Bentonite

1 Nonproprietary Names

BP: Bentonite

JP: Bentonite

PhEur: Bentonite

USP–NF: Bentonite

2 Synonyms

Albagel; bentonitum; E558; *Expanda*; mineral soap; *Polargel*; soap clay; taylorite; *Vanatural*; wilkinite.

3 Chemical Name and CAS Registry Number

Bentonite [1302-78-9]

4 Empirical Formula and Molecular Weight

$Al_2O_3 \cdot 4SiO_2 \cdot H_2O$ 359.16

Bentonite is a native colloidal hydrated aluminum silicate consisting mainly of montmorillonite, $Al_2O_3 \cdot 4SiO_2 \cdot H_2O$; it may also contain calcium, magnesium, and iron. The average chemical analysis is expressed as oxides, *see* Table I, in comparison with magnesium aluminum silicate.

Table I: Average chemical analysis of bentonite expressed as oxides in comparison with magnesium aluminum silicate.

	Bentonite	Magnesium aluminum silicate
Silicon dioxide	59.92%	61.1%
Aluminum oxide	19.78%	9.3%
Magnesium oxide	1.53%	13.7%
Ferric oxide	2.96%	0.9%
Calcium oxide	0.64%	2.7%
Sodium oxide	2.06%	2.9%
Potassium oxide	0.57%	0.3%

5 Structural Formula

The PhEur 9.2 describes bentonite as a natural clay containing a high proportion of montmorillonite, a native hydrated aluminum silicate in which some aluminum and silicon atoms may be replaced by other atoms such as magnesium and iron.

The USP 40–NF 35 S1 describes bentonite, purified benonite, and bentonite magma in three separate monographs. Bentonite is described as a native, colloidal, hydrated aluminum silicate; purified bentonite is described as a colloidal montmorillonite that has been processed to remove grit and nonswellable ore compounds; and bentonite magma is a mixture of bentonite and purified water, stirred or blended to form a uniform magma.

See also Section 4.

6 Functional Category

Adsorbent; suspending agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Bentonite occurs as a naturally occurring hydrated aluminum silicate used primarily in the formulation of suspensions, gels, and sols, for topical pharmaceutical applications. It is also used to suspend powders in aqueous preparations and to prepare cream bases containing oil-in-water emulsifying agents.

Bentonite may also be used in oral pharmaceutical preparations, cosmetics, and food products, *see* Section 18. In oral preparations, bentonite, and other similar silicate clays, can be used to adsorb cationic drugs and so retard their release.[1–3] Adsorbents are also used to mask the taste of certain drugs. *See* Table II.

Table II: Uses of bentonite.

Use	Concentration (%)
Adsorbent (clarifying agent)	1.0–2.0
Emulsion stabilizer	1.0
Suspending agent	0.5–5.0

8 Description

Bentonite occurs as a crystalline, claylike mineral, and is available as an odorless, pale buff, or cream to grayish-colored fine powder, which is free from grit. It consists of particles about 50–150 μm in size along with numerous particles about 1–2 μm. Microscopic examination of samples stained with alcoholic methylene blue solution reveals strongly stained blue particles. Bentonite may have a slight earthy taste.

9 Pharmacopeial Specifications

See Table III.

Table III: Pharmacopeial specifications for bentonite.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	+	+	—
Alkalinity	—	+	—
Microbial limit	—	≤10^3 cfu/g	+
Coarse particles	—	≤0.5%	—
pH (2% w/v suspension)	9.0–10.5	—	9.5–10.5
Loss on drying	5.0–10.0%	≤15%	5.0–8.0%
Arsenic	≤2 ppm	—	≤5 ppm
Lead	—	—	≤40 ppm
Heavy metals	≤50 ppm	—	—
Gel formation	+	—	+
Sedimentation volume	—	≤2 mL	—
Swelling power	≥20 mL	≥22 mL	≥24 mL
Fineness of powder	+	—	+

The USP 40–NF 35 S1 also contains specifications for bentonite magma and purified bentonite. *See* Section 17.

10 Typical Properties

Acidity/alkalinity pH = 9.5–10.5 for a 2% w/v aqueous suspension.

Flowability No flow.

Hygroscopicity Bentonite is hygroscopic.[4] *See also* Figure 1.

Moisture content 5–12%.

Solubility Practically insoluble in ethanol, fixed oils, glycerin, propan-2-ol, and water. Bentonite swells to about 12 times its