



BIOTECHNOLOGY & PHARMA UNIT



The TECNALIA Biotechnology & Pharma Division undertakes research and provides advanced technological services in the fields of **bioprocesses & conservation, pharmaceutical development and biomedical research**, generating business opportunities for the **food industry** and its **auxiliary companies**, as well as the **pharmaceutical industry**, through a highly-qualified, multi-disciplinary team supported by the latest equipment.

Our activities can be classified into three areas:



BIOPROCESSES & CONSERVATION

Research and technological services for the **food industry** through the development of **New food, Preservation and Enology**.



BIOMEDICAL RESEARCH

Improves **Prevention** and **Diagnosis** of pathologies, increases **safety** in the use of drugs and treatments and boosts **efficiency** in the use of health resources through efficient integration of basic and applied research in the field of **Bio-health**.



PHARMACEUTICAL DEVELOPMENT

Research for the **pharmaceutical and biotechnology industries** through a **comprehensive offering** to the pharmaceutical industry, covering the various phases that make up the drug development cycle, from **Galenic Development** to **Industrial Manufacture**.



R&D Activity

BIOPROCESSES & PRESERVATION

The **Bioprocesses & Preservation** area researches and offers **advanced technological services** for the **food industry and related sectors**, to become your technological partner on the road to innovation and improved competitiveness through the development of **New Foods Preservation and Oenology**, with a highly qualified, multidisciplinary team supported by cutting-edge equipment.

New Foods

We develop products in response to the needs of specific sectors of the population:

- **Healthier and/or more functional foods** and food supplements.
- **Bioactive compounds** derived from raw materials or by-products from the food industry using physicochemical and/or biotechnology processes.
- Processes and means for the **protection, addition and control of the release of bioactive compounds**. Micro and Nanoencapsulation.
- **Biotechnological processes**: alternatives for production processes and ingredient synthesis, whether through conventional processes or using immobilised microorganisms (porous matrices, microcapsules, etc.).
- Ingredient monitoring using **"in vitro" tests** (such as toxicity tests).
- **Bioactivity studies** on functional compounds.
- **Nutrigenomics** and clinical testing on functional foods (in collaboration with the Biomedical Research Unit).
- Advanced analytical techniques for the **identification and quantification of new chemical pollutants** and/or high value-added compounds in food matrices.

Preservation

- **Coatings and films** based on biopolymers, to increase the useful life of packaged products:
 - Form a barrier against moisture, oxygen, smells and/or fats.
 - Provide mechanical integrity and physical protection.
 - Include additives (antimicrobials, antioxidants, flavours, nutrients and colourants) in the packaged product.
- **Active packaging systems** based on biopolymers:
 - Formulation of packaged material. Characterisation.
 - Mixtures and modification of biopolymers.
 - Nanofillers: laminated silicates, cellulose and chitin nanofillers.
 - PVA determination, mechanical properties, solubility, opacity.
 - Incorporation of the material's active compound.
 - Efficacy studies (antimicrobial and antioxidant).
- **Smart packaging systems**. Freshness indicators.



R&D Activity

BIOPROCESSES & PRESERVATION

Enology

The research carried out in this field is the result of the multidirectional and complementary nature of the technologies used in the other focal areas researched by this field of application.

The main activity of this focal area is centred on the wine industry in Rioja Alavesa and relevant European wine-producing regions throughout France, Portugal and Italy.

The main research lines are:

- **Technologies** for the wine industry that **improve food quality and safety**: membrane, electromembrane and microencapsulation technologies.
- **Isolation, selection and immobilisation of indigenous wine yeasts.**
- Design and development of **new technologies for optimising the different production stages** from wine preparation to ageing.
- Fine-tuning of **analytical methods and analysis of specific compounds** for **grape and wine quality control**, as well as auxiliary materials such as **cork** or oak **wood** for wine barrel manufacturing.
- **Valorisation of by-products** of the wine-making process through the **recovery of molecules** that are useful for application in other industrial sectors such as **food, cosmetics and pharmaceuticals.**



R&D Activity

BIOMEDICAL RESEARCH

The Biomedical Research area improves the **prevention and diagnosis of pathologies, increases safety in the use of drugs and therapies, and boosts efficiency** in the use of health resources through efficient integration of basic and applied research in the field of biohealth.

