

- 16 El-Shattaway HH, *et al.* Erythromycin direct compression excipients: preformulation stability screening using differential scanning calorimetry. *Drug Dev Ind Pharm* 1982; 8(6): 937–947.

20 General References

European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2011; 23(4): 713–714. www.edqm.eu/site/-614.html (accessed 5 December 2011).

Green CE, *et al.* R-P trials calcium excipient. *Manuf Chem* 1996; 67(8): 55, 57.

Innophos Inc. Product data sheet: *Calipharm D*, 2008.

21 Author

RC Moreton.

22 Date of Revision

4 May 2017.

Calcium Phosphate, Tribasic

1 Nonproprietary Names

BP: Calcium Phosphate

PhEur: Calcium Phosphate

USP–NF: Tribasic Calcium Phosphate

2 Synonyms

Calcium orthophosphate; E341(iii); hydroxylapatite; phosphoric acid calcium salt (2:3); precipitated calcium phosphate; tertiary calcium phosphate; *TRI-CAFOS*; tricalcii phosphas; tricalcium diorthophosphate; tricalcium orthophosphate; tricalcium phosphate; *TRI-CAL WG*; *TRI-TAB*.

3 Chemical Name and CAS Registry Number

Tribasic calcium phosphate is not a clearly defined chemical entity but is a mixture of calcium phosphates. Several chemical names, CAS Registry Numbers, and molecular formulas have therefore been used to describe this material. Those most frequently cited are shown below.

Calcium hydroxide phosphate [12167-74-7]

Tricalcium orthophosphate [7758-87-4]

See also Sections 4 and 8.

4 Empirical Formula and Molecular Weight

$\text{Ca}_3(\text{PO}_4)_2$ 310.20

$\text{Ca}_5(\text{OH})(\text{PO}_4)_3$ 502.32

5 Structural Formula

See Sections 3 and 4.

6 Functional Category

Anticaking agent; buffering agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Tribasic calcium phosphate is widely used as a capsule diluent and tablet filler/binder in either direct-compression or wet-granulation processes. The primary bonding mechanism in compaction is plastic deformation. As with dibasic calcium phosphate, a lubricant and a disintegrant should usually be incorporated in capsule or tablet formulations that include tribasic calcium phosphate. In some cases tribasic calcium phosphate has been used as a disintegrant.⁽¹⁾ It is most widely used in vitamin and mineral preparations⁽²⁾ as a filler and as a binder.

In food applications, tribasic calcium phosphate powder is widely used as an anticaking agent. See Section 18.

See also Calcium phosphate, dibasic dihydrate.

8 Description

The PhEur 9.2 states that tribasic calcium phosphate consists of a mixture of calcium phosphates. It contains not less than 35.0% and not more than the equivalent of 40.0% of calcium. The USP 40–NF 35 S1 specifies that tribasic calcium phosphate consists of variable mixtures of calcium phosphates having the approximate composition $10\text{CaO}\cdot 3\text{P}_2\text{O}_5\cdot \text{H}_2\text{O}$. This corresponds to a molecular formula of $\text{Ca}_5(\text{OH})(\text{PO}_4)_3$ or $\text{Ca}_{10}(\text{OH})_2(\text{PO}_4)_6$.

Tribasic calcium phosphate is a white, odorless and tasteless powder.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for tribasic calcium phosphate.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Loss on ignition	≤8.0%	≤8.0%
Water-soluble substances	–	≤0.5%
Acid-insoluble substances	≤0.2%	≤0.2%
Carbonate	–	+
Chloride	≤0.15%	≤0.14%
Fluoride	≤75 ppm	≤75 ppm
Nitrate	–	+
Sulfate	≤0.5%	≤0.8%
Arsenic	≤4 ppm	≤3 ppm
Barium	–	+
Iron	≤400 ppm	–
Dibasic salt and calcium oxide	–	+
Heavy metals	–	≤30 ppm
Assay (as Ca)	35.0–40.0%	34.0–40.0%

10 Typical Properties

Acidity/alkalinity pH = 6.8 (20% slurry in water)

Density 3.14 g/cm³

Density (bulk)

0.3–0.4 g/cm³ for powder form;

0.80 g/cm³ for granular *TRI-TAB*.⁽³⁾