

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF COVER SHEET**

CODE: E-05

NAME: DIBASIC CALCIUM PHOSPHATE

(Version 3 of sign-off cover sheet of Rev.1 signed on June 15, 2011)

Amended Item: Add IP to the sign-off as new PDG member.

Harmonised attributes:

Attribute	EP	IP	JP	USP
Definition	+	+	+	+
Identification (1)	+	+	+	+
Identification (2)	+	+	+	+
Acid insoluble substances	+	+	+	+
Chloride	+	+	+	+
Sulfate	+	+	+	+
Carbonate	+	+	+	+
Barium	+	+	+	+
Loss on ignition	+	+	+	+
Assay	+	+	+	+

Legend

+: will adopt and implement

-: will not stipulate

Non-harmonised parts

EP	Characters, Identification: assay limits, Fluoride, Arsenic, Iron, Functionality-Related Characteristics (Particle-size distribution, Bulk density of powders, Powder flow)
IP	Category, Description, Arsenic, Fluorides and Storage
JP	Description, Arsenic, Containers and Storage
USP	Arsenic, Limit of Fluoride, Packaging and Storage

Reagents and reference materials

Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

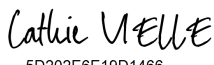
E-05

Revision 1, Version 3 of sign-off cover sheet

July 2026

[if applicable:] Each pharmacopoeia will consider actual titrant concentration in equations according to the local rules of calculation for titration.

European Pharmacopoeia

Signé par :

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Signature

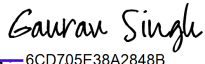
C. Vielle

3 September 2026

Name

Date

Indian Pharmacopoeia

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Gaurav Pratap Singh

07 AUG 2026

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Yoshiro Saito

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Name

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United States Pharmacopeia

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Kevin Moore

8/6/2026

Name

Date

Revision 1 – Stage 5B

DIBASIC CALCIUM PHOSPHATE

Dibasic Calcium Phosphate, Dihydrate

$\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$: 172.09 [7789-77-7]

Dibasic Calcium Phosphate contains not less than 98.0% and not more than 105.0% of $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$.

Identification

- (1) Dissolve 0.1g in 10mL of 2mol/L hydrochloric acid TS by warming, add 2.5mL of ammonia TS dropwise while shaking, and add 5mL of ammonium oxalate TS: a white precipitate is produced.
- (2) Dissolve 0.1g in 5mL of dilute nitric acid, add 2mL of ammonium molybdate TS after warming for 1 to 2 minutes at 70°C: a yellow precipitate is produced.

Purity

- (1) Acid-insoluble substances: Dissolve 5.0g in 40mL of water and 10mL of hydrochloric acid by boiling gently for 5 minutes. After cooling, collect the insoluble substances using ashless filter paper for assay. Wash with water until no more turbidity of the washing is produced when silver nitrate TS is added. Ignite to incinerate completely the residue and ashless filter paper for assay at $600 \pm 50^\circ\text{C}$: the weight is not more than 10mg (not more than 0.2%).
- (2) Chloride: Dissolve 0.20g in 20mL of water and 13mL of dilute nitric acid, by warming, if necessary, add water to make 100mL, and filter, if necessary. Transfer 50mL of this solution to a Nessler tube, and use as the test solution. Transfer 0.70mL of 0.01mol/L hydrochloric acid to another Nessler tube, add 6mL of dilute nitric acid and water to make 50mL, and use this solution as the control solution. Add 1mL of silver nitrate TS to the test solution and to the control solution, mix well, and allow to stand for 5 minutes protecting from direct sunlight. Compare the opalescence developed in both solutions against a black background by viewing downward or transversely. The opalescence developed in the test solution is not more than that of the control solution (not more than 0.25%).
- (3) Sulfate: Dissolve 0.5g in 5mL of water and 5mL of dilute hydrochloric acid, add water to make 100mL, and filter, if necessary. Transfer 20mL of this solution to a

Nessler tube, add 1mL of dilute hydrochloric acid and water to make 50mL, and use this solution as the test solution. Transfer 1.0mL of 0.005mol/L sulfuric acid VS to another Nessler tube, add 1mL of dilute hydrochloric acid and water to make 50mL, and use this solution as the control solution. Add 2mL of barium chloride TS to the test solution and to the control solution, mix well, and allow to stand for 10 minutes. Compare the white turbidity produced in both solutions against a black background by viewing downward or transversely. The turbidity produced in the test solution is not thicker than that of the control solution (not more than 0.5%).

(4) Carbonate: Mix 1.0g with 5mL of carbon dioxide-free water, and add immediately 2mL of hydrochloric acid: no effervescence occurs.

(5) Barium: Heat to boiling 0.5g with 10mL of water, add 1mL of hydrochloric acid dropwise while stirring, and allow to cool and filter, if necessary. Add 2mL of potassium sulfate TS to this solution, and allow to stand for 10 minutes: no turbidity appears.

Loss on ignition

24.5~26.5% (1g, 800~825°C, constant weight).

Assay

Weigh accurately about 0.4g, dissolve in 12mL of dilute hydrochloric acid, by heating on a water bath, if necessary, and add water to make exactly 200mL. Pipet 20mL of this solution, add exactly 25mL of 0.02mol/L disodium ethylenediaminetetraacetate VS, 50mL of water and 5mL of pH 10.7 ammonia-ammonium chloride buffer solution, and titrate the excess disodium ethylenediaminetetraacetate with 0.02mol/L zinc sulfate VS (indicator: 0.025g of eriochrom black T – sodium chloride indicator). Perform a blank determination in the same manner.

Each mL of 0.02mol/L disodium ethylenediaminetetraacetate VS = 3.442mg of $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$.

Reagents

Silver nitrate TS

Dissolve 17.5g of silver nitrate in water to make 1000mL (0.1mol/L). Preserve in light-resistant containers.

Barium chloride TS Dissolve 12g of barium chloride dihydrate in water to make 100mL (0.5mol/L).