Its activities are spread across two areas:

- **Clinical Testing Unit**
- **Molecular and Cell Biology**

Clinical Testing Unit

The Clinical Testing Unit focuses its activity mainly on **researching drugs** through the **complete experimental development** of clinical trials with a variety of objectives:

CLINICAL TESTING PHASES: I

- Bioequivalence development
- First administration in humans
- Pharmacokinetics/pharmacodynamics
- Interactions (drugs - food/alcohol)
- Drug tolerability and safety

CLINICAL TESTING PHASES: II AND III

Nutritional Clinical Research: Development of clinical trials in which the efficacy and safety of functional foods and food supplements is assessed

Clinical validation studies: biomarkers, diagnosis/prognosis systems, etc.

“The Biotechnology & Pharma Division follows **Good Clinical Practices and Standard Operating Procedures** and has **ISO9001 certification** for conducting Phase I clinical trials and bioequivalence trials. It also has a quality team and a clinical trial monitoring system.”

The Clinical Testing Unit's advanced technological services include

- Design and methodological and statistical evaluation of **protocols and associated documentation**.
- Editing and/or adaptation of **protocols and CRF**.
- Presentation of trials documentation to **CRECs and the AEMPS**.
- **Database design** (coding and filters).
- **Data input**. Database closure and freezing.



R&D Activity

BIOMEDICAL RESEARCH

- **PK/PD analysis.**
- **Pharmaceutical analysis** (WinNonlin).
- **Statistical analysis and reports** (WinNonlin, SPSS, etc.).
- Production and **evaluation of final reports.**
- Preparation of integrated **clinical and statistical reports.**
- **Presentation of results** to researchers.
- **Clinical expert reports** and assistance in fulfilling regulatory requirements and administrative tasks.
- **External monitoring** of clinical trials.

Molecular Biology

The Molecular Biology area conducts research of major biohealth interest within the fields of **Genetics** and **Functional Genomics**, using new, high performance technologies such as **DNA microarrays**, **gene sequencing by capillary electrophoresis** and **protein and cell analysis**.

The main areas of research are:

- **Pathogenomics:** the study of pathogen infection and host defence mechanisms for improving the treatment of infectious diseases.
- **Oncogenomics and Oncogenetics:** application of high-performance technologies to the study of tumours, specifically, the study of alterations in gene expression (DNA microarrays) as well as imbalances in genomic DNA (CGH arrays) and sequencing of candidate genes, for improving the diagnosis, treatment and prognosis of disease.
- **Nutritional Genomics:** application of Molecular Biology and high-performance genomic technologies, such as genotyping or DNA Microarrays, to the study of obesity and related diseases. Identification of guidelines for personalised hygiene/diet habits.
- **Functional foods and food supplements:** identification of mechanisms of action at molecular level of nutrients and/or specific food supplements.
- **Pharmacogenomics and pharmacogenetics:** identification of the greater or lesser susceptibility of an individual to the efficacy or toxicity of specific pharmacological compounds.
- **Toxicogenomics:** identification of the potential toxicity of a specific compound by characterising expression patterns induced in an experimental model and comparison of these patterns with those created by substances of known toxicity.
- **Clinical Genetics:** use of molecular techniques (sequencing, PCR, microsatellite analysis, LOH) for identification of specific genetic disorders, which are able not only to offer concrete diagnosis, but also to identify carriers of the alteration who might develop the disease in the future, or transmit this alteration to their descendants.



R&D Activity

PHARMACEUTICAL DEVELOPMENT

The Pharmaceutical Development area is composed of the **Galenic Development Unit** that has **Good Laboratory Practices (GLP) certification from the Ministry of Health** and the pharmaceutical laboratory **Laboratorium Sanitatis (LABSAN)**, authorised as a pharmaceutical laboratory for manufacturing drugs and investigational medicinal products and **certified in Good Manufacturing Practices (GMPs)**.

