



Dy. No. 1050/2025(DD-QA<)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Division of Quality Assurance & Laboratory Testing
Prime Minister's National Health Complex, Islamabad

Islamabad, the 13th February, 2025

The Chairman,
Pakistan Pharmaceutical Manufacturer's Association,
Islamabad.

SUBJECT: REQUEST FOR REVISION OF SHELF LIFE CRITERIA FOR IMPORTING INNOVATOR PRODUCT'S SAMPLE

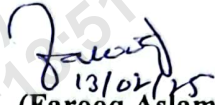
Reference is made to your application vide No. PPMA/CEO(DRAP)/2024/573 dated: 24-12-2024 regarding the applicability of criterion of 75% remaining shelf life on innovator's/reference drug product imported for comparative dissolution and product development studies on the subject cited above.

2. Registration Board in its 286th meeting held on 14-16th November, 2018 advised QA< Division to allow the import of finished product (innovator's/reference) for performing comparative dissolution profile for submission of data with registration application. Since the implementation of the decision, the innovator's/reference packs having remaining shelf life at least 75% are being imported by licensed pharmaceutical manufacturers under the Drugs (Import and Export) Rules, 1976.

3. However, Rule 12 of the Drugs (Import and Export) Rules, 1976 describes the conditions for import of small quantities of drugs (import of which is otherwise prohibited under the Act) for the purposes of clinical trial, examination, test or analysis and it does not include any shelf life requirement for the import. Similarly, Part-II of Appendix-B of Import Policy Order does not describe any condition related to shelf life requirement for small quantities of unregistered innovator's/reference finished product imported for comparative dissolution and product development studies for registration purpose.

4. In view of above, the condition of remaining shelf life of 75% is not applicable to the innovator's / reference finished product imported in small quantities for comparative dissolution and product development studies under the Drugs (Import and Export) Rules, 1976.

5. This issues with the approval of Chief Executive Officer, DRAP Islamabad.


13/02/25
(Farooq Aslam)
Deputy Director (QA<-VII)

Copy to:

- i. Additional Director / Officer Incharge Islamabad, Lahore, Karachi, Peshawar and Quetta
- ii. PS to CEO, DRAP Islamabad

Deputy Director (QA<-VII)