

# Custom Synthesis Expertise.

Put our passion to work for you.



# From route optimization to market approval: one partner for your success

Merck Millipore is a leading supplier to the global life science industry. With over 200 years of experience in API manufacturing, we are a trusted business partner to companies seeking one point of contact for their API synthesis needs. We can provide you with a full set of services throughout the entire development chain of your compound: from early stage development to commercial production. In today's competitive market, our custom synthesis services are a valuable tool to help reduce development and production costs with manufacturing capabilities, chemical know-how, and regulatory expertise that you can rely on. You can increase your flexibility and accelerate the passage of your new drug compounds through the pipeline with the help of our services and customized solutions.

Take advantage of our successful track record of reliability, speed, and expertise for the successful custom synthesis of your APIs or advanced intermediates. Merck Millipore has established processes providing service across the entire drug development and commercialization spectrum, including stereo-selective synthesis, small-scale GMP, process combination of microbiological fermentation, and classical chemical synthesis.

## Your partner through every stage of clinical development

Depending on your specific needs, our process development services can start with either route finding or first feasibility. It can be continued to scale up with the transfer and successful validation of the commercial process followed by commercial production. Dedicated teams support every step of your way in analytical development, risk assessment, and registration with regulatory authorities. Our formulation centers have extensive knowledge of our formulation offering and can advance your product even further. You can start working with our development and launch sites at any step of your product development, from the early pre-clinical stages up to the very late commercial phase.

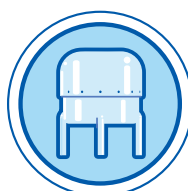


## Commercial production from milligrams to metric tons

Get your API in any quantity you need: from milliliter scale in glove boxes to a 12,500 liter reactor. The Merck Millipore production network offers an extensive set of production capacities: from dedicated development and launch sites up to commercial production in multi-thousand metric annual tons. Put our passion for custom synthesis to work for you – from key intermediates to APIs.



From grams



to kilograms



and even tons

# State-of-the-art European production sites

All of our API production sites are located in Western Europe. Not only do they comply with global regulatory requirements, but they have also been FDA-inspected multiple times. You can expect cGMP-certified development and production sites, the highest standards in analytical services, and state-of-the-art equipment covering a broad range of volumes. Put simply: we offer you concrete expertise and equipment, backed up by a diverse range of production technologies.

## Setting standards in regulatory services

Merck Millipore has been setting standards in regulatory services for many years. Extensive regulatory know-how together with chemical and pharmaceutical expertise and a comprehensive range of services that will help you to get your product to market more quickly. With our worldwide presence and dedicated teams, we constantly review regulatory developments in all the relevant markets to keep you one step ahead – today and tomorrow.

And when it comes to regulatory-compliant pharmaceutical starting material, we give you access to DMFs, CEPs, ASMFs, and other regulatory documents that are based on a thorough qualification process to provide maximum transparency. Our experienced staff handles all regulatory issues including elaboration and registration.



The typical technical data above serve to generally characterize the product. These values are not meant as specifications and they do not have binding character. The product specification is available separately, from the website: [www.merckmillipore.com](http://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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