F. No. 2-4/2024-DD (RRR)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
(Division of Pharmaceutical Evaluation & Registration)
Prime Minister's Health Complex, Chak Shahzad
****

Islamabad the 08th July, 2024

CIRCULAR

SUBJECT: **REGISTRATION BOARD DECISION REGARDING BIO-AVAILABILITY/BIOEQUIVALENCE (BA/BE) STUDIES**

The Drug Regulatory Authority of Pakistan (DRAP) is committed to ensure that all pharmaceutical drug products shall conform to acceptable standards of safety, efficacy and quality. The requirement of demonstration of bioequivalence has become the basis for approval of generic drugs globally. The submission of bioequivalence studies is requirement of Form-5F (Common Technical Document) notified vide SRO 713(I)/2018 dated 08.06.2018.

2. Moreover, DRAP is in process of benchmarking by WHO for achievement of status of WHO Listed Authority (WLA) and the demonstration of bioequivalence/bioavailability (BE/BA), when deemed necessary for approval of generic drug products, is a pre-requisite before grant of registration under Maturity Level-1 indicators of registrations & market authorization.

3. Keeping in view of above stated position and facts, Registration Board in its 338th meeting held on 04.07.2024 decided as under:

> *In the light of S.R.O 713(I)/2018 and requirement for WHO Listed Authorities i.e., in particular the Maturity Level-1(ML-1) "the procedures of regulatory approval related to registration of generic drugs, shall be made in line with the guidelines of international regulatory agencies, for which implementation of Bio-equivalence study should be initiated" The Board decided the systematic implementation of Bio-equivalence study in accordance with the WHO and International guidelines.*

8.7.24

(Muneeb Ahmed Cheema)
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Through e-office:

1. Director (MIS), DRAP Islamabad, with the request to upload circular on DRAP website