

Viresolve® Pro Magnus 2.1 Device

Catalogue Number: VPMG201NB1
Lot Number: C9CN85500

Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

Gamma-Irradiation

This product has been gamma irradiated with a dosage of 6-10 kGy prior to shipment.

Animal Origin Statement

All component materials used in the manufacture of this device are either animal free or in compliance with TMEA/410/01.

100% Manufacturing Integrity Test

Each unit must pass the Millipore Binary Gas Test.
Each unit exhibited an air diffusion flow rate of less than or equal to 20cc/min per device at 50 psig (3.4 bar) in water at 25° C.

Component Materials Toxicity

Component materials were tested and meet the Criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

Non-Fiber Releasing

This product was manufactured with products that meet or exceed the criteria for "Non-Fiber releasing filter" as defined in 21 CFR 210.3(b)(6).

European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

USP Bacterial Endotoxins

A sample aqueous extraction contains less than 0.25 FU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Membrane Bacteriophage Retention Test

Samples of the Viresolve Pro membrane exhibited equal to or greater than 4 LRV retention of ØX174 bacteriophage in the presence of a model protein at a minimum challenge level 10⁷ pfu/cm².

Device Bacteriophage Retention Test

Device samples exhibited equal to or greater than 4 LRV retention of ØX174 bacteriophage at a minimum challenge level 10⁷ pfu/cm² after gamma irradiation at 6-10 kGy.

Hydraulic Stress Test

Samples were tested for air/water diffusion before and after a forward stress to 60 psig (4.1 bar) at 25° C.

TOC and Conductivity

Effluent exhibited less than 500 ppb TOC per USP <643> and less than 1.3 µS/cm conductivity per USP <645> after gamma irradiation (1 cycle of 6-10 kGy dosage) and after a water flush of 100 L/m².

Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

Toxicity

This product is noncytotoxic per USP Cytotoxicity MEM Elution Test.



Peter Eicholt
Quality Manager

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