

Viresolve® Pro Val Kit

Catalogue Number: VPMCVALNB9
Lot Number: C9CN87166

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 EMEA/410/01.

100% Manufacturing Integrity Test

Each unit must pass the Millipore Binary Gas Test.

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 0.25EU/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 10^7 pfu/cm².

Device Bacteriophage Retention Test

Device samples exhibited equal to or greater than 4 LRV retention of ØX174 bacteriophage in the presence of a model protein at a minimum challenge level 10^7 pfu/cm² after gamma irradiation at 6-10 kGy.

Quality Performance Criteria

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

Component Materials Toxicity

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

TOC and Conductivity

Effluent post gamma irradiation after 100 L/m² water flush exhibited less than 500 ppb TOC and less than 1.3 µS/cm conductivity.

Non-Fiber Releasing

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



Peter Eichert
Quality Manager