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Bentonite

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CAS RN®: 1302-78-9.

DEFINITION

Bentonite is a native, colloidal, hydrated aluminum silicate.

IDENTIFICATION

• **A. X-Ray Powder Diffraction ⟨941⟩**

Sample A: Add 2 g in small portions to 100 mL of water, with intense agitation. Allow to stand for 12 h to ensure complete hydration. Place 2 mL of the mixture so obtained on a suitable glass slide, and allow to air-dry at room temperature to produce an oriented film. Place the slide in a vacuum desiccator over a free surface of ethylene glycol. Evacuate the desiccator, and close the stopcock so that the ethylene glycol saturates the desiccator chamber. Allow to stand for 12 h.

Sample B: Prepare a random powder specimen of Bentonite.

Analysis

Samples: *Sample A* and *Sample B*

Record the X-ray diffraction pattern of the samples, and determine the *d* values.

Acceptance criteria: The largest peak in the pattern of *Sample A* corresponds to a *d* value between 15.0 and 17.2 Å. The major peak in the region between 1.48 and 1.54 Å from the pattern of *Sample B* is between 1.492 and 1.504 Å.

IMPURITIES

Change to read:

• ▲**Arsenic ⟨211⟩, *Procedures, Procedure 1*▲** (CN 1-Jun-2023)

Test preparation: Transfer 8.0 g to a 250-mL beaker containing 100 mL of dilute hydrochloric acid (1 in 25), mix, and cover with a watch glass. Boil gently, with occasional stirring, for 15 min without allowing excessive foaming. Pass the hot supernatant through a rapid-flow filter paper into a 200-mL volumetric flask, and wash with four 25-mL portions of hot dilute hydrochloric acid (1 in 25), collecting the washings in the volumetric flask. Cool the combined filtrates to room temperature, and add dilute hydrochloric acid (1 in 25) to volume. Transfer 25 mL of this solution to a generator flask, and dilute with water to 35 mL.

Standard preparation: Transfer 5 mL of *Standard Arsenic Solution* (5 µg) to a generator flask, and dilute with water to 35 mL.

Analysis: Proceed as directed in the chapter, determining the absorbances.

Acceptance criteria: NMT 5 ppm; the absorbance due to any red color from the *Test preparation* does not exceed that produced by the *Standard preparation*.

• **Lead**

[Note—The *Standard solution* and the *Sample solution* may be modified, if necessary, to obtain solutions of suitable concentrations, adaptable to the linear or working range of the instrument. It may be necessary to correct the value obtained for the *Sample solution* for interference from the sample specimen matrix.]

Standard solution: On the day of use, dilute 3.0 mL of lead nitrate stock solution TS with water to 100 mL. Each mL of the *Standard solution* contains the equivalent of 3 µg of lead.

Sample solution: Transfer 3.75 g to a 250-mL beaker containing 100 mL of dilute hydrochloric acid (1 in 25), stir, and cover with a watch glass. Boil for 15 min, then cool to room temperature, and pass through a rapid-flow filter paper into a 400-mL beaker. Wash the filter with four 25-mL portions of hot water, collecting the washings in the 400-mL beaker. Concentrate the combined extracts by gentle boiling to approximately 20 mL. If a precipitate appears, add 2–3 drops of nitric acid, heat to boiling, and cool to room temperature. Pass the concentrated extracts through a rapid-flow filter paper into a 50-mL volumetric flask. Transfer the remaining contents of the 400-mL beaker through the filter paper and into the flask with water. Dilute with water to volume.

Instrumental conditions

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 283.3 nm

Lamp: Lead hollow cathode with deuterium arc background correction

Flame: Air and acetylene

Analysis: Determine the absorbances of the *Standard solution* and the *Sample solution*.

Acceptance criteria: The absorbance of the *Sample solution* is NMT that of the *Standard solution* (40 µg/g).

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** Meets the requirements of the test for absence of *Escherichia coli*

• **pH ⟨791⟩**
Analysis: Disperse 4.0 g in 200 mL of water, mixing vigorously to facilitate wetting.
Acceptance criteria: 9.5–10.5

• **Loss on Drying ⟨731⟩**
Analysis: Dry at 105° for 2 h.
Acceptance criteria: 5.0%–8.0%

• **Gel Formation:** Mix 6 g with 300 mg of magnesium oxide. Add the mixture, in several divided portions, to 200 mL of water contained in a blender of approximately 500-mL capacity. Blend thoroughly for 5 min at high speed, transfer 100 mL of the mixture to a 100-mL graduated cylinder, and allow to remain undisturbed for 24 h. NMT 2 mL of supernatant appears on the surface.

• **Swelling Power:** To 100 mL of water contained in a glass-stoppered cylinder of 100-mL capacity add 2 g in portions, dropping it upon the surface of the water, and allow each portion to settle before adding the next. The mass at the bottom gradually swells until it occupies an apparent volume of NLT 24 mL at the end of a 2-h period.

• **Fineness of Powder:** Sprinkle 2 g on 20 mL of water contained in a mortar. Allow to swell, disperse evenly with a pestle, and dilute with water to 100 mL. Pour the suspension through a No. 200 standard sieve, and wash the sieve thoroughly with water. No grit is felt when the fingers are rubbed over the wire mesh of the sieve.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Label it to indicate that absorption of atmospheric moisture should be avoided following the opening of the original package, preferably by storage of the remainder of the contents in a tight container.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BENTONITE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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