



Circular No. 3 / 2025

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نتقدم بثقة
Moving Forward
with Confidence



To All:

Drug Stores

Pharmaceutical Consultancy Services Companies

Local Pharmaceutical Industries

After compliments,

Sub: Analytical Requirements for Registration of Biological Products (Biosimilars)

As a part of the ongoing update to the registration process and requirements, and ensuring that the assessment and analysis of the product are completed prior to the registration process, this is to inform you that the following analytical documentation must be submitted along with the product registration dossier for biological products (biosimilars):

- Reference standards
- Columns
- Chemical reagents
- Minimum quantity of samples sufficient to conduct the analysis

We appreciate your cooperation in adhering to these requirements to ensure the smooth and timely processing of product registrations.

Yours faithfully,

Dr. Mohammed Hamdan Al Rubaie
Director General



Copy to:

- All directors in DSC
- All Section Heads in DG office.



DSC
مركز سلامة الدواء
Drug Safety Center



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