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UV SPECTROPHOTOMETRIC DETERMINATION OF CANDESARTAN CILEXETIL IN BULK DRUG

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ABSTRACT

Candesartan Cilexetil (Candesartan) is a medication utilized for the treatment of Hypertension. It is in a class of medication containing angiotensin receptor blocker (ARB). The main objective of the present work is to determine a simple, precise and cost effective UV Spectrophotometric The wavelength of Candesartan Cilexetil using UV Spectrophotometric was detected at 246nm in Acetonitrile and it obeys Beer's law in a concentration range of 4-24µg/ml with a correlation coefficient of 0.999. This method was validated for linearity, accuracy, precision, limit of detection, limit of quantification. The %RSD was found to be <2.0% in all cases and all the validation parameters were found to be within the limits. The proposed methods were suitable for the quantitative determination of Candesartan Cilexetil in bulk drug.

KEYWORDS: Candesartan Cilexetil, UV Spectrophotometer, Acetonitrile, Validation.

INTRODUCTION

Uv Spectrophotometer

UV/Visible Spectrophotometer is an important instrument in analytical chemistry. This technique deals with the study of interaction between electromagnetic radiation and matter.[1] This method is widely used in pharmaceutical analysis for quantitative, qualitative and structural analysis of a substance in solution.[2,3,6]

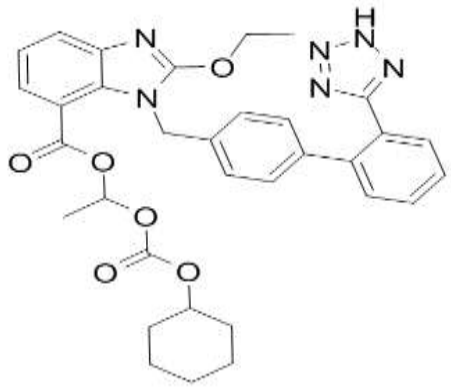
Beer-Lambert's law is the quantitative law which governs spectrophotometric analysis.

Beer-Lambert's law: When a beam of monochromatic light is permitted to pass through a translucent cell containing absorbing medium or material then it is directly proportional to the concentration of the material and the path length of the light through the solution.[4]
Scientifically it is expressed as,

$$A=act$$

Where,
A = Absorbance or optical density
a = Absorptivity (litre.gm^{-1}.cm^{-1})
c = Concentration (gm.lt^{-1})
t = Path length or thickness (1cm)

CANDESARTAN CILEXETIL



Candesartan cilexetil (candesartan) is a medication utilized for treating hypertension. It is an angiotensive receptor blocker (ARB) prodrug which swiftly converts to candesartan (active metabolite), through absorption from the gastrointestinal tract.[7]

Candesartan Cilexetil, chemically, 1-cyclohexyloxycarbonyloxyethyl2-ethoxy-3-[[4-[2-(2H-tetrazol-5-yl) phenyl] methyl] benzimidazole-4-carboxylate. It is also used to treat Congestive Heart Failure, First Line Agent to Delay Progression of Diabetic Nephropathy.[8] It is fine white powder and freely Soluble in Methanol, Acetonitrile and Acetone. Several methods have been developed for determination of candesartan cilexetil in pharmaceutical preparation by UV Spectrophotometry, HPTLC and HPLC.[9,10] The

proposed methods were validated in accordance with USP and as per ICH guidelines.

MATERIALS AND METHODS

Materials: Candesartan cilexetil was procured as a gift sample from Mylan Laboratories, Hyderabad, India. Acetonitrile (Qualigens) was used.

Instruments[5]: UV Spectrophotometer (Shimadzu, Pharmaspec1700), Digital pH meter and Digital weighing balance (MettlerToledo), Volumetric flask, Pipettes and burettes, Beakers (Borosil), Digital ultra sonicator (Fast clean).

VALIDATION

1. **Solvent used:** Acetonitrile
2. **Preparation of standard stock solution:** Pure candesartan cilexetil 10mg was accurately weighed and dissolved in 6ml of Acetonitrile in 10ml clean, dry volumetric flask and allowed to sonicate. Finally make up the volume with Acetonitrile.

Selection of Analytical Wavelength

From the standard stock solution, a mixture of dilutions ranging between 4-24µg/ml were prepared and scanned within the wavelength range of 400-200nm on spectrum mode, using diluent as blank. Candesartan Cilexetil shows λ_{max} at 246nm.

Selection of Analytical Concentration Range and Preparation of Calibration Curve

Appropriate aliquots were pipette out from the standard stock solution into a sequence of 10ml volumetric flask. The volume was made up to the mark with acetonitrile to get a set of solutions having the concentrations 4.8,12,16,20,24µg/ml and the absorbance was determined for the above concentrations at 246nm. A calibration curve was plotted against concentration. The drug obeys Beer-Lambert's law in the concentration range of 4-24µg/ml and the correlation coefficient was determined.

Precision

The prepared stock solution was consequently diluted to 12µg/ml and the absorbance was measured at 246nm using UV spectrophotometer against blank (acetonitrile). The method was analyzed on different days and the results were tabulated.

