R&D Services

FAMAR
we innovate

Famar's talented scientific team is responsible for the flawless project execution, following a Quality by Design methodology and on the basis of good practices on Project Management.

Our R&D centers of excellence in Alcorcon, Spain, Avlonas, Greece, and Baranzate, Italy are specialized in the development of medicinal and consumer care products.

A value proposition that comprises the majority of pharmaceutical forms and regulatory status (Rx/OTC/Hybrid/Medical Devices) requested by famar customers not just following EMA directives but FDA as well, and with a special focus on complex and HPAPI product (OEB 3A).

The Analytical & Technical Service Cluster is in charge of accompanying the development of a new product at all stages. From the early stage of physical-chemical characterization of the raw materials and the first prototypes to the development and validation of analytical methods, up to stability of finished products under ICH conditions.

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360° DEVELOPMENT AND MANUFACTURING SERVICE FOR YOUR FULL DEVELOPMENT PROJECT

INITIATION OF THE DEVELOPMENT

- Customer Orientation, Key Concepts, Positioning
- Product Categorization, Market Analysis

PRE-FORMULATION DEVELOPMENT SERVICES:

INITIAL RISK ASSESSMENT:

- Regulatory strategy & patent review
- Sourcing constraints
- Quality by Design approach: Preliminary design of Quality Target Product Profile (QTPP) and Critical Quality Attributes (CQA) to consider (drug substance and drug product)
- API physical-chemical characterization (Particle Size Distribution, Enantiomeric forms, Polymorphism)
- Excipients and packaging materials selection
- Compatibility studies between API and excipients
- Reverse engineering studies from existing products (when applicable)
- Toxicology assessment and substance categorization

FORMULATION DEVELOPMENT SERVICES:

- Optimization of formulation and manufacturing of small batches for toxicological animal studies
- Prototype generation and Design of Experiments (DoE)
- Design of qualitative-quantitative formula. Definition of QTPP and CQA

INVESTIGATIONAL MEDICINAL PRODUCT (IMP):

- Manufacturing, labelling & packaging & release of IMP & placebo
- Support on the preparation of the Investigational Medicinal Product Dossier (IMPD)
- Support on the design of clinical BE studies

INDUSTRIALIZATION SERVICES:

- Manufacturing Process Development and Critical Process Parameters (CPP) Definition
- Scientific and technical support on scale-up and engineering batches prior to full scale validation/registration batches to Third Manufacturers
- eCTD services like authoring, validating and e-publishing submissions in eCTD formats
- Tech Transfer Out
- Technical File Support | PIF completion

ANALYTICAL DEVELOPMENT SERVICES:

- Analytical Method Development and Validation for Drug Substance and Drug Product
- Analytical Method Development and Validation for Impurities, Related Substances and Preservatives
- Extractable & Leachable studies
- Forced degradation studies
- Comparative In Vitro Dissolution Tests
- In vitro – In vivo studies
- Pre-stability and ICH stability studies
- Analytical Method Development and Validation
- Validation of microbiological methods
- In vitro Release testing (IVRT)
- ICH for zone II, IV a, IVb, US&EU, semi permeable products. Stability Chambers housing.
- Consulting Services (eg. GAP, Training, Audit)