Novasip™ DV20

VIRUS REMOVAL FILTER CAPSULE

Process development and small-scale production

Description

The Novasip™ DV20 filter capsule is a disposable, junior-style steamable assembly incorporating an Ultipor® VF grade DV20 pleated membrane element, for removal of parvoviruses and other viruses as small as 20 nm from protein solutions up to 5 to 10 L. The Novasip DV20 capsule filter is supplied non-sterile.

Fig 1. Novasip DV20 filter capsule.

Features

- ≥ 3 log reduction value (LRV) for 20 nm viruses
- ≥ 6 LRV for ≥ 50 nm viruses
- Robust size exclusion mechanism
- Narrow pore size distribution
- Low binding for high protein yields
- Inherently water wettable
- Very low extractables
- Steamable *in situ*
- Autoclavable
- 100% integrity tested
- Individually serialized
- Manufactured for use in conformance with current good manufacturing practice (cGMP)
  - Pharmaceutical 'P' optimized with certificate of test provided
  - Clear housing for easy venting
  - New design sanitary valves:
    Non-removable for safety
    Non-threaded for cleanliness

Specifications

Materials of construction	
Filter medium	Hydrophilic polyvinylidene fluoride (PVDF) membrane
Support and drainage	Polyester
Core, cage and endcaps	Polypropylene
Housing shell	Polyetherimide
O-rings	Silicone elastomer, ethylene propylene rubber (EPR)

Dimensions (nominal)	
Length	84 mm (3.3 in.)
Diameter	123 mm (4.8 in.)
Filtration area (nominal)	0.07 m^2 (0.75 ft^2)
Connector	25.4/38.1 mm (1/1½ in.) sanitary flange

Virus removal
> 3 LRV for 25 nm PP7 bacteriophage
> 6 LRV for 53 nm PR772 bacteriophage

Operating conditions	
Suggested maximum operating pressure	1 to 2 bard (15 to 30 psid)
Maximum validated pressure	3 bar (45 psid)
Maximum assembly pressure differential	6.2 bard (90 psid) for short term during integrity testing

Integrity test
Forward flow, air test gas: 0.5 mL/min in 30% isopropyl alcohol (IPA)/water [1] at 5860 mbar (85 psi)

[1] Buffer or product wet parameters available. Contact us for test values.

Aqueous extractables non-volatile residue (NVR)
< 5 mg/capsule (aqueous at 20°C)

Flow/pressure (water, 25°C)
30 mL/min/2 bard (30 psid)

Quality/bio-safety	
Integrity (100% unit release test)	Correlated to viral (phage) retention
Biological tests	Meets USP biological reactivity, *in vivo*, for class VI-121°C plastics

Sterilization
Autoclavable/steamable *in situ* for 3 × 1 hour cycles at up to 125°C (non-irradiated product only)

Effluent quality tests (p tests)
Meets cleanliness per USP particulates in injectables
Non-fiber-releasing per Code of Federal Regulations (CFR) title 21
Non-pyrogenic per USP bacterial endotoxins (<0.25 EU/mL) meets total organic carbon and conductivity per USP purified water, pH per USP packaged waters

Ordering information

Media type	Rating	Product code
Hydrophilic PVDF	20 nm (LRV ≥ 3)	CLM05DV20P1G

NOTE: For suggested qualification protocols, test/validation discs, sizing and sterilizing recommendations, multi-element forward flow values or other information, please contact Cytiva or your local Cytiva distributor.

Specifications and availability: The information provided is a guide to the product code structure. Product availability may be subject to change without notice. All specifications are nominal. This literature was reviewed for accuracy at the time of publication. For current information on the product and test methodologies, consult your local Cytiva representative.

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For local office contact information, visit cytiva.com/contact

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