No-F-348-DRB-Addl-Dir (PER-I)/2025
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination

Islamabad, 17th July, 2025

NOTIFICATION

Subject: - **REQUIREMENT OF BIOEQUIVALENCE STUDIES AS PART OF REGISTRATION APPLICATION**

The Drug Regulatory Authority of Pakistan (DRAP) is statutorily mandated to ensure the access of the safe, efficacious and quality therapeutic goods. The aforementioned function is further augmented under Section 7(ix) of the DRAP Act, 2012, which outlines the Authority's functions to implement the international recognized standards including bioequivalence studies. In alignment with this legal framework and a continuous pursuit of best practices, DRAP adopts international standards in coordination with relevant stakeholders for effective implementation and compliance including World Health Organization's (WHO) Global Benchmarking of Pakistan's National Regulatory System (NRS) and provisions of S.R.O. 713(I)/2018 dated 8th June, 2018.

2. To implement bioequivalence studies as part of registration applications, DRAP convened six (06) comprehensive consultation meetings with stakeholders (PPMA, Pharma Bureau, BA/BE centers). Based on these extensive consultations and the resulting stakeholder consensus, the Registration Board, in its 348th meeting held on 1st & 2nd July 2025, deliberated upon the phased implementation of bioequivalence requirements. The Board affirmed that this implementation constitutes a significant advancement in enhancing the safety and efficacy of pharmaceutical products, aligning with its previous decision from the 338th Meeting held on 4th July, 2024.

3. **Phase-I** will commence from the date of issuance of this notification and will mandate the submission of Bioequivalence studies for the drug substances provided in **Annexure-I**. Registration Board will periodically review the list in subsequent phases, as and when required, based on the experience gained, evolving regulatory landscape and in adherence to ICH/WHO guidelines.

4. Accordingly, above decision of the Registration Board is hereby circulated for compliance by all relevant stakeholders.

17/07/2025

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

Distribution: -

i. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
iv. Director, MIS Division, with the request to upload on DRAP website.

Copy for information to: -

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

Annexure-I

Sr. No	Drug Substance	Pharmacological class	BCS Class	Therapeutic Window
1.	Abiraterone acetate	Anti-androgen (Prostate cancer)	IV	Large
2.	Acyclovir	Anti-viral	IV	Large
3.	Avacopan	Immunosuppressant	IV	Large
4.	Avapritinib	Anticancer	IV	Large
5.	Azathioprine	Immunosuppressant	IV	Large
6.	Clonidine	Cardio Vascular Drugs (Hypotensive agent)	I	Narrow ϕ
7.	Cyclosporin	Immunosuppressant	II	Narrow *, ǂ, ϕ
8.	Digoxin	Cardiac glycoside	IV	Narrow *, ǂ, ϕ
9.	Ethinyl Estradiol	Oral contraceptive	I	Narrow ϕ
10.	Everolimus	Immunosuppressant / anticancer	III	Narrow *, ł
11.	Haloperidol	Antipsychotic	IV	Large
12.	Isoprenaline	Cardio vascular drugs (Adrenergic drug)	III	Narrow ϕ
13.	Lapatinib	Anticancer	IV	Large
14.	Lithium Carbonate	Antipsychotic / anti manic	I	Narrow *, ǂ, ϕ
15.	Mercaptopurine	Immunosuppressant	IV	Large
16.	Methotrexate	Anticancer	IV	Narrow ϕ
17.	Mifepristone	Antiprogestogen for abortion	IV	Large
18.	Phenytoin Sodium	Anti-epileptic	II	Narrow *, ǂ, ϕ
19.	Ponesimod	Immunosuppressant	IV	Large
20.	Procainamide	Cardio vascular drugs (Antiarrhythmic)	III	Narrow ϕ
21.	Quinidine	Cardio vascular drugs (Antiarrhythmic)	I	Narrow ϕ
22.	Relugolix	Gonadotropin-releasing hormone receptor antagonists.	IV	Large
23.	Levothyroxine	Hormone	III	Narrow *, ǂ
24.	All Anti-TB drugs (both single ingredient as well as in combination requiring BE studies as per BCS criteria)			
25.	All Anti-HIV / AIDS Drugs (both single ingredient as well as in combination requiring BE studies as per BCS criteria)			

* USFDA, ł EMA, ǂ Health Canada, ϕ Japan