I I D C A

Instituto de Investigación y Desarrollo de Ciencia Aplicada

REQUESTED INFORMATION FOR RESEARCH WORK.
PROTOCOL ERLMCA012

Conducting drug discovery process requires multiple elements essential documentation of the test product , from its origin , molecular integration in the case of mixtures , such physicochemical considerations , mechanisms of action, metabolic pathways, processes of absorption , distribution, integration , metabolization biotransformation processes , secondary metabolites , persistence thereof secondary and side effects elimination pathways ; determine aspects of bio-safety, consider stabilizing elements of products , which implies certain uniformity of the raw material . To which is determined from the route of administration and the process of involvement either by gastric acid chamber, mixing with different elements such as water, food, etc.

As we can see the process requires careful analysis and constant receipt of data that establish theorizing as a starting point ; now all pharmacological study must be adequately supported and validation steps are taken strictly under specific research processes rather than anecdotally or by implication whether the beneficial effects that may have.

Before any therapeutic product can be administered to humans, it should be investigated and toxicological pharmacological activity in vitro systems and animal models, these products are systematically evaluated through biochemical, physiological, behavioral and pharmacological evidence the search for the desired activity. Critical path;

Summary of Product

Pharmaceutical - research

- Animal toxicity studies pharmacology
- pharmacology in humans (Phase I)
- Initial clinical - trials (Phases II and III)
- Comparative clinical trials (Phase III)
- Clinical Trials - specific pathology (Phase IV)

1. Budget Review
    1. Basic pharmacology tests
        1. spectrophotometry
        2. physicochemical
        3. bacteriological
    2. Protocol toxicity
        1. Installation of test specimens murine model 25
        2. Installation of test specimens leporid Model 25
        3. Histopathological evaluation and determination of metabolites

4. Canine model test, 10 specimens without necropsy, with cytometric, biochemical measurements, and quantification of metabolites in secretions.
5. Personnel
    1. Pharmacist
    2. Laboratory Technician
    3. Assistant

3. Phase 2 protocol
    1. Work materials
    2. Medical equipment
    3. Stationery
    4. Miscellaneous
    5. Testing Laboratory
        1. Cytometry
        2. Biochemistry
        3. Quantification of metabolites
    6. 30 patients on four occasions during the study
        1. Salaries for three months of staff
            1. Medical
            2. Nurse
            3. Office
4. Protocol therapeutic action in animal model (specific for melanoma)
    1. Assembly of genetically modified mouse model
    2. Histopathological evaluation

2. Dr. Luis Manuel Barcenas Reséndiz (Clinical Trial Lead Candidate)
    1. Mexican, 52 years old, graduated from the UNAM (National Autonomous University of Mexico) first career Veterinarian with honors.
    2. Specialization in Clinical Pharmacology, by UNAM.
    3. Second Race - Surgeon by UAM (Universidad Autónoma Metropolitana) being creditor of the University Merit medal.
    4. Chairs Professor of Physical Chemistry, General Physiology, Pharmacology and Professional Practice for 14 years.
    5. Director of Research and Development Centre for Cancer Research IAP.
    6. Director of the Institute for Ethno botany of Mexico AC.
    7. Founding member of the Lopez Portillo AC Foundation.
    8. Founding member and current director of the Institute for Research and Development of Applied Science AC.
    9. Member of the Mexican Society of Internal Medicine.
    10. Member of the Mexican Academy for the Study of Obesity AC.
    11. Member and current president of the Mexican Society for Advanced Studies in Community Health
3. Reference product analysis

1. One proceeds to the evaluation of product physicochemical aspects , obtaining the following information
    1. Proximal chemical analysis
        1. 96 % - moisture
        2. ash - 0.0%
        3. Ethereal extract - 0.8 %
        4. nitrogen derivatives - 2.8 %
        5. Carbohydrate - 0.4 %
        6. Raw - fiber - 0.0 %
        7. (OMAACH/90)
4. Microbiological analysis
    1. Aerobic Account - 720 CFU / ml
    2. Total count of yeast -10 CFU / ml
    3. pathogens :
        1. Absent Staphylococcus aureus
        2. Absent Pseudomonas aeruginosa
        3. Absent Escherichia coli Absent
        4. Absent Salmonella
5. Physicochemical Analysis
    1. Appearance: opalescent aqueous solution
    2. pH 6.8
6. Phases of clinical trial
    1. Phase I - Following pharmacological and toxicological studies in animals, healthy volunteers first product is supplied in a single dose with gradual increases and subsequent delivery in multiple doses, to cover the range of possible therapeutic doses. These studies were performed to obtain data on safety and pharmacokinetics, since the relevant symptoms to investigate therapeutic efficacy rare time are present in healthy patients. To set data starting dose of DL correlates in toxicological studies of the most sensitive species, through specific equations, generally considered six to nine patients per dose. Double-blind placebo administration is used , usually patients are hospitalized and are undergoing intensive supervision with implementation of daily physical examination, generally signologic determining further electrocardiographic and encephalographic record functional tests were further performed to detect hepatic , renal and hematological toxicity.
    2. Phase II - These are the first administration of medication to patients, assess the removal of the test product in your case because patients can metabolize different patients healthy way. These tests are classified into early and late , the first designed to evaluate the therapeutic potential and side effects , focuses on determining therapeutic dose ranges ; late are aimed primarily at establishing the efficacy of the product in terms of test demonstrations of a specific disease and to compare their effectiveness and adverse effects compared to other drugs or similar purpose.

3. Phase III - Correspond to the double-blind, randomized controlled executed in a sufficient number of patients in order to provide information to allow statistical analysis of the efficacy and safety of the product. The procedures used to evaluate clinical toxicity are similar to the Phase I studies, however considered more reliable to consider a larger sample. Depending on whether the results are satisfactory, the registration is done , presenting additional information as evidence to show efficacy for specific diseases , biosafety aspects , all paraclinical information and specific product data as chemical name as a mixture, list all ingredients, product monograph , instructions, patent reference which as a whole is evaluated by the appropriate government office and external consultants.
4. Phase IV - These studies are performed after the product has been licensed for commercialization.

7. The import-export document which was signed which normally corresponds to the product mobilize the courier company , given the prior assessment already carried out with DHL , so to expedite transportation information mentioned obviously will not match the handling test product , but sent to the Institute for technical evaluation .
8. The following inclusion criteria were considered in the protocol healthy subjects
    1. Age range between 30 and 40 years.
    2. Indistinct - sex
    3. Favorable health status, previous clinical and paraclinical examination.
    4. The applied dose corresponded to the suggestion EPH TECH. For therapeutic use.
    5. Patients were reviewed daily through the activities of community health club and sampled at intervals of 15 days.
9. Manifestations of clinical response to the administration of the product are summarized in significant improvement in inflammation processes in auto- immune above pictures; anemia correction process; special support of metabolic hyper catabolic patients with different tumor associated processes; Answer stabilization in cases of patients referred from different backgrounds tumor lineage and significant improvement in epidemiological processes.
10. The procedures are performed through the l drugs control department of the Ministry of Health Undersecretary regulatory and health promotion) and the Federal Commission for Protection against Health Risks (COFEPPRIS).

National legal framework

The General Health Law, Chapter IV of Title Twelfth provides that veterinary drugs require, expressly reserving to the regulations specific requirements that must be met for obtaining authorization.

Thus, the Regulations for Health Supplies, Articles 165 to 192, specifies the technical requirements for obtaining veterinary medicines attached to NOM - 257- SSA- 1-2013

At the moment it has the oral presentation and a sample via topical application to aerosol and cream.