Issue of Quality Report for Medical Product Issued by Drug Quality Control Laboratory

This service enables the owners of medical and pharmaceutical establishments, and members of their medical and technical teams, to appeal against the decisions of the Medical Licensing Committee.

Department name
Drug

Sector
Health Regulation

Main Service
Quality control of pharmaceutical products

Service Code
110-44-003-000

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 The assigned analyst will analyse the product and send a report to the laboratory supervisor for review.

03 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.

04 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 fees (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 attached
  - When 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
- **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

Requirements & Conditions

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

Service Channels

Payment of fees:
Customer Happiness Center - Dubai

Sample delivery:
Quality Control Laboratory

Resources

- User Manual - Registration Services

Average Service Time
A maximum of 20 days from sample delivery

Payment channels
E-Payment

Target Audience
Drug warehouses, and local pharmaceutical factories

Service Locations
- MoHAP website www.mohap.gov.ae
- Service Centers

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 500

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes
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FAQs

None