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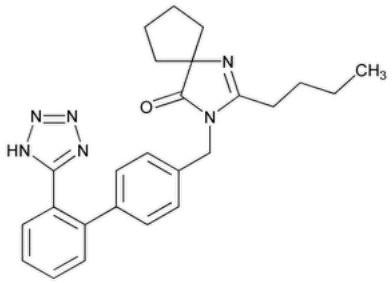
Irbesartan



$C_{25}H_{28}N_6O$ 428.53

1,3-Diazaspiro[4.4]non-1-en-4-one, 2-butyl-3-[[2'-(1*H*-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-;

2-Butyl-3-[*p*-(*o*-1*H*-tetrazol-5-ylphenyl)benzyl]-1,3-diazaspiro[4.4]non-1-en-4-one CAS RN®: 138402-11-6; UNII: J0E2756Z7N.

DEFINITION

Irbesartan contains NLT 98.0% and NMT 102.0% of irbesartan ($C_{25}H_{28}N_6O$), calculated on the anhydrous 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 *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: Phosphoric acid and water (v/v) (5.5:950). Adjust with triethylamine to a pH of 3.2.

Mobile phase: Acetonitrile and *Buffer* (330:670)

System suitability solution: 0.05 mg/mL each of USP Irbesartan RS and USP Irbesartan Related Compound A RS in methanol

Standard solution: 0.5 mg/mL of USP Irbesartan RS in methanol

Sample solution: 0.5 mg/mL of Irbesartan in methanol

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for irbesartan related compound A and irbesartan are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between irbesartan and irbesartan related compound A, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of irbesartan ($C_{25}H_{28}N_6O$) in the portion of Irbesartan taken:

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

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

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

C_S = concentration of USP Irbesartan RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• **Limit of Azide**

Mobile phase: 0.1 N sodium hydroxide solution

Standard stock solution: 0.25 mg/mL of sodium azide in *Mobile phase*

Standard solution: 0.312 µg/mL of sodium azide in *Mobile phase*, from the *Standard stock solution*

Sample solution: 20 mg/mL of Irbesartan in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Conductimetric with a suitable background suppressor unit

Column: 4.0-mm × 25-cm; L31 packing

Flow rate: 1 mL/min

Injection volume: 200 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Signal-to-noise ratio: NLT 10 for the azide peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the amount of azide, in ppm, in the portion of Irbesartan taken:

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

r_U = peak area of azide from the *Sample solution*

r_S = peak area of azide from the *Standard solution*

C_S = concentration of sodium azide in the *Standard solution* (µg/mL)

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

M_{r1} = molecular weight of azide, 42.02

M_{r2} = molecular weight of sodium azide, 65.01

F = unit conversion factor, 1000

Acceptance criteria: NMT 10 ppm

• **Organic Impurities**

Buffer and **Mobile phase:** Prepare as directed in the *Assay*.

Standard solution: Use the *System suitability solution*, prepared as directed in the *Assay*.

Sample solution: 1 mg/mL of Irbesartan in methanol

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of irbesartan related compound A in the portion of Irbesartan taken:

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

r_U = peak response of irbesartan related compound A from the *Sample solution*

r_S = peak response of irbesartan related compound A from the *Standard solution*

C_S = concentration of USP Irbesartan Related Compound A RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other impurity in the portion of Irbesartan taken:

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

r_U = peak response of any other impurity from the *Sample solution*

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

C_S = concentration of USP Irbesartan RS in the *Standard solution* (mg/mL)

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

Acceptance criteria

Irbesartan related compound A: NMT 0.2%

Any other impurity: NMT 0.1%

Total impurities: NMT 0.5%

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at a temperature below 30°.

• **USP Reference Standards ⟨11⟩**

USP Irbesartan RS

USP Irbesartan Related Compound A RS

1-Pentanoylamino-cyclopentanecarboxylic acid [2'-(1*H*-tetrazol-5-yl)-biphenyl-4-ylmethyl]-amide.

$C_{25}H_{30}N_6O_2$ 446.54

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

Topic/Question	Contact	Expert Committee
IRBESARTAN	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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