

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2023
Document Type: USP Monographs
DocId: GUID-C40B8C83-9FF3-4CB9-B5E3-DF0FD4C78628_2_en-US
DOI: https://doi.org/10.31003/USPNF_M7232_02_01
DOI Ref: mc04w

© 2025 USPC
Do not distribute

Add the following:

^Rivaroxaban Tablets

DEFINITION
Rivaroxaban Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of rivaroxaban (C₁₉H₁₈ClN₃O₅S).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV absorption spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**
Protect solutions containing rivaroxaban from light.
Solution A: 0.01 M [phosphoric acid](#)
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	92	8
13.0	49	51
13.1	92	8
16.0	92	8

Diluent: *Solution A* and *Solution B* (40:60)
Standard solution: 0.2 mg/mL of [USP Rivaroxaban RS](#) in *Diluent*
Sample solution: Nominally 0.2 mg/mL of rivaroxaban prepared as follows. Transfer Tablets (NLT 4) into an appropriate volumetric flask. Add a suitable amount of *Diluent* and sonicate to disintegrate and dissolve. Dilute with *Diluent* to volume. Pass the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: UV 250 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.
Column: 4.0-mm × 5.5-cm; 3-µm packing [L1](#)
Column temperature: 45°
Flow rate: 1 mL/min
Injection volume: 5 µL

System suitability
Sample: *Standard solution*
Suitability requirements
Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rivaroxaban ($C_{19}H_{18}ClN_3O_5S$) in the portion of Tablets taken:

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

r_U = peak response of rivaroxaban from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Buffer: 0.022 M [sodium acetate](#); adjusted with [sodium hydroxide](#) or [glacial acetic acid](#) to a pH of 4.5

Medium

For 2.5-mg Tablets: *Buffer*; 900 mL

For 10-mg Tablets: 0.2% [sodium dodecyl sulfate](#) in *Buffer*; 900 mL

For 15-mg and 20-mg Tablets: 0.4% [sodium dodecyl sulfate](#) in *Buffer*; 900 mL

Apparatus 2: 75 rpm

Times: 15 min for 10-mg, 15-mg, and 20-mg Tablets; 20 min for 2.5-mg Tablets

Mobile phase: [Acetonitrile](#) and [water](#) (40:60)

Standard stock solution: 0.55 mg/mL of [USP Rivaroxaban RS](#) in [acetonitrile](#)

Standard solution

For 2.5-mg Tablets: 0.003 mg/mL of [USP Rivaroxaban RS](#) from the *Standard stock solution* in *Medium*

For 10-mg Tablets: 0.01 mg/mL of [USP Rivaroxaban RS](#) from the *Standard stock solution* in *Medium*

For 15-mg and 20-mg Tablets: 0.02 mg/mL of [USP Rivaroxaban RS](#) from the *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 10-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.0-mm × 6.0-cm; 3-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL for 10-mg, 15-mg, and 20-mg Tablets; 20 μL for 2.5-mg Tablets

Run time: NLT 3 times the retention time of rivaroxaban

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rivaroxaban ($C_{19}H_{18}ClN_3O_5S$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response of rivaroxaban from the *Sample solution*

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

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