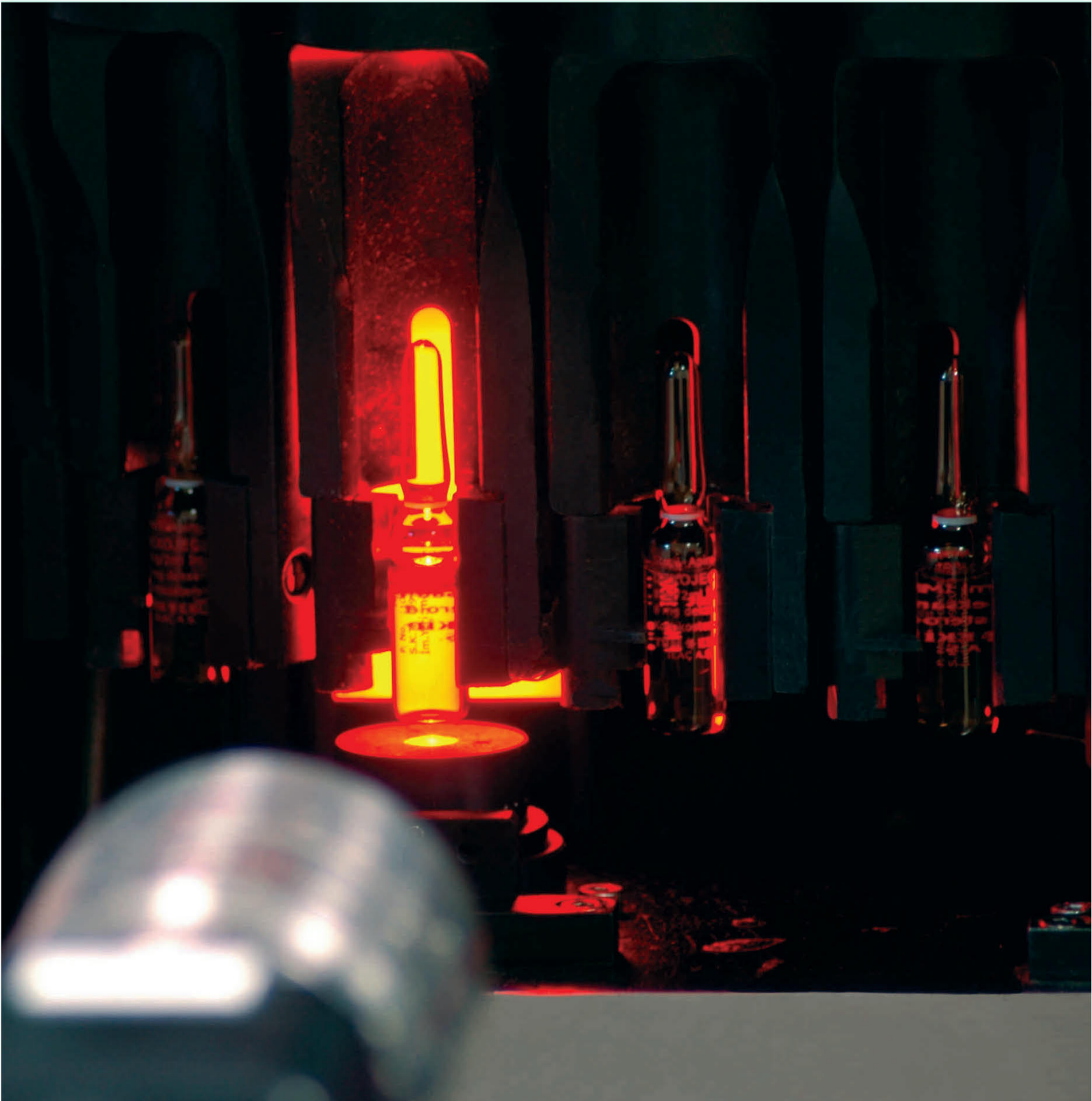




**mefar**





**discover mefar...**  
**a leading pharmaceutical contract manufacturer**



### **Together to health...**

Founded in 1985, Mefar is a leading pharmaceutical contract manufacturer of parenteral solutions for human and veterinary usage in ampoules, vials, lyophilised vials, BFS (blow-fill-seal containers) and 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, German, British (MHRA), Romanian, Ukrainian, Portuguese and Greek Health Authorities. It is 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.

