Issue of quality report for medical product issued by Drug Quality Control Laboratory

About the Service

This service enables an application for a quality report on a medical product issued by a drug quality control laboratory to ensure the product's usability.

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- The assigned analyst will analyse the product and send a report to the laboratory supervisor for review
- If the result of the analysis is conforming, it will be referred to the laboratory chairman for the issuance of a certificate of conformity and for accreditation
- If the result of the analysis is "non-conforming, it will be referred to the non-conformity committee for a decision about appropriate further action, such as analysis by another analyst. The result will be submitted to the laboratory chairman for the issuance of a certificate of conformity, if it does conform or a non-conformity certificate if it does not conform, and will then be transferred for accreditation

Required Documents

- Samples, and standard and reference materials for the product to be analyzed.
- Receipt of payment of analysis fee (or electronic application number with proof of payment of service fee).
- Receipt of payment of examination certificate issuance fee (or electronic application number with proof of payment of service fee).
- CD with all documents and information, such as eCTD.
- In the absence of eCTD of the product, the CD must 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, including active and inactive ingredients, their concentrations and specifications.Certificate of final product specifications.Method of final product analysis and test validation methods (validation report for test methods).Analysis certificate for 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 attachedWhen high-performance liquid chromatography (HPLC) or gas chromatography (GC) is used for analysis, the chromatogram must be attached, and evidence should also be provided when other methods, such as FTIR, TLC and UV spectrum, are used.
- 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, such 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, it 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.

Conditions & Requirements

1. All data must be provided in Arabic and English.
2. The approval of the Director of Drug Administration for re-examination of new samples is required.

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 - www.mohap.gov.ae
- MOHAP Smart App

Support

smartservicessupport@mohap.gov.ae

Payment channels

- E- Payment

Target audience

- Drug warehouses
- Local pharmaceutical factories

Resources

- User Manual - Registration Services
- 01_Issue of Quality Report for Medical Product Issued by Drug Quality Control Laboratory

Department name

Drug

Sector name

Health Regulation

Main service

Quality Control Laboratory for Medical Products

Service Code

110-44-003-000

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Related Services

- Analyzing and re-analyzing a medical product for a pharmaceutical institution and its subsidiaries

Number of Transactions

1518

Notes

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

Sustainable Goals

Good Health And Well-Being