Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 4 / 2025

21 -06 -1446 H
21-01 -2025

TO: ALL LOCAL PHARMACEUTICAL COMPANIES & PRIVATE DRUG STORES.

After Compliments

Sub: **Herbal Medicines Analysis at Daris Laboratory**

In reference to the above subject, we would like to inform you of an important update regarding the registration of all new herbal medicines. As part of our continuous commitment to ensure the highest standards of quality and safety in the herbal medicine industry, we have established a new requirement for the analysis of all new herbal medicine registrations.
Effective immediately, all new herbal medicines must undergo a comprehensive analysis at Daris Laboratory. This decision has been made to ensure that all products meet the necessary quality and safety standards before they are made available to the public.
To facilitate this process, please follow the steps below:

- The file submitted to the Drug Safety Center and will be evaluated by the Central Quality Control laboratory department and issuance of Form S with all analysis and stability requirements, then sending it to the regulatory department, herbal medicine registration section.
- The analysis request form is filled out by the herbal medicine analysis section at the Drug Safety Center and sent by email to the local agent, directing the local agent to analyze the product at Daris Laboratory, affiliated with the University of Nizwa.
- Local agents are required to transport the samples under suitable storage conditions.
- The local agent is responsible for delivering all analysis requirements, along with a CD containing (Composition Formula, Finished Product Specification, Certificate of Analysis, and Method of Analysis Supported with Chromatograms) directly to the Daris Laboratory by the local agent.
- In case of any additional requirements (columns, chemicals, etc.) from Daris Laboratory, they will request directly from the local agent via email with a copy to the herbal medicine analysis section at the Drug Safety Center.

Herbal Section e-mail address: samya.alharthi@moh.gov.om CQCL e-mail address: c-qcl@moh.gov.om

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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- Analysis and Evaluation Results:

1- If the analysis results meet the specifications, an email is sent to the concerned section at the Drug Safety Center, and Form S is issued accordingly.

2- If the analysis results do not meet the specifications, the university communicates with the agent via email and sends a copy to the laboratory.

- Daris Laboratory analyzes the sample three times by two analysts (1st & 2nd trials by the 1st analyst and the 3rd trial by the second analyst).
- Sample Raw Data is sent to the central laboratory (herbal medicine analysis section).

Best regards,

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة
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SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

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- DQCL
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