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Irbesartan Tablets

DEFINITION
Irbesartan Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of irbesartan ($C_{25}H_{28}N_6O$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Sample: Add 10 mL of methanol to 1 Tablet, and sonicate for 10 min. Pass the solution through a glass microfiber membrane filter of 0.45-µm pore size. Evaporate to dryness, using a stream of nitrogen. Mix approximately 1 mg of the residue and approximately 250 mg of potassium bromide to obtain a homogenous mixture.

Acceptance criteria: The IR absorption spectrum of the *Sample* exhibits maxima only at the same wavelengths as that of a similarly prepared standard using USP Irbesartan RS.

• **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: Dilute 5.5 mL of phosphoric acid in approximately 950 mL of water. Adjust by adding triethylamine, slowly and dropwise, to a pH of 3.0, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (400:600)

System suitability solution: 0.1 mg/mL each of USP Irbesartan RS and USP Irbesartan Related Compound A RS in methanol

Standard solution: 0.15 mg/mL of USP Irbesartan RS in methanol

Sample solution: Nominally 0.15 mg/mL of irbesartan in methanol prepared as follows. To a suitable amount of irbesartan from NLT 5 powdered Tablets add methanol to fill about 75% of the volume of the flask. Sonicate for 15 min, stirring at 5-min intervals. Dilute with methanol to volume, and pass through a glass microfiber membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 15 µL

System suitability

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

Suitability requirements

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

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of irbesartan ($C_{25}H_{28}N_6O$) in the portion of Tablets 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 = nominal concentration of irbesartan in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 1000 mL

Apparatus 2: 50 rpm

Time: 20 min

Standard solution: USP Irbesartan RS in *Medium*

Sample solution: Sample per *Dissolution* ⟨711⟩. Pass the *Sample solution* through a suitable acrylic copolymer on a nylon support filter[1] of 0.45-µm pore size, and dilute with *Medium*, if necessary, to a concentration that is similar to the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: 244 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of irbesartan ($C_{25}H_{28}N_6O$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of irbesartan from the *Sample solution*

A_S = absorbance of irbesartan from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 1000 mL

Tolerances: NLT 80% (Q) of the labeled amount of irbesartan ($C_{25}H_{28}N_6O$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Buffer, Mobile phase, System suitability solution, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

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

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity

r_T = sum of the responses of all the peaks

Acceptance criteria

Irbesartan related compound A: NMT 0.2%

Any other impurity: NMT 0.2%

Total impurities: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **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

[1] A suitable filter is Acrodisc, manufactured by Gelman Sciences and distributed by Pall Corp. (www.pall.com).

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

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

Chromatographic Database Information: Chromatographic Database

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