

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Dibasic Calcium Phosphate Dihydrate

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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	2.0
Category	New Inclusion (PDG Harmonized)
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	July, 2026
First draft published on IPC website for public comments	18.01.2024
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Further follow-up action as required.	

Change to: **Dibasic Calcium Phosphate Dihydrate**

This monograph has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia. Portions of the IP text that are not part of the PDG harmonized text, are marked with symbols (◆◆).

CaHPO₄·2H₂O

Mol. Wt. 172.1

Dibasic Calcium Phosphate Dihydrate contains not less than 98.0 per cent and not more than 105.0 per cent of CaHPO₄·2H₂O.

◆**Category.** Pharmaceutical aid.

Description. A white, crystalline powder.◆

Identification

- A. Dissolve 0.1 g by warming in 10 ml of 2 M hydrochloric acid, add drop wise 2.5 ml of dilute ammonia solution with shaking, and then add 5 ml of ammonium oxalate solution; a white precipitate is formed.
- B. Dissolve 0.1 g in 5 ml of dilute nitric acid, heat the solution to 70°, and add 2 ml of freshly prepared 10 per cent w/v solution of ammonium molybdate; a yellow precipitate is formed.

Tests

Acid-insoluble substances. Dissolve 5.0 g in a mixture of 40 ml of water and 10 ml of hydrochloric acid by boiling gently for 5 minutes. After cooling, filter the insoluble substance on ashless filter paper, wash with water until the last washing is free from chloride (No turbidity results from the addition of 0.1 M silver nitrate). Ignite to completely incinerate the residue and the ashless filter paper at 600 ± 50° (0.2 per cent).

Arsenic (2.3.10). Dissolve 3.3 g in 15 ml of brominated hydrochloric acid, add 45 ml of water and remove the excess of bromine with a few drops of stannous chloride solution AsT. The resulting solution complies with the limit test for arsenic (3 ppm).

Barium. Heat to boiling 0.5 g in 10 ml of water, and add 1 ml of hydrochloric acid drop wise and stirring after each addition. Cool, filter, if necessary, add 2 ml 1 per cent w/v solution of potassium sulphate to the filtrate; no turbidity is produced within 10 minutes.

Carbonate. Suspend 1.0 g in 5 ml of carbon dioxide-free water and immediately add 2 ml of hydrochloric acid; no effervescence is produced.

Chlorides (2.3.12). Not more than 0.25 per cent.

Test solution. Dissolve 0.2 g in a mixture of 20 ml of water and add 13 ml of dilute nitric acid by warming, if necessary, dilute to 100 ml with water, filter. Use 50 ml of the solution.

Reference solution. To 0.7 ml of 0.01 M hydrochloric acid, add 6 ml of dilute nitric acid and dilute to 50 ml with water. Add 1 ml of 0.1 M silver nitrate to, each of, the test solution and the reference solution and mix. After standing for 5 minutes, protected from light, any opalescence in the test solution by viewing vertically or horizontally against a black background is not more intense than in the reference solution.

Fluorides. Not more than 50 ppm.

NOTE – Prepare and store all solutions in plastic container.

Buffer solution. Dissolve 29.4 g of sodium citrate dihydrate in 100 ml of water.

Test solution. Transfer 2.0 g of the substance under examination to a beaker containing a plastic-coated stirring bar. Add 20 ml of water and 2.0 ml of hydrochloric acid and stir until dissolved. Add 50 ml of the buffer solution and sufficient water to make 100 ml.

Reference solution. Dissolve 0.1105 g of sodium fluoride IPRS in water. Transfer 20.0 ml of the solution to a 100-ml volumetric flask containing 50.0 ml of the buffer solution and dilute to volume with water. Each ml of this solution contains 100 µg of fluoride ion.

Electrode system. Use a fluoride-specific ion-indicating electrode and a silver-silver chloride reference electrode connected to a pH meter capable of measuring potentials with a minimum reproducibility of ± 0.2 mV.

Analysis. Transfer 50.0 ml of the buffer solution and 2.0 ml of *hydrochloric acid* to a beaker and add water to make 100 ml. Add a plastic-coated stirring bar, insert the electrode into the solution, stir for 15 minutes and read the potential in millivolts. Continue stirring and at 5 minutes interval add 100, 100, 300 and 500 μ l of the reference solution, reading the potential 5 minutes after each addition. Plot the logarithms of the cumulative fluoride ion concentration (0.1, 0.2, 0.5 and 1.0 μ g/ml) versus potential in millivolts.

Rinse and dry the electrodes, insert them into the test solution, stir for 5 minutes and read the potential in millivolts. From the measured potential and the reference solution response line determine the concentration (c) in μ g/ml of fluoride ion in the test solution.

Calculate the content of fluoride in ppm, using following expression;

$$\text{Fluoride content (in ppm)} = \frac{V \times C}{W}$$

Where,

V = test solution volume (ml),

C = concentration of fluoride ion determined from the reference solution reference line in the test solution (μ g/ml),

W = weight of the test sample (g).

Sulphates (2.3.17). Not more than 0.5 per cent.

Test solution. Dissolve 0.5 g in a mixture of 5 ml *water* and add 5 ml of *dilute hydrochloric acid* and dilute to 100 ml with *water*, filter if necessary. To 20 ml of the solution add 1 ml of *dilute hydrochloric acid* and dilute to 50 ml with *water*.

Reference solution. To 1.0 ml of 0.005 M *sulfuric acid*, add 1 ml of *dilute hydrochloric acid* and dilute to 50 ml with *water*.

Add 2 ml of a 12 per cent w/v solution of *barium chloride* to, each of, the test solution and the reference solution and allow to stand for 10 minutes. Any opalescence in the test solution by viewing vertically or horizontally against a black background is not more than that in the reference solution.

Loss on ignition (2.4.20). 24.5 to 26.5 per cent, determined on 1.0 g by igniting at 800° to 825° to constant weight.

Assay. Dissolve 0.4 g of the substance under examination in 12 ml of *dilute hydrochloric acid* with the aid of gentle heating, if necessary, and dilute to 200.0 ml with *water*. To 20.0 ml of the solution, add 25.0 ml of 0.02 M *disodium edetate*, 50 ml of *water*, 5 ml of *ammonium chloride buffer solution pH 10.7* and 25 mg of *eriochrom black T mixture*. Titrate the excess of *disodium edetate* with 0.02 M *zinc sulphate*. Carry out a blank titration.

1 ml of 0.02 M *disodium edetate* is equivalent to 0.003442 g of $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$.

♦**Storage.** Store protected from moisture. ♦

Solubility. Practically insoluble in water and in ethanol (95 per cent).