Teva api Offers

New API Sterilization Service

Sterilization capability designed for your needs

Teva api is now offering API sterilization services using the aseptic filtration technique applicable for quantities ranging from a few kilograms to hundreds of kilograms. We will be able to support a wide variety of products with different characteristics (i.e. OHC levels, volumes).

Our sterilization services are applicable both to

1. Molecules within Teva api portfolio, for which we can provide an end-to-end solution including API synthesis and its sterilization.
2. APIs from other sources.

Aseptic Filtration

Aseptic filtration is a process where, under aseptic conditions, a dissolved API is filtered through a membrane to ensure the removal of all biological contamination. This technology reduces the risk of contamination, which may occur with direct human contact in old-fashioned clean rooms.

Unlike other sterilization methods (like heat and gamma irradiation), it has significant advantages over other methods:

- It does not damage the API, which is essential for sensitive products
- It does not form new impurities during the sterilization process.

You are now able to rely on our vast

expertise, state of the art facilities and latest best-in-class resources to address your product formulation needs and achieve your goals. Sterilization provides another valuable solution that may factor into your consideration set when selecting an API supplier.

Providing sterile micronization services

Teva api teams have the knowledge and extensive experience with designing API physical properties, especially when it comes to sensitive products and complex formulations. Control and uniformity of particle size distribution, are reached through well-designed and robust crystallization processes, as well as by milling or micronization. A milling machine and micronizer are integrated within the isolator system to ensure aseptic processing and safe handling of the material.

Dedicated facility producing quality results

Our scientific know-how and rigorous standards are incorporated in all aspects of our new manufacturing facility in Croatia. With an excellent regulatory record, cGMP certified and approved by the FDA, this site is working with customers from around the world.

The facility has reached operational readiness, with the first batches of sterilized products ready to ship in Dec 2019.

Stringent processes for sterility.

Teva api sterilization facility is using dual packaging to ensure sterility of the final API, which can be configured to meet the customer's requirements.

An on-site microbiological lab is monitoring API sterility and the sterility of the facility itself to ensure we use the best processes to avoid product contamination.

Anticipating a need for aseptic filtration?

Contact us to find out how we can help. One of our account managers or customer experience experts will be happy to answer your questions and discuss your specific API sterilization needs.

Teva api portal (through www.teva-api.com)

Why Teva api?

Teva api is the leading international supplier of APIs. With the industry's broadest portfolio of more 400 high quality API products, we serve more than 1,000 customers in over 100 countries.

A standalone unit within Teva Pharmaceutical Industries, our history in the generic API industry dates back over 80 years.

- **16** Manufacturing sites worldwide
- **95%** customer satisfaction rate for requests related to service
- Largest API portfolio in the industry, with more than 400 molecules
- R&D consultation available during your API project
- Areas of technological expertise include peptides, vitamins,fermentation, high potency, synthetic products, oligonucleotides and more
- An online customer platform to manage your API projects with access to more than **5,000** API regulatory documents for self-download

Supporting our customers throughout the API project lifecycle Selection

Teva api customers engage with our professional teams in marketing, intellectual property and R&D to help them plan their API project. If they need product samples, most are sent within 24 hours.

Development

Throughout the development process our experts strive to ensure that all required specifications are met.

Our Customer Experience team can supply detailed documentation, which is also available on Teva api portal, our self-service customer portal.

Submission

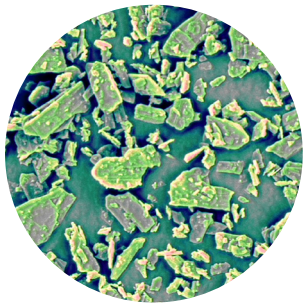
Teva api has more than 300 US DMFs, more than 300 EU DMFs and 155 CEPs, and our global and local regulatory teams support customers through the entire submission process. We work with each customer's submission dates and targeted markets, and support them with relevant regulatory files, including deficiency letters.

Pre-launch

Our in-house experts begin planning support for our customers' launches many years in advance. We strive to help our customers reach their desired markets efficiently, effectively and on time.

Commercial

Teva api global supply chain experts work to provide customers the best solution with on-time delivery under GDP guidelines, without compromising on quality at our manufacturing sites around the world.



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