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 OHSAS 18001 certificates.



As a business partner with an impressive global customer base, Mefar provides flexible customized services with over 600 employees with a full commitment to quality.

Mefar's integral relationship with its sister company, Birgi, a leading empty glass ampoule and vial manufacturer, creates a synergy that generates significant cost-savings and unmatched flexibility 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 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 finished products to its customers in the fast growing Turkish market and export markets such as Germany, the UK and the Balkans.

As an independent company, Mefar does not manufacture its own pharmaceutical products, and is completely dedicated to serving our business partners with loyalty and in an environment free of any conflict 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.



# 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.

Mefar also provides full service packaging and warehousing services for your parenteral or cold-chain products.

**Our wide range of production capabilities includes;**

**Ampoules:**

- Aseptic or terminal filling of 1 ml to 30 ml on state-of-the-art production lines
- Fully-automated inspection machines

**Vials:**

- Compounding & filtration (up to 2.400 lt)
- Aseptic or terminal filling of 2 ml to 300 ml on state-of-the-art production lines

**Lyophilization:**

- Vial form lyophilization on state-of-the-art lyophilizers

**Pre-filled Syringes (PFS):**

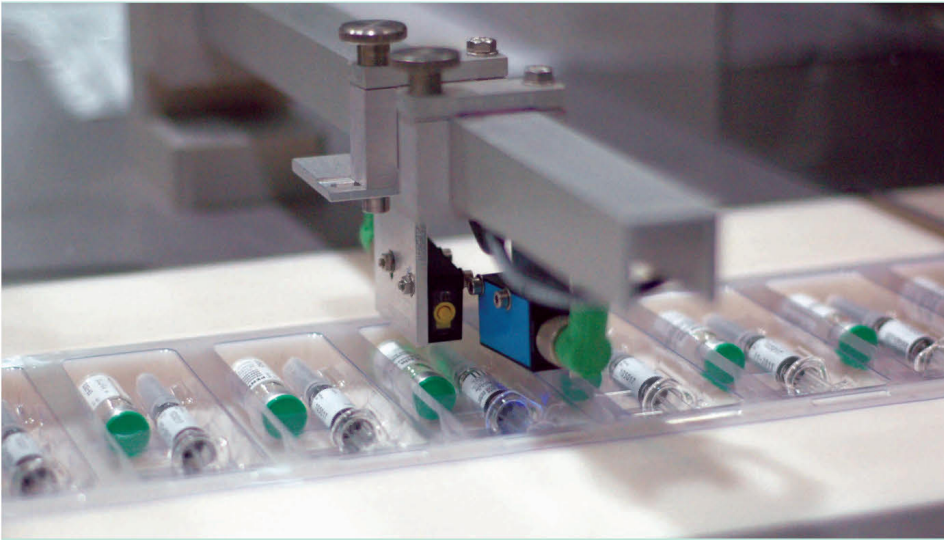
- Aseptic filling of 0.5 ml to 50 ml
- Fully-automated inspection machine
- Labeling and back-stop insertion machines

**Blow-fill-seal (BFS):**

- Aseptic filling in drop bottles of 5 ml to 50 ml
- Twist-off, strip or screw cap bottle capabilities



# Products & Services



## 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.
- Track and Trace (T&T) capabilities in accordance with regulations for anti-counterfeiting and 2D barcode quality verification systems

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 3.000 pallets capacity for finished products and packaging materials.

Our customers are also able to access their up-to-date 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 600 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.*

### Defar:

Established in 2006 by BirgiMefar, Defar provides our customers warehousing and logistics services under the cGMP and QA of BirgiMefar policies.

We offer storage, packaging as well as specific warehousing such as cold storage (2°C - 8°C), management of quarantined goods, handling of returns, auditing and distribution services.

Defar's all closed areas are moisture and temperature controlled and are recorded continuously.



