

Technical Bulletin

Sterility Assurance Level Testing for BIOEAZE™ Gamma Irradiated Bags

Assuring the sterility of BIOEAZE™ disposable bioprocess bags is of utmost importance to SAFC Biosciences. Preventing contamination requires quality bags that are manufactured under controlled conditions and sterilized with validated processes. BIOEAZE™ bags are manufactured and assembled (by Advanced Scientifics, Inc., Millersburg, PA) in a Class 10,000 HEPA filtered clean room in accordance with Current Good Manufacturing Practices (cGMPs). The bags are sterilized post-manufacturing by gamma irradiation at Steris Isomedix Services (Whippany, NJ).

To validate SAFC Biosciences gamma irradiation procedures and the sterility of BIOEAZE™ bags, Sterility Assurance Level (SAL) testing was performed. The testing services were contracted through Nelson Laboratories (Salt Lake City, Utah), and were performed according to ANSI/AAMI/ISO 11137: Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization. The testing follows international and US guidelines for sterilization of medical devices by radiation. The study was also performed in accordance with the US FDA 21 CFR Part 58 (Good Laboratory Practice for Non-Clinical Laboratory Studies).

BIOEAZE™ Ethyl Vinyl Acetate (EVA) Bags

Bioburden tests were conducted on three lots of EVA bags (30 bags) as part of the dose setting experiments. This determined a target verification dose of 6.1 ± 0.6 kGy to assure a SAL of 10^{-2} . One hundred bags were sterilized by gamma irradiation at the verification dose and subjected to sterility testing. It was determined that all bags passed the sterility test and none were bacteriostatic or fungistatic. Based on the bioburden and sterility test results, the recommended dose of gamma irradiation to achieve a SAL of 10^{-6} is 18.8 kGy for EVA BIOEAZE™ bags. As a further measure of assurance, all BIOEAZE™ bags, associated ports and tubing are routinely sterilized at 25-45 kGy; a Certificate of Processing is included in each shipment of BIOEAZE™ bags.

BIOEAZE™ Polyethylene (PE) Bags

Bioburden tests were conducted on three lots of PE bags (30 bags) as part of the dose setting experiments. This determined a target verification dose of 9.2 ± 0.9 kGy to assure a SAL of 10^{-2} . One hundred bags were sterilized by gamma irradiation at the verification dose and subjected to sterility testing. It was determined that all bags passed the sterility test and none were bacteriostatic or fungistatic. Based on the bioburden and sterility test results, the recommended dose of gamma irradiation to achieve a SAL of 10^{-6} is 22.8 kGy for PE BIOEAZE™ bags. As a further measure of assurance, all BIOEAZE™ bags, associated ports and tubing are routinely sterilized at 25-45 kGy; a Certificate of Processing is included in each shipment of BIOEAZE™ bags.

For more information about this subject or other SAFC Biosciences' products and services, please call our Technical Services department or e-mail us at technicalservices@sial.com.

United States

SAFC Biosciences, Inc.
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584
E-mail info-na@sial.com

Europe

SAFC Biosciences Ltd.
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412
E-mail info-eu@sial.com

Asia Pacific

SAFC Biosciences Pty. Ltd.
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656
E-mail info-ap@sial.com

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United States

SAFC Biosciences, Inc.
13804 W. 107th Street
Lenexa, Kansas 66215
USA

Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584
E-mail info-na@sial.com

Europe

SAFC Biosciences Ltd.
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM

Phone +44 (0)1264-333311
Fax +44 (0)1264-332412
E-mail info-eu@sial.com

Asia Pacific

SAFC Biosciences Pty. Ltd.
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA

Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656
E-mail info-ap@sial.com