POLFA TARCHOMIN S.A.

Polish Pharmaceutical Company

About Us

Polfa Tarchomin S.A. with headquarters in Warsaw is one of the largest generic companies operating in Poland and one of the oldest pharmaceutical companies in the world. Company history dates back to 1823, when the first production of medical preparations began.

Our mission:

we love life

we accept challenges

we treat effectively

About Us

Core of our business

Polfa Tarchomin specializes in development, authorization, production and sale of different pharmaceutical product. We cooperate with partners in the field of sale & distribution, co-development and contract manufacturing.

We care about our people

Polfa Tarchomin follows a motto that employees are the greatest asset of a company and they are major contributors to profits and worth of an organization. Polfa Tarchomin currently employs specialized personnel who have extensive experience in the field of chemical synthesis, pharmaceutical technology, optimization and technology transfer and quality requirements forms.

Sustainability

The environment has been for many years one of the main concerns of Polfa Tarchomin S.A. Reducing the environmental impact of the plant is carried out, among others, by using environmentally friendly production facilities and conducting processes in a manner that minimizes impact on the environment.

Core Activities

1 Research & Development

Polfa Tarchomin S.A. conducts research & development processes in respect to new formulations , APIs, analytical methods and its validations, preparation of regulatory dossiers and other activities related with pharmaceutical products.

2 Production

Almost all our products are manufactured in our facilities. In general, we are in position to produce: tablets and coated tablets; hard gelatinous capsules; dry bottled syrups; powders for injections; dermatological aerosols; solutions; gels; insulin cartridges and ampoules.

3 Sale & Distribution

Polfa Tarchomin S.A. has a network of medical representatives that effectively promote products in hospitals and clinics, among GPs. Over the years Polfa Tarchomin S.A. has earned a strong position of a reliable partner on domestic and international markets.

Research & Development

▶Caring for the continuous development of the company, our R&D are looking for new interesting drugs and technologies that could expand our product portfolio and improve our competitive position.

▶The organizational structure of the Research and Development Divisions contains the following departments:

- Department of Chemistry Research
- Technological Laboratory of Pharmaceutical Forms
- Analytical Laboratory of Pharmaceutical Forms
- Medical Department
- Regulatory Affairs Department

Production

▶Our drugs are manufactured in buildings that meet strict requirements and quality standards. The quality of our products is confirmed by GMP certificates.

- The organizational structure of the Production Department, contains the following divisions:
- Penicillin (solid and injectables)
- Insulin (cartridges)
- Tableting and Packaging Department (solid forms)
- Aerosol, Gels & Ointments (semisolid forms)
- Lyophilisation (injectables)
- Synthesis (API)
- Logistic and Warehousing

Quality Standards

The main goal of Polfa Tarchomin S.A. as a professional manufacturer of medicinal products is to produce medications of good quality, efficacy and safety.

The Quality Assurance System functioning in Polfa Tarchomin S.A., based on the requirements of European GMP (Good Manufacturing Practice), oversees all activities in the manufacture of medicinal products and ensures their proper quality, therapeutic efficacy and patient safety.

- **EU** GMP
- **HACCP**
- **HALAL**

Domestic Structure of Sales

(2022)

Polfa Tarchomin S.A. is a leader in the field of anti-infective drugs. In the group of insulin, psychotropic drugs and dermatological preparations we have a significant market position.

Polfa Tarchomin S.A. specializes in prescription medicine. Our offer is supplemented by OTC products.

Antibiotics

56,9 %

CNS

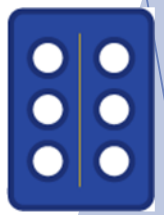
18,4 %

Insulins

12,2 %

Dermo

6,6 %



OTC

2,9 %

Global Presence

Lithuania
Latvia
Georgia
Azerbaijan
Bulgaria
Vietnam
Belarus
Hungary
Greece
Moldova

Czech Republic Slovakia
Kazakhstan Turkmenistan
Uzbekistan Mongolia
Kyrgyzstan
Malta
Albania
Iraq
China
Macedonia

Israel
Estonia
Austria
Netherla
Uganda
Kosovo
Croatia
Serbia
Bosnia and Herzegovina
Laos
Cyprus
Ukraine

B2B Opportunities

1

API

Polfa Tarchomin S.A, is integrated company producing some APIs for its own use mainly. We posses a new facility where API synthesis can be preformed.

2

FDF

In total, Polfa Tarchomin S.A. offers over 100 medicinal products used to effectively treat people. Our products can be offered for export or in out-licensing model.

3

CDMO/CMO

Polfa Tarchomin S.A. is active on CDMO and CMO markets offering several technology platforms and production facilities for different requirements of clients.

