No. 9-2/2022-PEC
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
TF Complex Sector G-9/4
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Islamabad, 18th December, 2023

Subject: - **Guidance Document Regarding Application of Drug Product Specifications.**

I am directed to refer to the subject captioned above. Drug Regulatory Authority of Pakistan in its 176th meeting held on 06.12.2023 deliberated the matter of drug product specifications under Section 7(c)(iv) of the DRAP Act, 2012, keeping in view the recommendations of the Registration Board, decided to issue following directions/ guidelines to the pharmaceutical industry regarding finished product specifications in line with the DRAP Act 2012 and The Drug (Specification) Rules 1978.

A. If the monograph of drug product has become published in Pharmacopoeias as specified in Drug Specification Rules, 1978, the firm shall adopt specifications from any of those pharmacopoeias as per the procedure mentioned in the relevant pharmacopia within one year and shall apply to the Registration Board DRAP for its approval. Till the approval from the Registration Board:-

   i. The previously approved specifications by the Registration Board will be valid,

   ii. if no specification is mentioned on the registration letter and product is available in pharmacopoeia, specification given at S.No. 2, Column 1 of rule No. 2 of the Drugs (Specifications) Rules, 1986 will apply in the same order of preference

   iii. Cases where neither specification is mentioned on the label nor the product is available in the pharmacopoeia, specifications of the innovator /manufacturer products specifications as approved by regulatory authority of reference country will be valid.

B. The pharmacopeial specifications are accordingly acceptable, subject to approval from Registration Board, for their relevant products, which are approved by pharmacopeias of reference regulatory authorities of countries approved by Registration Board including USA, Canada, Australia, Japan, United Kingdom, Germany, France, Switzerland, Netherlands, Austria,

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Denmark, Sweden, Belgium, Iceland, Finland, Ireland, Norway, Spain and Italy along with regulatory agencies of EMA and WHO, OR

C. In case a drug product is not yet available in pharmacopeias as specified in the Drug Specification Rules, 1978

i. the firm can apply for the innovator/manufacturer products specifications as approved by regulatory authority of reference country. These specifications, however, shall be valid only till inclusion of the product in any of the official pharmacopoeia as specified in Drug Specification Rules, 1978. On the publication in the recent Pharmacopia, the firm shall adopt specifications from that pharmacopoeia as per the procedure in that pharmacopia and shall apply, within one year, to the Registration Board DRAP, for its approval. Till the approval from the Registration Board, the previously approved specifications will be valid. OR

ii. A generic applicant if prefer to manufacture with its own (manufacturer's) specifications, the applicant shall submit following data for review and approval by Registration Board as manufacturer's specifications:

a. Analytical method development and validation report including performance of accuracy, precision, specificity, linearity, ruggedness and robustness parameters as per ICH Q2 (R2) guideline for assay, dissolution and impurities (as applicable), against innovator's product.

b. The proposed analytical method shall be based upon similar principles (e.g., chromatographic, spectroscopic, titration) as declared by the innovator drug product literature.

c. Comparison between proposed drug product specifications and available innovator's/Reference drug product specifications wherein it could be established that proposed specifications are either equivalent or stringent than the innovator's/Reference specifications.

d. Comparative pharmaceutical equivalence against innovator's/Reference product including comparative dissolution profiling (if applicable).

e. Stability study data of the product for accelerated and real time period (using stability indicating method) as per the guidelines approved by Registration Board.

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2. Accordingly, above decision of Drug Regulatory authority of Pakistan is hereby circulated for information and compliance by relevant stakeholders / manufacturers.

18/12/2023.

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Deputy Director, PE&R Division

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