COMPANY PROFILE

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Since its establishment in **1951**, Bosnalijek has become the largest industrial manufacturer of medicines in Bosnia and Herzegovina. The company is continuously committed to its customers. Bosnalijek strives to expand its product range yearly, with new products adapted to customer needs.

We are strategically **focused** on improving the quality of our business and manufacturing processes, abiding by the fundamental principles of continuous professional improvement and careful analysis and planning.

The development of Bosnalijek is **based** on the modernisation of the manufacturing plant, education and continuous training of employees and compliance of our business operations with global pharmaceutical standards. For decades, Bosnalijek has been dedicated to the consistent application of **quality standards** in all aspects of its business, operations and processes. This approach allows the company to produce medicines of the highest quality and justifiably rank alongside internationally competitive pharmaceutical companies.

Bosnalijek's **quality system** is in full compliance with national and international statutory regulations and standards for good manufacturing practice, meeting the expectations and justifying the confidence of our patients, partners and the regulatory authorities.

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MARKETING AND SALES

are organised through three territorial and organisational units:

1) **Southeast Europe region**

2) **Middle East, Africa and Turkey region**

3) **Eurasia region**

Today, Bosnalijek markets its products in **23 countries** on three continents. In line with its strategic commitment, Bosnalijek continues to enter new and fast-growing markets.

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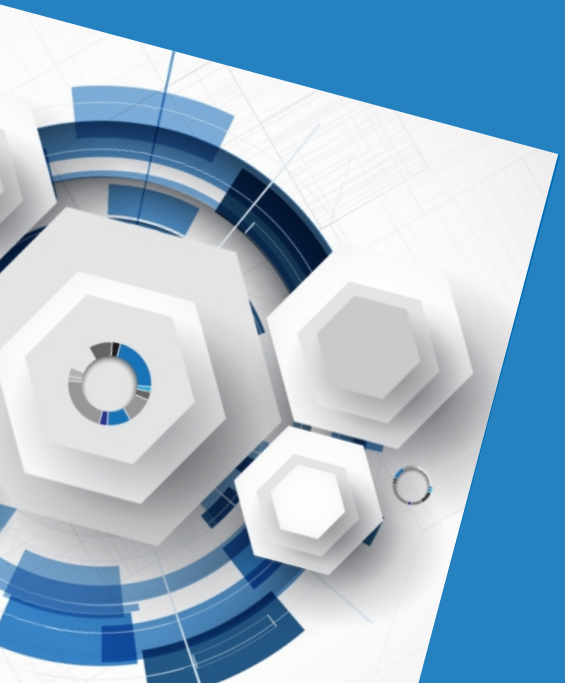
INTEGRATED SYSTEM



- Research & Development
- Manufacturing
- Regulatory Activities
- Quality Assurance and Control Division

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Research capabilities

- **Cell culture assays** (available cell bank with different healthy and tumour cell lines)**, evaluation of viability, proliferation and cell death**
- **Western blotting**
- **PCR**
- **Flow cytometry**
- **Evaluation of lysozyme activity in different samples**
- **Microbiological assays** (diffusion, dilution, biofilm formation, MALDI TOF identification)

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Development capabilities

- Development of finished dosage forms (solids, semisolids and liquids, non-sterile)
- Production and packaging of test samples and placebo for different purposes (i.e. science, preclinical and clinical trials)
- Production of lab scale (up to 10 kg) and pilot scale batches (up to 30 kg)
- Analytical method development, method upgrades and method validation
- Development and validation of analytical method for cleaning procedure
- In vitro testing
- Technology transfer and analytical method transfer
- Stability tests in accordance with ICH guidelines (stress stability 55°C/75%RH, accelerated stability 40°C/75%RH, intermediate 30°C/65%RH, long term stability - zone II, IV a & IV b, bulk stability, photo-stability)
- Packaging technology and primary packaging material proposals

Out licensing

- The focus of the product range structure is on medicines of mass therapeutic application.
- The product range includes medicines for oral, parenteral and topical administration with effects on the digestive system and metabolism, cardiovascular system, systemic infections, skin, musculoskeletal, nervous and respiratory system, and systemic hormonal medicines, with the exception of sex hormones
- In addition to medicines, our wide product range also includes dietary supplements, medical devices, special use cosmetics and disinfectants with wide scope of applications

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MANUFACTURING

- Manufacturing and packaging of bulk products (tablets/capsules)
- Serialisation
- Filling purified water in bulk packages (barrels, casks) from the purified water production systems
- Validation of chambers (air condition, fridges, autoclaves)
- Preparation of specifications of user requests and risk analysis for procurement of manufacturing equipment, measuring instruments etc.
- Evaluation of offers, installation and qualification of equipment
- Preparation of patterns for blister machines
- Milling machine services (manufacture of spare parts made of steel, stainless steel, etc.)
- Engineering services (services of mechanical and electrical engineers)

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REGULATORY ACTIVITIES

- Regulatory Strategy, Guidance & Support
- Registration dossier development and upgrade (Module 1- Module 5)
- Advice on national or EU regulation for drugs and medical devices
- Compilation and submission of Marketing Authorisation applications /renewal applications to Regulatory Authorities
- Filing Variations
- Medical writing and updating (labelling, leaflets and SmPC)
- Regulatory compliance for food supplements
- Writing of PSUR and RMP
- Expert advice on PV system requirements, PV trainings for PV and non-PV personnel
- Providing QP for Pharmacovigilance and for Materiovigilance
- Preparation and submissions for regulatory approvals for clinical studies
- Review (regulatory requirements) and submission of promotional materials to Regulatory Authorities
- Electronic submissions in eCTD and non-eCTD electronic submission (NEES) and conversion from CTD to eCTD

QUALITY ASSURANCE AND QUALITY CONTROL

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cGMP Quality Control Testing/analytical quality control laboratories fully equipped to conduct test programs for pharmaceutical clients, according to the pharmacopoeia (e.g. EP, USP, BP and JP) and to in-house specifications for raw materials (excipients and active pharmaceuticals ingredients), finished products and intermediate products, packaging materials, purified and tap water.

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QUALITY ASSURANCE AND QUALITY CONTROL

We offer a wide range of analytical techniques, including the following key techniques:

CHROMATOGRAPHY

- TLC
- HPLC/UPLC (with UV, PDA, RI Detectors)
- GC/HS (with FID Detectors)

SPECTROSCOPY:

- UV/Vis
- IR, FTIR
- Atomic absorption spectroscopy – flame / graphite / VGA
- MALDI TOF mass spectrometry for microbial identification
- TOC (Total Organic Carbon) analysis

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CHEMICAL, PHYSICAL AND PHYSICOCHEMICAL TESTING SERVICES

- Assay and Purity (e.g. Chromatography, Titration, Limit Tests)
- Identity (e.g. Spectroscopy, Chromatography)
- Dissolution Test (On Line / Off Line)
- Pharmaceutical Water Analysis (E.g. TOC)
- Water Content (Loss on Drying, KF Titration)
- Disintegration, Friability
- Appearance (e.g. Clarity, Opalescence)
- pH and Conductivity
- Uniformity of Mass etc.

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Microbiology testing:

- Microbial Limits Tests
- Microbial Contaminant Identification
- Preservatives Testing And Microbial Challenges
- Bacterial Endotoxins
- Environmental Monitoring
- Water Systems Validation
- Production Facility Qualification
- Cleaning Validation

Pharmaceutical Quality Assurance

- Business consulting in the process of establishing a quality management system according to national and international standards (ISO 9001, ISO 14001, ISO 18001, cGMP)

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