Labtainer Pro BioProcess Container (BPC) quality and integrity testing

Introduction

As technology advances and innovation takes place within the bioproduction industry, single-use technologies have become more common within the drug and vaccine manufacturing space. Some of the well-established advantages of single-use systems are lower costs, reduced contamination risks, decreased facility footprint, and increased flexibility and production capabilities. In addition to conferring advantages, the single-use products selected for use should complement bioproduction workflow requirements, which differ depending on the application and workflow processes. In response, the Thermo Scientific™ Labtainer™ Pro BPC was developed to meet a variety of bioproduction workflow needs—providing improved ease of use, increased flexibility, and assured quality—without compromise.

Lot-based Labtainer Pro BPC testing

Labtainer Pro BPCs use the same reliable materials as the existing Thermo Scientific™ BPCs—meaning no changes in contact materials. This helps to ensure the consistency of contact materials throughout your workflow.

To achieve the highest level of quality assurance, we have implemented lot-based bacterial endotoxin testing (BET) and particulate analysis testing (PAT) of Labtainer Pro BPCs to United States Pharmacopoeia (USP) <788> and USP <85> standards. Each lot is tested according to these standards using in-process samples to ensure that the finished Labtainer Pro BPCs meet the quality standards we've established and the industry has come to expect.

Testing methods

Endotoxin

BET, or the limulus amebocyte lysate (LAL) test, is an *in vitro* assay used to detect and quantify bacterial endotoxin, a component of the cell wall of Gram-negative bacteria. Standard controls and a positive product control (PPC) are used in a compliant assay. A PPC recovery range of 50–200% indicates that the test solution is free of interfering factors given the specific conditions of the test. If applicable, dilutions are calculated into the reported endotoxin level.

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The following batch endotoxin testing was performed in compliance with US FDA Good Manufacturing Practice (GMP) regulations 21 CFR Parts 210, 211, and 820:

- Tested per USP <85> via the kinetic turbidimetric method, using Charles River reagents at a sensitivity of 0.005 EU/mL
- Test acceptance criteria is not more than 0.25 EU/mL (Table 1)

Particulate

Particulate matter is defined in the USP as "extraneous, mobile, undissolved substances, other than gas bubbles, unintentionally present in or on a solution or device" [1]. The following batch particulate testing was performed in compliance with US FDA GMP regulations 21 CFR Parts 210, 211, and 820:

- Tested per USP <788> particulate matter in injections standards
- Tested using the large-volume method
- Test acceptance criteria is not more than 25 particles/mL ≥10 µm in size and 3 particles/mL ≥25 µm in size
- Testing was performed using the HIAC/Royco™ Liquid Particle Counting System; the counter detects and sizes particles using a light-obscuration sensor

Figure 1. Technician conducting a BPC visual inspection.

Table 1. Testing specifications.

Test conducted	Frequency
Automated inspection	
• On BPCs with grommets, grommet concentricity to chamber is checked and adjusted on the machine, so two halves of the grommet can be snapped together by machine • On BPCs with handles, the machine is adjusted by the operator so that the handle can be inserted into the chamber • Statistical process control: monitors seal pressure and temperature to verify that critical process parameters are within qualified boundaries and within the capability of the machine • Gauge verifies the seal to end-of-port is within tolerance range of >0.060 and <0.100	Each BPC
Visual inspection	
100% visual inspection for any manufacturing defects and irregularities	Each BPC
Integrity/leak testing	
Helium	Each BPC
Endotoxin	
USP <85>, aqueous extracts contained <0.25 EU/mL as determined by the LAL test	Each lot
Particulate	
USP <788>, particulate matter in injections light obscuration particulate count test	Each lot

References

1. United States Pharmacopeial Convention (2018). The United States Pharmacopeia: The National Formulary. Rockville, MD: The United States Pharmacopeial Convention.

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