Accuracy (Recovery Studies)

The recovery studies were carried out in triplicate form as per the test method to acquire the concentration of drug equivalent to 50%, 100%, 150%. The average % recovery was calculated.

RESULTS AND DISCUSSION

Selection of Wave Length

Scan standard solution in UV spectrophotometer between 200 nm to 400 nm on spectrum mode, using diluent as a blank. Candesartan cilexetil shows λ_{max} at 246nm.

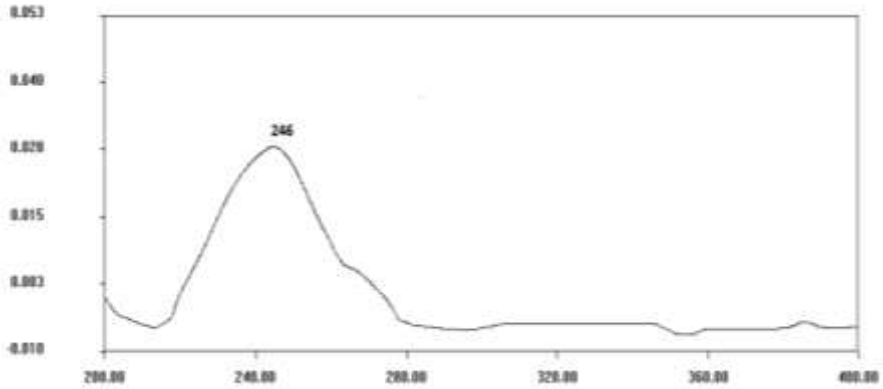


Fig. 1: Wavelength of Candesartan Cilexetil Optical Characteristic of Candesartan Cilexetil with Acetonitrile.

Table-1: Optical Characteristics by Candesartan Cilexetil.

Parameter	UV method
λmax (nm)	246
Beer's law range (µg/ml)	4-24
Molar Extinction Coefficient	0.02
Slope	0.027
Intercept	0.001
Correlation Coefficient	0.999
LOD(µg/ml)	0.048
LOQ(µg/ml)	0.148

Linearity

Table-2: Linearity Data of Candesartan.

S.No	Concentration (mcg/ml)	Absorbance
1	0	0
2	4	0.111
3	8	0.220
4	12	0.335
5	16	0.442
6	20	0.551
7	24	0.660

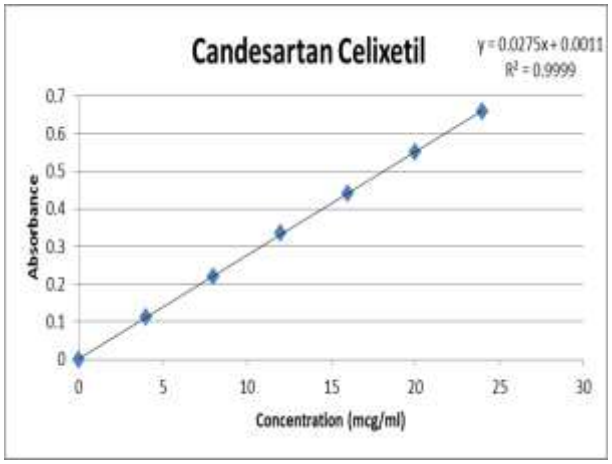


Fig. 2: Calibration Graph of Candesartan.

Linearity plot

The plot of concentration(X) versus the average peak area(Y) data of candesartan cilexetil is a straight line.

$$Y = m x + c$$

Slope (m) = 0.027
Intercept (Y) = 0.001
Correlation coefficient (r) = 0.999

Precision

Precision was performed on intra-day and inter-day and % assay was determined.

Table-3: Data Regarding Precision.

Sample No.	%Assay	
SET	**Intraday**	**Interday**
1	101.54	100.92
2	101.54	100.61
3	101.23	100.92
4	101.23	100.92
5	100.92	100.92
Mean	101.29	100.86
SD	0.259	0.138
%RSD	0.255	0.136

Accuracy

The recovery studies were calculated for different set of concentrations such as 50%, 100%, 150%. The average % recovery was calculated.

Table-4: Data Regarding Accuracy.

Concentration	Sample Added	Amount Found	% Recovery	Statistical Analysis
50	8	8.07	100.87	Mean-101.04 %RSD-0.290
	8	8.11	101.38	
	8	8.07	100.87	
100	12	12.11	100.92	Mean-100.89 %RSD-0.05
	12	12.10	100.83	
	12	12.11	100.92	
150	16	16.25	101.56	Mean-101.35 %RSD-0.217
	16	16.22	101.37	
	16	16.18	101.12	

CONCLUSION

In the present investigation, a simple, sensitive, precise and accurate UV Spectrophotometry method was developed for Candesartan Cilexetil in bulk drug. The solvent system used in this method was economical. The %RSD values were within 2.0% and the methods were found to be precise. This method can be used for the routine quantitative determination of Candesartan Cilexetil in bulk drug.

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