Methenamine Hippurate Tablets

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. 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

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Further follow-up action as required.	

Methenamine Hippurate Tablets

Methenamine Hippurate Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of methenamine hippurate, $C_6H_{12}N_4,C_9H_9NO_3$.

Usual strength. 1 g.

Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *methenamine hippurate IPRS* or with the reference spectrum of methenamine hippurate.

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 900 ml of *water*,
Speed and time. 100 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter. Dilute the filtrate with the medium, if necessary. Measure the absorbance of the resulting solution at the maximum at about 227 nm (2.4.7). Calculate the content of methenamine hippurate, $C_6H_{12}N_4,C_9H_9NO_3$ in the medium from the absorbance obtained from a solution of known concentration of *methenamine hippurate IPRS* in the dissolution medium.

Q. Not less than 80 per cent of the stated amount of $C_6H_{12}N_4,C_9H_9NO_3$.

Uniformity of dosage units (2.5.4). Complies with the test stated under Uniformity of dosage units.

Other tests. Complies with the tests stated under Tablets.

Assay. Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.7 g of Methenamine Hippurate in 50 ml of *ethanol (95 per cent)*. Titrate with *0.1 M sodium hydroxide*, using *thymolphthalein solution* as indicator. Carry out a blank titration.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.03194 g of $C_6H_{12}N_4,C_9H_9NO_3$.

Storage. Store protected from moisture, at a temperature not exceeding 30°.