

Preformulation & Analytical Services

Preformulation Screening | Analytical Development and Quality
Control | Analytical | Stability | CMC Packaging Services





BROAD EXPERIENCE IN MODERN THERAPEUTIC SOLUTIONS

TZF Polfa S.A. is the oldest pharmaceutical company in Poland that manufactures both active pharmaceutical ingredients and finished dosage forms. Our integrated approach delivers end-to-end solutions – from development and manufacturing to advanced analytical services that enhance the value of the products.

In 2025, we opened a state-of-the-art facility dedicated to highly potent parenteral products (up to OEB 5), setting new standards in quality and safety. Our services cover chemical and microbiological analyses with release for circulation, along with full-scope stability studies.



OUR CAPABILITIES



Preformulation Screening



Analytical/Stability



Analytical Development and Quality Control



CMC Packaging Services





ACTIVE PHARMACEUTICAL INGREDIENT CHARACTERIZATION

- Solid state characterization
- Photostability
- pH solubility profiles
- Water content
- Excipient compatibility
- Laser diffraction particle size analysis
- Morphology analysis
- Elemental analysis (ICP-MS)
- Hygroscopicity
- X-ray diffraction (XRD)
- Polymorph identification
- Crystalline/amorphous evaluations
- Differential Scanning Calorimetry (DSC)
- Thermogravimetric analysis (TGA)
- Raman analysis
- Stability studies
- BET surface area



FINISHED DOSAGE FORM CHARACTERIZATION

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



INSTRUMENTS

- Scanning electron microscope – Phenom ProX G6, Thermo Fisher Scientific
- Dual Vapor Gravimetric Sorption Analyzer – Resolution, Surface Measurement Systems
- Particle size and shape analyzer – Morphologi G4, PANalytical
- ICP-MS for elemental analysis – Thermo Scientific iCAP RQ
- X-ray diffractometer for powders – PANalytical Empyrean 3G
- Differential Scanning Calorimetry – DSC3, Mettler Toledo
- Thermogravimetric analysis – TGA2, Mettler Toledo
- Confocal Raman microscope – InVia Qontor, Renishaw
- Volumetric gas sorption instrument – NOVAtouch LX2, Anton Paar
- Digital microscope – VHX-7000, Keyence



STABILITY STUDIES

- Restricted access control, stability storage rooms set as per ICH stability conditions
- Forced degradation and photostability studies for developing stability
- Stability chambers are available at conditions to cater for all climatic zones as per ICH guidelines
- Analytical capabilities including microbiology testing
- Impurity identification and qualification
- Protocol, data analysis and final report
- Long-term drug ICH stability studies
- Accelerated ICH stability studies
- Shelf-life assessment
- In-use studies
- Short-term temperature excursion studies
- Freeze-thaw & temperature cycling



THE ACCREDITED LABORATORY (PCA ACCREDITATION NUMBER: AB 1878) OFFERS THE FOLLOWING TESTS:

Material/product tested	Type of activity/parameter/ characteristic tested	Reference documents
Filtering half masks	Thermal resistance Range: (-30 ÷ 70) °C	PN-EN 149+A1:2010 point 8.3.2 PN-EN 13274-5:2004
	Mechanical strength	PN-EN 149+A1:2010 point 8.3.3 PN-EN 143:2021-07 point 7.4.2
	Flammability Single burner method	PN-EN 149+A1:2010 point 8.6 PN-EN 13274-4:2021-03
	Penetration of sodium chloride	PN-EN 149+A1:2010 point 8.11 PN-EN 13274-7:2019-07
	Penetration of paraffin oil	
Medical face masks	Breathability Differential pressure	PN-EN 14683+AC:2019-09 point 5.2.3



CONTACT US!

Let's discuss how our preformulation and analytical services can accelerate your pharmaceutical projects. Get in touch today!

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TZ Polfa

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our services

