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# Candesartan Cilexetil Tablets

**DEFINITION**

Candesartan Cilexetil Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of candesartan cilexetil (C<sub>33</sub>H<sub>34</sub>N<sub>6</sub>O<sub>6</sub>).

**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 absorption spectra of the major peak of the *Sample solution* exhibit maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the Assay.

**ASSAY**

**Change to read:**

• **PROCEDURE**

**Mobile phase:** ▲[Acetonitrile](#) and [water](#) (55:45). To each liter, add 1.0 mL of [trifluoroacetic acid](#). ▲ (USP 1-Dec-2022)

**Diluent:** [Acetonitrile](#) and [water](#) (70:30)

**Standard solution:** 0.8 mg/mL of [USP Candesartan Cilexetil RS](#) in *Diluent*. Sonication may be necessary for complete dissolution. ▲ (USP 1-Dec-2022)

**Sample solution:** Nominally 0.8 mg/mL of candesartan cilexetil in *Diluent* prepared as follows. Transfer a number of Tablets (see [Table 1](#)) to a suitable volumetric flask.

Table 1

| Tablet Strength<br>(mg) | Number of<br>Tablets<br>(NLT) |
|-------------------------|-------------------------------|
| 4                       | 10                            |
| 8                       | 10                            |
| 16                      | 5                             |
| 32                      | 5                             |

Add *Diluent* to about 70% of the total volume and sonicate for about 25 min with intermittent shaking. Allow to cool and dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 282 nm. For *Identification B*, use a diode array detector ▲ in the range of 210–400 nm. ▲ (USP 1-Dec-2022)

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

**Column temperature:** 30°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

**Run time:** NLT 2.7 times the retention time of candesartan cilexetil

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT ▲1.0% ▲ (USP 1-Dec-2022)

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of candesartan cilexetil ( $C_{33}H_{34}N_6O_6$ ) in the portion of Tablets taken:

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

$r_U$  = peak response ▲ of candesartan cilexetil ▲ (USP 1-Dec-2022) from the *Sample solution*

$r_S$  = peak response ▲ of candesartan cilexetil ▲ (USP 1-Dec-2022) from the *Standard solution*

$C_S$  = concentration of [USP Candesartan Cilexetil RS](#) in the *Standard solution* (mg/mL)

$C_U$  = nominal concentration of candesartan cilexetil in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

**Change to read:**

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

### Medium

**For Tablets labeled to contain 4, 8, or 16 mg:** 0.35% [polysorbate 20](#) in 0.05 M phosphate buffer, pH 6.5 ▲ (dissolve 6.8 g of [potassium phosphate, monobasic](#) in a suitable container containing 500 mL of [water](#); add 3.5 mL of [polysorbate 20](#) and dilute with [water](#) to 1 L; adjust with 2 N sodium hydroxide solution to a pH of 6.5); ▲ (USP 1-Dec-2022) 900 mL

**For Tablets labeled to contain 32 mg:** 0.70% [polysorbate 20](#) in 0.05 M phosphate buffer, pH 6.5 ▲ (dissolve 6.8 g of [potassium phosphate, monobasic](#) in a suitable container containing 500 mL of [water](#); add 7.0 mL of [polysorbate 20](#) and dilute with [water](#) to 1 L; adjust with 2 N sodium hydroxide solution to a pH of 6.5); ▲ (USP 1-Dec-2022) 900 mL

**Apparatus 2:** 50 rpm

**Time:** 45 min

**Mobile phase:** ▲ [Acetonitrile](#) and [water](#) (55:45). To each liter, add 1.0 mL of [trifluoroacetic acid](#). ▲ (USP 1-Dec-2022)

**Standard stock solution:** 0.45 mg/mL of [USP Candesartan Cilexetil RS](#) in [acetonitrile](#). Sonication may be necessary for complete dissolution.

**Standard solution:** ▲ (L/900) mg/mL of [USP Candesartan Cilexetil RS](#) from the *Standard stock solution* in *Medium*, where L is the label claim in mg/Tablet ▲ (USP 1-Dec-2022)

**Sample solution:** Pass a portion of solution under test through a suitable filter of 0.45-μm pore size.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 254 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 1.8 times the retention time of candesartan cilexetil

### 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 candesartan cilexetil ( $C_{33}H_{34}N_6O_6$ ) dissolved:

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

$r_U$  = peak response ▲ of candesartan cilexetil ▲ (USP 1-Dec-2022) from the *Sample solution*

$r_S$  = peak response ▲ of candesartan cilexetil ▲ (USP 1-Dec-2022) from the *Standard solution*

$C_S$  = concentration of ▲ [USP Candesartan Cilexetil RS](#) in ▲ (USP 1-Dec-2022) the *Standard solution* (mg/mL)

$V$  = volume of *Medium*, 900 mL

$L$  = label claim (mg/Tablet)

**Tolerances:** NLT 80% (Q) of the labeled amount of candesartan cilexetil ( $C_{33}H_{34}N_6O_6$ ) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements