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Development and Estimation of Carvedilol Tablet in Oral Dosage form Using HPLC Method

Shinde Rutuja Rajendra[1], Dawkar Akshata Krishnakumar[2], Bansode Dipti Datta[3], Sukale Pramit Shitalkumar[4], Mr. Kute C.G.[5]
[1],[2],[3],[4] Students[5] & Guide[5] *(M. Pharma Pharmaceutics)*
Aditya Pharmacy College, Beed
Dr. Babasaheb Ambedkar Technological University, Lonere

Abstract: *Introduction: Analytical chemistry is the study of the separation, identification, and quantification of the chemical components of natural and artificial materials. It deals with methods for determining the chemical composition of samples of matter. Materials and Methods: Chemicals and standards used as a material and methods to performing the task. Many trials were performed. Results: The present investigation reported in the thesis was aimed to develop a new method development and validation for the estimation of carvedilol by reversed-phase high-performance liquid chromatography (RP-HPLC) method. The literature reveals that there are no analytical methods reported for the estimation carvedilol by RP-HPLC method. Hence, it was felt that there is a need of new analytical method development for the estimation of carvedilol in pharmaceutical dosage form. Conclusion: A new method was established for estimation of Carvedilol by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Carvedilol using Phenomenex C18 column (4.6 × 150 mm) 5 µ, flow rate was 1.0 ml/min, mobile phase ratio was pH 3.4 Phosphate: meoH (65:35% v/v), and detection wavelength was 284 nm.*

Keywords: Carvedilol, Chromatography, Reversed-phase high-performance liquid chromatography

I. INTRODUCTION

Analytical chemistry is the study of the separation, identification, and quantification of the chemical components of natural and artificial materials. It deals with methods for determining the chemical composition of samples of matter. A Qualitative Method yields information about the identity of atomic or molecular species or the functional groups in the sample. A Quantitative Method, in contrast, provides numerical information as to the relative amount of one or more of these components. Pharmaceutical analysis may be defined as a process or a sequence of processes to identify and/or quantify a substance or drug, the components of a pharmaceutical solution or mixture or the determination of the structures of chemical compounds used in the formulation of pharmaceutical product. Analytical procedure refers to the way of performing the analysis. It should describe in detail the steps necessary to perform each analytical test. This may include but is not limited to: The sample, the reference standard and the reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, etc. The Table 1 lists the names of instrumental methods that are based upon various analytical signals.

II. CHROMATOGRAPHY

Chromatography is a technique, in which the components of a mixture are separated based on the rates at which they are carried through a stationary phase by a gaseous or liquid mobile phase. Chromatography involves two phases chosen such that the components of the sample have differing affinities in each phase and a sample (or sample extract) being dissolved in a mobile phase (which may be a gas, a liquid or a supercritical fluid). The mobile phase is then forced through the stationary phase. A component with high affinity toward the stationary phase will take longer to travel through it than a component with low affinity toward the stationary phase and high affinity toward the mobile

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phase. As a result of these differences in mobilities, sample components will become separated from each other as they travel through the stationary phase [Table 2].[1-10]

III. HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

HPLC also known as high-pressure or high-price or high-speed liquid chromatography, HPLC is a

Table 1: Classification of instrumental methods based on various analytical signals

Signal	Instrumental Methods
Emission of radiation	Emission spectroscopy (X-ray, UV, visible, electron, Auger); fluorescence, phosphorescence, and luminescence
Absorption of radiation	Spectrophotometry and photometry (X-ray, UV, visible, IR); photoacoustic spectroscopy; nuclear magnetic resonance; electron spin resonance spectroscopy
Scattering of radiation	Turbidimetry; nephelometry; and Raman spectroscopy
Refraction of radiation	Refractometry and interferometry
Diffraction of radiation	X-ray and electron diffraction methods
Rotation of radiation	Polarimetry; optical rotary dispersion; and circular dichroism
Electrical potential	Potentiometry and chronopotentiometry
Electrical charge	Coulometry
Electrical current	Polarography and amperometry
Electrical resistance	Conductometry
Mass-to-charge ratio	Mass spectrometry
Thermal properties	Thermal conductivity and enthalpy
Radioactivity	Activation and isotope dilution methods

Form of column chromatography used frequently in analytical chemistry and biochemistry to identify, separate, and quantify compounds. It is a powerful tool in analysis. It is basically an improved form of column chromatography

