CDER Standards Information Sheet

Recognition Category: ☐ Revision ☑ Reaffirmation ☐ New recognition

CDER Recognition Number: 2025-005

Standards Developing Organization (SDO) Name: ASTM

Standard Number: E3042-16 (Reapproved 2024)

Title of Standard: Standard Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment

Scope/Abstract:
Parts 1.1 to 1.4 of the scope provided on the ASTM website:

1.1 This practice assures effective inactivation of ≥4 log10 of infectious rodent retrovirus (that is, reduction from 10 000 to 1 infectious rodent retrovirus or removal of 99.99 % of infectious rodent retroviruses) in the manufacturing processes of monoclonal antibodies or immunoglobulin G (IgG) Fc fusion proteins manufactured in rodent-derived cell lines that do not target retroviral antigens. Rodent retrovirus is used as a model for rodent cell substrate endogenous retrovirus-like particles potentially present in the production stream of these proteins.

1.2 The parameters specified for this practice are clarification, Triton X-100 detergent concentration, hold time, pH, and inactivation temperature.

1.3 This practice can be used in conjunction with other clearance or inactivation unit operations that are orthogonal to this inactivation mechanism to achieve sufficient total process clearance or inactivation of rodent retrovirus.

1.4 This detergent inactivation step is performed on a clarified, cell-free intermediate of the monoclonal antibody or IgG Fc fusion protein.

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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