



Government of Pakistan  
Ministry of National Health Services, Regulation and Coordination  
Drug Regulatory Authority of Pakistan  
(Pharmaceutical Evaluation & Registration Division)

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"SAY NO TO CORRUPTION"

No.F.3-5/2020-I&VII (M-297)

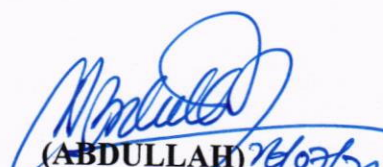
Islamabad, the 26<sup>th</sup> July, 2021

**CIRCULAR**

Subject: **COMPLIANCE WITH PHARMACOPEIAL SPECIFICATION.**

In continuation of this Authority's circular of even number dated 27<sup>th</sup> January, 2021 on the subject captioned above. The subject matter was again discussed in 307<sup>th</sup> & 309<sup>th</sup> meetings of Registration Board; wherein, the Registration Board extended timelines and made minor amendment in its previous decision as follows: -

- i. All registration holders shall follow official Pharmacopeial specifications for all such formulations for which official monographs of drug product is available in the most recent edition of such pharmacopeia.
  - ii. The manufacturers/importers having stringent/equivalent product specifications for all parameters than official Pharmacopeial specifications, shall apply to Registration Board for its approval.
  - iii. The Board allowed timeline of further six months (w.e.f. 27<sup>th</sup> July, 2021) to the manufacturer/importer for implementation of above decision.
2. Accordingly, above decision of Registration Board is hereby circulated for compliance by all manufacturers/importers for all registered drug products.

  
(ABDULLAH) 26/07/21  
Additional Director (PE&R)/  
Secretary, Registration Board

**Distribution:-**

- i. Secretary, Provincial Quality Control Boards of the Punjab, Sindh, Khyber Pakhtunkhwa, Balochistan and Islamabad Capital Territory.
- ii. All Pharmaceutical Manufacturers/Importers.
- iii. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
- iv. Executive Director, Pharma Bureau, Karachi.
- v. Executive Director/Chairman, Pakistan Chemist & Druggists Association, Karachi.
- ✓vi. Director (MIS), DRAP with the request to upload the same on DRAP's website.

**Copy for information to:-**

- a. PS to Chief Executive Officer, DRAP, Islamabad.
- b. APS to Director (PE&R)/Chairman, Registration Board.