mefar

Excellence in Global Contract Manufacturing and Development of Sterile Solutions

Ampoules, Vials, Lypohilized Vials & Ampoules, Pre-Filled Syringes (PFS), Blow-Fill-Seal (BFS), Technology Transfer and R&D Services

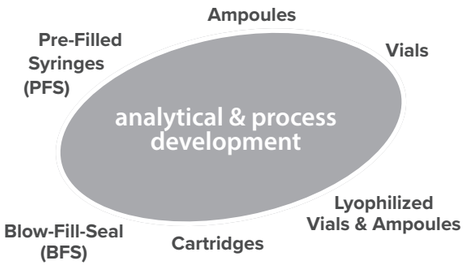
About Us

A leading CDMO in Turkey with a proven track record and experience in manufacturing products across all small volume injectable dosage forms for local and multinational pharmaceuticals.

Our Mission: To provide products and services at high quality standards at optimum costs in accordance with the United Nations Sustainable Development Goals, which we prioritize, by making use of the experience and technical know-how of our experienced human resources for sustainable public health.

Our Vision: To become a Sterile Production Service Center serving sustainable public health in line with the United Nations Sustainable Development Goals and creating value for stakeholders in the light of good governance principles, while being preferred by global players to enter the top 10 among the CDMOs providing sterile production services based in Europe in 2025.

The key success factors in achieving our mission, Flexibility, long-term collaboration, customer & employee satisfaction, on time delivery, environmental consciousness and a commitment to proactively follow and implement all regulatory changes.



- Analytical Method Validation
- Scale-up Batch Production
- Technology Transfer
- Process Validation
- Stability Studies
- Cold-Chain Management
- Packaging
- Serialization
- Controlled Drug Management
- EU GMP Certifications and others

serving sterile health...

Founded in 1985, Mefar is a leading pharmaceutical development & contract manufacturer of parenteral solutions for human usage in ampoules, vials, lyophilized vials and ampoules, BFS (blow-fill-seal containers) and PFS (pre-filled syringes).

Mefar was the first company to fill vaccines in Turkey, our state-of-the-art sterile facility is designed to maximize transparency by the use of floor-to-ceiling hygienic glass partitions while preventing any form of waste of capacities, staff and other resources through its well-thought layout. The facility is designed to increase employee productivity and to achieve operational excellence with its heavy use of modern production and quality control technologies.

Mefar is certified to cGMP / cGLP by Turkish, EMA for all European Union countries such as Germany, the UK, Portugal, Greece as well as certifications from EEU, Ukraine, SFDA, Croatia, South Korea and Russia.

We are actively improving the lives of millions of patients throughout Europe and other regions of the World by delivering high quality and cost competitive products and services.

In 2022, one of the region's largest holding companies, ADQ, has taken over Birgi Mefar Group.

We are aware of the limited resources of our planet and importance of well-being of our employees and thus continuously strive to act at the highest level of social and environmental responsibility through aimed programs. As a result of our efforts, Mefar has acquired ISO 14001 and ISO 45001 (formerly OHSAS 18001) certificates along with an award of the first Most Environmental Facility in its category. Mefar attaches importance to the compatibility of every step with its sustainability vision.

As a business partner with an impressive global customer base, Mefar provides flexible customized services with over 800 employees with a full commitment to quality. Mefar's integral relationship with its sister company, Birgi, a leading empty glass ampoule and vial manufacturer (a primary packaging organization), creates a synergy that generates significant cost-savings and unmatched fl exibility on delivery schedules. This relationship also enables customers to focus on their strengths rather than dealing with several suppliers.

Mefar is located just a few kilometers away from Istanbul's Sabiha Gokcen International Airport (SAW) and in close proximity to Europe as well as to the western part of Asia and the Middle East. This strategic location enables Mefar to receive APIs easily as well as deliver fi nished products to its customers in the fast growing Turkish market and export markets such as Germany, the UK, MENA and CIS countries.

As an independent company, Mefar does not own any pharmaceutical product licenses and is completely dedicated to serving our business partners with loyalty and in an environment free of any confl ict of interest. Mefar has a strong commitment to pursuing this strategy in the future and will continue to be a reliable contract manufacturing service partner to prestigious pharmaceutical companies both locally and internationally.

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Products & Services

Based on our extensive experience and expertise in the manufacturing of aseptically or terminally filled injectable products, Mefar applies a full-range of cutting-edge technologies in sterile production while ensuring conformity to the agreed quality specifications and regulatory requirements. We provide full service packaging and warehousing services for your parental or cold-chain products. Also with its dedicated Technology Transfer Department, Mefar enables easy and swift completition of any new projects.

