FORMULATION AND STABILITY OF COSMETICS AND MEDICINES FOR HUMAN AND VETERINARY USE

Description

A research team from the Institute of Industrial Pharmacy of the Complutense University of Madrid offers the methodology and equipment necessary for the **FORMULATION** of both cosmetics and medicines for human and veterinary use. The team is specialized in the design and development of formulations:
- solid
- liquid
- semi-solid

for their administration orally, by different parenteral routes (intravenous, intramuscular, subcutaneous, local routes), and cutaneous, mainly.
The team has experience in the development of immediate release formulations, and also in the development of modified release systems (coated and matrix systems, microparticles, nanoparticles, liposomes, microemulsions, implants...), either seeking to prolong the duration of the effects, or looking for a selective release of the active molecule at the level of its therapeutic target, or favoring the passage of the active substance through biological barriers such as the intestinal mucosa, the skin or the blood-brain barrier.

A wide variety of dosage forms are covered such as tablets, capsules, granules, oral solutions and suspensions, oral self-emulsifying drug delivery systems; injectable solutions, suspensions and emulsions, parenteral powders, in situ forming implants, creams, ointments, gels, pastes, lotions...

The offering is complemented with the evaluation of the **STABILITY** of medicines and cosmetics, determining the causes of instability, proposing stabilization resources, and determining the shelf life of these products by carrying out stability studies in accordance with the regulations required by the regulatory authorities.

How does it work?

For the formulation of a new medicine or a new cosmetic, numerous studies are necessary that imply a high degree of professional specialization and the application of a methodology that guarantees the quality of the final product, that is, its safety, its efficacy and its stability.
The methodology defined by our research team includes carrying out different studies, of greater or lesser length depending on the characteristics of the active substance and the pharmaceutical or cosmetic form to be developed. We offer the following types of studies:
1.- preformulation studies: carried out on the active substance. It includes:
- The characterization of powder solids, by determining the particle size, specific surface area, apparent density and porosity, fluidity and compactability.
- Polymorphism studies: identification and characterization of different internal structures, and the causes of transformation.
- Determination of solubility, dissolution rate and partition coefficient.
- Hygroscopicity studies.
- Determination of the causes of instability (temperature, oxygen, radiation, pH).
- Identification of critical characteristics of the active ingredient at a biopharmaceutical, stability and technological level.

2.- formulation studies:
- Experimental designs.
- Definition of the design space (QbD) from formulation and the elaboration process variables.
- Compatibility studies among the components of the formulation.
- Application of stabilization resources.
- Comparative stability studies.
- Selection of packaging materials.
- Release tests simulating physiological conditions.
- Formulation of generic medicines: with an expired patent, with a new patent-free active, with a product patent, seeking galenic innovations or therapeutic improvements...
- Dissolution tests for the evaluation of bioequivalence.
- Validation of analytical methods for the finished product.

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3.- In vitro efficacy/toxicity studies: in different cell models.
4.- Formal stability studies: long-term, accelerated and in-use studies in accordance with the ICHQ1 guidelines.

Advantages

The formulation of a new medicine or a new cosmetic requires a high investment in rooms, laboratory equipment, resources and time, which often represents a barrier to the development of new products by many pharmaceutics or cosmetic laboratories. No less important is the high professional specialization required for the development of a certain formulation, and the difficulty for a company having specialist formulators in different pharmaceutical or cosmetic forms, conventional release or modified release.

We offer the possibility of outsourcing these activities, looking to a group of experts with up-to-date knowledge and extensive experience in the development of new formulations and in solving formulation and stability problems for a wide variety of pharmaceutical and cosmetic forms.

Where has it been developed?

At the University Institute of Industrial Pharmacy, located in the Faculty of Pharmacy, we have all the necessary equipment for the characterization of active substances, for the preparation of different pharmaceutical and cosmetic forms, and for their characterization and control. We have viscometers, particle size analyzer (microtrac and Z-sizer), disintegrator, dissolutor, fracturometer, friabilometer, diffusion cells, thermostated baths, conductivity meter, agitators and homogenizers, rotary evaporator, microfluidic system, tableting machines, manual encapsulation machines , automatic coating equipment, lyophilizer, drying chambers , spray drier, mixers, spheronizer, micronizer, autoclave, filtration equipment, centrifuges, climate chambers, photostability chamber, IR drying balance, spectrophotometers, HPLC, DSC.. We also have of our own fully equipped cell culture unit.

And moreover

The following services are offered:

- Development of new drug and cosmetic formulations.
- Pharmaceutical development of generic drugs.
- Resolution of formulation problems.
- Resolution of stability problems.
- Determination of the shelf life.
- Preparation of technical reports.
- Advisory service.

Researcher in charge

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