DRAFT REVISION FOR COMMENTS

Published on: 03 June 2024 **Last date for comments:** 18 July, 2024

This draft revision contains revised monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to further revisions prior to publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed revised monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	**Details**
Document version	1.0
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Monograph revisions proposed for inclusion in	--
Tentative effective date of monograph revisions	--
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Further follow-up action as required.	

Metformin Hydrochloride Prolonged-release Tablets. Page 2877

Dissolution (2.5.2).
Change **to**:
Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 1000 ml of *phosphate buffer pH 6.8*,
Speed and time. 100 rpm and 1 hour, 3 hours and 10 hours.
Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtrate, suitably diluted with the dissolution medium, if necessary, at the maximum at about 233 nm (2.4.7). Calculate the content of $C_4H_{11}N_5$. HCl in the medium from the absorbance obtained from a solution of known concentration of *metformin hydrochloride IPRS* in the dissolution medium.

Calculate the content of $C_4H_{11}N_5$. HCl in the medium.

The percentages of the labelled amount of metformin hydrochloride, $C_4H_{11}N_5$. HCl dissolved at the times specified conform to 2.5.2 Dissolution test, Acceptance Table 2.

At 1 hours, not less than 20 per cent and not more than 40 per cent; at 3 hours, not less than 45 per cent and not more than 65 per cent and at 10 hours, not less than 85 per cent.