Our wide range of production capabilities includes;

Ampoules
- Aseptic or terminal filling of 1 ml to 30 ml
- Fully automated inspection machines

Vials
- Compounding &filtration (up to 2400 lt)
- Aseptic or terminal filling of 2 ml to 300 ml

Lyophilization
- Vial and ampoule lyophilization

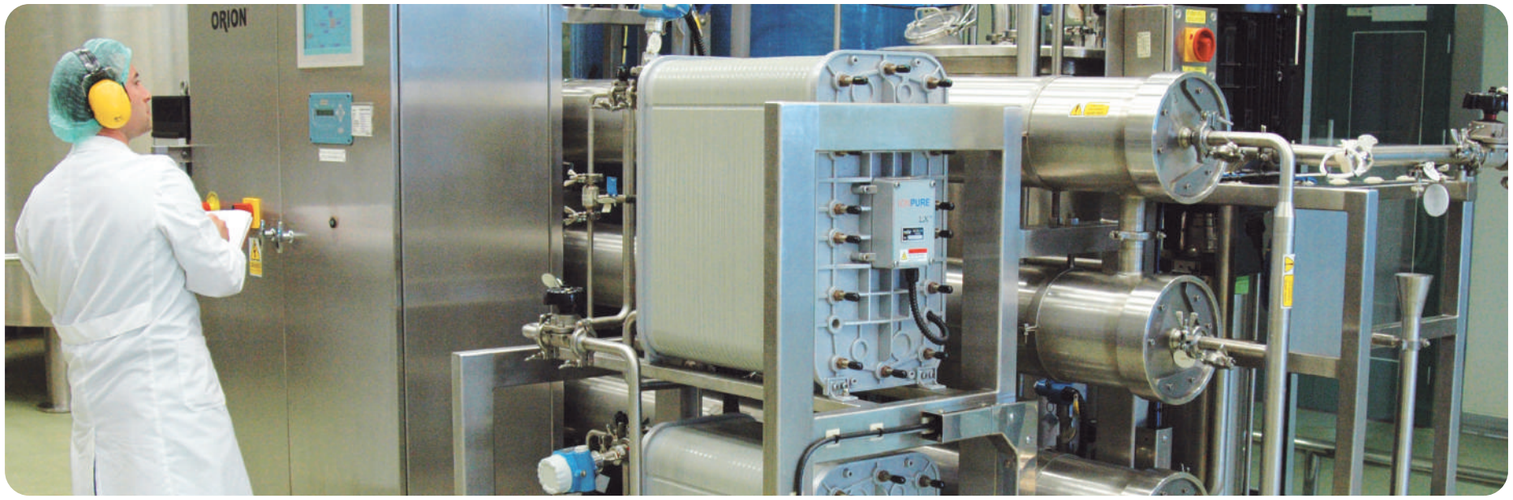
Pre-filled Syringes (PFS)
- Aseptic filling of 0.5 ml to 20 ml
- Fully-automated inspection machine
- Labelling and back-stop insertion machines

Blow-Fill-Seal (BFS)
- Aseptic filling in drop bottles of 2.5 ml to 50 ml
- Strip, twist-off and screw cap capabilities

Products & Services

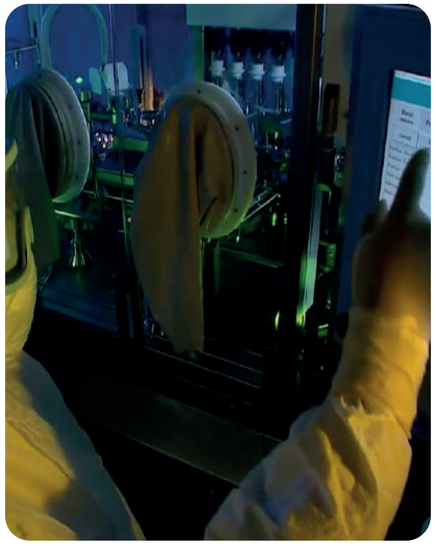
Mefar has state-of-the-art pure-steam generators, Water for Injection (WFI) and CIP/SIP units in place that are built for faster future expansions. Mefar has extensive cold-chain management capabilities and experience throughout the plant with over 900 pallets cold-room capacity. Our temperature controlled warehouse boosts over 3000 pallets capacity for finished products and packaging materials. Our customers are also able to access their up-todate inventory information through our website whenever they need an inventory report.

The source of our strength and success is due not only to modern technologies and commitment to international guidelines, but also to our more than 700 highly skilled and dedicated employees. Mefar invites you to join us at our sterile production plant for any of your sterile production needs today or in the future.



All products have;

- In process controls and continuous monitoring of all stages according to GMP guidelines
- Advanced labeling services with ring code, pharma code and print control systems
- Fully automated blistering capabilities –sealed or unsealed
- Packaging in full or semi-automatic machines with pharma code, print and leaflet control systems. All packaging lines have checkweighers.
- Serialization capabilities in accordance with regulations for anti-counterfeiting 2D barcode quality verification systems.



