

Certificate of Analysis

Product: Example - GenClone® Cell Culture Dishes

Catalog Number: Example

Lot Number: FB6C23A70426

Exp. Date: Refer to product label

Quality System Compliance: GenClone products are manufactured, inspected, and certified in compliance with ISO 9001:2015 and ISO 13485:2016 quality management systems.

Quality Control Testing: Representative production samples are collected and inspected in accordance with current applicable product specifications.

Visual Attribute: PASS

Functional Test: PASS

Tissue Culture Treated: Products labeled tissue culture treated are tested for growth with Human kidney epithelial cells. Cell attachment tests are regularly performed to ensure the highest quality control.

Sterility: Products are sterilized by electron beam irradiation according to ISO 11137. Product meets a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

Non-Pyrogenic: Products are tested non-pyrogenic by LAL (Limulus Amebocyte Lysate) test to a limit of less than 0.01EU/mL (0.4EU/device) per USP <85>.

DNase & RNase Free: RNase contamination $<1 \times 10^{-9}$ Kunitz unit/uL, DNase contamination $<1 \times 10^{-6}$ Kunitz unit/uL and Human DNA <2 pg.

Cytotoxicity: Cytotoxicity test is conducted to qualify all material resins using ISO 10993-5 standards for cytotoxicity and have been shown to be non-toxic.

U.S. Pharmacopeia (USP): Products are manufactured from Polystyrene (PS) and High Density Polyethylene (HDPE) materials compliant with USP Class VI.

BSE/TSE Statement: Products are manufactured wholly from synthetic or manufacture materials and do not contain any raw material produced from, or substances derived of animal origin. The manufacturing process does not use any ingredient of animal origin nor do products come in contact with animal products during storage and transportation. Finished products comply with EU 999/2001 and EMA 410/01.

RoHS / REACH: All resins used in manufacturing are free of Bisphenol A and substances restricted by EU Directive 2015/863 (RoHS3), including Lead, Mercury, Cadmium, Hexavalent Chromium, PBBs, PBDEs, and listed phthalates, below threshold limits. Resins do not contain Substances of Very High Concern (SVHC) as defined under REACH Regulation (EC) No. 1907/2006.

Genesee Scientific Quality Control