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# Agar

CAS RN®: 9002-18-0.

## DEFINITION

Agar is the dried, hydrophilic, colloidal substance consisting of the polysaccharides extracted from *Gelidium cartilagineum* (L.) Gaillon (Fam. Gelidiaceae), *Gracilaria confervoides* (L.) Greville (Fam. Sphaerococcaceae), and related red algae (Class Rhodophyceae).

## IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**
- **B.** Iodine TS colors some of the fragments of Agar bluish black, with some areas reddish to violet.
- **C.**

**Analysis:** Boil a sample with 65 times its weight of water for 10 min, with constant stirring, and subsequently adjust with hot water to a concentration of 1.5%, by weight.

**Acceptance criteria:** Agar forms a clear liquid that congeals at 30°–39° to form a firm resilient gel, which does not liquefy below 80°.

## IMPURITIES

***Change to read:***

**Inorganic Impurities**

- ▲Arsenic ⟨211⟩, *Procedures, Procedure 2*▲ (CN 1-Jun-2023) : NMT 3 ppm
- ▲Lead ⟨251⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) : NMT 10 ppm
- **Articles of Botanical Origin, *Acid-Insoluble Ash* ⟨561⟩:** NMT 0.5%, on a dry-weight basis

**Organic Impurities**

- **Procedure 1: Limit of Gelatin**

**Sample solution:** Dissolve 1 g of sample in 100 mL of boiling water. Allow to cool to about 50°.

**Analysis:** To 5 mL of the *Sample solution* add 2–3 drops of a mixture of 0.2 M potassium dichromate solution and 3 N hydrochloric acid (4:1).

**Acceptance criteria:** No yellow precipitate is formed.

- **Procedure 2: Limit of Foreign Starch**

**Sample solution:** Boil 0.10 g in 100 mL of water.

**Acceptance criteria:** The *Sample solution* does not, upon cooling, produce a blue color upon the addition of iodine TS.

- **Procedure 3: Limit of Foreign Insoluble Matter**

**Sample dispersion:** Add sufficient water to 7.5 g of sample to make 500 g, boil for 15 min, and readjust to the original 500 g.

**Analysis:** To 100 g of the uniformly mixed *Sampledispersion* add hot water to make 200 mL. Heat almost to boiling, filter while hot through a tared filtering crucible. Rinse the container with several portions of hot water, and pass these rinsings through the crucible. Dry the crucible and its contents at 105° to a constant weight.

**Acceptance criteria:** NMT 15 mg (1.0%) remains in the crucible.

- **Procedure 4: Articles of Botanical Origin, *Foreign Organic Matter* ⟨561⟩:** NMT 1.0%

## SPECIFIC TESTS

- **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed $10^3$ cfu/g, and the total combined molds and yeasts count does not exceed $10^2$ cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.
- **Water Determination, *Method III* ⟨921⟩**

**Analysis:** If necessary, cut a sample into pieces from a 2- to 5-mm square, and dry at 105° for 5 h.

**Acceptance criteria:** The sample loses NMT 20.0% of its weight.

- **Articles of Botanical Origin, *Total Ash* ⟨561⟩:** NMT 6.5%, on a dry-weight basis
- **Water Absorption**

**Sample:** 5.0 g

**Analysis:** Place the *Sample* in a 100-mL graduated cylinder, fill to the mark with water, mix, and allow to stand at 25° for 24 h. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100-mL graduated cylinder.

**Acceptance criteria:** NMT 75 mL of water is obtained.

- **Botanic Characteristics**

**Agar:** Usually occurs in bundles consisting of thin, membranous, agglutinated strips or in cut, flaked, or granulated forms. It may be colored weak yellowish orange, yellowish gray to pale yellow, or colorless. It is tough when damp, brittle when dry.

**Histology:** When mounted in water, Agar appears granular and somewhat filamentous; a few fragments of the spicules of sponges and a few frustules of diatoms may be present. In Japanese Agar, the frustules of *Arachnoidiscus ehrenbergii* Baillon often occur, being disk-shaped and 100–300 µm in diameter.

**Powdered agar:** White to yellowish white or pale yellow; in chloral hydrate TS, its fragments are transparent, more or less granular, striated, and angular, and occasionally they contain frustules of diatoms.

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. No storage requirements are specified.
- **USP Reference Standards** ⟨11⟩
  USP Agar RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| AGAR | Documentary Standards Support | CE2020 Complex Excipients |

**Chromatographic Database Information:** Chromatographic Database

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