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DEVELOPMENT OF UV-VISIBLE SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF CARVEDILOL IN BULK AND PHARMACEUTICAL FORMULATION

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ABSTRACT

A clear, highly accurate and sensitive spectrophotometric techniques has been developed to measure carvedilol in pharmaceutical formulation and in bilk drug. In this study methanol was determined to have the highest assay sensitivity and sufficient drug solubility. In the 200-400nm wavelength range, the absorbance of carvedilol was recorded at 245nm. In the concentration range of 10-60ug/ml, beer's law was followed. Additionally, the correlation coefficient slope, intercept were also calculated. The medication in both its pure and tablet dose form has been successfully analysed using suggested method. The percentage recovery results indicate that the presence of common excipients has no effect on the procedure sensitivity and precision tests were used to validate the approach, demonstrating its applicability for routinely estimating carvedilol in pharmaceutical formulation and bulk. Carvedilol interacts with ninhydrin in the presence of a base producing a yellowish orange complex with a maximum fall in visible region. When the drug and chromogenic agent combine, a yellowish orange solution is produced, with the maximum absorbance being measured at 405nm. The UV spectrophotometric and colorimetric techniques were thoroughly tested in accordance with ICH guidelines and all the parameters were within the acceptable range with a correlation of 0.9925 and a% RSH of 0.6441. The linearity was evaluated and found to be between 100-600ug/ml. The techniques developed in this study offer a practical and precise means of estimating carvedilol.

KEYWORD:- Carvedilol, UV-spectrophotometric estimation, Colorimetric estimation, Method development, Method validation.

INTRODUCTION

Carvedilol is a potent antihypertensive agent in human beings andin animals. According to research studies on its mechanism of action, the molecule is a vasodilator and a beta- adrenoceptor antagonist both of which support the antihypertensive effect it produces. The decrease in blood pressure produced by carvedilol is associated with a reduction in peripheral vascular resistance which is an indicative of arterial vasodilation. Carvedilol is also used to treat mild sever chronic heart failure, myocardial infraction in clinically stable patients following left ventricular dysfunction.

Carvedilol reduces systemic blood pressure, pulmonary artery pressure, and pulmonary capillary wedge pressure via inhibiting alpha1 receptors which causes vasodilation. Blocking beta-receptor decreases heartrate and increases diastolic filling time. Carvedilol inhibits the binding to these receptors, slowing heart rhythm and decreasing the force of the heart pumping.

Chemically, carvedilol (2RS)-1-(9H-Carbazol-4Yloxy)-3((2-(2- Methoxy phenoxy)ethyl)amino)propan-2-ol is a nonselective beta and alpha1 adrenergic receptor blocking agent. It also has multiple spectrum of activities such as antioxidant property, inhibition of smooth muscle proliferation and calcium antagonistic blocking activity.

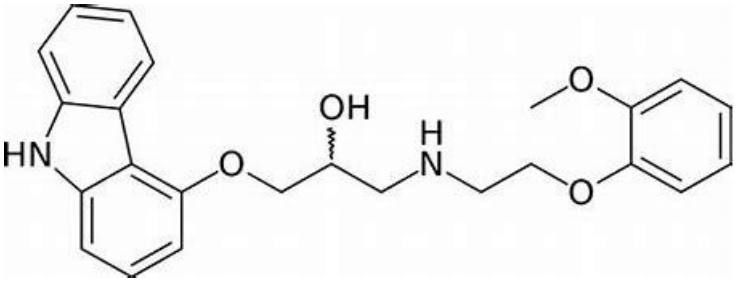

Fig. no. 1 Structure of carvedilol.

Analytical methods play a vital role in drug development process including preformulation and formulation studies, stability studies, quality control testing and in quality assurance programmes. A new simple, sensitive UV spectrophotometric method was developed for estimation of carvedilol in pharmaceutical dosage forms without the necessary of sample pretreatment. The proposed method was developed and validated according to the validation parameters.

MATERIALS AND METHODS

Materials

Carvedilol was obtained from Aurobindopharma Hyderabad. All analytical grade solvents and chemicals were supplied by Nips laboratories, India. Carvedilol marketed tablets were purchased from local market.

Equipments

UV-Visible spectrophotometer (Ts2080plus), company electronic analytical balance analytical technologies Ltd-Infra digi, Model No-200).

Solvents used: Methanol, distilled water

Method development

Weighed accurately about 100mg of carvedilol crude drug and was transferred into a 100ml volumetric flask. The drug was dissolved by slowly adding methanol and final volume was made up to100 ml with methanol (Stock solution-A).The concentration of the solution was (1000µg /ml). From that solution 1ml was taken and was made up to 100ml with methanol (Stock solution-B) and its concentration was (10µg/ml).

1ml of solution-B (10µg/ml) can be diluted to 10ml and it was transferred into quartz cuvettes. It was scanned in the wave length range between 200-400nm (UV region). From the above observations carvedilol shows maximum absorbance at a wavelength of 245nm in methanol.

Preparation of calibration curve

From **Solution-A** (1000µg/ml) to pipette out 10ml and it can be diluted to 100ml with methanol (100µg/ml) .From that solution to pipette out an aliquots of 1ml, 2ml, 3ml, 4ml, 5ml and 6mlwere pipetted out into different 10ml volumetric flasks (previously calibrated) and diluted to 10ml with methanol to get concentrations of 10µg/ml, 20µg/ml, 30µg/ml, 40µg/ml, 50µg/ml and 60µg/ml respectively. Absorbance of resulting solution was measured at 245nm using UV-Visible Spectrophotometer against blank (methanol).

Procedure for dosage forms (tablets)

- 20 tablets of carvedilol (Brand name-carvedilol) of label claim 6.25mg were weighed. Average weight was determined. The tablets were finely powdered and equivalent weight was calculated based on label claim.
- 3.648 gm of carvedilol powder (equal to100mg) was taken in 100ml volumetric flask. Small quantity of methanol was added and shaken for 30 minutes. Final volume was made up to 100ml with methanol.
- The solution was filtered to get stock solution of 1000µg/ml **(Solution-A).**
- From solution-A, an aliquot of 10ml was withdrawn and it was diluted to 100ml with methanol to get a solution of 100µg/ml. From that solution to take 3ml, 4ml, 5ml was pipetted out into 10ml volumetric flasks and final volume was made up to 10ml with methanol to get concentrations of 30µg/ml, 40µg/ml, 50µg/ml. The absorbance of resulting solutions was measured at 245nm using UV-Visible Spectrophotometer against blank (Methanol).

Colorimetric method

Preparation of reagents

Preparation of 0.3% Ninhydrinreagent: 0.3g of Ninhydrin reagent was taken into a 100ml volumetric flask. It was dissolved by slowly adding 95 volumes n-heptanol and 5 volumes of 2M Acetic acid.

Preparation of 1% of Sodium hydroxidesolution: 1g of sodium hydroxide was taken into a 100ml volumetric flask. It was dissolved in distilled water finally volume made up to 100ml.

Blank solution: Ninhydrin and Sodium hydroxide solutions were used as blank solution.

Colour: Yellowish - Orange.

Preparation of stock solution

Carvedilol stock solution was prepared by weighing 100mg of carvedilol transferring in to a 100ml volumetric flask and volume was made up to 100ml with ethanol to get a concentration of 1000µg/ml **(Solution-A).**

Selection of analytical wavelength

Pipetted out 1ml of 1000µg/ml solution **(Solution-A)** of carvedilol mixed with 2ml of Ninhydrin, 0.5ml of Sodium hydroxide and was made upto 10ml with distilled water. After the solution was shaken, the intensity of colour was scanned in the wavelength range of 400-800nm. From the absorbance readings between 400-800nm the wavelength which gives maximum absorbance was recorded. It was found to be **405nm**.

A graph was plotted by taking Wavelength on X-axis and Absorbance on Y-axis. From the graphical observations the λmax for carvedilol was found to be 405nm and it was used for further analysis of carvedilol.

Preparation of calibration curve

From the **Solution-A** an aliquot of (1.0-6.0ml) of 1000µg/ml of Carvedilol were transferred into a series of 10ml volumetric flasks. To that added 2ml of 0.3% Ninhydrin followed by 0.5ml of 1% Sodium hydroxide. The contents were shaken well and diluted up to 10 ml with distilled water. A calibration curve was plotted by taking Concentration (µg/ml) on X-axis and Absorbance on Y-axis.

Procedure for dosage forms (tablets)

- 10 Tablets of carvedilol (carvedilol) having a label claim of 6.25mg were weighed. Average weight was determined. The tablets were finely powdered and equivalent weight was calculated based on label claim, equal to 10mg.
- 0.3648gm of carvedilol powder (equivalent weight) was taken in 100ml volumetric flask. Small quantity of ethanol was added and shaken for 30 minutes. Final volume was made up to 100ml with ethanol.
- The solution was filtered to get a stock solution of conc.1000µg/ml **(solution-A).**From that solution to pipette out 2ml, 4ml and 6ml were withdrawn, and added 2ml of Ninhydrin, 0.5ml of Sodium hydroxide and the final volume was made up to 10ml with distilled water and the intensity of colour was measured at 405nm.

Method validation

The International Conference on Harmonization (ICH) guidelines were followed in the validation of proposed method.

Linearity

A graph of absorbance verses concentration is shown in fig 1 and fig 2.

It was evident that the plot was linear in the concentration range of 10-60µg/ml and with correlation coefficient (r^2) of 0.9936 and in colorimetry ,concentration range of 100-600µg/ml and r^2 of 0.9925.

Accuracy (recovery study)

Accuracy of developed method was ascertained by recovery studies and the results are expressed in Mean% recovery.

Mean % recovery of carvedilol was found in the range of 99.42% - 99.6%.

The data was shown in table 1.

Precision (Repeatability)

By measuring the absorbance three times on the same day and three separate days, intraday and interday precision were ascertained.

The obtained data are shown in table 1.

LOQ and LOD

The Limit of quantification and Limit of detection are separately determined as per ICH guidelines. The results were shown in table 1.

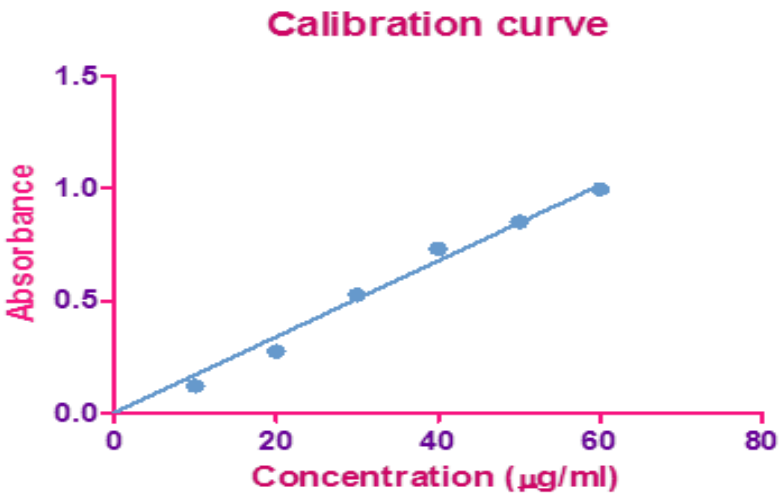

Fig. no. 1: Calibration curve of carvedilol by uv spectroscopy.

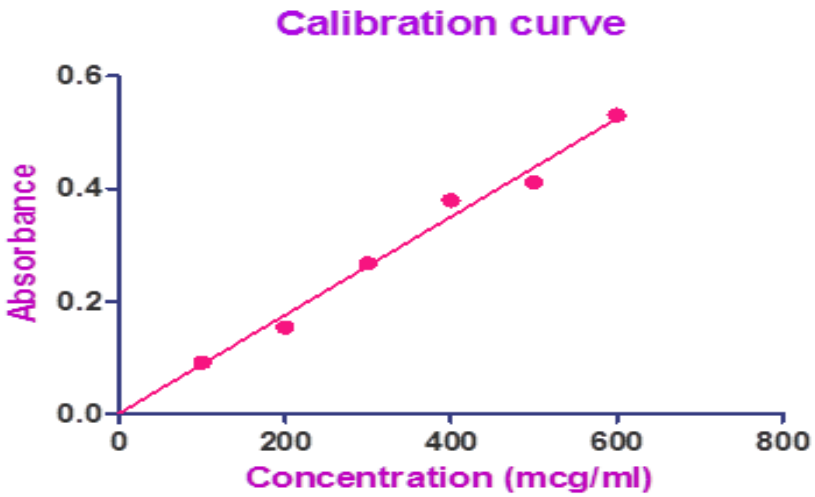

Fig. no. 2: Calibration curve of carvedilol by colorimetry.

RESULTS AND DISCUSSION

Estimation of Carvedilol in dosage form by UV and Visible Spectrophotometry was carried out using optimised conditions, the percentage of Carvedilol found in formulations and the results of analysis shows that the amount of drug was in good agreement with the label claim of the formulations. All the validation and quantification parameters and system suitability studies were carried out and the comparative results are shown. Validation parameters for UV Spectrophotometry and Colorimetry method were shown in **Table -1**. The proposed methods for quantification of Carvedilol in tablets were simple, precise, accurate, rapid and sensitive. The methods are linear in the concentration range reported. The developed methods are free from interference due to the recepients present in the tablets and can be used for routine quantitative estimation of Carvedilol in tablets. In conclusion the results have shown that UV & Visible methods can be used for quantitative estimation of Carvedilol.

Table 1: Summary of validation parameters.

S. NO	Parameter	Results	
		UV	Colorimetry
1	Linearity range (µg/ml)	10-60µg/ml	100-600 µg/ml
2	Correlation coefficient (r)	0.9936	0.9925
3	R^2	0.9874	0.9851
4	Intercept	0.0572	0.0459
5	Slope	0.018307	0.029631
6	Standard deviation (SD)	0.2239	0.2784
7	Standard error (SE)	0.0132	0.0212
8	Limit of detection (LOD) (ng/ml)	931.04	181.72
9	Limit of Quantification (LOQ) (ng/ml)	3125.682	2981.467
10	% RSD	0.7784	0.6441
11	Intra day (%RSD)	0.01	0.0055
12	Inter day (%RSD)	0.00725	0.0176
13	Molar absorptivity	$4.4525x10^4$	2.571×10^4
14	Accuracy	99.42%	99.6%

SUMMARY AND CONCLUSION

The methods discussed in the present work provide a convenient and accurate way for estimation of Carvedilol. Percent label claim for Carvedilol in tablet by all the two methods, was found in the range of 99.97% to 100.253%. Standard deviation and percentage RSD for six determinations of tablet sample by both the methods was found to be less than ±2.0 indicating the precision of both the methods. Accuracy of proposed methods was ascertained by recovery studies and the results are expressed in Mean % recovery. Mean percent recovery for Carvedilol was found in the range of 99.42% to 99.6%, values of standard deviation and % RSD were in the range of ±0.2239 to ±0.3194 and 0.6441 to 0.7784 respectively indicating the accuracy of the proposed methods. Based on the results obtained, it is found that the proposed methods are accurate, precise, reproducible and economical methods for the estimation of Carvedilol in Bulk drug and its Pharmaceutical formulations.

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