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Add the following:

^Prasugrel Tablets

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DEFINITION

Prasugrel Tablets contain an amount of prasugrel hydrochloride ($C_{20}H_{20}FNO_3S \cdot HCl$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of prasugrel ($C_{20}H_{20}FNO_3S$).

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 spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Mobile phase: [Acetonitrile](#) and 0.1% [phosphoric acid](#) (30:70)

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard stock solution: 0.55 mg/mL of [USP Prasugrel Hydrochloride RS](#) in *Diluent* prepared as follows. Transfer an appropriate amount of [USP Prasugrel Hydrochloride RS](#) to a suitable volumetric flask. Add *Diluent* to about 70% of the volume of the flask and sonicate. Dilute with *Diluent* to volume.

Standard solution: 0.055 mg/mL of [USP Prasugrel Hydrochloride RS](#) from *Standard stock solution* in *Diluent*. Pass a portion of the solution through a suitable filter of 0.45- μ m pore size and use the filtrate.

Sample stock solution: Nominally equivalent to 0.5 mg/mL of prasugrel prepared as follows. Transfer Tablets (NLT 10) to an appropriate volumetric flask, add *Diluent* to about 75% of the final volume of the flask, and sonicate with intermittent shaking to disperse the Tablets completely. Continue mixing with a suitable magnetic stirrer for 30 min. Dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter of 0.45- μ m pore size and use the filtrate.

Sample solution: Nominally equivalent to 0.05 mg/mL of prasugrel from *Sample stock solution* in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 2.9 times the retention time of prasugrel

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 prasugrel ($C_{20}H_{20}FNO_3S$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$



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

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

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

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

M_{r1} = molecular weight of prasugrel, 373.44

M_{r2} = molecular weight of prasugrel hydrochloride, 409.90

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

▲Test 1▲ (RB 1-Aug-2021)

Solution A: 0.023 M [citric acid](#) prepared by dissolving 4.83 g of [citric acid](#) in 1000 mL of [water](#)

Solution B: 0.026 M [dibasic sodium phosphate anhydrous](#) prepared by dissolving 3.69 g of [dibasic sodium phosphate anhydrous](#) in 1000 mL of [water](#)

Medium: *Solution A* and *Solution B* (50:50). Adjust with *Solution A* or *Solution B* to a pH of 4.0; 900 mL

Apparatus 2: 75 rpm

Time: 20 min

Mobile phase: [Acetonitrile](#) and 0.1% [phosphoric acid](#) (30:70)

Standard stock solution: 0.3 mg/mL of [USP Prasugrel Hydrochloride RS](#) in [acetonitrile](#). Sonicate to dissolve.

Standard solution

For Tablets labeled to contain 5 mg/Tablet: 0.003 mg/mL of [USP Prasugrel Hydrochloride RS](#) prepared as follows. Dilute 4 mL of *Standard stock solution* with *Medium* to 200 mL in a suitable container and mix. Immediately dilute 5 mL of this solution with [acetonitrile](#) to 10 mL. Pass a portion of the solution through a suitable filter of 0.45-μm pore size.

For Tablets labeled to contain 10 mg/Tablet: 0.006 mg/mL of [USP Prasugrel Hydrochloride RS](#) prepared as follows. Dilute 4 mL of *Standard stock solution* with *Medium* to 100 mL in a suitable container and mix. Immediately dilute 5 mL of this solution with [acetonitrile](#) to 10 mL. Pass a portion of the solution through a suitable filter of 0.45-μm pore size.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Immediately dilute 5 mL of this solution with [acetonitrile](#) to 10 mL.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 50 μL

Run time: NLT 2.6 times the retention time of prasugrel

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 prasugrel ($C_{20}H_{20}FNO_3S$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

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

r_s = peak response of prasugrel from the *Standard solution*

C_s = concentration of [USP Prasugrel Hydrochloride RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of prasugrel, 373.44

M_{r2} = molecular weight of prasugrel hydrochloride, 409.90

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of prasugrel ($C_{20}H_{20}FNO_3S$) is dissolved.

▲ **Test 2:** If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*.

Medium: Citrate phosphate buffer pH 4.0 (Dissolve 4.63 g of [dibasic sodium phosphate dihydrate](#) and 4.83 g of [citric acid](#) in 1000 mL of [water](#). Adjust with 0.2 M [dibasic sodium phosphate dihydrate](#) or 0.1 M [citric acid monohydrate](#) to a pH of 4.0.); 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Buffer A: Dissolve 1.36 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#). Adjust with 5% [sodium hydroxide](#) solution to a pH of 6.5.

Buffer B: Dissolve 1.36 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#). Adjust with 1% [phosphoric acid](#) to a pH of 4.0.

Mobile phase: [Acetonitrile](#) and *Buffer B* (85:15)

Diluent: [Acetonitrile](#) and *Buffer A* (50:50)

Standard stock solution: 0.25 mg/mL of [USP Prasugrel Hydrochloride RS](#) in *Diluent*. Sonicate to dissolve.

Standard solution

For Tablets labeled to contain 5 mg/Tablet: 0.002 mg/mL of [USP Prasugrel Hydrochloride RS](#) prepared as follows. Dilute 5 mL of *Standard stock solution* with *Medium* to 200 mL. Dilute 5 mL of this solution with *Diluent* to 15 mL.

For Tablets labeled to contain 10 mg/Tablet: 0.004 mg/mL of [USP Prasugrel Hydrochloride RS](#) prepared as follows. Dilute 5 mL of *Standard stock solution* with *Medium* to 100 mL. Dilute 5 mL of this solution with *Diluent* to 15 mL.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size. Discard NLT 7 mL of filtrate. Immediately dilute 5 mL of this solution with *Diluent* to 15 mL.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)

Temperatures

Autosampler: 7°

Column: 40°

Flow rate: 1 mL/min

Injection volume: 50 μ L

Run time: NLT 1.5 times the retention time of prasugrel

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prasugrel ($C_{20}H_{20}FNO_3S$) dissolved:

$$\text{Result} = (r_U/r_s) \times C_s \times V \times (M_{r1}/M_{r2}) \times D \times (1/L) \times 100$$

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

r_s = peak response of prasugrel from the *Standard solution*

C_s = concentration of [USP Prasugrel Hydrochloride RS](#) in the *Standard solution* (mg/mL)