Attapulgite

1 Nonproprietary Names

BP: Attapulgite

2 Synonyms

Actapulgite; *Attaclay*; *Attacote*; *Attagel*; attapulgus; palygorscite; palygorskite; *Pharmsorb Regular*.

3 Chemical Name and CAS Registry Number

Attapulgite [12174-11-7]

4 Empirical Formula Molecular Weight

Attapulgite is a purified native hydrated magnesium aluminum silicate consisting of the clay mineral palygorskite, with the empirical formula $Mg(Al_{0.5-1}Fe_{0-0.5})Si_4O_{10}(OH)\cdot 4H_2O$.

5 Structural Formula

See Section 4.

6 Functional Category

Adsorbent.

7 Applications in Pharmaceutical Formulation or Technology

Attapulgite is widely used as an adsorbent in solid dosage forms. Colloidal clays (such as attapulgite) absorb considerable amounts of water to form gels and in concentrations of 2–5% w/v usually form oil-in-water emulsions. Activated attapulgite, which is attapulgite that has been carefully heated to increase its absorptive capacity, is used therapeutically as an adjunct in the management of diarrhea.

8 Description

Attapulgite occurs as a light cream colored, very fine powder. 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°[1]
Density: 2.2 g/cm^3
Density (tapped): 0.33 g/cm^3 [1]
Flowability: 20.9–29.6% (Carr compressibility index)[1]
Particle size distribution:
<2 μm in size for powder
2–5 μm in size for aggregate.[1]

Table I: Pharmacopeial specifications for attapulgite.

Test	BP 2001
Identification	+
Character	+
Acidity or alkalinity (5% w/v aqueous suspension)	7.0–9.5
Adsorptive capacity	5–14%
Arsenic	≤8 ppm
Heavy metals	≤20 ppm
Acid-insoluble matter	≤12.5%
Water-soluble matter	≤0.5%
Loss on drying	≤17.0%
Loss on ignition	15.0–27.0%

11 Stability and Storage Conditions

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

12 Incompatibilities

Attapulgite may decrease the bioavailability of some drugs such as loperamide[2] and riboflavin.[3] Oxidation of hydrocortisone is increased in the presence of attapulgite.[4]

13 Method of Manufacture

Attapulgite occurs naturally as the mineral palygorskite.

14 Safety

Attapulgite is widely used in pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material. It is not absorbed following oral administration. In oral preparations, activated attapulgite up to 9 g is used in daily divided doses as an adjunct in the management of diarrhea.[5]

LD_{50} (rat, IP): 0.34 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection, gloves, and a dust mask are recommended. Attapulgite should be handled in a well-ventilated environment and dust generation should be minimized. When heated to decomposition, attapulgite emits acrid smoke and irritating fumes.

16 Regulatory Status

Included in nonparenteral medicines licensed in a number of countries worldwide including the UK and US.

17 Related Substances

Activated attapulgite; magnesium aluminum silicate.

Activated attapulgite

Comments: activated attapulgite is a processed native magnesium aluminum silicate that has been carefully heated to increase its adsorptive capacity. Monographs for activated attapulgite are included in the BP 2001, USP 25, and other pharmacopeias. The USP 25 also includes a monograph for colloidal activated attapulgite.

18 Comments

—

19 Specific References

1 Viseras C, López-Galindo A. Characteristics of pharmaceutical grade phyllosilicate powders. *Pharm Dev Technol* 2000; 5(1): 47–52.

2 Mboya SA, Bhargava HN. Adsorption and desorption of loperamide hydrochloride by activated attapulgites. *Am J Health Syst Pharm* 1995; **52**: 2816–2818.

3 Khalil SAH, Mortada LM, Shams-Eldeen MA, El-Khawas MM. Effect of attapulgite on the bioavailability of a model low dose drug (riboflavine) in humans. *Drug Dev Ind Pharm* 1987; **13**: 369–382.

4 Cornejo J, Hernosin MC, White JL, *et al.* Oxidative degradation of hydrocortisone in the presence of attapulgite. *J Pharm Sci* 1980; **69**: 945–948.

5 Sweetman SC, ed. *Martindale: the Complete Drug Reference*, 33rd edn. London: Pharmaceutical Press, 2002: 1212.

20 General References

Anonymous. The silicates: attapulgite, kaolin, kieselguhr, magnesium trisilicate, pumice, talc. *Int J Pharm Compound* 1998; 2(2): 162–163.

Viseras C, Yebra A, López-Galindo A. Characteristics of pharmaceutical grade phyllosilicate compacts. *Pharm Dev Technol* 2000; 5(1): 53–58.

21 Author

A Palmieri.

22 Date of Revision

29 July 2002.