Analyze Medical Product for A Pharmaceutical Company and Its Subsidiaries

This service allows the analysis of medical products to ensure that their ingredients, active substance and preservatives are suitable for use.

Department name
Drug

Sector
Health Regulation

Main Service
Quality control of pharmaceutical products

Service Code
110-44-001-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Service Process

01 To apply for e-services, create an account on MOHAP website or smart app with a username and password.

02 Fill in the product data in the assigned fields and attach the required documents on the online system.

03 Pay the fees and submit the application.

04 Transfer the examination request to the quality control lab for technical review and determination of the analysis requirements electronically.

05 Perform the required testing for the sample and issue the results:
- If the results conform: The certificate of conformance will be issued.
- If the results do not conform: The certificate of nonconformance will be issued and re-analysis request can be submitted by the applicant.

Required Documents

- Electronic application form
- CD with all documents and information, such as eCTD
- **In the absence of eCTD of the product, the CD should contain:**
  - Certificate of final product analysis for three batches
  - Certificate of analysis of standard substances if the compound contains a therapeutic substance
  - Statement of composition certificate, listing the active and inactive ingredients, their concentrations and specifications
  - Certificate of final product specifications
  - Statement of method of analysis of final product and test validation methods (validation report for test methods)
  - Analysis certificate of active and inactive ingredients in the finished product
  - If the analysis is constitutional, a copy of the most recent version of the constitution must be attached
  - When high-performance liquid chromatography (HPLC) or gas chromatography (GC) are used in analysis, the chromatogram must be provided, and evidence of other methods, such as FTIR, TLC and UV spectrum, should also be provided.
- **Sufficient number of samples of the final product (enough to analyze the product three times) must be provided**
  - Primary reference standard as USP and EP
  - Working standard with an attached certificate of analysis of all details
  - Related substance and degradation product standard for the active and preservative ingredients
  - If a special type of HPLC column was used, this must be provided to the laboratory
- External packaging of the product and the enclosed leaflet, including all necessary data (batch number, date of manufacture and validity, storage conditions, name of commercial compound, name of manufacturer and country of origin, directions for use, capacity or volume, drug code if applicable, and any necessary warnings) must be provided
- Copy of outer packaging
- Copy of internal leaflet

Requirements & Conditions

- The technical file should consist of three main parts: analysis, stability study, and bioavailability and equivalence study (for chemical and biopharmaceuticals only), and should be submitted to the Drug Registration Department.
- The drug's uses should be clarified.
- The quantity of the sample should be sufficient, as per the requirements of the pharmaceutical form.

Service Channels

MoHAP Website: www.mohap.gov.ae

MoHAP Smart App

Quality Control Laboratory and research for medical products (for technical file and analysis requirements submission)

Resources

-

Average Service Time
A maximum of 30 working days from date of receiving samples and analysis requirements.

Payment channels
E-Payment

Target Audience
Drug warehouses, and local pharmaceutical factories

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

Service Fees

AED 3000

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes

-

FAQs

-