drug delivery system. *Mater Sci Eng C Mater Biol Appl* 2014; 42: 715–725.
7 Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients 2004*. Tokyo: Yakuji Nippo, 2004: 74–75.

20 General References

Ferro Corporation. Material safety data sheet: *Synpro*, 2010.
Santa Cruz Biotechnology, Inc. Material safety data sheet: Aluminum monostearate, 2011.

21 Authors

J Shur, ME Quinn.

22 Date of Revision

4 May 2017.

Aluminum Oxide

1 Nonproprietary Names

USP–NF: Aluminum Oxide

2 Synonyms

Activated alumina; activated aluminum oxide; alpha aluminum oxide; alumina; alumina, calcined; alumina, tabular; aluminum oxide alumite; aluminum trioxide; gamma aluminum oxide.

3 Chemical Name and CAS Registry Number

Aluminum oxide [1344-28-1]

4 Empirical Formula and Molecular Weight

Al_2O_3 101.96

5 Structural Formula

Aluminum oxide occurs naturally as the minerals bauxite, bayerite, boehmite, corundum, diaspore, and gibbsite.

6 Functional Category

Adsorbent; dispersing agent.

7 Applications in Pharmaceutical Formulation or Technology

Aluminum oxide is used mainly in tablet formulations.[1] It is used for decoloring powders and is particularly widely used in antibiotic formulations. It is also used in suppositories, pessaries, and urethral inserts.

Table I: Pharmacopeial specifications for aluminum oxide.

Test	USP 40–NF 35 S1
Identification	+
Arsenic	≤4 ppm
Heavy metals	≤60 ppm
Chloride	≤10 000 ppm
Sulfate	≤10 000 ppm
Microbial limits	
Bacteria	≤1000 cfu/g
Molds and yeasts	≤100 cfu/g
Clarity of solution	+
Alkaline impurities	+
Neutralizing capacity	+
Assay	47.0–60.0%

Aluminum oxide in the form of nanoparticles has been investigated for glidant properties in tablet formulation. It was shown to be effective but produced a large reduction in tablet tensile strength.[2]

Hydrated aluminum oxide (*see* Section 18) is used in cosmetic formulations.

8 Description

Aluminum oxide occurs as a white crystalline powder in two crystalline forms: α-aluminum oxide is composed of colorless hexagonal crystals, and γ-aluminum oxide is composed of minute colorless cubic crystals that are transformed to the α-form at high temperatures.

9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

10 Typical Properties

Boiling point 2977°C
Density (bulk) 0.9–1.1 g/cm^3
Flammability Nonflammable.
Hardness (Mohs) 8.8
Hygroscopicity Very hygroscopic.
Melting point 2050°C
Solubility Slowly soluble in aqueous alkaline solutions with the formation of hydroxides; practically insoluble in nonpolar organic solvents, diethyl ether, ethanol (95%), and water.
Specific gravity 2.8 (becomes 4.0 at 800°C)
Vapor pressure 133.3 Pa at 2158°C

11 Stability and Storage Conditions

Aluminum oxide should be stored in a well-closed container in a cool, dry place. It is very hygroscopic.

12 Incompatibilities

Aluminum oxide should be kept well away from water. It is incompatible with strong oxidizers and chlorinated rubber. Aluminum oxide also reacts with chlorine trifluoride, ethylene oxide, sodium nitrate, and vinyl acetate. Exothermic reactions above 200°C with halocarbon vapors produce toxic hydrogen chloride and phosgene fumes.