Kaolin

1 Nonproprietary Names

BP: Heavy Kaolin

JP: Kaolin

PhEur: Kaolin, Heavy

USP–NF: Kaolin

Note that the PhEur 9.2 contains a monograph on heavy kaolin. The BP 2017, in addition to the monograph for heavy kaolin, also contains monographs for light kaolin (natural) and light kaolin.

See also Sections 4 and 9.

2 Synonyms

Argilla; bolus alba; China clay; E559; kaolinite; kaolinum ponderosum; *Lion*; porcelain clay; *Sim 90*; weisserton; white bole.

3 Chemical Name and CAS Registry Number

Hydrated aluminum silicate [1332-58-7]

4 Empirical Formula and Molecular Weight

$Al_2H_4O_9Si_2$ 258.16

The USP 40–NF 35 S1 describes kaolin as a native hydrated aluminum silicate, powdered and freed from gritty particles by elutriation. The BP 2017 similarly describes light kaolin but additionally states that it contains a suitable dispersing agent. Light kaolin (natural) BP contains no dispersing agent. Heavy kaolin is described in the BP 2017 and PhEur 9.2 as a purified, natural hydrated aluminum silicate of variable composition. The JP XVII describes kaolin as a native hydrous aluminum silicate.

5 Structural Formula

See Section 4.

6 Functional Category

Adsorbent; suspending agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Kaolin is a naturally occurring mineral used in oral and topical pharmaceutical formulations.

In oral medicines, kaolin has been used as a diluent in tablet and capsule formulations; it has also been used as a suspending vehicle. In topical preparations, sterilized kaolin has been used in poultices and as a dusting powder.[1]

8 Description

Kaolin occurs as a white to grayish-white colored, unctuous powder free from gritty particles. It has a characteristic earthy or claylike taste, and when moistened with water it becomes darker in color and develops a claylike odor.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Acidity/alkalinity pH = 4.0–7.5 for a 20% w/v aqueous slurry

Hardness (Mohs) 2.0, very low

Hygroscopicity At relative humidities between about 15–65%, the equilibrium moisture content at 25°C is about 1% w/w, but at relative humidities above about 75%, kaolin absorbs small amounts of moisture.

Particle size distribution Median size = 0.6–0.8 μm

Refractive index 1.56

Solubility Practically insoluble in diethyl ether, ethanol (95%), water, other organic solvents, cold dilute acids, and solutions of alkali hydroxides.

Specific gravity 2.6

Spectroscopy

IR spectrum *see* Figure 1.

NIR spectrum *see* Figure 2.

Raman spectrum *see* Figure 3.

Table I: Pharmacopeial specifications for kaolin.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	–	+	–
Acidity or alkalinity	+	+	–
Microbial limit	–	≤10^3 cfu/g	+
Loss on ignition	≤15.0%	–	≤15.0%
Acid-soluble substances	+	≤1.0%	≤2.0%
Organic impurities	–	+	–
Foreign matter	+	–	–
Adsorption power	–	+	–
Swelling power	–	+	–
Plasticity	+	–	–
Arsenic	≤2 ppm	–	–
Calcium	–	≤250 ppm	–
Carbonate	+	–	+
Chloride	–	≤250 ppm	–
Heavy metals	≤50 ppm	–	–
Iron	≤500 ppm	–	+
Lead	–	–	≤0.001%
Sulfate	–	≤0.1%	–

SEM 1: Excipient: Kaolin USP; manufacturer: Georgia Kaolin Co.; lot no.: 1672; magnification: 60×; voltage: 10 kV.