No. F-347-DRB-Addl-Dir (PER-I)/2025
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
Prime Minister's National Health Complex, Park Road, Islamabad.
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Islamabad, 14th October, 2025

Subject: **MANDATORY SOURCING REQUIREMENTS FOR ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)/DRUG SUBSTANCES (DS) IMPORTED FOR PRODUCT DEVELOPMENT, STABILITY STUDIES AND COMMERCIAL MANUFACTURING.**

I am directed to refer to the Registration Board's (DRB) decisions in its 264th meeting held on 28-29th December, 2016, as communicated vide Letter No. F. No. 1-10/2016-Add: Dir (R.J)/M-264 dated 30th March, 2017 regarding sourcing of API/DS. The Drug Regulatory Authority of Pakistan (DRAP) is facilitating the local pharmaceutical industry by exercising regulatory flexibility and promoting product development to foster indigenous production and ensure continuous access to quality medicines.

2. Registration Board in its 286th meeting (14-16th November 2018) and 293rd meeting (6-8th January 2020) consolidated its guidelines as mentioned in aforementioned letter. The Board emphasized on the importance of adherence to guidelines for regulating the source and quality of APIs/drug substances utilized during product development, stability studies and subsequent commercial manufacturing, recognizing that the integrity of these materials is paramount to ensuring the quality and safety of the final product.

3. To ensure compliance with national laws and international best regulatory practices, all pharmaceutical firms are hereby directed to adhere to the following mandatory requirements for the import of APIs/drug substances for the aforementioned purposes:

i. Only APIs/drug substances of pharmacopoeial grade and in case of non-availability in pharmacopoeia, the APIs/drugs substance shall be of pharmaceutical grade only.
ii. One of the following documents (either submitted as hard copy or verifiable from online database of the relevant regulatory authority), for granting permission to import of API/Drug substance:
    a. Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin.
    b. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
    c. Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP) issued by EDQM (European Directorate for the Quality of Medicine & Healthcare).
    d. GMP certificates issued by any of the Reference Regulatory Authorities adopted by Registration Board in its 275th meeting.
iii. All such consignments must obtain official endorsement and clearance from the relevant DRAP field office as an evidence for sourcing of API for application dossiers.

4. This directive is issued for compliance by all stakeholders.

14/10/2025

(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. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
4. Director, MIS Division, with the request to upload on the DRAP's website.

Copy for Information to:
1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
2. Director, Biological Evaluation & Research, DRAP, Islamabad.
3. Director, Quality Assurance and Lab Testing, DRAP, Islamabad
4. PS to Chief Executive Officer, DRAP Islamabad.
5. Office File.