

Technical Bulletin

imMEDIATE ADVANTAGE™ Small Volume Media Program

Introduction

At SAFC Biosciences we recognize that rapid access to high-quality, customized cell culture media products is essential to the product development scientist. That is why SAFC Biosciences offers its quick response and flexible imMEDIATE ADVANTAGE™ media services.

The imMEDIATE ADVANTAGE™ program benefits the scientist by offering:

- a quality alternative with smaller minimum volumes not available through our Good Manufacturing Practices (cGMP) production facilities;
- a cost-effective means of evaluating specialized formulations without having to commit to large lots of material; and
- time savings because the period from order to product delivery is quicker than what a large scale manufacturing facility can provide.

Every attempt is made to ensure that imMEDIATE ADVANTAGE™ manufacturing processes are reflective of those utilized for cGMP manufacturing.

There are distinctions that should be considered when comparing imMEDIATE ADVANTAGE™ products and those produced in our cGMP environment.

Raw Materials

Most components used in imMEDIATE ADVANTAGE™ manufacturing:

- are the same as those used in SAFC Biosciences' cGMP manufacturing;
- receive full testing by SAFC Biosciences' Quality Control; and
- meet SAFC Biosciences' Raw Material Specifications.

However, raw material components are not required to have or meet specifications, nor is it a requirement that they are fully tested or released before use.

High quality Milli-Q® water is used to produce imMEDIATE ADVANTAGE™ products.

Facilities & Personnel

imMEDIATE ADVANTAGE™ manufacturing takes place in a standard laboratory where:

- access is restricted;
- sterile filtration of all products is performed in Class I laminar-flow hoods that are certified on a biannual basis;
- training records are maintained for all of personnel involved with the production of imMEDIATE ADVANTAGE™ products; and
- appropriate attire is required, including lab coats, safety glasses, masks, gloves and personal protective equipment (PPE) for all technicians.

The manufacturing environment, although a controlled area, is not required to meet any specifications regarding air quality or room classification and environmental monitoring is not mandated.

Packaging

The same high quality plastic bottles and flexible media bags are used in both cGMP and imMEDIATE ADVANTAGE™ product packaging.

Additionally, labeling for all imMEDIATE ADVANTAGE™ products includes:

- full product description;
- product code;
- date of manufacture;
- storage recommendations; and
- a unique, traceable lot number.

United States

SAFC Biosciences
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

Europe

SAFC Biosciences
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412

Asia Pacific

SAFC Biosciences
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

Quality

All equipment, scales, hoods, pH meters, osmometers and pipettes, are maintained, calibrated and certified on a routine basis.

Testing of imMEDIate ADVANTAGE™ for liquid media formulations includes documentation of:

- pH;
- osmolality;
- physical appearance;
- sterility (abbreviated by incubating samples at 37 C for no less than 3 days prior to shipment of the order); and
- solubility for dry powder formulations.

Standard Operating Procedures and batch records are required for all imMEDIate ADVANTAGE™ manufacturing processes and finished products. Control of the manufacturing processes and documentation is different from that of a cGMP environment in that document review and product release are not performed by Quality Assurance for every lot manufactured.

A qualified staff member reviews batch records for each imMEDIate ADVANTAGE™ product prior to release. Quality Assurance performs internal audits of the imMEDIate ADVANTAGE™ department on a regular basis, which include a random review of various documentation and batch records.

Validations are not required for any of the manufacturing or cleaning processes employed.

For more information about imMEDIate ADVANTAGE™ or other SAFC Biosciences' products and services, please contact Customer Services at the phone number listed or e-mail us at info-na@sial.com.

Warranty, Limitation of Remedies

SAFC Biosciences warrants to the purchaser for a period of one year from date of delivery that this product conforms to its specifications. Other terms and conditions of this warranty are contained in SAFC Biosciences' written warranty, a copy of which is available upon request. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXCLUDED. In no case will SAFC Biosciences be liable for any special, incidental, or consequential damages arising out of this product or the use of this product by the customer or any third party based upon breach of warranty, breach of contract, negligence, strict tort, or any other legal theory. SAFC Biosciences expressly disclaims any warranty against claims by any third party by way of infringement or the like. THIS PRODUCT IS INTENDED FOR PURPOSES DESCRIBED ONLY AND IS NOT INTENDED FOR ANY HUMAN OR THERAPEUTIC USE.

Additional Terms and Conditions are contained in the product Catalog, a copy of which is available upon request.

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Milli-Q® is a registered trademark of Millipore Corporation

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SAFC Biosciences
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
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Andover, Hampshire SP10 3LF
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Phone +61 (0)3-9362-4500
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