




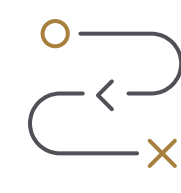


Issue of a Certificate of Accreditation for a Center of Clinical Studies or Bioequivalence

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

 <p>Department name Drug</p>	 <p>Sector Health Regulation</p>	 <p>Main Service Medical, Pharmaceutical and Drug Licencing and Registration</p>	 <p>Service Code 110-04-022-000</p>
--	--	--	---

 <p>Service Classification Transactional</p>	 <p>Variation / Auxiliary Variation</p>	 <p>Service Type Government to Business</p>
---	---	---



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, freezers, 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, freezers, 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



Notes

-