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Recent Advances in Analytical Method Development for Candesartan Cilexetil: A Review

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Abstract:

Candesartan cilexetil is an angiotensin II receptor blocker commonly prescribed for the management of hypertension. Accurate and reliable analytical methods are essential to ensure its quality, safety, and efficacy in pharmaceutical formulations. Various analytical techniques, including spectrophotometric and chromatographic methods, have been reported for the estimation of candesartan cilexetil. This article provides a concise overview of hypertension, antihypertensive therapy, candesartan cilexetil, general analytical methods, and a summarized literature review of reported analytical techniques. The review highlights the diversity of existing methods and emphasizes the importance of systematic and reliable analytical approaches for routine quality control.

Keywords: Candesartan cilexetil; Hypertension; Antihypertensive drugs; Analytical methods; Literature review; Pharmaceutical analysis

1. General Introduction of Hypertension and Anti - Hypertensives

Hypertension is a chronic medical condition in which the arterial blood pressure remains persistently elevated above **140/90 mmHg**. It is often asymptomatic but significantly increases the risk of heart disease, stroke, and kidney failure. Common contributing factors include age, genetics, obesity, sedentary lifestyle, excess salt intake, and alcohol consumption. Blood pressure is expressed as **systolic/diastolic** values, and consistent elevation on multiple readings confirms the diagnosis.

Hypertension is broadly classified into:

1. **Primary (Essential) Hypertension** – Most common type; develops gradually and is linked to lifestyle and genetic factors.
2. **Secondary Hypertension** – Caused by underlying conditions such as renal disorders, endocrine abnormalities, or certain medications.

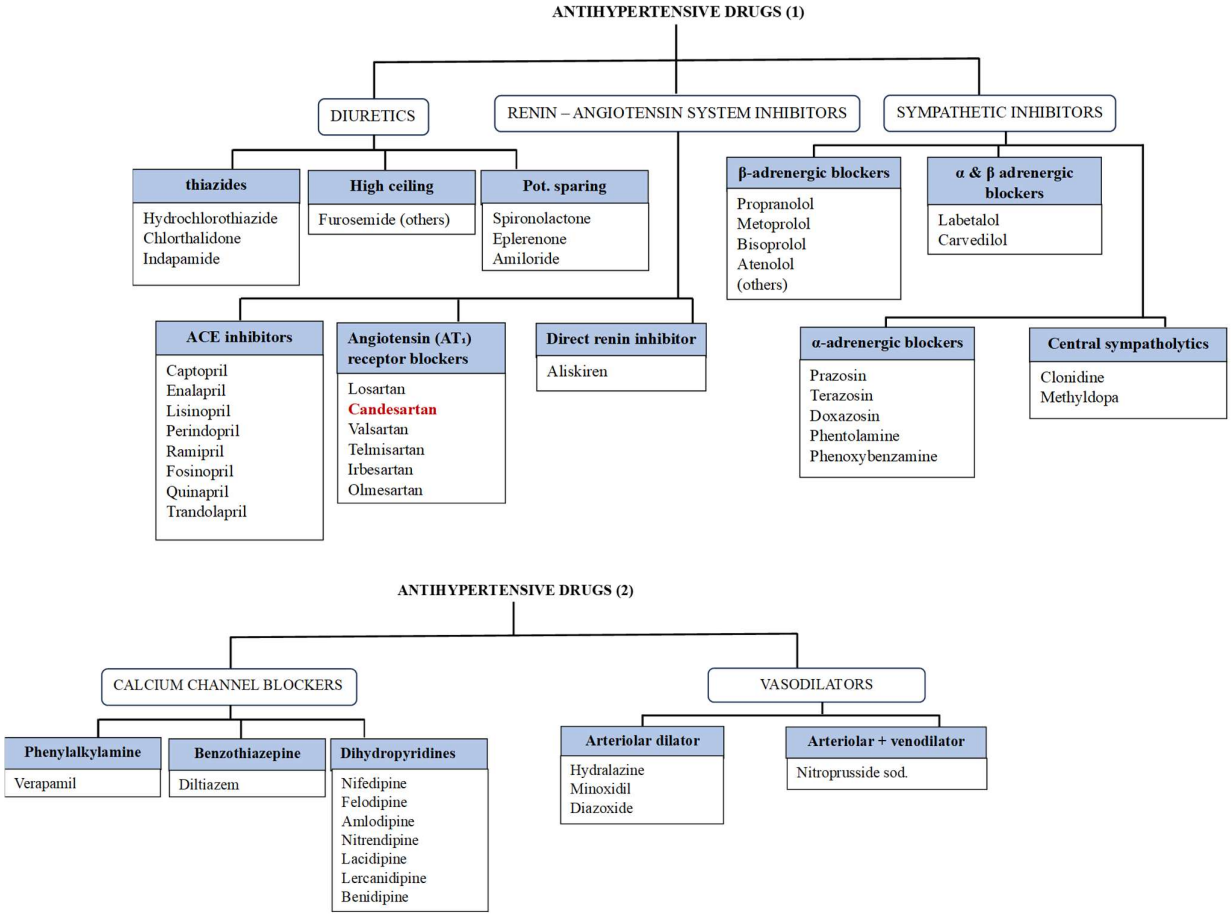
Pattern-based classifications include:

- **White-coat hypertension** – High in clinic, normal at home
- **Masked hypertension** – Normal in clinic, high at home
- **Sustained hypertension** – High in all settings
- **Nocturnal hypertension** – Elevated blood pressure during sleep

General Introduction of Antihypertensives:

Antihypertensive drugs lower elevated blood pressure by relaxing blood vessels, reducing blood volume, or blocking vasoconstrictor hormones. Therapy is individualized based on patient factors and disease severity, and many patients require combination treatment. These medications help prevent serious complications such as heart attack, stroke, and renal damage. Most antihypertensives are taken orally as daily tablets.

