



İMARETÇİOĞLU



www.imaretcioглу.com



The Company

- Imaretcioğlu Ltd is located in Samsun Free Zone, Turkey.
- It was established to produce pharmaceutical ampoules in 1990.
- In 2007, a new state-of-the-art production plant for sterile parenteral liquid forms was launched.
- Imaretcioğlu Ltd is specialized in producing small volume sterile parenteral liquid forms.
- We are able to provide custom contract manufacturing for small volume parenterals to our customers according to their specifications.
- Our company works strictly in accordance to the Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and documented Standard Operating Procedures (SOP)

Services

Pharmaceutical Ampoule Production

- Seven Moderne Mechanique machines
- Automatic cosmetic inspection devices on each production lines (Vimec, Netherlands)
 - Cosmetic inspection detects chips, dirt, scratches, glass particles and cracks
- Ampoule printing
- One cut point (OPC)
- Color break rings
- Color code ring

Annual Capacity: 150 million

Ampoule Filling

- Formats
 - 1 mL, 2 mL, 3 mL, 4 mL, 5 mL, 6 mL, 10 mL and 15 mL
- Equipments
 - Two Bosch filling lines
 - Two Autoclaves (Fedegari and De Lama)
 - Three automatic inspection machines (2 Brevetti and 1 GF)
- Water For Injection (WFI) System (Concept Design, Germany)
 - pH, conductivity, temperature and TOC of water is automatically controlled and recorded.
- HVAC System (Sauter, Switzerland)
 - Control of air pressure, humidity and temperature
- Customized packaging
- Product traceability

Annual Capacity: 150 million



Other Services

- A.P.I supply from suppliers with GMP certificates
- Stability studies
- Process validations
- A.P.I analysis
- Packaging material supply



Quality Control and Quality Assurance Departments

Quality Control Department is divided into two divisions

- Chemical QC
- Microbiological QC

Services of these divisions contains:

- Testing of starting, intermediate and finished products
- Validation of test methods
- Sterility tests
- Endotoxin tests (gel clot and KTA)
- Stability studies

Quality Assurance Department is responsible of:

- Quality • Documentation • Validation and qualification of each system
- Environmental monitoring • Purchasing • Manufacturing • Quality Control
- Storage • Technical services • Training

The Quality Assurance System is build on the requirements imposed by Turkish Ministry of Health and the European GMP guidelines.

Certificates

GMP Certificate



ISO Certificate





LOCATION

- Our company is located in Samsun Free Zone, in Black Sea region of Turkey
- Convenient location enables us to transport products with air, sea and road transportation to all around the world.



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