It offers **all the services that the pharmaceutical industry currently requires**, in the fields of formulation and development of drug manufacturing processes, including in this process **all the development phases**, from formula definition, fine-tuning the control methods and manufacturing the registration batches, to the subsequent industrial manufacture.

It has highly-qualified staff, as well as facilities and equipment for galenic development, analysis and manufacture of drugs in **different pharmaceutical forms and a multitude of application and transfer systems**.

Galenic Development Unit

We carry out **Galenic Development of innovative drugs in new pharmaceutical forms**. Our services cover the design and development of **innovative, generic and over-the-counter drugs, analytical development, stability studies and analysis of drugs in biological samples**.

Pharmaceutical Laboratory

LABSAN is specially equipped to **develop custom drugs** thanks to its **innovative infrastructure that places it at the forefront of the pharmaceutical industry**.

It has facilities and machinery located in a large 1,500 m² **area** with space for future expansion, meaning that the possibilities for manufacturing new drugs, new presentations and new drug release systems, are a unique **differentiating factor with respect to the rest of the pharmaceutical industry**. Always within the strictest environment with regard to applying and meeting GMPs.

It is also authorised for the manufacture of a wide variety of pharmaceutical forms, for both **oral and topical administration, in multiple presentations**:

- **Solid forms** (tablets, capsules, extemporaneous suspensions, etc.)
- **Semi-solid forms** (creams, emulsions, gels, etc.)
- **Liquid forms** (syrups, drops, etc.)
- **Sterile liquids** (ampoules and vials) (Pending authorisation)



Services

ADVANCED MOLECULAR BIOLOGY TECHNOLOGICAL SERVICES:

Determination of genetic alterations: mutations, polymorphisms, loss of heterozygosity, epigenetics, analysis of variations in the number of copies, etc. (sequencing and fragment analysis, CGH Microarrays, DNA Methylation Microarrays, miRNA Microarrays, etc.).

Gene expression analysis (DNA Microarrays, real-time PCR, etc.). Bioinformatics analysis and biological interpretation:

- Conversion and standardisation of the results.
- Quality Control: identification and discrimination of non-informative genes (reduction of background noise).
- Identification of alterations in gene expression in the various groups under study.
- Ontological analysis or biological contextualisation of the selected genes.
- Analysis of altered or modified intracellular pathways in the various groups, identification of relations between genes, etc.
- Identification of gene expression patterns or groups of genes with similar expression profiles (hierarchical clustering algorithms and/or K-means).

Analysis and quantification of the protein profile in two dimensions

In Vitro studies: flow cytometry, enzyme activity, immunoassays, cell viability and quantification tests, etc.

ADVANCED TECHNOLOGICAL PHARMACEUTICAL DEVELOPMENT SERVICES:

Galenic development

- Pre-formulation Studies.
- Design and galenic development of innovative, generic and over-the-counter drugs.
- Design and galenic development of new pharmaceutical forms.
- Compatibility studies on active ingredients and excipients.
- Design of manufacturing processes.
- Transfer of manufacturing technology.
- Production of Expert Reports.

Analytical development

- Pharmacopoeia-based characterisation of raw materials.
- Fine-tuning and validation of analytical techniques.
- Quantification of active ingredients, impurities and degradation products in active ingredients and end products.
- Transfer of analytical techniques.
- In-vitro dissolution profiles.



Services

ADVANCED TECHNOLOGICAL PHARMACEUTICAL DEVELOPMENT SERVICES:

Stability studies

- Short- and long-term Stability studies according to ICH guidelines

Bioanalysis (analysis of biological samples) and bioequivalence studies (pharmacokinetic analysis)

- Quantification of drugs in biological samples.
- Pharmacokinetics and Drug metabolism studies
- Bioavailability and Bioequivalence Studies

Manufacture of drugs and investigational medicinal products

- Pilot batches of investigational medicinal products.
- Biobatches for clinical trials.
- Third-party manufacture of industrial batches of marketed drugs.
- Validation of manufacturing processes.
- Validation of cleaning processes.
- Drug masking processes for clinical testing.
- Transfer and optimisation of manufacturing technology.

Quality control and release of drug batches



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