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which has been optimized to provide rapid high resolution separations. Early LC used gravity fed open tubular columns with particles 100 s of microns in size; the human eye was used for a detector and separations often took hours or even days to develop. HPLC as compared with the classical technique is characterized by:

- Small diameter (2–5 mm), reusable stainless steel columns without repacking and regeneration
- Column packings with very small (3, 5, and 10 µm) particles and the continual development of new substances to be used as stationary phases
- Relatively high inlet pressures and controlled flow of the mobile phase
- Precise sample introduction without the need for large samples
- Special continuous flow detectors capable of handling small flow rates and detecting very small amounts
- Automated standardized instruments
- Rapid analysis
- Greater reproducibility due to close control of the parameters affecting the efficiency of separation
- Capable of handling macro molecule and viscous solutions
- Efficient analysis of labile natural products
- Reliable handling of inorganic or other ionic species.

General Classification	Specific Method	Stationary Phase	Type of Equilibrium
Liquid Chromatography (LC) (mobile phase: liquid)	Liquid-liquid (partition)	Liquid adsorbed on a solid	Partition between immiscible liquids
	Liquidbonded phase	Organic species bonded to a solid surface	Partition between liquid and bonded surface
	Liquid-solid (adsorption)	Solid	Adsorption
	Ion exchange	Ion-exchange resin	Ion exchange
	Size exclusion	Liquid in interstices of a polymeric solid	Partition/sieving
Gas Chromatography (GC) (mobile phase: gas)	Gas-liquid	Liquid adsorbed on a solid	Partition between gas and liquid
	Gas-bonded phase	Organic species bonded to a solid surface	Partition between liquid and bonded surface
	Gas-solid	Solid	Adsorption
Supercritical Fluid Chromatography (SFC) (mobile phase: supercritical fluid)	—	Organic species bonded to a solid surface	Partition between supercritical fluid and bonded surface

Table 2: Classification of column chromatographic methods

HPLC is probably the most universal type of analytical procedure. In addition, HPLC also ranks as one of the most sensitive analytical procedures and is unique in that it easily copes with multi-component mixtures. Its application areas include quality control, process control, forensic analysis, environmental monitoring, and clinical testing. It has

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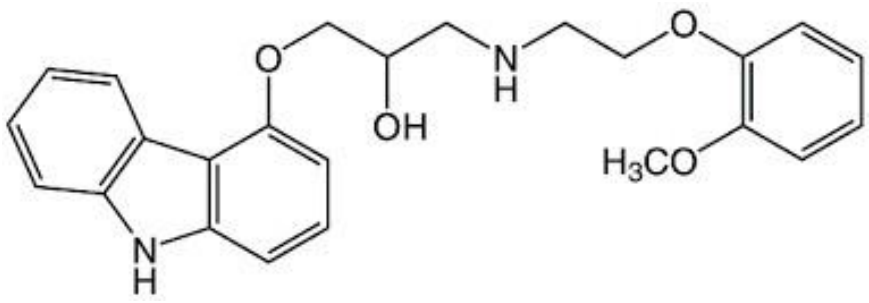
achieved this position as a result of the constant evolution of the equipment used in LC to provide higher and higher efficiencies at faster and faster analysis times with a constant incorporation of new highly selective column packings.

IV. DRUG PROFILE



Carvedilol Structure

- Molecular formula: C24H26N2 O4
- Molecular mass: 406.474 g/mol
- IUPAC name: -[3-(9H-carbazol-4-yloxy)-2- hydroxypropyl][2-(2methoxyphenoxy)ethyl] amine
- Description: White or almost white, slightly hygroscopic powder •
- Solubility: Very soluble in water, freely soluble in methanol
- Drug Category: Anti-hypertensive Drug
- Class: Selective beta-blocker
- Pka: 8.77 • Half Life: 7–10 h
- Excretion: Primarily excreted in the bile and feces.

Mechanism of action

Carvedilol inhibits exercise induce tachycardia through its inhibition of beta-adrenoceptors. Carvedilol's action on alpha-1 adrenergic receptors relaxes smooth muscle in vasculature, leading to reduced peripheral vascular resistance and an overall reduction in blood pressure. At higher doses, calcium channel blocking and antioxidant activity can also be seen. The antioxidant activity of carvedilol prevents oxidation of low density lipoprotein and its uptake into coronary circulation.