Classification of Antihypertensives



Introduction of Candesartan Cilexetil

Candesartan cilexetil is a white to off-white ester prodrug that is rapidly converted in the gastrointestinal tract to its active form, **candesartan**, an Angiotensin II Receptor Blocker (ARB). It is widely used for the management of **hypertension and heart failure**, administered once daily in strengths of 8 mg, 16 mg, or 32 mg. Candesartan is a highly selective AT_1 receptor blocker with no agonist activity, offering effective and well-tolerated blood pressure control. It is marketed globally under brands such as **Atacand®, Blopress®, and Amias®**, including fixed-dose combinations with hydrochlorothiazide.

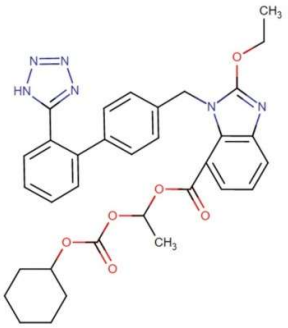


Figure 1. Structure of Candesartan cilexetil

History

Candesartan cilexetil was first approved by the **FDA on June 4, 1998** for adult hypertension. In **October 2009**, it was additionally approved for treating hypertension in children ≥12 months. The drug was originally developed by **Astra Merck Inc.** (later AstraZeneca) and is registered under **NDA 20-838**.

Mechanism of Action

Candesartan cilexetil is an inactive prodrug that is converted by esterases to candesartan, its active metabolite. Candesartan selectively blocks the angiotensin II type-1 (AT_1) receptors, preventing the vasoconstrictor and aldosterone-secreting effects of angiotensin II. This results in vasodilation, reduced peripheral resistance, lowered blood pressure, and protection against hypertensive complications.

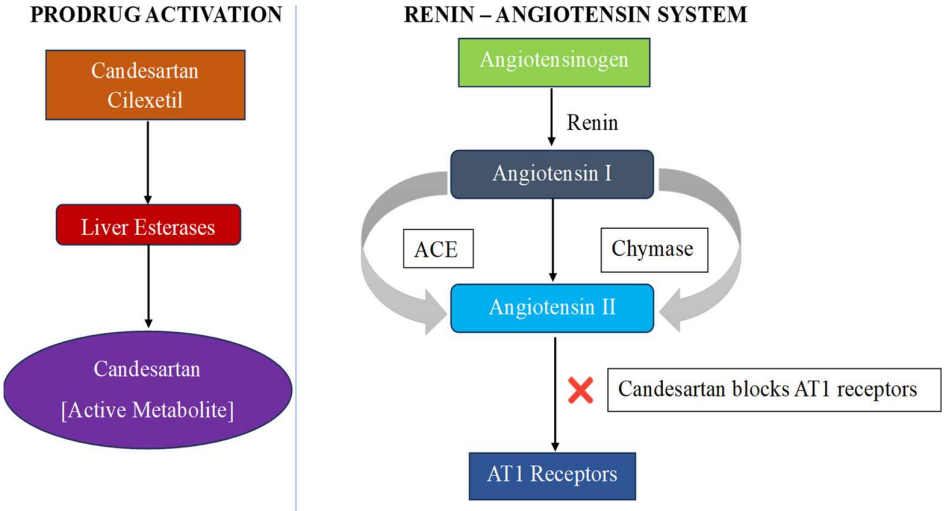


Figure 2: Mechanism of Candesartan cilexetil

2. LITERATURE REVIEW OF CANDESARTAN CILEXETIL

Table 3.1. Official method for Candesartan cilexetil:

Sr. No.	Official in	Method	Description	Reference No.
1.	IP (2022)	**Liquid Chromatography** (API)	**Stationary phase:** A stainless steel column (150 x 3.9 mm) packed with octadecylsilane bonded to porous silica (4 µm). **Mobile phase:** Acetonitrile : Glacial acetic acid : Water (57:1:43 %v/v/v) **Flow rate:** 0.8 mL/min. **Wavelength:** 254 nm	18

Table 3.2. Reported method for Candesartan Cilexetil :

Sr. No.	Method/Title	Description	Ref. No.
UV VISIBLE SPECTROSCOPY			
1	Stress Degradation Studies on Candesartan Cilexetil Bulk Drug and Development of Validated Method By **UV Spectrophotometry** In Marketed Tablet	**Model:** Shimadzu UV-1601 double-beam UV/VIS Spectrophotometer **Solvent:** Methanol **Wavelength:** 253nm **Linearity:** 2- 25 µg/mL	19

