



No. 14-1/2022-PEC
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
TF Complex Sector G-9/4

Islamabad, 16th January, 2023

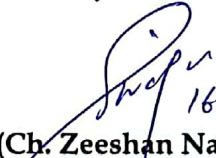
NOTIFICATION

Subject: - **Submission of image/picture/snapshot of the innovator/reference/comparator pack against which Pharmaceutical equivalence / Comparative Dissolution Profile studies are performed.**

I am directed to refer to the subject captioned above. Registration Board in its 296th meeting approved a Guidance document for submission of application on form 5-F (CTD) for registration of pharmaceutical drug products for human use (available online: <https://www.dra.gov.pk/wp-content/uploads/2022/01/Guidance-Documents-on-CTD-Doc-No.-PER-GL-AF-004.pdf>). Submission of data of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) is required under section 3.2.P.2.2.1 (Formulation Development). In order to further harmonize the submission of such data and ensure data integrity, Registration Board in its 322nd meeting held on 8th & 10th November, 2022 decided as under:

Firm shall submit the image/picture/snapshot of the innovator/reference/comparator pack against which Pharmaceutical equivalence / Comparative Dissolution Profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator/reference/comparator product in the section 3.2.P.2.2.1 (Formulation development) of Form 5F.

2. Accordingly, above decision of Registration Board is hereby circulated for information and compliance by relevant stakeholders / applicants.


16/1/2023
(Ch. Zeeshan Nazir Bajar)
Additional Director (PE&R)/ Secretary,
Registration Board

Distribution:

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

Through E-Office:

- i. Director (PE&R)/Chairman, Registration Board.
- ii. 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.

Additional Director (PE&R)/
Secretary, Registration Board