BIOMEDICA FOSCAMA- COMPANY PROFILE

BIOMEDICA FOSCAMA S.p.A.
INDUSTRIA CHIMICO FARMACEUTICA

Who we are

Biomedica Foscama is a long established, leading Italian Pharmaceutical company at the forefront of its industry.

Biomedica's exceptional quality standards of our pharmaceutical products are certified by EU GMP certification. We're an international company, supplying over 15 markets worldwide (including CIS, China and far East countries)

Biomedica takes pride in being flexible and ready to adapt its production capabilities to market and customer needs thanks to approx. 540 m^2 area available

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Key elements to do business with us

Flexibility and ability to expand capacity modularly

- Ready to expand to new department areas
- High performance filling line already identified

Vertical Integration

- Biomedica is a partner able to cover the entire value chain from the API production the filling and packaging of the finished product and commercialization of pharmaceutical products relying on high quality standards and advanced technologies

Operation excellence

- Biomedica pursues a corporate policy aimed at a continuous and ambitious improvement that is achieved through the active participation of a team of reliable and professional managers as well as highly skilled workforce capable to handle development process and production of pharmaceutical products of both well established products and new projects implementation.

Outstanding quality culture

- The plant is designed to ensure the highest quality production standards in accordance with the GMP (Good Manufacturing Practices) and operate in full compliance with the EU regulations

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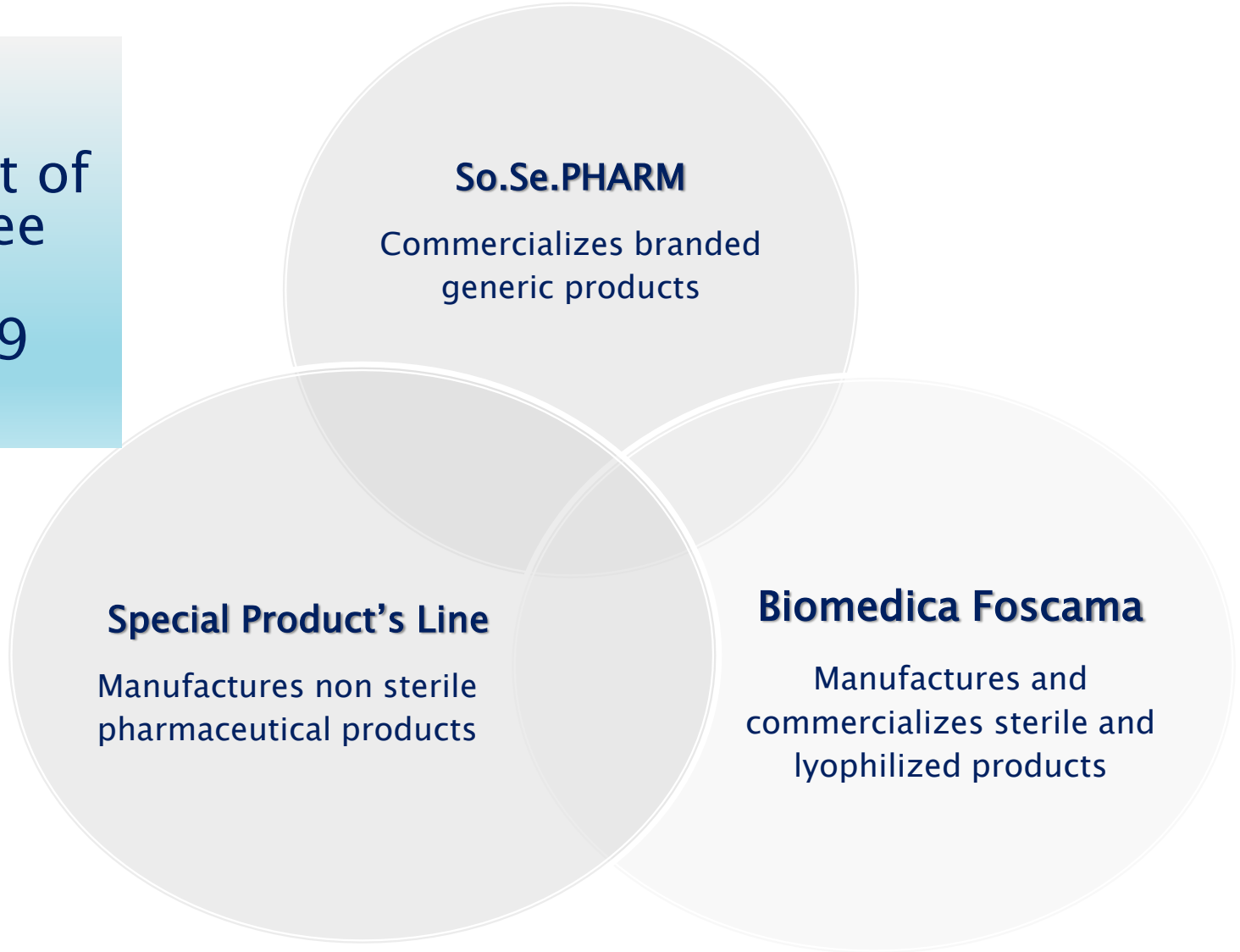
The structure of the group

