Methenamine Hippurate

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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

Description	**Details**
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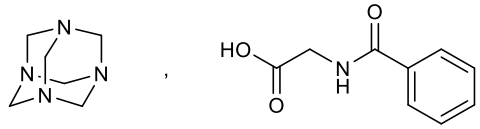
Further follow-up action as required.	

Methenamine Hippurate



$C_6H_{12}N_4,C_9H_9NO_3$ Mol. Wt. 319.4

Methenamine Hippurate is Glycine, *N*-benzoyl, compound with 1,3,5,7-tetraazatricyclo[3.3.1.1^{3,7}]decane.

Methenamine Hippurate contains not less than 95.5 per cent and not more than 102.0 per cent of $C_6H_{12}N_4,C_9H_9NO_3$ and not less than 54.0 per cent and not more than 58.0 per cent of $C_9H_9NO_3$, calculated on the dried basis.

Category. Antibacterial

Description. A white crystalline powder.

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

Content of Hippuric Acid. Dissolve 1.0 g of the substance under examination in 50 ml of *water* and titrate with *0.1 M sodium hydroxide* using *phenolphthalein solution* as indicator. Carry out a blank titration.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.01792 g of $C_9H_9NO_3$.

Sulphate. Dissolve 0.2 g of the substance under examination in 10 ml of *water*, add 5 drops of *3 M hydrochloric acid* and 5 drops of *barium chloride solution*. No turbidity appears within 1 minute.

Sulphated Ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 1.0 per cent, determined on 1.0 g by drying at 60° under vacuum for 1 hour.

Assay. Dissolve 0.7 g of the substance under examination, in 50 ml of *glacial acetic acid*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M perchloric acid* 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°.

Solubility. Soluble in *water*; freely soluble in *ethanol*.