



**“We are committed to take your product forward”**

## OUR PURPOSE & VISION

**Archivel Farma** offers a wide range of services to help biotech and pharma companies to develop projects. Due to its dimensions and characteristics, the Archivel **GMP** plant is especially suitable to manufacture from experimental to clinical batches.

## QUALIFIED TEAM

We have a dynamic and very enthusiastic team of pharmacists, biologists and biotechnologists. We are looking forward to share the experience acquired over more than 15 years developing a TB vaccine and collaborating in external pharma projects.

Our personnel is fully trained in handling bio-hazardous samples and working under biosafety standards

Archivel Farma will provide you **agile, flexible and customized services.**



## QUALITY CERTIFICATIONS

### Manufacturing Authorization

(Nº 4202E issued by AEMPS):

- Quality Control, Batch Certification of Medicinal Products (Human and veterinary, both commercial and investigational).
- Manufacturing operations of investigational medicinal products (sterile and biological).

**GMP certification** for the activities included in the manufacturing authorization (last inspection 2021).

## CLEAN ROOMS

### Class A/B biosafety level 3 room

A Class B biosafety level 3 room (**BSL-3**) is 36 m<sup>2</sup> to handle pathogenic microorganisms classified as Group 3 under sterile conditions. **Negative pressure** is maintained inside the room

It is equipped with 3 biological safety cabinets (type IIA), -80°C freezer, scales, a bead-mill fragmentator, four incubators, a pasteurization baths and a centrifuge.

### Class A/B cleanroom

A class B cleanroom with a class A unidirectional flow (15 m<sup>2</sup>).

This room is used for aseptic productions. It is equipped with scales, a -20°C freezer, a **freeze dryer** (Lyobeta 20), and a capping device.

HEPA filtered air supply maintains a positive pressure.

### Class C area

Consists in 3 class C rooms to carry out some production activities including material preparation and **drug manufacture.**

Equipped with an autoclave and a depyrogenation oven.

### Class D weighing room

Equipped with a scale and a weighing cabinet.

## ANALYTICAL LABORATORY FOR QUALITY CONTROL AND R&D



- Characterization of products
- Set-up and validation of analytical methods according to ICHs, PhEur and USP criteria
- Analysis of raw materials, samples, in process control (IPCs), bulk and finished products.



### PHYSICO-CHEMICAL ANALYSIS

Particle size by Zetasizer, visible particles, water content determination and spectrophotometry.



### BIOLOGICAL ANALYSIS

Biological activity, protein analysis, cell culture, cytotoxicity assays and nucleic acids analysis.

**GET IN TOUCH**

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