



F.No. 1-2/2022-DMC
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
TF Complex Sector G-9/4

Islamabad the 13th June, 2023

NOTIFICATION

Subject: - Data requirements of Form 5-F for pharmaceutical drug products having multiple strengths / fill volumes.

I am directed to refer to the subject captioned above. On the recommendations of Registration Board in its 324th meeting held on 24-26 January, 2023, the DRAP Authority in its 161st meeting held on 5th and 6th April 2022 decided to endorse as specified below along with respective conditions

"For such drug products, having multiple strengths or fill volumes complete Form 5F may be submitted for only one of the strength/fill volume or one of the strengths while for remaining strengths/fill volumes the 3.2.S part of CTD will be optional and applicant may refer to its complete dossier for this data.

Conditions:

- i. *An undertaking by the applicant that all strengths/fill volumes shall be manufactured by same source of drug substance.*
 - ii. *If different Lot/Batch no. of same source of drug substance has been used in manufacturing of various strengths/fill volumes of applied product, then Certificate of Analysis of such lots / batch nos. of drug substance (by drug substance and drug product manufacturers) will be submitted by the applicant."*
2. Accordingly, above decision of the Registration Board and Authority is hereby circulated for information and compliance by all relevant stake holders / applicants.


(ASIF JALIL)
Deputy Director (PE&R) /
Incharge PEC

Distribution:

- i. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
- ii. Executive Director, Pharma Bureau, Karachi.
- iii. Executive Director, Pakistan Chemist & Druggist Association, Karachi.

Through E-Office:

- i. PS to CEO, DRAP, Islamabad
- ii. Director (PE&R)/ Chairman, Registration Board.
- iii. Director (MIS), DRAP for uploading on DRAP's website.
- iv. Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction.


13/06/2023
Deputy Director (PE&R) /
Incharge PEC