STOK PARTİ DETAY			
Stok Grup 1 : HA Stok Grup 2 : 112 Stok Grup			
Parti No	Kontrol No	Tarih	Açıklama
000004	0000173000	11.08.2011	DEVİLER
12/01/080	0000180450	11.08.2011	DEVİLER
12/01/080	0000185400	20.09.2011	KURTULDUY ANKUL Hİ
12/00/000	0000135200	11.08.2011	DEVİLER
100448	0000136400	11.08.2011	DEVİLER
000039	0000098011	11.08.2011	DEVİLER
0001	0000136970	11.08.2011	DEVİLER

# Quality



## 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.

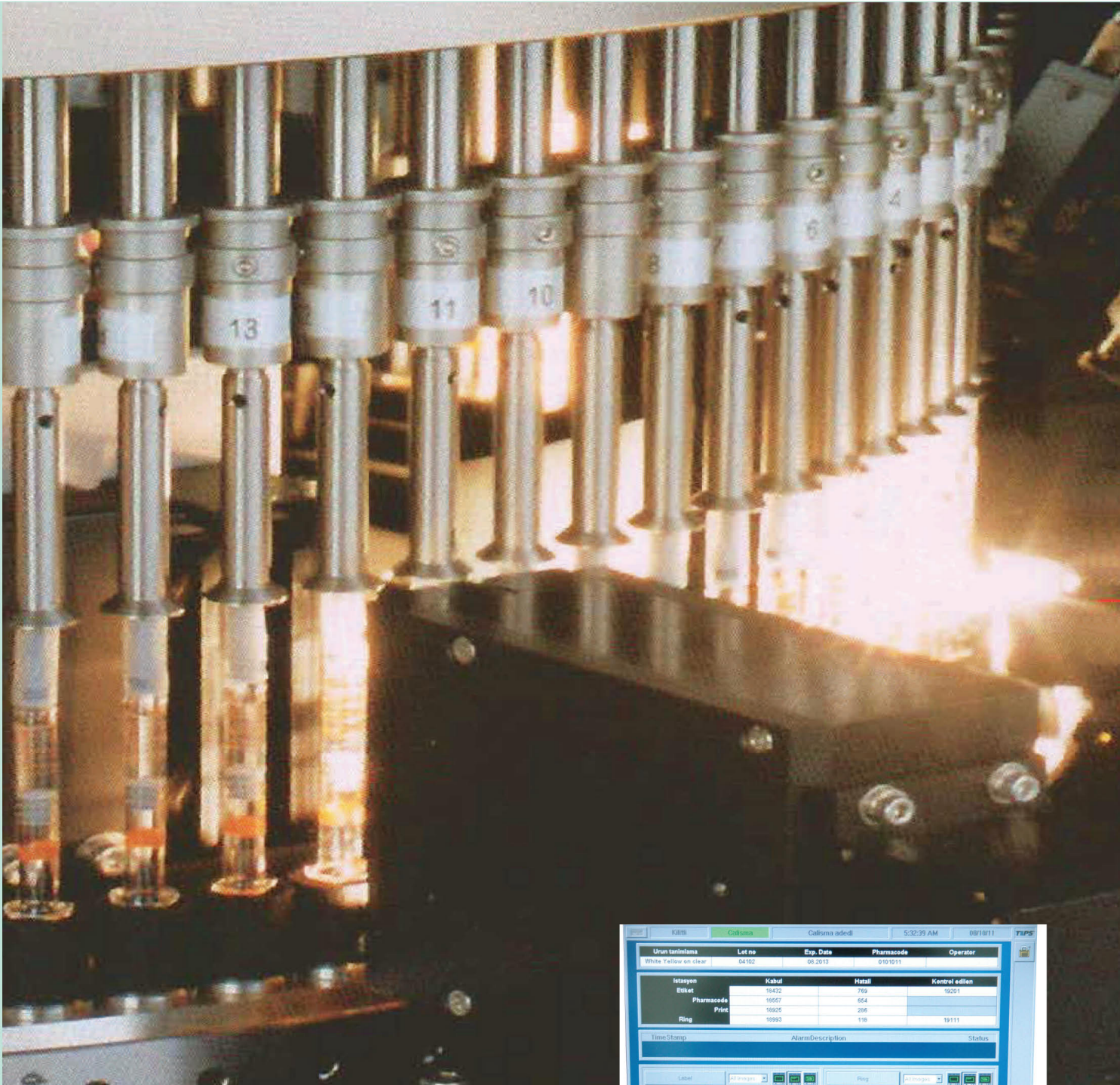
With its modern chemical, microbiological and physical laboratories, Mefar has an extensive experience in running method validation, stability studies as well as routine product and raw material analysis with its well-trained, devoted staff of pharmacists, chemists and chemical engineers.

