

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-Jun-2022
 Document Type: USP Monographs
 DocId: GUID-95D11B03-F07D-419F-B031-1B6557FE732D_6_en-US
 DOI: https://doi.org/10.31003/USPNF_M754_06_01
 DOI Ref: y8x06

© 2025 USPC
 Do not distribute

Aprepitant Capsules

DEFINITION

Aprepitant Capsules contain NLT 95.0% and NMT 105.0% of the labeled amount of aprepitant ($C_{23}H_{21}F_7N_4O_3$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), [Ultraviolet-Visible Spectroscopy: 197U](#)

Wavelength range: 200–400 nm

Standard solution: 0.1 mg/mL of [USP Aprepitant RS](#) in methanol. Use sonication to dissolve.

Sample solution: Transfer the contents of Capsules, equivalent to 100 mg of aprepitant, to a 100-mL volumetric flask, add about 75 mL of methanol, and sonicate for about 5 min with intermittent shaking. Cool, dilute with methanol to volume, further dilute with methanol to obtain a solution containing 0.1 mg/mL of aprepitant, and pass through a nylon filter of 0.45-μm pore size.

Acceptance criteria: Meet the requirements

- **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

Dilute phosphoric acid: Dilute 1 mL of phosphoric acid with water to 1 L.

Mobile phase: Acetonitrile and *Dilute phosphoric acid* (45:55)

Standard solution: 0.05 mg/mL of [USP Aprepitant RS](#) in *Mobile phase*. Use sonication as necessary to dissolve.

Sample solution: Nominally 0.05 mg/mL of aprepitant in *Mobile phase*, prepared as follows. Mix the contents of NLT 20 Capsules, and transfer a portion of the contents, equivalent to 100 mg of aprepitant, to a 100-mL volumetric flask. Add about 75 mL of *Mobile phase* and sonicate for about 10 min with intermittent shaking. Cool, dilute to volume with *Mobile phase*, further dilute with *Mobile phase* to obtain a solution containing 0.05 mg/mL of aprepitant, and pass through a nylon filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 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 aprepitant ($C_{23}H_{21}F_7N_4O_3$) 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 Aprepitant RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)**Test 1** ▲▲ (ERR 1-Jun-2022)**Medium:** 2.2% sodium dodecyl sulfate in water; 900 mL**Apparatus 2:** 100 rpm, with sinkers. [NOTE—A suitable sinker is available from www.agilent.com, catalog number 12-3050. Proper placement of the Capsules is in the sinkers with the cap facing the fixed prong end.]**Time:** 20 min**Dilute phosphoric acid:** ▲ Dilute 1 mL of phosphoric acid with water to 1 L. ▲ (ERR 1-Jun-2022)**Mobile phase:** Acetonitrile and *Dilute phosphoric acid* (50:50)**Standard solution:** ($L/900$) mg/mL of [USP Aprepitant RS](#) in *Medium*, where L is the label claim in mg/Capsule. Dissolve first in a minimal amount of methanol (using NMT 2% of the final volume) prior to diluting with *Medium*.**Sample solution:** Pass a portion of the solution under test through a suitable filter.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 220 nm**Column:** 4.6-mm × 15-cm; 5-μm packing L7**Flow rate:** 1.5 mL/min**Injection volume:** 50 μL for Capsules containing 40 mg/Capsule; 10 μL for all other strengths**System suitability****Sample:** *Standard solution***Suitability requirements****Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of aprepitant ($C_{23}H_{21}F_7N_4O_3$) dissolved:

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

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of [USP Aprepitant RS](#) in the *Standard solution* (mg/mL) V = volume of *Medium*, 900 mL L = label claim (mg/Capsule)**Tolerances:** NLT 80% (Q) of the labeled amount of aprepitant ($C_{23}H_{21}F_7N_4O_3$) is dissolved.**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium:** 2.2% sodium dodecyl sulfate in water; 900 mL**Apparatus 2:** 100 rpm, with wire helix sinkers or other suitable sinkers**Time:** 30 min**Dilute phosphoric acid** and **Mobile phase:** Proceed as directed in the Assay.**Standard solution:** ($L/900$) mg/mL of [USP Aprepitant RS](#) in *Medium*, where L is the label claim in mg/Capsule. Dissolve first in a minimal amount of methanol (using NMT 2% of the final volume) prior to diluting with *Medium*.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.**Chromatographic system:** Proceed as directed in the Assay, except use an autosampler temperature of 15°.**System suitability****Sample:** *Standard solution***Suitability requirements****Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of aprepitant ($C_{23}H_{21}F_7N_4O_3$) dissolved:

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

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of [USP Aprepitant RS](#) in the *Standard solution* (mg/mL)