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Aminobenzoate Potassium Capsules

DEFINITION
Aminobenzoate Potassium Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of aminobenzoate potassium ($C_7H_6KNO_2$).

IDENTIFICATION

• **A.**

Sample: 1 g of the Capsule contents

Analysis: Dissolve the *Sample* in 25 mL of water, add 5 mL of 3 N hydrochloric acid, and wash the precipitate with two 5-mL portions of cold water. Recrystallize from alcohol the precipitate so obtained, and dry at 110° for 1 h.

Acceptance criteria: The *p*-aminobenzoic acid melts between 186° and 189°.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 1.5% acetic acid prepared as follows. Mix 690 mL of water with 10 mL of acetic acid and pass through a filter of 0.45-µm pore size.

Mobile phase: Methanol and *Solution A* (15:85)

Standard solution: 0.1 mg/mL of USP Aminobenzoate Potassium RS in *Mobile phase*

Sample solution: Nominally 0.1 mg/mL of aminobenzoate potassium prepared as follows. Remove as completely as possible, and combine the contents of NLT 10 Capsules. Transfer a portion of the combined contents, equivalent to 10 mg of aminobenzoate potassium to a 100-mL volumetric flask, dissolve in 70 mL of *Mobile phase*, sonicate for 3–4 min, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: 280 nm

Column: 3.0-mm × 15-cm; 3.5-µm packing L11

Flow rate: 0.35 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of aminobenzoate potassium ($C_7H_6KNO_2$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Aminobenzoate Potassium RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of aminobenzoate potassium in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 270 nm

Standard solution: A known concentration of USP Aminobenzoate Potassium RS in *Medium*

Sample solution: Filter portions of the solution under test, and dilute with *Medium*, if necessary, in comparison with the *Standard solution* concentration.

Analysis: Calculate the percentage of the labeled amount of aminobenzoate potassium ($C_7H_6KNO_2$) dissolved.

Tolerances: NLT 75% (*Q*) of the labeled amount of aminobenzoate potassium ($C_7H_6KNO_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Solution A, Mobile phase, and **Chromatographic system:** Prepare as directed in the *Assay*.

Standard solution: 1 µg/mL each of USP Aminobenzoate Potassium RS, USP 4-Nitrobenzoic Acid RS, and USP Benzocaine RS in *Mobile phase*

Sensitivity solution: 0.1 µg/mL of USP Aminobenzoate Potassium RS in *Mobile phase* from the *Standard solution*

Sample solution: Nominally 1 mg/mL of aminobenzoate potassium in *Mobile phase* prepared as follows. Remove as completely as possible, and combine, the contents of NLT 10 Capsules. Transfer a portion of the combined contents, equivalent to 10 mg of aminobenzoate potassium, to a 10-mL volumetric flask. Dissolve in 7 mL of *Mobile phase*, sonicate for 3–4 min, and dilute with *Mobile phase* to volume.

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 1.5 between benzocaine and 4-nitrobenzoic acid, *Standard solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual unspecified degradation product in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of any individual unspecified degradation product from the *Sample solution*

r_S = peak response of aminobenzoate from the *Standard solution*

C_S = concentration of USP Aminobenzoate Potassium RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of aminobenzoate potassium in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminobenzoic acid	1.0	—
Benzocaine[a]	2.0	—
4-Nitrobenzoic acid[a]	2.1	—
Any individual unspecified degradation product	—	0.10
Total impurities	—	1.0

[a] These are process impurities controlled in the API and are included in this table for identification purposes only. They are not reported in the drug product and should not be included in the total impurities.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

- **USP Reference Standards** ⟨11⟩

USP Aminobenzoate Potassium RS
USP Benzocaine RS
USP 4-Nitrobenzoic Acid RS

4-Nitrobenzoic acid.
$C_7H_5NO_4$ 167.12

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

Topic/Question	Contact	Expert Committee
AMINOBENZOATE POTASSIUM CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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