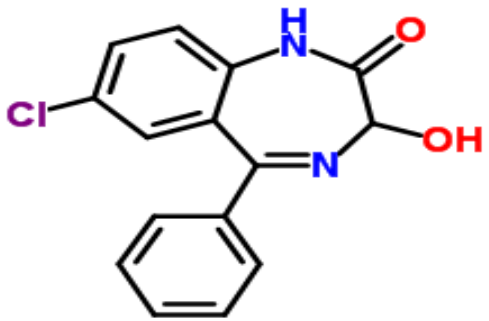
API

Polfa Tarchomin S.A. possesses new facility dedicated for synthesis of active pharmaceutical ingredients

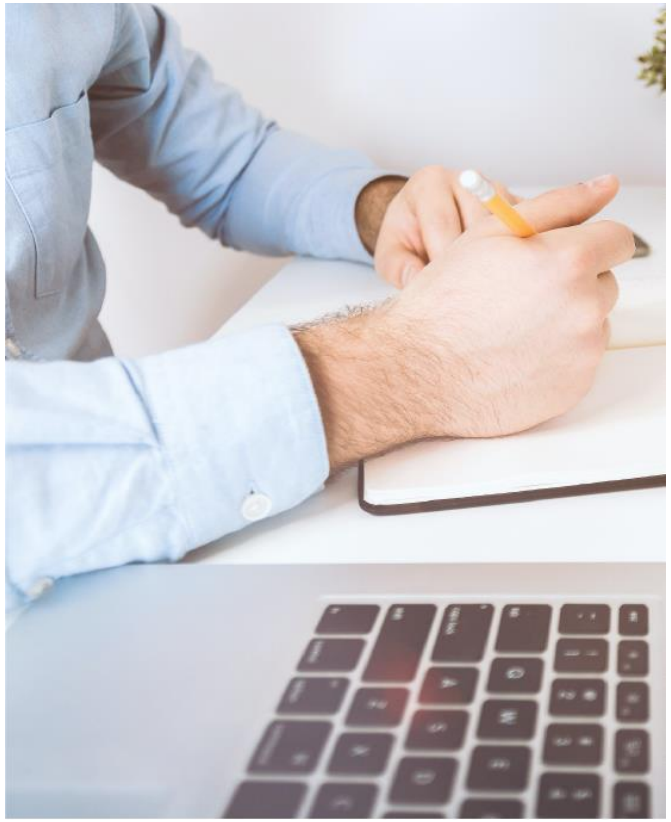
The facility possesses 3 technological lines for the synthesis of various products including antibiotics. The following operations can be performed on installations: synthesis at -10 ÷ 110^{0}C, crystallization at: -10 ÷ 80^{0}C, vacuum and pressure filtration, vacuum distillation, vacuum drying at temperature up to 80^{0}C, grinding, micronisation and ultrafiltration

API offered, EP grade :

- Tetracycline hydrochloride micronized
- Doxycycline hyclate
- Erythromycin base
- Erythromycin cyclic 11,12- carbonate
- Clonazepam
- Estazolam
- Lorazepam
- Oxazepam



Out-licensing of FDF



▶All dossiers are prepared in CTD format in accordance with the guidelines contained in Directive 2001/83/EC and the supplementing regulations.

▶Polfa Tarchomin S.A., by meeting all requirements for quality assurance and registration documentation, offers sales of finished products together with the documentation allowing their registration.

CDMO

R&D technological platforms:

Synthesis of API (Active Pharmaceutical Ingredients)

Development and manufacturing of FDF (Finished Dosage

- **Solid Dosage Forms** - powders; granules; tablets (ODT, IR, MR); hard capsules (available in blisters, cachets and bottles)
- **Liquid dosage forms** – solutions (available in bottles)
- **Sterile Dosage Forms** - injections lyophilizates, powders, solutions, suspensions (available in vials and ampoules)
- **Dermatological dosage forms** – cutaneous sprays; aerosols; gels (available in bottles, monoblocs and tubes)
- **High potent products** – lyophilizates, powders, solutions, suspensions (available in vials and prefilled syringes) (available 2025)

R&D Services

API characterization

- Solid state characterization
- Photostability
- pH solubility profiles
- Water content (Karl Fischer)
- Excipient compatibility
- Laser diffraction particle size analysis
- Morphology analysis
- Elemental analysis (ICP-MS)
- X-Ray diffraction (XRD)
- Polymorph identification
- Crystalline/amorphous evaluations
- Differential Scanning Calorimetry (DSC)
- Thermogravimetric Analysis (TGA)
- Dynamic vapour sorption analysis (DVS)

