

GMP Pilot Plant

Location: Alcorcon, Spain

FAMAR
we innovate

FAMAR consolidates one of its pillars of growth and expansion offering new services and technologies at the service of our clients. With a constructed area of **more than 1,000 m²**, the new Plant will be in compliance with **the highest cGMP standards** and equipped to house state-of-the-art technology to develop and scale-up our customers' projects from benchlab of early phases to clinical trial manufacturing. **Our clean rooms** have been designed to work with operational

flows under a strict level of containment through pressure gradients, airlocks and decontamination zones that guarantee the safety of the personnel and the product and allow us the production of **HPAPI up to GMP conditions Safebridge 3A HPAPIs**. Furthermore, the area would be ready to manufacture other coated and uncoated tablets using a dry and wet granulation processes and direct compression among other technologies.

The scope of this investment is to run projects of manufacturing GMP scale-up batches, bio batches, clinical batches and registration batches up to 30 Kg.





THE OBJECTIVE is to have a GMP area for solid forms that could cover all the manufacturing processes for solid forms, **for batch sizes till 30 Kg** and capability of handling substances with OEB-3 ($>1 \mu\text{g}/\text{m}^3$) “Safe Bridge” classification material. This corresponds to OEB-4 according to Famar internal classification system.

Furthermore, the area will be capable to handle substances with OEB-5 ($0.03\text{-}1 \mu\text{g}/\text{m}^3$; according to Famar internal classification system, which corresponds also to OEB-3 “Safe Bridge” classification material) in solid forms, liquids and semisolids in low quantities (order of grams) for manufacturing phase I clinical trials.

The rooms will be versatile with the idea of placing different moveable pieces of equipment according to the requirements of each manufacturing process.

PILOT PLANT OPERATIONS:

Weighing

Scales up to 30 Kg,
Laminar flow cabinets, Isolators
Room with ATEX conditions

Wet Granulation

High shear mixer and Fluid bed dryer
up to 30 kg, IPC
Room with ATEX conditions

Sieving

Conical mills up to 180 Kg
and Oscillating mills up to 1 Kg

Compression

Isolator, Laminar flow cabinets,
IPC controls, Metal Detector, Deduster
Batch size: up to 30 Kg

Blending

Bin blender with different
interchangeable bins
IPC controls
Batch size: up to 20 Kg

Encapsulation

Isolator, Laminar flow cabinets,
IPC controls
Batch size: up to 30 Kg

Dry Granulation

Freund Vector
machinery up to 30 kg
IPC controls

Coating

Coating pan up to 38 Kg
Room with ATEX conditions