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

Islamabad, 20th November, 2025

CIRCULAR

The Drugs Regulatory Authority of Pakistan (DRAP) is striving to enhance the operational efficiency and integrity of regulatory compliance mechanisms within the pharmaceutical sector. Pursuant to Rule 26 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, as amended vide S.R.O. 713(I)/2018 dated 8th June, 2018, all human drug registration applications mandate the submission of comprehensive stability data and supporting product development evidence.

2. Furthermore, to ensure the scientific validity and reliability of the data submitted, the Registration Board has already laid down minimum batch size criteria, as outlined in the CTD Guidance Document (Doc No. PER-GL-AF-004). These criteria establish the minimum quantities of controlled substances required for R&D purposes and are summarized below:

Batch Requirement	Dosage Form	Minimum Batch Size
For 2 Batches	Oral Solid Dosage Form	5,000 Units
	Oral Liquid/Suspension	2,000 Bottles
	Injectable	2,000 Units
	Aerosol and Specialized Preparations	500 Units
For 3 Batches	All Forms	Scientifically rational batch size, sufficient for complete testing until the claimed shelf life.

3. Currently, DML holders are required to route quota allocation applications for controlled drug substances through the Pharmaceutical Evaluation & Registration (PE&R) Division, leading to final allocation by the Controlled Drugs Division (CDD). To Optimize the Regulatory function and streamline the regulatory process, effective immediately, all applications for quota allocation of controlled drug substances for R&D and stability purposes will be submitted directly to the Controlled Drugs Division. The Controlled Drug Division shall evaluate the requested quantities against the guidelines specified in aforementioned guideline and allocate the quota, accordingly.

4. This decision is also hereby circulated for information and compliance for all relevant stakeholders.

20/11/2025

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

Distribution: -

1. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
2. Executive Director, Pharma Bureau, Karachi.
3. Director, MIS Division, with the request to upload on DRAP website.
4. Director Controlled Drugs, DRAP, Islamabad.

Copy for information to: -

1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
2. PS to Chief Executive Officer, DRAP Islamabad.
3. Office File.

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