Jump higher – land with confidence

Chemically defined cell culture media portfolio from Merck Millipore

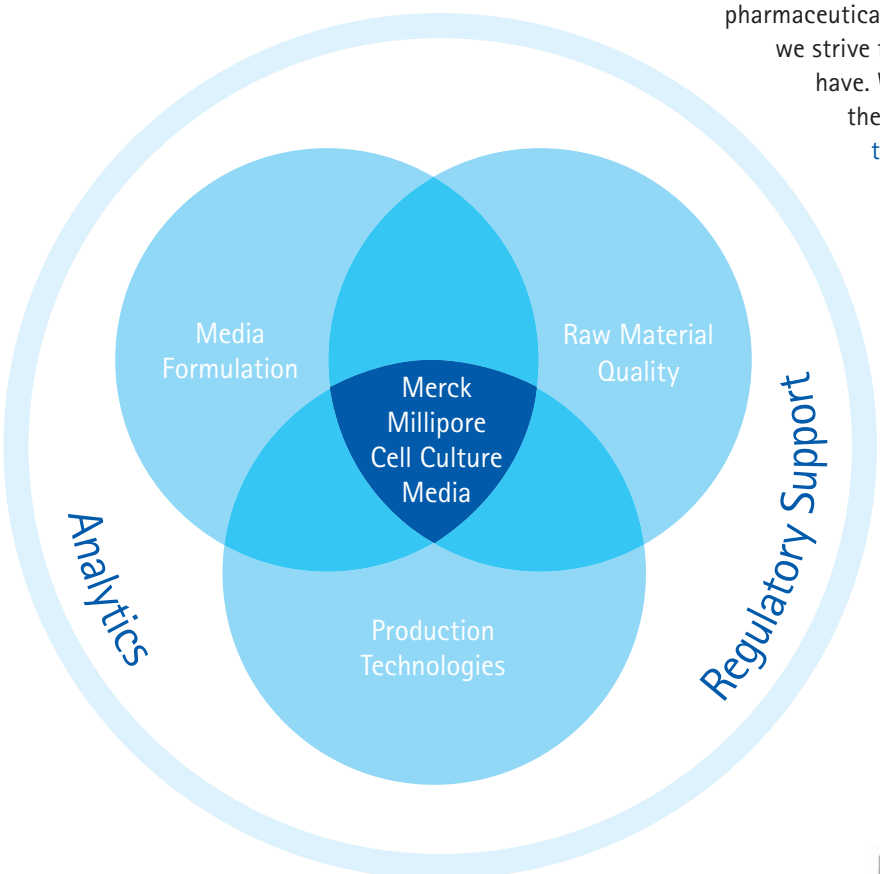
Merck Millipore is a division of MERCK

Merck Millipore – your partner for cell culture media

If you want your next product to fly high, it pays to use the best mammalian cell culture media you can find during upstream development. In addition to boosting volumetric productivity, this can help you to increase the traceability and quality of your biopharmaceutical molecule, and enhance cost effectiveness.

As the world's oldest pharmaceutical and chemical company, we have centuries of experience in synthesizing chemicals and producing highly effective pharmaceuticals. In applying that expertise to cell culture media, we strive for the same standards of excellence as we always have. With customized and proprietary media formulations, the finest raw materials, and state-of-the-art production technologies for consistent, homogeneous deliveries.

The bottom line? Reliable, high-performance products you can count on to meet your requirements every time. All backed by unrivalled regulatory support and state-of-the art analytics designed to secure your performance today – and take it higher still tomorrow.



Media formulation

For optimum cell growth, viability, and productivity, you need a cell culture medium that matches your cell line perfectly. That means you need a partner with two key qualities: outstanding research and development skills, and the expertise to apply them effectively – by designing specific media that perform just as well in production as they did earlier on during process development.

At Merck Millipore, we leverage our global R&D resources to design formulations that fit your specific cell line requirements perfectly. We do this in several ways – for example, by enhancing component solubility and concentration in existing recipes or by developing media products off the shelf for specific cell line applications.

