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Nateglinide Tablets

DEFINITION
Nateglinide Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of nateglinide ($C_{19}H_{27}NO_3$).

IDENTIFICATION
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**

Diluent: Acetonitrile and water (11:9)

Mobile phase: Acetonitrile and 0.05% solution of trifluoroacetic acid (23:27)

Standard solution: 0.72 mg/mL of USP Nateglinide RS prepared as follows. Transfer USP Nateglinide RS to a suitable volumetric flask, and add acetonitrile to 40% of the volume of the flask. [Note—Sonicate to dissolve.] Add water equivalent to 30% of the final volume, mix, cool the solution to room temperature, and dilute with *Diluent* to volume.

Sample solution: Place 20 Tablets into a 500-mL volumetric flask, and add 60 mL of water to disintegrate the Tablets. [Note—Sonicate with cooling, if necessary.] Add 280 mL of acetonitrile, and shake by mechanical means for at least 30 min. Dilute with *Diluent* to volume. Pass a portion through a 0.45-µm glass microfiber filter, discarding the first 10 mL of the filtrate, or use centrifugation to obtain a clear solution. Dilute an aliquot of this solution with *Diluent* to obtain a solution having a concentration of 0.72 mg/mL based on the label claim.

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

Mode: LC

Detector: UV 210 nm

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

Flow rate: 1.5 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled quantity of $C_{19}H_{27}NO_3$ in the portion of Tablets 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 the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**

Medium: 0.01 N hydrochloric acid containing 0.5% (w/v) of sodium lauryl sulfate; 1000 mL

Apparatus 2: 50 rpm

Time: 30 min

Determine the quantity of $C_{19}H_{27}NO_3$ dissolved by employing the following method.

Solution A: 6.9 mg/mL of monobasic sodium phosphate. Adjust with phosphoric acid to a pH of 2.5.

Mobile phase: Acetonitrile and *Solution A* (45:55)

Standard stock solution: 0.3 mg/mL of USP Nateglinide RS prepared as follows. Transfer USP Nateglinide RS to a suitable volumetric flask, dissolve in a small volume of acetonitrile not exceeding 5% of the final volume, and dilute with *Medium* to volume.

Standard solution: 0.12 mg/mL of USP Nateglinide RS in *Medium*, from the *Standard stock solution*

Sample solution: Pass through a suitable filter with pore size of 0.7 µm.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

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

Flow rate: 1.5 mL/min

Injection size: 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 $C_{19}H_{27}NO_3$ dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of *Medium*, 1000 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of $C_{19}H_{27}NO_3$ is dissolved.

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **USP Reference Standards ⟨11⟩**

USP Nateglinide RS

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

Topic/Question	Contact	Expert Committee
NATEGLINIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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