Inclusion of Dissolution Test in Prolonged-release Formulations in the IP and Adoption of Flexible Monograph Approach

IPC had discussion with the stakeholders on the proposal to include dissolution test in prolonged-release formulations in the IP. Dissolution profiles of prolonged-release formulations vary from manufacturer to manufacturer and may significantly affect the pharmacokinetic efficacy and safety of the product. It has been agreed that IPC would start including the dissolution tests in prolonged release monographs which are under development. Simultaneously, revision of official monographs will also be taken up by IPC for inclusion of dissolution specifications based on three point criteria:

- Dissolution profile of the first product approved by the CDSCO,
- Dissolution profile recommended by OGD/USP,
- Dissolution profile proposed by the stakeholders (to be accompanied with clinical data/ IVIVC data of their equivalence with first product approved by the CDSCO.)

In order to address the issue of different dissolution profiles of different brands currently being marketed in India, flexible monograph approach will be adopted in the IP with multiple dissolution specifications in one monograph to assess the quality of all approved products. Accordingly, labelling requirements of such products would specify the dissolution method number on the label of the product for effective implementation of the flexible monographs.

If there will a proposal from stakeholders to include a different dissolution profile in the IP monograph, bioequivalence data with International reference product or first product approved by the CDSCO will be required before including alternative dissolution specifications in the IP. Monographs on the widely used drugs, such as Metformin, Sodium valproate, Domeperidone and Rabeprazole, to be prioritized for setting dissolution specifications in the IP.

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