No.14-1/2022-PEC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination

Islamabad, 06th August, 2025

NOTIFICATION

Subject: - **Streamlining The Evaluation and Processing of Form 5F (Common Technical Document) Applications Under S.R.O. 713(I)/2018**

The Drug Regulatory Authority of Pakistan (DRAP) is dedicated to promote a functional, efficient, and science-driven regulatory environment. Our mandate encompasses ensuring the availability of safe, efficacious, and quality therapeutic goods, a responsibility continually upheld through adherence to national statutes and the progressive alignment with international best regulatory practices. To this end, DRAP actively seeks opportunities to streamline the evaluation and processing of Form-5F application (Common Technical Document format), thereby enhancing regulatory predictability and expediting market access by reducing approval timelines for essential medicines, without compromising the integrity of the established regulatory framework.

2. In pursuit of better regulatory efficiency and to reduce unnecessary duplication in dossier submissions, DRAP has deliberated on optimizing the review process for liquid injectable products. Accordingly, the Authority, in its 206th meeting held on June 4th, 2025, formally approved revised procedures for the submission of registration dossiers for liquid injectable products that possess the same strength per unit but are presented in varying fill volumes. Accordingly, for such products (e.g., Water for Injection (WFI), Normal Saline, or other similar formulations that may vary based on **fill volume considerations**), the Authority decided as under:

> *A **complete Form-5F (CTD dossier) shall be required for only one designated representative fill volume.** For all other varying fill volumes of the same formulation, the submission requirements shall be limited to **Module 1 of Form 5F**, provided the following conditions are fulfilled:*
>
> *i. All fill volumes must originate from the same API/Drug Substance source.*
> *ii. The container-closure system must be identical across all submitted fill volumes.*
> *iii. The product must consistently maintain the same strength per unit irrespective of the varying fill volumes.*

3. This decision is hereby circulated for the information, and compliance of all relevant stakeholders.

06/08/2025

(Hafiz M. Ali Tayyab)
Additional Director (PE&R)/
Secretary, Registration Board

Distribution:

1. Chairman, Pakistan Pharmaceutical Manufacturers Association (PPMA), Islamabad.
2. Executive Director, Pharma Bureau, Karachi.
3. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
4. Director, MIS Division, DRAP (with request to upload this Circular on the official DRAP website).

Copy for Information:

1. Chief Executive Officer, DRAP, Islamabad (Attn: PS to CEO).
2. Director, Pharmaceutical Evaluation & Registration (PE&R), DRAP, Islamabad.
3. Director, Biological Evaluation & Registration (BE&R), DRAP, Islamabad.
4. Office File.