- Since October 2019, Biomedica Foscama is part of a group composed by three companies.
- Today the group has 439 employees



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History

- **1947** – Foundation of the company from the union of Biomedica International and Foscama
- **1961** – Esafosfina (Fructose-1,6-diphosphate) launched in Italy
- **1990**– TAD (Glutathione) launched in Italy

- **October 2019** – Acquisition of the site from SPL by auction
- **November 2019**–Complete revamping to re-activate the site
- **July 2020**– GMP certiifcate for Finished dosage form
- **August 2020**– GMP certificate for API

- **Investment for site expansion**:
- **2020**: New injectable ampoules area included tunnel, autoclave for terminal sterilization
- **2021**: New lyophilization area to increase current production capacity
- **2021**: new dedicated area for vaccins

Certification– Finished Product

BIOMEDICA FOSCAMA S.p.A.
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Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/84/H/2020***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:
The manufacturer: ***BIOMEDICA FOSCAMA INDUSTRIA CHIMICO FARMACEUTICA SPA***
Site address: ***Via Morolense 87, Ferentino (FR), 03013, Italy***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***aM84/2020*** in accordance with Art. 40 of Directive 2001/83/EC .

Other :
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-07-30*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids 1.1.1.6 Other: Powders(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

1.6.4: LAL test. DUE TO COVID -19 PANDEMIC PUBLIC HEALTH CRISIS, THE GMP CERTIFICATE WAS GRANTED ON THE BASIS OF A DISTANT ASSESSMENT/REMOTE INSPECTION. AN ON-SITE INSPECTION WILL BE CONDUCTED WHEN CIRCUMSTANCES PERMIT, AS SOON AS THERE IS A CONSENSUS THAT THE PERIOD OF THE PUBLIC HEALTH CRISIS HAS PASSED. THE GMP CERTIFICATE IS VALID UNTIL 31 DECEMBER 2021.

Certification– API

BIOMEDICA FOSCAMA S.p.A.
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AIFA AGENZIA ITALIANA DEL FARMACO

Certificate No: IT-API/221/H/2020

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer BIOMEDICA FOSCAMA INDUSTRIA CHIMICO FARMACEUTICA S.P.A.
Site address VIA MOROLENSE, 87 - 03013 FERENTINO (FR)

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2020/09/22, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Part 2

Name and address of the site:
BIOMEDICA FOSCAMA INDUSTRIA CHIMICO FARMACEUTICA S.P.A.
VIA MOROLENSE, 87, 03013 FERENTINO (FR)

Name of the active Substances manufactured or imported:

FRUCTOSE 1,6-BISPHOSPHATE SODIUM SALT STERILE
GLUTATHIONE SODIUM STERILE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances
FRUCTOSE 1,6-BISPHOSPHATE SODIUM SALT STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3. Salt formation / Purification steps: salt formation
3.4	**Manufacture of sterile active substance**
	3.4.1. Aseptically prepared
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation,drying,milling **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of th material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.3.** Microbiological testing (including sterility testing)