2	Development and Validation of a Stability-indicating **UV Spectroscopic** Method for Candesartan in Bulk and Formulations	**Model:** Shimadzu model 1700 UV–VIS Spectrophotometer **Solvent:** Methanol : water (9:1 % v/v) **Wavelength:** 254 nm **Linearity:** 10–90 µg/mL	20
3	Validated **UV spectrophotometric** method for quantitative determination of Candesartan cilexetil in bulk and pharmaceutical dosage form	**Model:** ELICO Double beam SL 210 UV-VIS spectrophotometer **Solvent:** Methanol **Wavelength:** 258 nm **Linearity:** 10–50 µg/mL	21
4	**UV Spectrophotometric** method for the estimation of candesartan cilexetil in bulk and pharmaceutical dosage form	**Model:** ELICO UV/Visible spectrophotometer **Solvent:** Isopropyl alcohol **Wavelength:** 306 nm **Linearity:** 10-90 µg/mL	22
5	A validated ultra **high-pressure liquid Chromatography method** for separation of candesartan cilexetil impurities and its Degradents in drug product.	**Stationary phase:** BEH Shield™ RP-18 UPLC column (Waters Acquity UPLC system) **Mobile phase:** Mobile Phase A: 0.01 M phosphate buffer (pH 3.0, adjusted with orthophosphoric acid) Mobile Phase B: 95% acetonitrile + 5% water **Flow rate:** 0.35 mL/min **Wavelength:** 254 nm (impurities), 210 nm (trityl alcohol and MTE impurity)	23

6	Development and validation of the **liquid chromatography**-tandem mass spectrometry method for quantitative estimation of candesartan from human plasma	**Stationary phase:** Betasil C_8 column (100 × 2.1 mm, 5 µm) **Mobile phase:** Methanol : ammonium trifluoroacetate buffer with formic acid (60:40 %v/v) **Flow rate:** 0.45 mL/min	24
7	A Stability Indicating **UPLC Method** for Candesartan in Bulk Drug Samples	**Stationary phase:** Zorbax Extended C_{18} (50 × 4.6 mm, 1.8 µm) **Mobile phase:** Mobile Phase A: 0.1% triethylamine in water (pH 2.2, TFA) Mobile Phase B: 0.1% TFA in acetonitrile : water (95:5 %v/v), **Flow rate:** 0.4 mL/min **Wavelength:** 210 nm	25
8	Development and Validation of Simplified **RP-HPLC Method** for Quantification of Candesartan Cilexetil in Commercial Formulations	**Stationary phase:** Zorbax SB C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile : 0.1% orthophosphoric acid (pH 2.5) in (35:65 %v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 258 nm	26
9	Development and validation of a dissolution test with reversed-phase **high performance liquid Chromatographic** analysis for Candesartan cilexetil in tablet dosage forms	**Stationary phase:** Agilent Zorbax C_8 column (150 × 4.6 mm, 5 µm) **Mobile phase:** Phosphate buffer (pH 2.5) : Acetonitrile (15:85 %v/v) **Flow rate:** 1.0 mL/min	27

		Wavelength: 215 nm	
10	**RP-HPLC Method** Development and Validation of candesartan cilexetil in bulk and their pharmaceutical dosage forms	**Stationary phase:** Hypersil ODS C_{18} (250 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile : 0.05 M KH_2PO_4 buffer (65:35 %v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 254 nm	28
11	Response surface based optimization of system variables for **liquid Chromatographic** analysis of candesartan cilexetil.	**Stationary phase:** C_{18} column (250 x 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile : water (0.05% O-phosphoric acid) with an optimized concentration of 80% acetonitrile (v/v) in water (0.05% OPA) **Flow rate:** 0.8 mL/min **Wavelength:** 255 nm	29
12	Development and validation of **HPLC method** for the determination of Candesartan in human plasma.	**Stationary phase:** C_{18} HPLC column **Mobile phase:** 0.02M Phosphoric acid Buffer : acetonitrile (50:50 % v/v) **Flow rate:** 1.1 mL/min **Wavelength:** Fluorescence detector excitation at 248 nm and emission at 392 nm (Fluorescence detection)	30
HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY			

13	**HPTLC–Densitometric** Analysis of Candesartan Cilexetil and Hydrochlorothiazide in Tablets	**Stationary phase:** Silica gel 60 F_{254} plates **Mobile phase:** Ethyl acetate : chloroform : acetone : methanol (3:3:3:0.5 % v/v) **Wavelength:** 280 nm	31

3. CONCLUSION

Candesartan cilexetil is an important antihypertensive agent that requires accurate analytical methods for its quality assessment in bulk drug and pharmaceutical dosage forms. A wide range of spectrophotometric and chromatographic methods have been reported in the literature, demonstrating different analytical approaches for its estimation. The reviewed studies indicate continuous efforts toward developing reliable and sensitive methods suitable for routine analysis. This article presents a concise theoretical overview and literature summary, providing a strong foundation for future analytical method development and experimental studies.

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