Our experts at the R&D Center for Media and Feed Development in Woburn (USA) can design media formulations that match both the needs of the cell and the desired quality of the target protein – thanks to automated, high-throughput experiments and state-of-the-art laboratory equipment. They also explore how different factors can affect cell metabolism and cell culture performance and test different concentrations of various key components sequentially.

At our R&D Center for Material Science in Darmstadt, we road-test the formulations developed in Woburn thoroughly to make sure they really do work in production. Once we are satisfied, we apply our expertise in material science to translate the formulations into top-quality dry powder media. Among other things this includes raw material selection, pre-treatments, and the evaluation of solubility issues.

While the steps involved in R&D are complex, the goal itself is always clear: to develop outstanding products that support your process and shorten your time-to-market. That's our recipe for your success.

1 g/L pre-treated amino acid *4 g/L pre-treated amino acid* *4 g/L untreated amino acid*

Pre-treating raw materials can enhance their solubility. In standard media formulations this permits concentrations that are several times higher.

Raw material science, selection, and qualification

To ensure the highest standards, we subject all raw materials to rigorous, repeated scrutiny before approving them for use. All materials are either manufactured in-house, or sourced from suppliers whose standards meet our high expectations – and who have undergone a strict qualification process to prove it. Many of the raw materials even fulfill our EMPROVE® qualification standard. Key requirements for qualification include certification of non-animal origin and agreements on process changes to ensure full transparency and traceability.

Next, we analyze samples from every single raw material to see whether they meet our specifications for mammalian cell culture media.

In order to pass qualification successfully, candidates have to meet a special quality marker, which acts as a benchmark for future deliveries. All subsequent batches are then analyzed, and any that fail to meet our benchmark standards are rejected.

Finally, we road-test new raw materials to see how well they actually perform in realistic conditions. By comparing results, we can then select the most suitable candidates for each specific application. This exhaustive selection procedure is your guarantee of strong, consistent performance later on.

Production technologies

Once the raw materials have been selected, they need to be processed extremely gently to create consistent, high-quality cell culture media.

With over 20 years of experience, we are experts at mixing and milling complex products and mixtures. Our GMP-certified production plant can supply anything from a few kilos to a several hundred tons – and as we use the same state-of-the-art technology for pilot and production scale orders, outstanding consistency is assured at every stage.

The cell culture medium produced by Merck Millipore (A) appears as a homogenous powder, whereas the cell culture media of other suppliers (e.g., B) show crystals and inhomogeneous blending.

Product homogeneity

To safeguard homogeneity, we use a consistent process that keeps particle size distribution constant from pilot to production scale. This minimizes the risk of materials de-mixing during transportation – and maximizes the chance that every portion of media you weigh out from the bag will contain exactly the same balance of raw materials.

Visual differences of dry powder media from different suppliers. Powder media of supplier A and B have white appearance whereas the Merck Millipore medium preserves the pinkish color (resulting e.g. from Vitamin B), underlining the gentle production process.

Gentle milling

Since raw materials are delicate, we use extra gentle milling technology to mill raw materials that are sensitive to oxygen or temperature. At our R&D Center in Darmstadt, we even analyze what impact different milling technologies may have on cell growth profiles and the quality of target proteins.

Regulatory support

To simplify your registration processes, we provide a comprehensive Regulatory Information Package for each cell culture medium we manufacture. This package provides extensive documentation on the manufacture, characterization, and control of the cell culture media – for example, a Certificate of Analysis, GMP Statement, or TSE/BSE Certificate. The packages' structure is in line with the format of CTD Module 3 in order to support the compilation of your registration dossier.

Analytics

Our independent on-site analytics unit can assist you in not one, but three different ways. We develop analytical methods; we support procedure transfers (for instance, by adopting your preferred measuring method); and we offer consulting on other suitable methods for individual media and applications.

In addition to widespread physico-chemical analytics and a range of microbial burden tests, our analytics team also focuses on method development for media-specific issues, in order to gain new product insights.

For example, we apply NIR (near infra-red) spectroscopy for in-process control over particle size distribution, and to collect forecasting information about a medium's performance. Our analytics experts also support the material science development team to help them better understand the impact of individual raw materials in various media.

The typical technical data above serve to generally characterize the cell culture media in industry-relevant expression systems.
The product information is available separately from the website www.merckmillipore.com

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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