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Bioproduction

Advanced Granulation Technology (AGT) media format: frequently asked questions

Introduction

Choosing the optimal cell culture media format is essential to optimizing your biopharmaceutical manufacturing workflow. During research and development, liquid media are an accessible option as they are ready to use, requiring no additional preparation steps. As you look to scale up to larger production volumes, switching to a dry powder media (DPM) format can alleviate many potential logistical challenges associated with liquid media, such as large storage requirements and high shipping costs.

However, the preparation of standard DPM can add additional complexity. In particular, the need for pH and osmolality adjustments during preparation can be time-consuming and introduce the risk of errors that cause variability. From a safety perspective, rehydrating DPM can also generate large amounts of dust, resulting in potential respiratory hazards and requiring implementation of mitigation measures. These challenges can negatively impact your manufacturing process by reducing overall process productivity.

To help simplify production and improve process consistency, Thermo Fisher Scientific offers the Gibco[™] Advanced Granulation Technology[™] (AGT[™]) media format. So, what is AGT format and what makes it different from traditional alternatives? To help you learn more about Thermo Fisher Scientific's most advanced media format, and how it can help you optimize your process, we have provided answers to some of the most frequently asked questions about AGT format.

Frequently asked questions What is AGT media format?

The AGT media format is a well-established, scalable dry media format manufactured through a technologically advanced process that enables the production of complete media formulations in a granular form rather than a dry powder.

How does the manufacturing process for AGT media differ from that of traditional DPM?

AGT media are manufactured in a unique multi-step process. While a formulation begins in a format much like DPM, AGT media are produced using fluid bed granulation technology. Dry nutrient powder components are suspended using a continuous column of conditioned air and then sprayed with a fine mist of aqueous solutions. Once the components have dried, there are free-flowing, porous, highly water-soluble granules. These granules are then sized before being blended into the final product.

How can AGT format help improve process efficiency during manufacturing?

AGT media format has many beneficial attributes that can help improve manufacturing efficiency. With granules having higher solubility than fine-milled powders and generating less dust, rehydration time is significantly reduced. Additionally, AGT format has both pH and osmolality preadjusted, removing the need for additional workflow steps to further facilitate preparation. Together, these benefits have led to users reporting more than 50% reduction in labor time and costs when using AGT format [1].



Why is AGT format sometimes described as a "single-component" or "one-part" solution?

Supplementary components that are typically added to media during preparation, such as L-glutamine, recombinant insulin, and other growth factors, can be added into the AGT formulation. As a result, it can reduce the cost and time required for planning, procurement, preparation, and testing of additional raw materials. Eliminating the need to use multiple filters throughout the process can also help you further lower manufacturing costs.

How can AGT format help improve process consistency?

The removal of numerous manual handling steps needed during DPM preparation, including pH and osmolality adjustments, can reduce the potential for human error, helping decrease the risk of batch-to-batch inconsistency. Additionally, fluid bed granulation allows for more homogeneous distribution of trace elements throughout the medium, helping to further improve consistency.

Can AGT format help reduce safety risks in my process?

Prioritizing safety is paramount during biopharmaceutical manufacturing. AGT format can help reduce safety risks by minimizing respiratory hazards often associated with DPM preparation, and removing the need for acid/base handling.

In terms of performance, how do media in AGT format compare to media in traditional formats?

There are significant data demonstrating comparable performance between media in AGT format and traditional liquid and DPM formats, so you can be confident in the equivalent performance of AGT media.

Can AGT media be used throughout development?

From bench-scale research and development to commercial production, AGT format can be used at every development stage and has been designed to support your process, independent of scale.

Are there any differences in the regulatory requirements when using AGT format compared to traditional formats?

No, regulatory bodies around the world are already familiar with and have approved products manufactured using AGT media across a range of application types. Additionally, Thermo Fisher has experienced regulatory and technical support groups that can provide in-depth technical consultation and documentation for both catalog and custom AGT products.

What catalog Gibco[™] products are available in AGT format?

Thermo Fisher offers a wide range of catalog products in AGT format, including media and feeds for a variety of applications, such as protein and viral vector production, as well as different process types like perfusion. You can view the full range of catalog Gibco products in AGT format <u>here</u>.

What support can you provide to help us manufacture our proprietary formulation in AGT format?

We can provide extensive technical support to help you convert your proprietary formulation into AGT format. The Gibco[™] Media by Design[™] Services team has in-depth knowledge of format conversion and the capabilities to help accelerate your transition. This includes the Gibco[™] Rapid Prototyping Service which can enable you to test the manufacturability and scalability of your formulation in AGT format and gain insights from our experienced production team.

Do you have redundant manufacturing capacity for AGT products?

We have made considerable investments in maintaining equivalency in processes and quality within our manufacturing network. With manufacturing harmonization between our sites in Grand Island, New York, USA and Paisley, Scotland, we can offer global manufacturing redundancy and adequate capacity for both catalog and custom AGT products. This can help you reduce supply risks, allowing you to incorporate AGT media into your manufacturing process with confidence.

Reference

 Deets Beat, Inc. (2014) Advanced Granulation Technology[™] (AGT[™] dry media format) Culture Media - Benefits and Case Studies. http://assets.thermofisher. com/TFS-Assets/LSG/brochures/AGT_CaseStudy_White_Paper_FINAL. pdf?ICID=bpd_cc_white_paper_agt_benefits_case_studies_agt

Learn more about the AGT media format at thermofisher.com/agt



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