Viresolve® Pro PD Kit

Catalogue Number: VPMCPDKNB9
Lot Number: C9AN69923

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.

Quality Assurance Lot Release Criteria

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

USP Bacterial Endotoxin

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/cm^2.

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/cm^2 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/m^2 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 filter" as defined in 21 CFR 210.3(b)(6).

Peter Eichert
Quality Manager

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