Mefar continuously monitors and records particles in class A and air flow 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 Certificates



## Quality Policy

I. All of our products are manufactured in accordance with Good Manufacturing Practices (cGMP) rules and quality.

To this end;

- current rules and technologies are pursued,
- the necessary measures are taken to ensure continuous improvement and development,
- customers' expectations are met at a maximum level,
- the end-user is enabled to use our products in a fully secure manner.

II. In accordance with this policy, the senior management of the company completely fulfills the requirements of the quality management system and commits to increase its efficiency continuously.

III. In order to fulfill this commitment, the management sets new targets for all processes every year and evaluates those targets periodically.

IV. The senior management of the company:

- acts with transparency, equity and integrity in all of its relations with suppliers, customers and employees
- enables a democratic atmosphere to flourish in the company
- prioritizes the interests of the society and the protection of nature in all kind of work carried out
- trains and develops its personnel on a continuous basis.
- considers labor health and security of utmost importance

Executive Committee


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.

**Department of Health**  
**MEDICINES and HEALTHCARE PRODUCTS**  
**REGULATORY AGENCY**  
**INSPECTION and INVESTIGATION**  
 Phone: 0312 334 20 20, 334 20 20  
 107 Floor, Maras Towers 1366 Elm Lane London SW8 5NQ  
 Telephone: +44 (0)20 7966 0800 (toll free)

**RESPECTED - COMMERCIAL**  
**Mefar İlaç Sanayi A.Ş.**  
 Bahçeşehir Hacıoğlu Parkı Cadde No 18  
 P.O. Box 147 Kat: 10  
 Beşiktaş  
 Turkey

Date: 27th Dec 2004  
**Dear Mr. Tuncali,**  
**UK MEDICINES ACT 1968**  
**PRODUCT LICENCE NO:**  
 PLO15000001R - PLO15000001R - PLO15000001R - PLO15000001R - PLO15000001R

I refer to the inspection carried out at your company's premises at Katipçe on 7<sup>th</sup>, 10<sup>th</sup> and 11<sup>th</sup> of November 2004 by myself and Dr. Resley.

The inspection findings and your response allow us to recommend to the UK Licensing Authority that the site inspection may continue to be used as a manufacturing site on the above product licence.

Any issues arising from this inspection will be reviewed at the next inspection.

Yours sincerely,  
 Sue Nelson  
 GMP Inspector


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.



**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.



**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.



**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.

- GMP certification from German Health Authorities since 1997
- GMP certification from MHRA since 2003
- GMP certification from Romania since 2010
- GMP certification from Ukraine (terminally sterilised) since 2013
- GMP certification from Portugal since 2014 for BFS eye drops
- GMP certification from Greece (terminally sterilised vials) since 2014

\* The GMP certifications shown on this page may have been updated and/or new GMP certifications are added, therefore please ask us our current GMP certifications at [business@mefar.com](mailto:business@mefar.com)


**REPUBLIC OF TURKEY**  
**MINISTRY OF HEALTH**  
 General Directorate of Pharmaceutical Affairs  
 ANEKA  
 15049811  
 Sertifikasyon No: 4723  
 Issued by: 05/08/2014  
**GMP CERTIFICATE**  
 Mefar İlaç Sanayi A.Ş.  
 5086 Katipçe-İstanbul  
 This is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and shall be maintained in accordance with the requirements of the GMP as recommended by the World Health Organization in respect of products to be sold or distributed within the country or exported or to be exported.





The founder of our group of companies, Adnan Birgi left a successful banking career in 1947 to become the pioneer of the tubular glass container industry in Turkey. His continuous quest for perfection and his limitless energy has always been a source of inspiration to those around him. The family atmosphere and a strong sense of belonging is a direct result of his intense personal involvement and human interest. We are proud to follow his legacy of total dedication to perfection in the service of our customers.





Ramazanođlu Mah. Ensar Cad. No: 20 TR-34906 Kurtky / İstanbul / TURKEY  
Phone: + 90 216 378 44 00 Fax: + 90 216 378 44 11  
e-mail: [business@mefar.com](mailto:business@mefar.com) [www.birgimefar.com](http://www.birgimefar.com)