R&D Services

FDF characterization

- Quantitative & qualitative characterization of the finished dosage form
- Raman mapping
- Scanning electron microscopy (SEN)
- PSD determination
- Polymorph identification (API & excipients)
- Elemental analysis (ICP-MS)
- Stability studies

Stability studies

- Stability testing for all climatic zones in accordance with ICH Q1A, WHO, FDA, EMA and regional guidelines
- Stress testing: influence of temperature and humidity. Temperature range from -20°C to 80°C, relative humidity range from 30%RH to 90%RH
- „Thermal cycling" stability studies to establish shipping conditions
- Photostability testing in accordance with ICH Q1B guideline. Very short testing time due to use of metal halide lamps

Contract Manufacturing

Parenteral dosage forms – dry fill/lyo (containment upto OEB 5 possible)

Forms :

- powders for suspension/solution for injection/infusion
- lyophilizated powders for suspension/solution for injection/infusion

Technological platforms:

washer and sterilisation tunnel , sterile filling (80mg – 5g), Isolator technology Class A, freeze drying (shelf area 15 m^2), vial capping, visual inspection, labelling;

batch size range depending on product to be dosed

Primary packaging:

- glass vials (sterile filling) 10R, 20R, 20H, 50R, 50H, 100H, 200H, flip-off cap
- glass vials (sterile filling/lyophilisation) 2R, 6R, 10R, 20R, 30R, 50R flip-off cap

Secondary packaging :

- Folding boxes for individual vials

Availability 2025 (sterile filling/lyophilisation)

Contract Manufacturing

Parenteral dosage forms – liquids

- solutions in glass ampules ;
- solutions or suspensions in glass cartridges ;
- solutions in glass vials

Technological platforms:

washing and sterilisation tunnel , aseptic filling, terminal sterilisation, open rabs technology Class A, capping and closing, visual inspection, labelling;

batch sizes 50 -250L

Primary packaging:

- ampules 2 ml and 5 ml
- cartridges 3 ml
- vials 2R, 6R, 10R, 20R, 30R, 50R

Secondary packaging :

- Folding boxes for individual vials and for 5 or 10 for ampules and cartridges

Availability : 2025 (vials)

Contract Manufacturing

High-potent parenteral dosage forms products possibilities (up to OEB 5)

Forms :

- solutions in glass vials;
- solutions in Prefilled syringes
- lyophilized powder for injection

Technological platforms:

external washer, aseptic filling, Isolator (robotic arm) technology Class A, lyo unit, capper, coding station, autoclaves, visual inspection, labelling;

batch sizes to 150L (Lyo shelfs area 5 m^2)

Primary packaging:

- PFS 0,5 ml; 1 ml; 5 ml
- vials 2R, 8R, 10R , 30R, 50R

Secondary packaging :

- Folding boxes for individual vials/PFS

Availability : 2025

Contract Manufacturing

Solid oral dosage forms

Forms :

- Tablets & film coated tablets (sugar-coated, film-coated); size 5 mm - 19 mm;
- Hard gelatine capsules; size 3 - 00
- Dry powders/granulates for oral suspensions; dose 3 - 30 g

Technological platforms:

mixing, direct compression, dry & wet granulation, drying, film coating; batch size range 60 kg -600 kg depending on technology

Primary packaging:

- Blistering Alu-Alu, Alu -PVC, Al- PVdC,
- containers and jars (for tablets and capsules)
- bottles (glass , plastic) in different sizes 30 – 200 ml (for powders and granulates)

Secondary packaging :

- Folding boxes in different sizes and configurations

Contract Manufacturing

Semisolid and aerosol non-sterile production possibilities

Forms :

▪ topical gels;

▪topical ointments;

▪ topical pressure aerosols;

Technological platforms:

mixing, homogenization filling of tubes and monoblocks;

batch sizes 500 L (semisolid) 50-500 kg (aerosols)

Primary packaging:

▪ aluminium tubes 5-50 g

▪ PE tubes 5-15g

▪aluminium monoblocks (50 - 110 ml)

Secondary packaging :

▪Folding boxes for individual tube and monoblock

Contract Manufacturing

API

- **Active pharmaceutical ingredients and Intermediates production possibilities**
- **Technological platforms:** synthesis at -10 ÷ 110°C, crystallization at: -10 ÷ 80°C, vacuum and pressure filtration, ultrafiltration, vacuum distillation & drying, grinding, jet-milling micronisation;
- Batch size 100- 1000 L

Auxiliary Services

- Procurement of all raw and packaging materials
- Chemical, microbiological, pharmaceutical analysis
- Release for circulation by QP
- Warehousing possibilities
- Technical and technological support

Contacts

Out- licensing

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