- Generic name: Carvedilol Tablets IP
- Brand Name: CardiVas 3.125 mg.

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V. MATERIALS AND METHODS

Chemicals and standards used **[Table 3]**

Chemicals	Manufacturer Name	Grade
Water	Merck	HPLC grade
Methanol	Merck	HPLC grade
Ortho phosphoric acid	Merck	G.R
KH2PO4	Merck	G.R
K2HPO4	Merck	G.R
0. 22µ Nylon filter	Advanced lab	HPLC grade
0.45µ filter paper	Millipore	HPLC grade
Carvedilol	In-House	In-House

Instruments used **[Table 4]**

Instrument	Specification / Model
UV-Visible Spectrophotometer	Shimadzu UV 1800
UV-Visible Spec. Software	UV Probe
HPLC Software	OpenLab Software
HPLC System	Agilent 1260 Infinity Binary Pump
Ultrasonicator	Remi
pH Meter	Systronics 335
Electronic Balance	Shimadzu
Syringe	Agilent Manual Syringe
HPLC Column	Zorbax C18 (250 × 4.6 mm, 5 µm)

Method development for the simultaneous estimation of uridine Triacetate using RP-HPLC

- Selection of mobile phase
- Selection of detection wavelength
- Selection of column
- Selection of solvent delivery system Selection of flow rate
- Selection of column temperature
- Selection of diluents

Selection of test concentration and injection volume.

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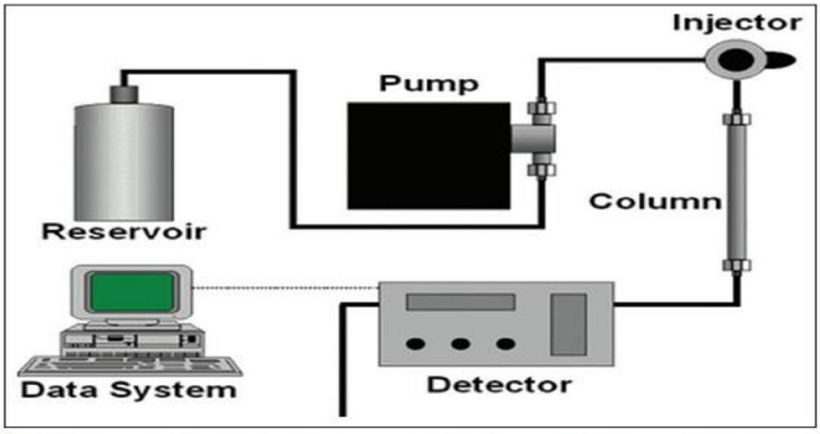

Figure 1: Schematic diagram of high-performance liquid chromatography basic instrumentation

Chromatographic trials for simultaneous estimation of Carvedilol by RP- HPLC [Figures 1-5]

Trial-1

Chromatographic conditions

- Column: Phenomenex (150 × 4.6 mm) 5µ
- Mobile phase ratio: Methanol: 0.1% OPA (50:50%v/v) Detection wavelength: 285 nm
- Flow rate: 1.0 ml/min
- Injection volume: 10 µl
- Run time: 10 min
- Retention time: No peak.

