

21 *Food Chemicals Codex*. [online] Bethesda, MD: United States Pharmacopeia. <http://publications.usp.org> (accessed 31 March 2017).

Stegink LD, Filer LJ, eds. *Aspartame, Physiology and Biochemistry*. New York: Marcel Dekker, 1984.

20 General References

Marie S. Sweeteners. In: Smith J, ed. *Food Additives User's Handbook*. Glasgow: Blackie, 1991: 47–74.
Roy GM. Taste masking in oral pharmaceuticals. *Pharm Technol Eur* 1994; 6(6): 24, 26–2830–3234, 35.
Spectrum Chemical. Material safety data sheet: Aspartame, 2009.

21 Author

ME Quinn.

22 Date of Revision

4 May 2017.

Attapulgit

1 Nonproprietary Names

BP: Attapulgit

2 Synonyms

Actapulgit; *Attaclay*; *Attacote*; *Attagel*; attapulgit; palygorskite; palygorskite; *Pharmasorb Colloidal*; *Pharmasorb Regular*.

3 Chemical Name and CAS Registry Number

Attapulgit [12174-11-7]

4 Empirical Formula and Molecular Weight

$\text{Mg}(\text{Al}_{0.5-1}\text{Fe}_{0-0.5})\text{Si}_4\text{O}_{10}(\text{OH})\cdot 4\text{H}_2\text{O}$

5 Structural Formula

See Section 4.

6 Functional Category

Adsorbent; tablet and capsule binder; suspending agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Attapulgit is widely used as an adsorbent in solid dosage forms. Colloidal clays, such as attapulgit, absorb considerable amounts of water to form gels and in concentrations of 2–5% w/v usually form oil-in-water emulsions.

8 Description

Attapulgit occurs as a light cream-colored, very fine powder containing crystalline fibers.⁽¹⁾ Particle size ranges depend on the grade and manufacturer.

9 Pharmacopeial Specifications

See Table I. See also Section 17.

10 Typical Properties

Acidity/alkalinity pH = 9.5 (5% w/v aqueous suspension)

Angle of repose 37.2–45.2°⁽²⁾

Density 2.2 g/cm³

Density (tapped) 0.33 g/cm³ ⁽²⁾

Flowability 20.9–29.6% (Carr compressibility index)⁽²⁾

Particle size distribution

<2 μm in size for powder;

2–5 μm in size for aggregate.⁽²⁾

11 Stability and Storage Conditions

Attapulgit can adsorb water. It should be stored in an airtight container in a cool, dry, location.

12 Incompatibilities

Attapulgit may decrease the bioavailability of some drugs such as loperamide⁽³⁾ and riboflavin.⁽⁴⁾ Oxidation of hydrocortisone is increased in the presence of attapulgit.⁽⁵⁾

13 Method of Manufacture

Attapulgit is a purified native hydrated magnesium aluminum silicate that occurs naturally as the mineral palygorskite.

14 Safety

Attapulgit is widely used in pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material when used as an excipient. It is not absorbed following oral administration. In oral preparations, activated attapulgit up to 9 g is used in daily divided doses as an adjunct in the management of diarrhea.⁽⁶⁾ The Cosmetic Ingredient Review (CIR) Expert Panel have assessed attapulgit and concluded that the material is safe as used in cosmetics and personal care products.⁽¹⁾

The bulk material may be harmful if absorbed into the body by inhalation. The lungs may be affected by repeated or prolonged exposure to fibers, resulting in fibrosis.⁽⁷⁾ Attapulgit is suspected to be carcinogenic to humans.^(7,8)

Table I: Pharmacopeial specifications for attapulgit.

Test	BP 2017
Identification	+
Characters	+
Acidity or alkalinity (5% w/v aqueous suspension)	7.0–9.5
Adsorptive capacity	5–14%
Arsenic	≤8 ppm
Heavy metals	≤20 ppm
Acid-soluble matter	+
Water-soluble matter	+
Loss on drying	≤17.0%
Loss on ignition	15.0–27.0%