

Ca Calcium Carbonate

1 Nonproprietary Names

BP: Calcium Carbonate

JP: Precipitated Calcium Carbonate

PhEur: Calcium Carbonate

USP–NF: Calcium Carbonate

2 Synonyms

Balcarb; *Cal-Carb*; *calcii carbonas*; *calcii carbonas praecipitatus*; calcium carbonate (1:1); *Calcipress*; *Calopake*; carbonic acid calcium salt (1:1); *creta preparada*; *Destab*; E170; *MagGran CC*; *Pharma-Carb*; precipitated calcium carbonate; precipitated carbonate of lime; precipitated chalk; *Sturcal*; *Vicality*; *Vivapress*; *Witcarb*; *Vivapress Ca*.

3 Chemical Name and CAS Registry Number

Carbonic acid, calcium salt (1:1) [471-34-1]

4 Empirical Formula and Molecular Weight

CaCO₃ 100.09

5 Structural Formula

See Section 4.

6 Functional Category

Buffering agent; opacifier; tablet and capsule binder; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Calcium carbonate, employed as a pharmaceutical excipient, is mainly used in solid-dosage forms as a diluent.⁽¹⁻⁵⁾ It is also used as a base for medicated dental preparations,⁽⁶⁾ as a buffering agent, and as a dissolution aid in dispersible tablets. Calcium carbonate is used as a bulking agent in tablet sugar-coating processes and as an opacifier in tablet film-coating.

Calcium carbonate is also used as a food additive.

8 Description

Calcium carbonate occurs as an odorless and tasteless white powder or crystals.

9 Pharmacopeial Specifications

See Table I. See also Section 18.

10 Typical Properties

Acidity/alkalinity pH = 9.0 (10% w/v aqueous dispersion)

Density (bulk) 0.8 g/cm³

Density (tapped) 1.2 g/cm³

Flowability Cohesive.

Melting point Decomposes at 825°C.

Moisture content see Figure 1.

Particle size see Figure 2.

Refractive index 1.59

Solubility Practically insoluble in ethanol (95%) and water.

Solubility in water is increased by the presence of ammonium salts or carbon dioxide. The presence of alkali hydroxides reduces solubility.

Table I: Pharmacopeial specifications for calcium carbonate.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	–	+	+
Characters	+	+	–
Loss on drying	≤1.0%	≤2.0%	≤2.0%
Acid-insoluble substances	≤0.2%	≤0.2%	≤0.2%
Fluoride	–	–	≤50 ppm
Arsenic	≤5 ppm	≤4 ppm	≤3 ppm
Barium	+	+	+
Chlorides	–	≤330 ppm	–
Lead	–	–	≤3 ppm
Iron	–	≤200 ppm	≤0.1%
Heavy metals	≤20 ppm	–	≤20 ppm
Magnesium and alkali (metals) salts	≤0.5%	≤1.5%	≤1.0%
Sulfates	–	≤0.25%	–
Mercury	–	–	≤0.5 ppm
Assay (dried basis)	≥98.5%	98.5%–100.5%	98.0%–100.5%

Specific gravity 2.7

Specific surface area 6.21–6.47 m²/g

Spectroscopy

IR spectrum see Figure 3.

NIR spectrum see Figure 4.

Raman spectrum see Figure 5.

11 Stability and Storage Conditions

Calcium carbonate is stable and should be stored in a well-closed container in a cool, dry place.

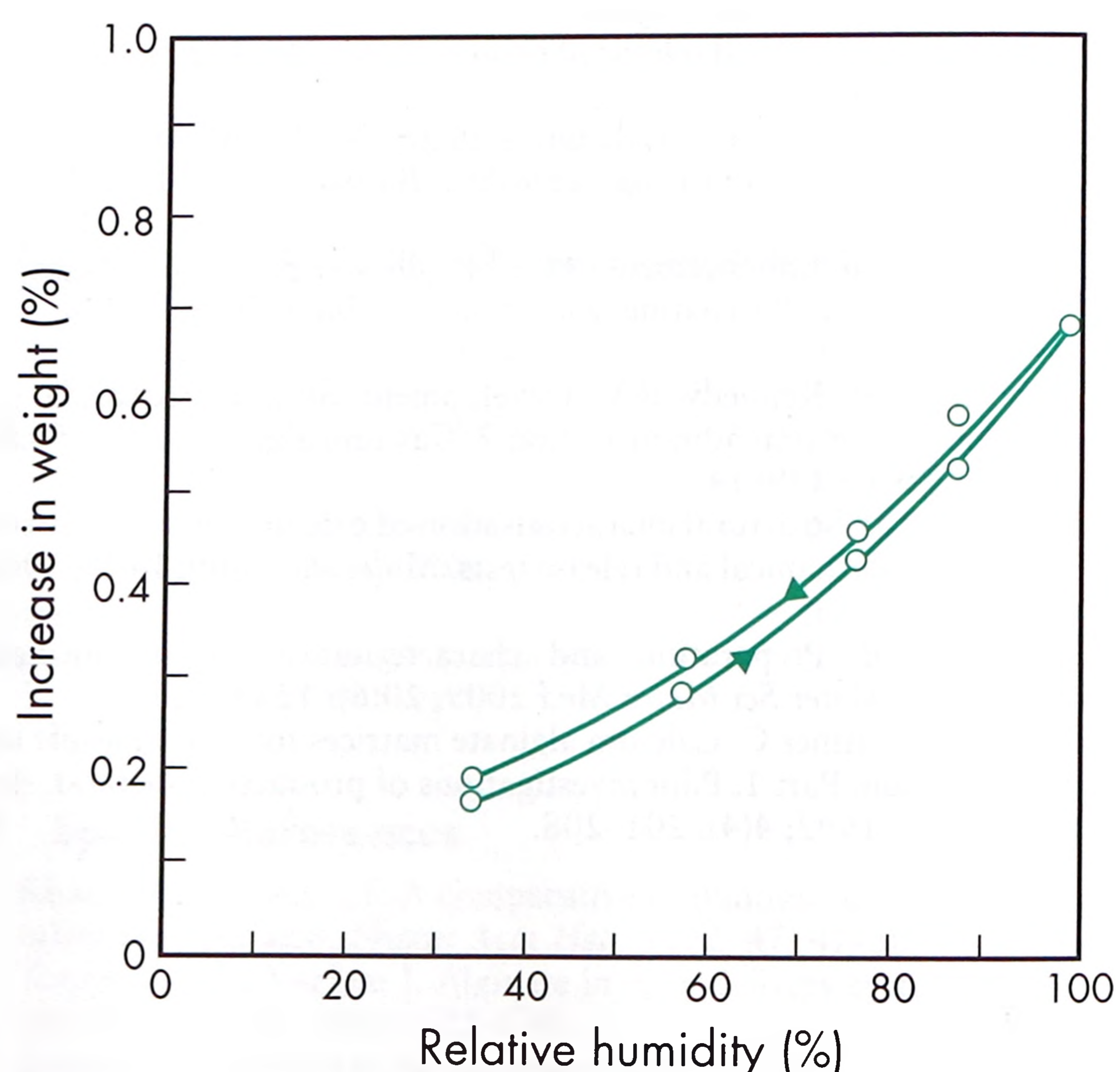


Figure 1: Moisture sorption–desorption isotherm of calcium carbonate.