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Add the following:

▲Arginine Hydrochloride Compounded Oral Solution

DEFINITION

Arginine Hydrochloride Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of arginine hydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$).

Prepare Arginine Hydrochloride Compounded Oral Solution 100 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Arginine Hydrochloride powder	10 g
Methylparaben	0.05 g
Propylparaben	0.025 g
Purified Water, a sufficient quantity to make	100 mL

In an appropriately sized container, add the *Methylparaben* and *Propylparaben* to about 80 mL of *Purified Water*. Stir until dissolved. [Note—May heat up to 50° to facilitate dissolution.] Dissolve the *Arginine Hydrochloride powder* in the previously prepared solution of *Methylparaben* and *Propylparaben*. Bring to final volume with *Purified Water*.

ASSAY

• **Procedure**

Solution A: 20 mM ammonium acetate solution adjusted with glacial acetic acid to a pH of 6

Mobile phase: Acetonitrile and *Solution A* (22:78). Pass through a membrane filter of 0.22-µm pore size.

Standard solution: 0.5 mg/mL of arginine hydrochloride prepared from USP Arginine Hydrochloride RS in water

Sample solution: Transfer 1 mL of Oral Solution to a 200-mL volumetric flask, add approximately 160 mL of water, and vortex. Dilute with water to volume and mix.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-µm packing L10

Temperatures

Autosampler: 4°

Column: 30°

Flow rate: 1 mL/min

Injection volume: 60 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for arginine hydrochloride is about 5.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of arginine hydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$) in the portion of Oral Solution taken:

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

r_U = peak response of arginine hydrochloride from the *Sample solution*

r_S = peak response of arginine hydrochloride from the *Standard solution*

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

C_U = nominal concentration of arginine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature

• **Labeling:** Label it to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Arginine Hydrochloride RS▲ (USP 1-May-2020)

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

Topic/Question	Contact	Expert Committee
ARGININE HYDROCHLORIDE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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