

Gaiker

MEMBER OF
BASQUE RESEARCH
& TECHNOLOGY ALLIANCE

Fast

Customized
advice

100%
customer-
oriented

Innovative

PHARMACEUTICAL Sector

At GAIKER we offer a wide range of tests for the **research and development** of active pharmaceutical ingredients (API) and products that can be **tailored** to the **needs of the client**. To do this, we use **state-of-the-art** techniques and equipment that allow us to provide **highly reliable** scientific data.

We have multiple physiological models *in vitro* and *ex vivo*, and the strategies we use include **cell biology** and **transcriptomic technologies**, among others. Thanks to this, we are able to support **all stages of development**, from **preclinical** studies to **clinical** phases.

Solutions for pharmaceutical companies and CROs

Custom R&D Studies

Central Nervous System

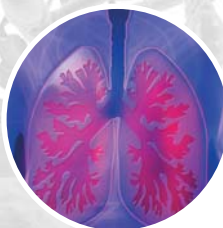
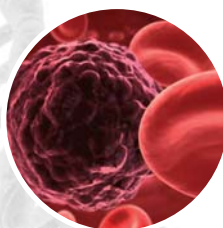
- Test of products through the modelling of pathologies and human neurological disorders in organoids.
- Test of the blood-brain barrier passage potential of APIs.

Skin

- Studies for the development and characterization of topical products in human skin explants and reconstituted tissue models.
- Experts in studies with both healthy skin, and skin with pathologies and injuries.

Digestive System

- *In vitro* assessment of stomach and intestinal digestive processes' effect on an API.
- Absorption through the intestinal barrier determination.



Blood

- Specialists in the research of different blood populations in healthy individuals and in individuals with pathologies.
- Compound activity analysis in the total blood population or in purified and / or differentiated subtypes.

Respiratory System

- Study of candidates in human nasal / pulmonary epithelium, both healthy, or with pathologies.
- Evaluation of the epithelium response to prolonged exposure to single / repeated doses of the products through a nebulization system.

ADME-TOX Studies

Since 1998, we have carried out ADME-TOX studies under the guarantee of **Good Laboratory Practices (GLPs)**, a certificate granted by the Spanish Ministry of Health and Social Policy.



Absorption

- Intestinal barrier. Caco-2 model
- Dermal absorption (OECD 428). Franz Diffusion Cells
- Blood-brain barrier
- Human lung and nasal epithelium



Distribution

- Plasma protein binding
- Chemical stability in gastric and intestinal fluid



Metabolism

- Metabolic stability: metabolization percentage, intrinsic clearance rate, half-life (hepatocytes, microsomes, S9, recombinant enzymes)
- Stability in human plasma
- Enzymatic phenotyping
- Identification and characterization of metabolites (phase I and phase II)



Bioavailability

- Semi-solid product *in vitro* release test, IVRT (FDA-SUPAC-SS). Franz Diffusion Cells



Drug-drug interactions

- Inhibition of CYP450-high throughput screening: fluorescent substrates, recombinant CYP450
- Inhibition of CYP450: substrates and specific CYP450 inhibitors
- Induction of CYP450



Bioanalytical method development

- UPLC/MS/MS, UPLC/PDA, HPLC/FL, HPLC/PAD



Organ-specific toxicity

- Organ-specific toxicity tests



Toxicity mechanisms

- Tailor-made assays: apoptosis / necrosis, oxidative stress, inflammation, DNA damage, intracellular calcium, etc.



Genotoxicity

- Ames test (OECD 471)
- Mutagenicity in mammalian cells (OECD 476)
- Micronucleus test (OECD 487)



Hemolysis test

- Invitox n°37



Eye-tests

- Eye irritation and damage (OECD 492, Het-Cam)



Dermal tests

- Corrosion / skin irritation (OECD 431, OECD 435, OECD 439)
- Phototoxicity (OECD 432)
- Oral, nasal, vaginal and gingival irritation



Inhalation tests

- Nasal, bronchial inhalation
- Toxicological study of inhaled products (ALI)



Gene and protein regulation

- Toxicogenomics
- Toxicoproteomics



Physicochemical analysis

- API characterization
- Solubility, stability, partition coefficient, etc.

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