBD |
| Sterisart® NF gamma | 6 cm metal needle for open containers (gamma sterilized, double-packed) | Box of 10 | 16467 GBD |
| Sterisart® NF gamma Septum | with dual-needle metal spike for closed containers and with septum (gamma sterilized, double-packed) | Box of 10 | 16466 GSD |
| Sterisart® NF gamma Septum | with 6 cm metal needle for open containers and with septum (gamma sterilized, double-packed) | Box of 10 | 16467 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 and 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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