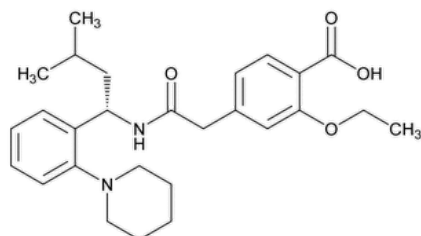


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Repaglinide



$C_{27}H_{36}N_2O_4$ 452.59

(S)-2-Ethoxy-4-[2-{methyl-1-[2-(1-piperidinyl)phenyl]butylamino}-2-oxoethyl]-benzoic acid;

(+)-2-Ethoxy- α -[[(S)- α -isobutyl-o-piperidinobenzyl]carbonyl]-p-toluic acid CAS RN[®]: 135062-02-1; UNII: 668Z8C33LU.

DEFINITION

Repaglinide contains NLT 98.0% and NMT 102.0% of repaglinide ($C_{27}H_{36}N_2O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *System suitability solution*, as obtained in the test for *Enantiomeric Purity*.

ASSAY

PROCEDURE

Buffer: 1 g/L of monobasic potassium phosphate solution, adjusted with phosphoric acid to a pH of 2.5

Mobile phase: Methanol and *Buffer* (8:2)

Standard solution: 0.5 mg/mL of [USP Repaglinide RS](#) in methanol

Sample solution: 0.5 mg/mL of Repaglinide in methanol

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm $\times$ 12.5-cm; 5- μ m packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of repaglinide ($C_{27}H_{36}N_2O_4$) in the portion of Repaglinide 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 = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Ignition temperature: 600° ± 25°

Acceptance criteria: NMT 0.1%

• ORGANIC IMPURITIES

Solution A: 3 mg/mL of monobasic potassium phosphate solution, adjusted with 1 N sodium hydroxide to a pH of 7.0

Solution B: Methanol

Identification solution: 6 mg/mL of [USP Repaglinide RS](#), 60 µg/mL of [USP Repaglinide Related Compound A RS](#), 60 µg/mL of [USP Repaglinide Related Compound B RS](#), and 60 µg/mL of [USP Repaglinide Related Compound C RS](#) in methanol

Sample solution: 6 mg/mL of Repaglinide in methanol

Standard solution: 0.06 mg/mL of repaglinide in methanol, from the *Sample solution*

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	50	50
2	30	70
8	30	70
12	5	95
15	5	95

Return to original conditions and re-equilibrate the system.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 12.5-cm; 5-µm packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 10% of repaglinide, *Standard solution*

Analysis

Samples: *Identification solution*, *Sample solution*, and *Standard solution*

Chromatograph the *Identification solution*, and identify the components on the basis of their relative retention times, given in [Table 2](#).

Calculate the percentage of each impurity in the portion of Repaglinide taken:

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

r_U = peak response of each impurity from the *Sample solution*