Analyze/ Re-Analysis of a Medical Product for A Pharmaceutical Company and Its Subsidiaries

About the Service

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

Service Process

- Login to the MoHAP website or smart app using the UAE PASS.
- Fill in the product data in the assigned fields and attach the required documents on the online system.
- Pay the fees and submit the application.
- Transfer the examination request to the quality control lab for technical review and determination of the analysis requirements electronically.
- 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 a 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.
- Standard samples and materials: A 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.

Conditions & Requirements

1. 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.
2. The drug's uses should be clarified.
3. The quantity of the sample should be sufficient, as per the requirements of the pharmaceutical form.

FAQ’s

Service completion duration

- A maximum of 30 working days from date of receiving samples and analysis requirements.

Service fees

Service channels

Service locations

- Mohap Website
- MOHAP Smart Application
- Quality control Laboratory and research for medical products (for technical file and analysis requirements submission)

Support

smartservicessupport@mohap.gov.ae

Payment channels

- E- Payment

Target audience

- Drug warehouses
- Local pharmaceutical factories

Resources

- User Manual - Registration Services
- Infographic - Analyze Medical Product for A Pharmaceutical Company and Its Subsidiaries

Department name

Drug

Sector name

Health Regulation

Main service

Quality Control Laboratory for Medical Products

Service Code

110-44-001-000

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Related Services

- This service is linking to other services as below:

Service Bundle

This service is not linked with any service packages

Number of Users

54

Number of Transactions

1518

Notes

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

Sustainable Goals

Good Health And Well-Being