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 214

AIFA AGENZIA ITALIANA DEL FARMACO

3 - Manufacturing Operations - Active Substances
GLUTATHIONE SODIUM STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3. Salt formation / Purification steps: salt formation
3.4	**Manufacture of sterile active substance**
	3.4.1. Aseptically prepared
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.3.** Microbiological testing (including sterility testing) **3.6.4.** Biological testing

Restrictions or clarifying remarks:

Due to the restriction caused by COVID-19, it was verified by distant assessment that the aseptic process of sterile active substances is performed according to GMP, including Annex 1, as laid down in Dir. 2003/94/EC and an on-site inspection will be performed once the restrictions are over. The GMP certificate is valid until 31 December 2021, except for AIFA re-evaluation.

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Plant Capabilities

➢Biomedica is authorized to manufacture sterile products and is primarily focused in the production of small and large volume for injection, either as lyophilized powder or ready-to-use solutions. Capabilities include:

- Sterile freeze drying
- Filling in sterile vials and ampoules (powders and liquids)
- Packaging of ampoules, vials and syrups

The site strives for quality and the highest efficiency for all process. Thanks to a long term entrepreneurial vision, that allowed the group to stay ahead of changes in the industry and invest in cutting edge solutions, Biomedica takes pride in having all the equipment high-technology

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Plant Capabilities

- Biomedica Foscama has been completely revamped

- Present: available capacity 40 mio vials
- Future: capacity can be to easily expanded up to 140 mio vials through a new department

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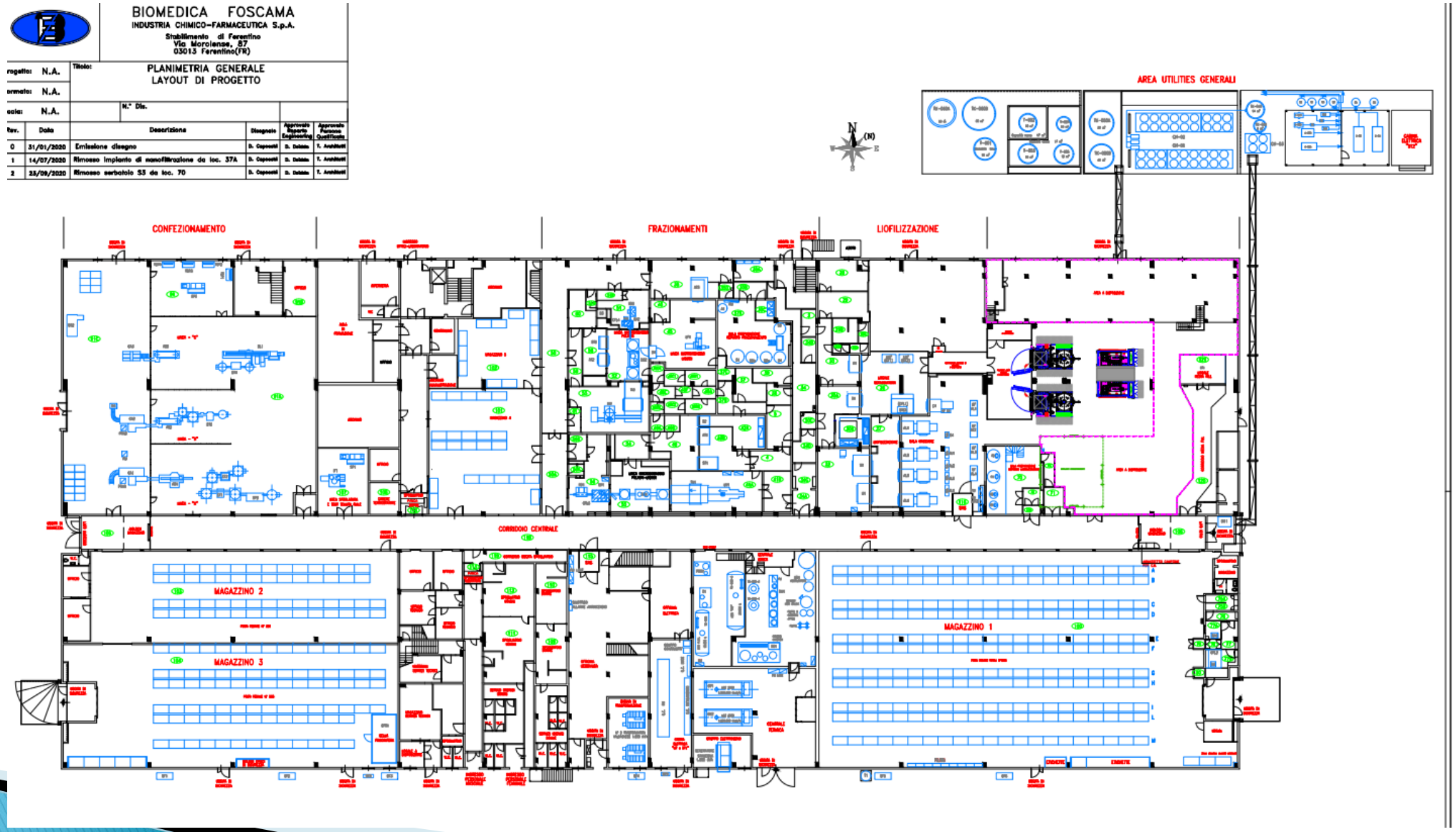
Plant Layout



