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Aminobenzoic Acid Gel

DEFINITION

Aminobenzoic Acid Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of aminobenzoic acid (C₇H₇NO₂).

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

Change to read:

- B. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-MAY-2020)

Sample solution: 5 µg/mL in alcohol

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Methanol, glacial acetic acid, and water (30:1:69). Allow the mixture to cool, and pass, if necessary, through a suitable microporous membrane filter, and degas.

Internal standard solution: 7 mg/mL of salicylic acid in methanol; dissolve by sonicating.

Standard stock solution: 0.42 mg/mL of [USP Aminobenzoic Acid RS](#) in methanol; dissolve by sonicating.

Standard solution: 0.042 mg/mL of [USP Aminobenzoic Acid RS](#) in methanol prepared as follows. Transfer 5 mL each of *Standard stock solution* and *Internal standard solution* into a 50-mL volumetric flask, and dilute with methanol to volume. Pass through 0.6-µm filter paper. Throughout the preparation, protect against actinic light.

Sample solution: Nominally 0.042 mg/mL of aminobenzoic acid in methanol prepared as follows. Transfer a quantity of Gel, equivalent to 4.2 mg of aminobenzoic acid, into a 100-mL volumetric flask. Add 10.0 mL of *Internal standard solution* and 50 mL of methanol. Shake or sonicate, as necessary, and dilute with methanol to volume. Filter, if necessary, through filter paper (Whatman No. 41 or equivalent). Pass through 0.6-µm filter paper. Throughout this preparation, protect against actinic light.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L11

Flow rate: 1.0 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Chromatograph replicate 15-µL injections of the *Standard solution* until the response ratio variability is within 1.0% of average.

[NOTE—The relative retention times for aminobenzoic acid and salicylic acid are about 1.0 and 3.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between aminobenzoic acid and salicylic acid peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of aminobenzoic acid (C₇H₇NO₂) in the portion of Gel taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of aminobenzoic to salicylic acid from the *Sample solution*

R_S = peak response ratio of aminobenzoic to salicylic acid from the *Standard solution*

C_S = concentration of [USP Aminobenzoic Acid RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of aminobenzoic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

- [ALCOHOL DETERMINATION, Method II\(611\)](#): 42.3%–54.0% (w/w) of C₂H₅OH

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

SPECIFIC TESTS

- [pH \(791\)](#): 4.0–6.0

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Aminobenzoic Acid RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
AMINO BENZOIC ACID GEL	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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