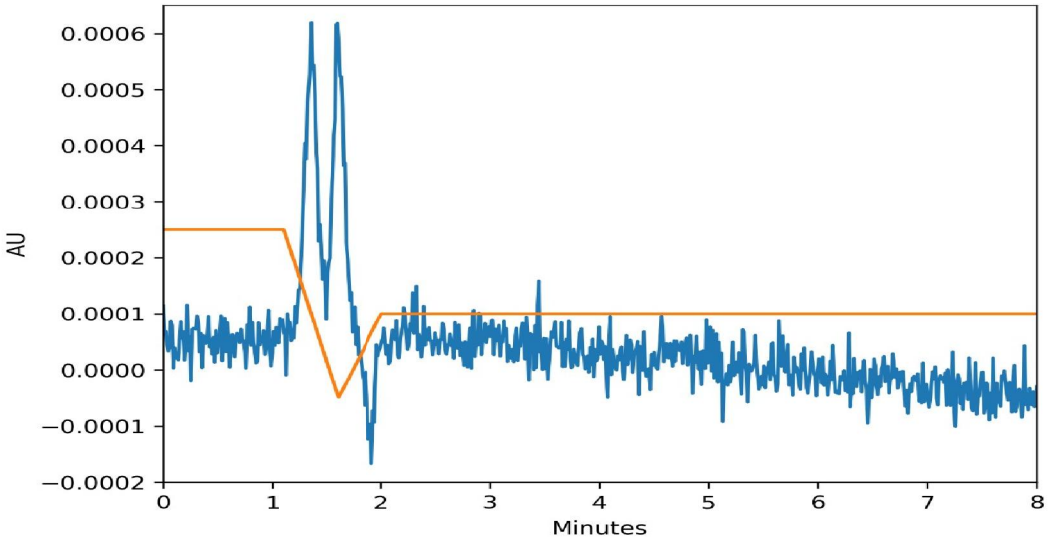

Figure 2: Chromatogram showing trial 1 injection

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Observation

The trial shows no good peak separation, so more trials were required for obtaining peaks.

Trial-2

Chromatographic conditions

- Column: Phenomenex (150 × 4.6 mm) 5µ
- Mobile phase ratio: Methanol: 0.1% OPA (70:30 %v/v)
- Detection wavelength: 285 nm
- Flow rate: 1.0 ml/min • Injection volume: 10 µl
- Run time: 10 min
- Retention time: 1.217.

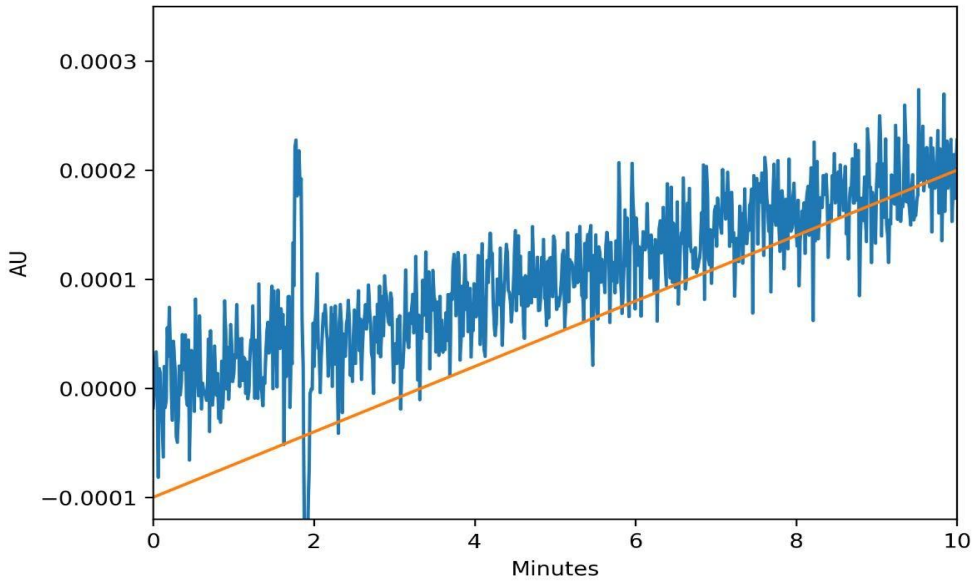

Figure 3: Chromatogram showing trial-2 injection

Observation

In this trial, no proper peak separation was observed; still, more trials were required for good peaks.

Trial-3

Chromatographic conditions

- Column: Phenomenex C18 (150 × 4.6 mm) 5µ
- Mobile phase ratio: MeOH: pH 3.4 Phosphate buffer (50:50%v/v)
- Detection wavelength: 285 nm
- Flow rate: 1.0 ml/min • Injection volume: 10 µl
- Run time: 10 min
- Retention time: 1.817 MIN.

Observation

In this trial, Carvedilol was eluted, but there is no proper baseline and retention time; still, more trials were required for better peak.