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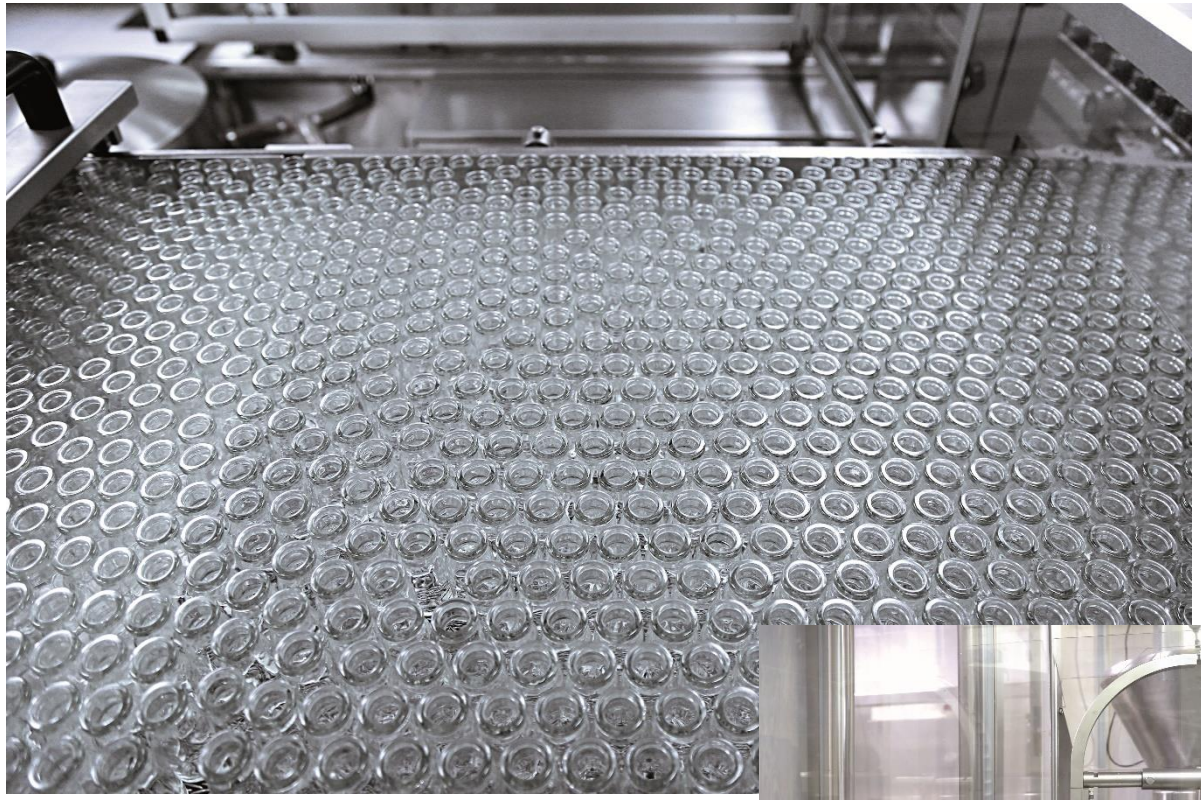
Highlights: Vial sterile line



