

CDER Standards Information Sheet

Recognition Category: Revision Reaffirmation New recognition

CDER Recognition Number: 2024-004

Standards Developing Organization (SDO) Name: ASTM

Standard Number: E3259-22

Title of Standard: Standard Practice for Process to Remove Retroviruses by Small Virus Retentive Filters

Scope/Abstract:

1.1 This practice assures 6.0 log₁₀ removal of retrovirus (for example, MuLV).

1.2 This practice is applicable to monoclonal antibody (mAb), immunoglobulin G (IgG) fusion proteins, recombinant proteins, or other proteins produced using mammalian cell lines (for example, Chinese hamster ovary (CHO), murine hybridomas, murine myelomas, or human embryonic kidney (HEK) 293).

1.3 The step is performed on cell-free intermediates.

1.4 The log removal claim for retrovirus by small virus retentive filters can be used in conjunction with other clearance unit operations (for example, low pH inactivation, or inactivation of virus by surfactant) to assure sufficient total process clearance of potential virus contaminants, which would be supportive of early phase (clinical phase 1 or phase 2a trials) regulatory filings.

1.5 Retrovirus removal claim by filtration is limited to small virus retentive filters, as defined in the PDA Technical Report No. 41 Virus Filtration (July 2022) in the context of this standard.

Extent of Recognition:

Complete Recognition

Rationale for Complete Recognition:

This standard is relevant to products regulated by CDER and is recognized based on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant Regulations, Guidance and/or Supporting Publications:

Guidance for industry Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from

Cell Lines of Human or Animal Origin (January 2024)

Guidance for industry Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (February 1997)

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