Quality, Technology Transfer /

Our commitment to health & patient

Built and equipped according to the latest cGMP/cGLP and ISO Standards, and incorporating the most advanced technologies and concepts currently in use in the pharmaceutical industry; Mefar enthusiastically meets the challenge of ever increasing emphasis on the utmost quality in the manufacture of pharmaceutical products and clearly acknowledges its ultimate responsibility to the individual patient.

With its modern chemical, microbiological and physical laboratories, Mefar has an extensive experience in running method validation, stability studies as well as routine product and raw material analysis with its well trained, devoted staff of pharmacists, chemists and chemical engineers. Mefar continuously monitors and records particles in class A and air fl ow velocity throughout the plant by its Building-Management-System (BMS) while ensuring the continuity of its high standard of quality. Careful attention is given at each and every step of our production cycle from the first commercial initiative to the production of process validation batches and finally to your product's departure from the warehouse.

Our dedicated team of Product Transfer experts helps you throughout the transferring period and at later stages, so that you can concentrate on your strengths while having a seamless process.

Our facility is regularly audited by local and international authorities for certification within the scope of regulatory audits. Moreover, existing and new customers periodically inspect Mefar for their routine annual GMP audits while rigorous internal inspections for each department and process are completed annually. Finally, Mefar has a robust supplier qualification program that includes strict auditing of the suppliers.

Quality and Sustainability

Quality Policy

Mefar İlaç Sanayii A.Ş.; complies with the requirements of the standards for the Good Manufacturing Practices (GMP) rules, ISO 9001:2015 Quality Management System, ISO 14001:2015 Environmental Management System, ISO 45001:2018 Occupational Health and Safety Management System and ISO 13485:2016 Medical Devices Quality Management System, and develops and produces error-free, effective and reliable products by following the innovations and current technology in the pharmaceutical sector, with sustainable quality targets, within the framework of current national and international quality systems, as well as the legal conditions in Turkey and other countries, where the products manufactured on behalf of customers are presented to the market, as a requirement of its fulfillment.

Every employee of Mefar İlaç Sanayii A.Ş. knows that they are responsible for ensuring the quality of the products produced, as well as the safety and satisfaction of the end-use, the patient. Within the framework of this purpose, continues his work in accordance with the context and strategies of the organization, together with cGMP, medical device legislation requirements and integrated management system, national and international standards in production and product quality, which are implemented in our company.

Achieving those targets depends on:

Reliability

Manufacturing of the products at Mefar İlaç Sanayii A.Ş. production facility within the scope specified in the production site permit issued by the Ministry of Health in accordance with the methods and specifications in the product's registration license; to comply exactly with the distribution of responsibilities specified in the bilateral quality agreement signed with the customer companies; in this direction, ensuring that customer expectations are fulfilled; ensuring and monitoring production in accordance with national and international cGMP guidelines are part of the principles of reliability.

Quality

Mefar İlaç Sanayii A.Ş. manufactures products according to cGMP guidelines, determined quality standards and product registration licenses. For this purpose;

- Supports production and work in accordance with current quality practices in all processes,
- Ensures the reliability of all processes employs qualified personnel in all areas, and supports them with continuous training in line with current quality requirements,
- Follows the control of the general management and quality system,
- Continuously develops process and production areas by using up-to-date technologies,
- Working in cooperation with the authorities, supplier and the customer

Sustainability

In order to leave a livable world to future generations, Birgi Mefar Group consider environmental, social and economic issues intertwined with its field of activity, and give importance to ensure that every step is compatible with the sustainability vision. In 2021, BMG published its first Sustainability Report and awarded its process with Silver Ecovadis Medal by Ecovadis Sustainability Platform.

You can access our report from the QR code and the sustainability section of out website:

www.mefar.com

Quality Certificates

- GMP certification from Turkish Ministry of Health since 1986
- GMP certification from German Health Authorities since 1997
- ISO 9001 certification since 2003
- GMP certification from MHRA since 2003
- ISO 14001 certification since 2012;
- ISO 45001 (OHSAS 18001) certification since 2012
- GMP certification from Ukraine since 2013
- GMP certification from Portugal since 2014
- GMP certification from Greece since 2014
- GMP certification from Denmark and Greece since 2015
- Belarus export license since 2015
- Most Environmental Facility Award was given to Mefar (2015)
- GMP EMA Certification for all European countries has been issued in 2016
- GMP certification from Cote D'Ivoire Health Authorities since 2016
- GMP Compliance Notification from Canada Health Authorities since 2016
- GMP certification from CECMED since 2017
- GMP certification from SFDA since 2018
- GMP certification from Russia since 2018
- GMP certification from Croatia since 2019
- ISO 13485 certification since 2021

**The GMP certifications shown on this page may have been updated and/or new GMP certifications are added, therefore please ask us our curr ent GMP certifications at business@mefar.com*