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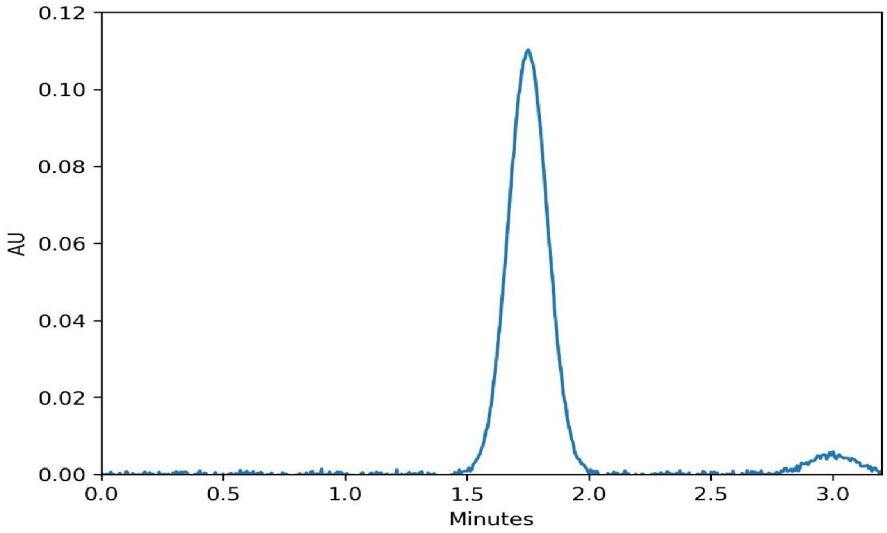

Figure 4: Chromatogram showing trial-3 injection

Trial-4 (Optimized method)

Chromatographic conditions

- Column: Phenomenex (150 × 4.6 mm) 5 µ
- Mobile phase ratio: MeOH: pH 3.4 Phosphate buffer (65:35%v/v)
- Detection wavelength: 285 nm
- Flow rate: 1.0 ml/min
- Injection volume: 10µl
- Run time: 7 min
- Retention time: 2.497 min.

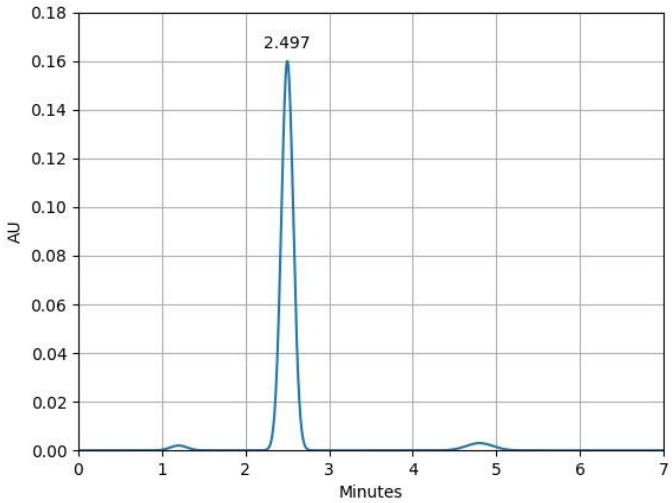

Figure 5: Chromatogram showing trial-4 injection

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Observation

The separation was good, peak shape was good, so we conclude that there is no required for increase the retention times of peak, so it is taken as final method.

Assay calculation

$$\text{Assay } (\%) = \frac{\text{Sample area}}{\text{Standard area}} \times \frac{\text{Dilution sample}}{\text{Dilution of Standard}} \times \frac{P}{100} \times \frac{\text{Avg wt}}{L_c} \times 100$$

Avg. wt = average weight of tablets
P = Percentage purity of working standard
LC= Label Claim of Uridine Triacetate mg/ml.

VI. RESULTS AND DISCUSSION

The present investigation reported in the thesis was aimed to develop a new method development and validation for the estimation of carvedilol by RP-HPLC method. The literature reveals that there are no analytical methods reported for the estimation carvedilol by RP-HPLC method. Hence, it was felt that there is a need of new analytical method development for the estimation of carvedilol in pharmaceutical dosage form.

Method development

The detection wavelength was selected by dissolving the drug in diluent to get a concentration of 10 µg/ml for individual and mixed standards. The resulting solution was scanned in U.V range from 200 to 400 nm. The spectrums are shown in Figure 6. The chromatographic method development for the estimation of carvedilol was optimized by several trials for various parameters as different column, flow rate, and mobile phase; finally, the following chromatographic method was selected for the separation and quantification of carvedilol in API and pharmaceutical dosage form by RP-HPLC method.

