

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Sodium Bicarbonate Tablets

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This draft proposal contains 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 revisions before 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 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
Monograph proposed for inclusion	IP Addendum 2024
Tentative effective date of monograph	July, 2024
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Draft revision published on IPC website for public comments	-
Further follow-up action as required.	

Sodium Bicarbonate Tablets

Sodium Hydrogen Carbonate Tablets

Sodium Bicarbonate Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of sodium bicarbonate, NaHCO_3 .

Usual strengths. 500 mg; 650 mg; 1 g.

Identification

A. To 5 ml of a 5.0 per cent w/v solution in *carbon dioxide-free water* (Solution A), add 0.1 ml of *phenolphthalein solution*; a pale pink colour is produced. On heating, a gas is evolved and the solution becomes red.

B. Solution A gives the reactions of sodium salts (2.3.1).

Tests

Disintegration (2.5.1). Not more than 30 minutes using *gastric juice, artificial* in place of *water*.

Other tests. Comply with the tests stated under Tablets.

Assay. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 2 g of Sodium Bicarbonate in 100 ml of *water* and titrate with *1M hydrochloric acid*, using *methyl red solution* as indicator add the acid slowly, with constant stirring, until the solution becomes faintly pink. Heat to boil the solution and cool, continue the titration until the pink color no longer fades after boiling.

1 ml of *1 M hydrochloric acid* is equivalent to 0.08401 g of NaHCO_3 .

Storage. Store protected from moisture.