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Highlights: Sterile freeze drying

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Distribution

ITALY

- Dedicated, highly professional and well trained scientific and technical advertisers/representatives assure constantly up-to-date materials and information for doctors and physicians
- Italian market directly distributed by Biomedica. Distribution platform is based on a main warehouse that stocks the goods and arrange replenishment to peripheral warehouses, shipment to wholesalers and pharmacies
- Biomedica has an extensive network of distribution through some of the main Italian wholesalers, e.g. Comifar to cover the whole territory

EXPORT

- Biomedica is also active in the international market thanks to distribution agreements with local major companies. Consolidated partnerships have been already established especially outside EU as the group is constantly seeking for international expansion.
- A well established export department successfully manages the day-to-day business with existing partners and develops synergic relationships with new partners (importers, distributors and/or other pharmaceutical companies) in order to expand the presence of Biomedica in new markets.
- Main partners are in China, Philippines, CIS countries, Vietnam

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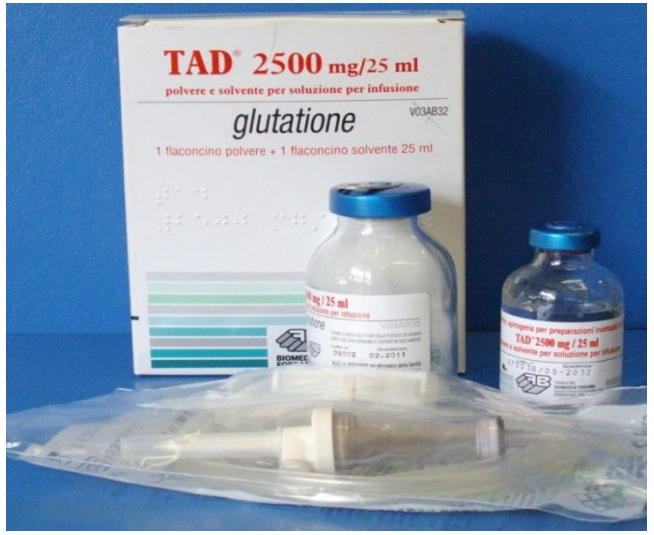
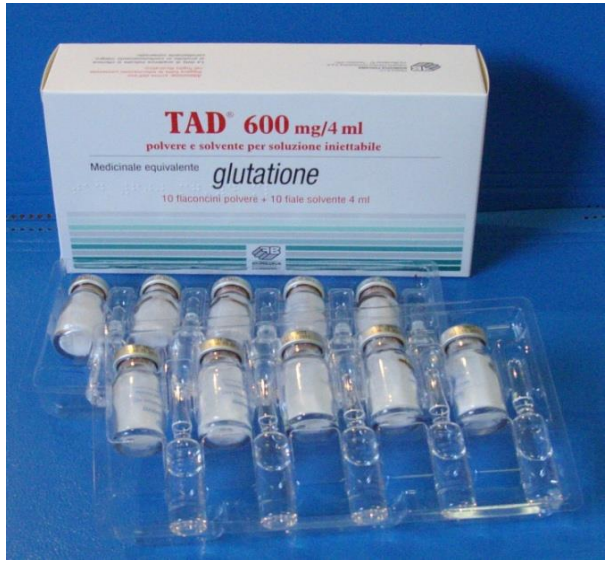
OUR BLOCKBUSTERS

TAD

- **Active ingredient**: reduced Glutathione
  - 600 mg / 4ml (10 vials)
  - 2,5 g / 25ml (1 vial)





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OUR BLOCKBUSTERS

ESAFOSFINA

- **Active ingredient**: Fructose-1,6-diphosphate
  - 0.5 gr / 10 ml
  - 5g / 50 ml
  - 100 ml ready to use