Optimized chromatographic conditions for simultaneous estimations Carvedilol by RPHPLC method

Chromatographic conditions

- Column: Phenomenex (150×4.6mm) 5µ
- Mobile phase ratio: MeOH: pH 3.4 Phosphate buffer (65:35%v/
- Detection wavelength: 285 nm
- Flow rate: 1.0 ml/min

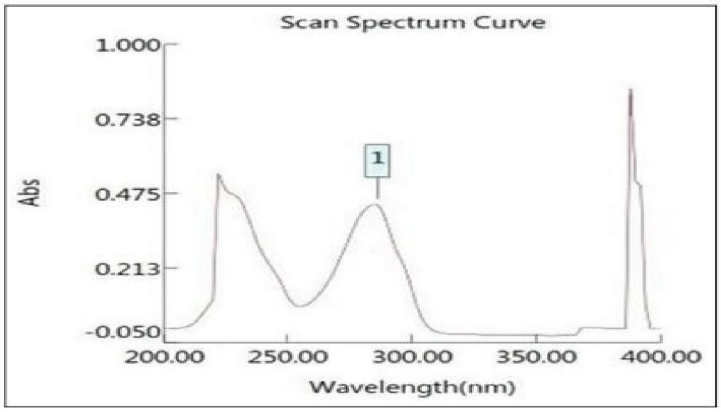

Figure 6: Spectrum showing overlapping spectrum of Carvedilol

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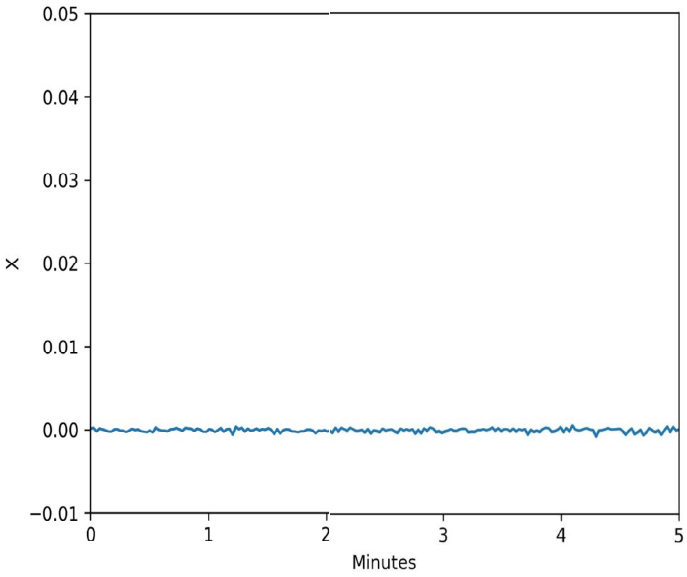

Figure 7: Chromatogram showing blank preparation (mobile phase)

Table 5: Linearity results for carvedilol

Concentration (µg/ml)	Area
20	264840
Concentration (µg/ml)	**Area**
40	491415
60	677620
80	873311
100	1048958

- Injection volume: 10µl
- Run time: 7 min
- Retention time: 2.497 min.

Assay calculation for carvedilol

The assay study was performed for the Carvedilol. Each three injections of sample and standard were injected into chromatographic system. The chromatograms are shown in Figures 1-7 and results are tabulated in Tables 3-5.

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VII. SUMMARY AND CONCLUSION

A new method was established for estimation of Carvedilol by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Carvedilol using Phenomenex C18 column (4.6 × 150 mm) 5 µ, flow rate was 1.0 ml/min, mobile phase ratio was pH 3.4 Phospahte: meoH (65:35% v/v), and detection wavelength was 284 nm. The instrument used was Agilent 1260 infinity binary pump HPLC, Open laboratory software. The retention times were found to be 2.425 min. The percentage purity of Carvedilol was found to be 99.94%. The system suitability parameters for Carvedilol such as theoretical plates.and tailing factor were found to be 4187, 1.5. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Carvedilol was found in concentration range of 20–100 µg and correlation coefficient (r2) was found to be 0.999, % recovery was found to be 99.95%, % RSD for repeatability was 0.2, and % RSD for intermediate precision was 0.1. The precision study was precision, robustness and repeatabilty. LOD value was 3.06 and LOQ value was 10.14. Hence, the suggested RP-HPLC method can be used for routine analysis of Carvedilol in API and pharmaceutical dosage form.

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