CDER Standards Information Sheet

Recognition Category: ☐ Revision ☐ Reaffirmation ☑ New recognition

CDER Recognition Number: 2024-003

Standards Developing Organization (SDO) Name: ASTM

Standard Number: E2888-12 (Reapproved 2019)

Title of Standard: Standard Practice for Process for Inactivation of Rodent Retrovirus by pH

Scope/Abstract:

1.1 This practice assures 5 log10 inactivation of non-defective C-type retroviruses, which are endogenous to murine hybridoma and CHO cells and are potentially present in the production stream of biopharmaceutical processes that use rodent derived cell culture.

1.2 The process parameters specified in this practice consistently assure 5 log10 inactivation of murine retrovirus by adjusting the pH of a process solution after initial affinity capture chromatography purification.

1.3 This practice is applicable to mAb, IgG fusion, or other recombinant proteins produced from rodent cell lines (for example, CHO or murine hybridoma), which do not target retroviral proteins. Additionally, the low pH step is performed on a cell-free intermediate, post initial capture using protein A chromatography.

1.4 The 5 log10 inactivation of murine retrovirus claimed by using this practice will be utilized in conjunction with other clearance unit operations (for example, chromatography and virus retentive filtration) to assure sufficient total process clearance of murine retroviruses, which will be supportive of early phase regulatory filings.

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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