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

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

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-022-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Service Process

01 The client shall submit the application online through MOHAP e-services.

02 The application must include the documents required in accordance with Section 09 of the bioavailability/bioequivalence documentation application form.

03 The officer in charge will review the documents and application for initial approval.

04 The technical committee/higher committee shall evaluate the application for conventional drug registration.

05 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)
  - Vital security software
- **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:
      - Data entry (tabulation, verification of transcript data, software used)
      - 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)

Requirements & Conditions

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

Service Channels

MoHAP Website: www.mohap.gov.ae

MoHAP Smart App

Resources

-

FAQs

None

Average Service Time
4 months

Payment channels
E-Payment

Target Audience
Medical warehouses, local pharmaceutical manufacturers

Service Locations
- MoHAP website www.mohap.gov.ae
- MoHAP Smart App

Related Services
This service is not linked to other services

Service Bundle
This service is not linked to any other bundle

Contact Details
Email:
smartservicessupport@mohap.gov.ae
drugreg.inquiries@mohap.gov.ae

Service Fees

Application fees:
AED 100

Approval certificate of clinical studies or bioequivalence center:
AED 2000

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes

-