Issue of a Certificate of Accreditation for a Center of Clinical Studies or Bioequivalence

About the Service

This service enables clients to apply for the accreditation of GCC-approved centers for clinical or bioequivalence studies.

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- The application must include the documents required in accordance with Section 09 of the bioavailability/bioequivalence documentation application form
- The officer in charge will review the documents and application for initial approval
- The technical committee/higher committee shall evaluate the application for conventional drug registration
- The certificate will be issued

Required Documents

- The following documents are required, according to each stage in the service:
- Phase I (at the Center): Application form.Latest inspection report issued by competent authority (if any).Notarized Copy of the operating license issued by the competent authority in the country of origin.Copy of the Contract(s) of Leasing of the Clinical Unit and of the Rendering of Services of Laboratory Analysis (if applicable).Training schedule for employees.Curricula of the main researchers and the persons responsible for the clinical, analytical and statistical stages.List of SOP's , and 5 SOP's from the above mentioned should be provided.Organizational chart of the center and the study plan.Background of the Bio equivalence Center (Site, Master file), including total number of studies conducted and list of those submitted to other health authorities.Notarized copy of accreditation certificates.
- Clinical Phase: Notarized copy of the operating license issued by the competent authority in the country of origin (in case of outsourcing).Staff training schedule.List of the equipment and instruments used.The following SOPs: collecting samples , emergency care of subjects, hospitalization of subjects, cleaning and preparation of areas for hospitalization of subjects.
- Clinical Laboratory Analysis Stage: Notarized copy of the operating license issued by the competent authority in the country of origin (in case of outsourcing).Staff training schedule.List of the equipment and instruments used.List of technicians in the area with the technical qualifications for each professional.Models of the control file / control records used (temperature of the refrigerators, freezes, room temperature, room humidity, calibration of pipettes, reagents and standards).Bio-safety programs.
- Analysis Phase: Notarized copy of the operating license issued by the competent authority in the country of origin (in case of outsourcing).Staff training schedule.List of the equipment and instruments used.List of area technicians with technical qualifications for each professional.Models of the control file / control records used (temperature of the refrigerators, freezes, room temperature, room humidity, calibration of pipettes, reagents and standards).
- Statistics Stage: Standards Operation Procedures, contemplating of the following points:a. Data entry ((tabulation, verification of transcript data, software used).b. Data processing and statistical analysis (methods of calculating pharmacokinetic parameter methods to identify factors to define the outliers, variance analysis, confidence interval calculation and program used).Proof of contract between the bio-equivalence center and the person in charge of

statistics (in case of outsourcing).

Conditions & Requirements

1. This application should be submitted by the pharmaceutical company or the local agent which contracted with BA/BE center along with letter of authorization.
2. The service is not required for bioavailability/bioequivalence centers approved by GCC countries.

Service completion duration

- 4 months

Service fees

Service channels

Service locations

Mohab Website

Support

- smartservicessupport@mohap.gov.ae
- drugreg.inquiries@mohap.gov.ae

Payment channels

- E- Payment

Target audience

- Medical warehouses
- Local pharmaceutical manufacturers

Resources

- Infographic Issue of a Certificate of Accreditation for a Center of Clinical Studies or Bioequivalence

Department name

Drug

Sector name

Health Regulation

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service Code

110-04-022-000

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Number of Transactions

2

Notes

This service accepts documents authenticated with the UAE PASS Digital Seal.

Sustainable Goals

Good Health And Well-Being