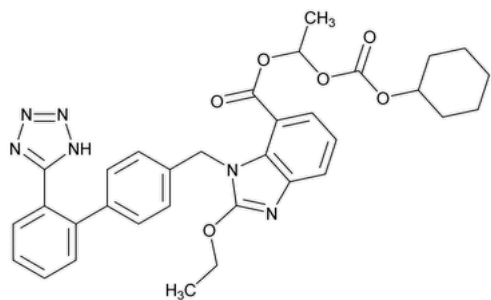


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Candesartan Cilexetil

Change to read:



$C_{33}H_{34}N_6O_6$ Δ 610.67 Δ (USP 1-Dec-2022)
1*H*-Benzimidazole-7-carboxylic acid, 2-ethoxy-1-[[2'-(1*H*-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-, 1-[[[(cyclohexyloxy)carbonyl]oxy]ethyl ester, (±); (±)-1-Hydroxyethyl 2-ethoxy-1-[*p*-(*o*-1*H*-tetrazol-5-ylphenyl)benzyl]-7-benzimidazolecarboxylate, cyclohexyl carbonate (ester);
 Δ 1-Cyclohexyloxy carbonyloxyethyl 2-ethoxy-1-[[2'-(1*H*-tetrazol-5-yl)biphenyl-4-yl]methyl]benzimidazole-7-carboxylate Δ (USP 1-Dec-2022) CAS
RN[®]: 145040-37-5; UNII: R85M2X0D68.

Change to read:

DEFINITION

Candesartan Cilexetil contains NLT Δ 98.0% Δ (USP 1-Dec-2022) and NMT Δ 102.0% Δ (USP 1-Dec-2022) of candesartan cilexetil ($C_{33}H_{34}N_6O_6$), calculated on anhydrous basis.

IDENTIFICATION

Change to read:

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** Δ 197A or Δ (USP 1-Dec-2022) 197K. If the spectra obtained show differences, proceed with the samples prepared as follows. Separately dissolve a quantity of [USP Candesartan Cilexetil RS](#) and Candesartan Cilexetil in [alcohol](#). [NOTE—Heating the solution may be necessary for complete dissolution.] Cool the solution in an ice bath, filter the crystals, and dry at 105°.

Change to read:

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Δ Assay. Δ (USP 1-Dec-2022)

ASSAY

Change to read:

PROCEDURE

Δ **Solution A:** [Acetonitrile](#) and [water](#) (57:43). To each liter, add 10 mL of [glacial acetic acid](#).
Solution B: [Acetonitrile](#) and [water](#) (90:10). To each liter, add 10 mL of [glacial acetic acid](#).
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
3	100	0
33	0	100
33.1	100	0

Diluent: Acetonitrile and water (60:40)	
Standard solution: 0.04 mg/mL of USP Candesartan Cilexetil RS in <i>Diluent</i> . Sonicate as necessary.	0
Sample solution: 0.04 mg/mL of Candesartan Cilexetil in <i>Diluent</i> . Sonicate as necessary.	

Chromatographic system(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 254 nm**Column:** 3.9-mm × 15-cm; 4-μm packing [L1](#)**Flow rate:** 0.8 mL/min**Injection volume:** 10 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of candesartan cilexetil ($C_{33}H_{34}N_6O_6$) in the portion of Candesartan Cilexetil taken:

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

 r_U = peak response of candesartan cilexetil from the *Sample solution* r_S = peak response of candesartan cilexetil from the *Standard solution* C_S = concentration of [USP Candesartan Cilexetil RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Candesartan Cilexetil in the *Sample solution* (mg/mL) ▲ (USP 1-Dec-2022)**Acceptance criteria:** ▲98.0%–102.0%▲ (USP 1-Dec-2022) on the anhydrous basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#)**Sample:** 1 g**Acceptance criteria:** NMT 0.1%**Change to read:**• **ORGANIC IMPURITIES****▲Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system:** Proceed as directed in the Assay.▲ (USP 1-Dec-2022)**System suitability solution:** ▲0.4 mg/mL of [USP Candesartan Cilexetil RS](#), and 0.4 μg/mL each of [USP Candesartan Cilexetil Related Compound A RS](#), [USP Candesartan Cilexetil Related Compound B RS](#), [USP Candesartan Cilexetil Related Compound D RS](#), [USP Candesartan Cilexetil Related Compound F RS](#), and [USP Candesartan Cilexetil Related Compound G RS](#) in *Diluent*▲ (USP 1-Dec-2022)**Standard solution:** ▲0.4 μg/mL▲ (USP 1-Dec-2022) of [USP Candesartan Cilexetil RS](#) in *Diluent***▲Sensitivity solution:** 0.2 μg/mL of [USP Candesartan Cilexetil RS](#) in *Diluent*, from *Standard solution*▲ (USP 1-Dec-2022)**Sample solution:** 0.4 mg/mL of Candesartan Cilexetil in *Diluent*

▲▲ (USP 1-Dec-2022)

System suitability▲▲ (USP 1-Dec-2022)**Samples:** *System suitability solution*, ▲*Standard solution*, and *Sensitivity solution*[NOTE—See [Table 2](#) for the relative retention times.]▲ (USP 1-Dec-2022)**Suitability requirements****Resolution:** ▲NLT 4.0 between candesartan cilexetil related compound A and candesartan cilexetil related compound B; NLT 2.0 between candesartan cilexetil and candesartan cilexetil related compound D, *System suitability solution*▲ (USP 1-Dec-2022)**Tailing factor:** NMT 1.5 for candesartan cilexetil, ▲*Standard solution*▲ (USP 1-Dec-2022)**Relative standard deviation:** NMT ▲5.0%▲ (USP 1-Dec-2022) for candesartan cilexetil, ▲*Standard solution***Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲ (USP 1-Dec-2022)**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of ▲any specified and unspecified▲ (USP 1-Dec-2022) impurity in the portion of Candesartan Cilexetil taken: