Calcium Acetate Capsules

DEFINITION

Calcium Acetate Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium acetate $(C_4H_6CaO_4)$.

IDENTIFICATION

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

 B. <u>IDENTIFICATION TESTS—GENERAL (191)</u>, Chemical Identification Tests, Acetate Sample solution: 67 mg/mL of calcium acetate from Capsule contents Acceptance criteria: Meet the requirements for test B

ASSAY

- Procedure
 - **Solution A:** 0.75 mM <u>dipicolinic acid</u> and 1.7 mM <u>nitric acid</u> in <u>water</u>. [Note—Warm <u>water</u> may be required to dissolve <u>dipicolinic acid</u>.]

Mobile phase: <u>Acetone</u> and *Solution A* (10:90). Pass through a suitable filter of 0.2-µm pore size. **Standard solution:** 0.08 mg/mL of <u>USP Calcium Acetate RS</u> in <u>water</u>

Sample stock solution: Nominally 6.7 mg/mL of calcium acetate prepared as follows. Transfer an appropriate portion of the contents of NLT 20 Capsules to a suitable volumetric flask. Add <u>water</u> to about 40% of the final volume of the flask and sonicate for 20 min with intermittent shaking. Dilute with <u>water</u> to volume. Pass through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally 0.08 mg/mL of calcium acetate in <u>water</u> from the *Sample stock solution* **Chromatographic system**

(See Chromatography (621), System Suitability.)

Mode: Ion chromatography

Detector: Conductivity

Column: 4.0-mm × 15-cm; 5-µm packing <u>L76</u>

Column temperature: 35°

Flow rate: 0.9 mL/min

Injection volume: 10 µL

Run time: NLT 1.5 times the retention time of the calcium peak

System suitability

Sample: Standard solution

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: Standard solution and Sample solution