Sodium Phosphate

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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. 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

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Further follow-up action as required.	

Sodium Phosphate. Page 3623

Change **to**: **Sodium Phosphate**

Disodium Hydrogen Phosphate; Dibasic Sodium Phosphate

Na_2HPO_4	Mol. Wt. 142.0 (anhydrous)
Na_2HPO_4,H_2O	Mol. Wt. 159.9 (monohydrate)
$Na_2HPO_4,2H_2O$	Mol. Wt. 178.0 (dihydrate)
$Na_2HPO_4,7H_2O$	Mol. Wt. 268.1 (heptahydrate)
$Na_2HPO_4,12H_2O$	Mol. Wt. 358.1 (dodecahydrate)

Sodium Phosphate is dried or contains one, two, seven or twelve molecules of water of hydration.

Sodium Phosphate contains not less than 98.0 per cent and not more than 100.5 per cent of Na_2HPO_4, calculated on the dried basis.

Category. Cathartic; Pharmaceutical aid (buffering agent).

Description. A white hygroscopic powder (anhydrous); Colourless or white; granular or caked salts, efflorescent in warm and dry air for hydrate forms.

Identification

Dissolve a portion equivalent to 1 part of Na_2HPO_4 in 30 parts of *distilled water*, gives the reactions of sodium salts and of phosphates (2.3.1).

Tests

Insoluble substances. Dissolve a portion equivalent to 5.0 g of Na_2HPO_4 in 100.0 ml of hot *water,* filter through a tarred crucible, and wash the insoluble residue with hot water and dry at 105° for 2 hours. The weight of the residue is not more than 0.4 per cent.

Arsenic (2.3.10). Dissolve a portion equivalent to 0.625 g of Na_2HPO_4 in 35 ml of *water.* The solution complies with limit test for arsenic (16 ppm).

Chlorides (2.3.12). A portion equivalent to 0.42 g of Na_2HPO_4 complies with the limit test for chlorides (0.06 per cent).

Heavy metals (2.3.13). Dissolve a portion equivalent to 2.0 g of Na_2HPO_4 in 10 ml of *water*, adding 4 ml of *1 M acetic acid* and dilute to 25 ml with *water.* The solution complies with the limit test for heavy metals, Method A (l0 ppm).

Sulphates (2.3.17). A portion equivalent to 0.075 g of Na_2HPO_4 complies with the limit test for sulphates (0.2 per cent).

Loss on drying (2.4.19). Not more than 5.0 per cent (anhydrous), 10.3 to 12.0 per cent (monohydrate), 18.5 to 21.5 per cent (dihydrate), 43.0 to 50.0 per cent (heptahydrate) and 55.0 to 64.0 per cent (dodecahydrate), determined on 1.0 g by drying in an oven at 130º to constant weight.

Assay. Transfer a quantity equivalent to 2.5 g of Na_2HPO_4, to a 250-ml beaker, add 50 ml of *water* and 40.0 ml of *1 M hydrochloric acid*, stir to dissolve. Titrate potentiometrically with *1M sodium hydroxide* to the first inflection point at about pH 4 and record the burette reading (x). Continue the titration with *1 M sodium hydroxide* until the second inflection point at about pH 8.8 is reached, record the burette reading (y). Carry out a blank titration, record the burette reading (z).

Calculate the volume of *1 M sodium hydroxide* consumed at first inflection, A= (z) – (x)
Calculate the volume of *1 M sodium hydroxide* consumed between the two inflections, B= (y) – (x)

Where A is equal to or less than B, 1 ml of the volume (A) of *1 M sodium hydroxide* is equivalent to 0.142 g of Na_2HPO_4, and where A is more than B, 1 ml of the volume (2B-A) of *1 M sodium hydroxide* is equivalent to 0.142 g of Na_2HPO_4.

Storage. Store protected from moisture.

Labelling. The label states whether it is anhydrous, monohydrate, dihydrate, heptahydrate or dodecahydrate.

2.4.26. Solubility

Sodium Phosphate. Page 293
Change **to**: **Sodium Phosphate**. Freely soluble in *water* and practically insoluble in *ethanol (95 per cent)* (anhydrous form); Freely soluble in *water* and very slightly soluble in *ethanol (95 per cent)* (hydrate forms).