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Novel Ultrasensitive Eco-Friendly Spectrophotometric Determination of Carvedilol in Pharmaceutical Preparations and Environmental Wastewater Samples: Application to Content Uniformity Testing

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ABSTRACT

A simple, novel, accurate, precise, rapid, economical and sensitive Ultra violet spectrophotometric method has been developed for the determination of Carvedilol in pharmaceutical preparations and environmental wastewater samples, which shows maximum absorbance at 242 nm in methanol. Beer's law was obeyed in the range of 0.5 -10 µg/ ml, with molar absorptivity of 5.4467×104 L.mol-1.cm-1, relative standard deviation of the method was less than 1.6%, and accuracy (average recovery %) was 100 ± 1.3. No interference was observed from common excipients and additives often accompany with Carvedilol in pharmaceutical preparations. The method was successfully applied to the determination of Carvedilol in some pharmaceutical formulations (tablets) and industrial wastewater samples. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of Carvedilol in true samples.

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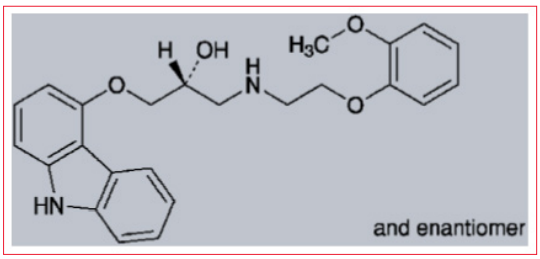
Introduction

Carvedilol is a non-cardioselective beta blocker. It has vasodilating properties, which are attributed mainly to its blocking activity at alpha1 receptors; at higher doses calcium-channel blocking activity may contribute. It also has antoxidant properties. Carvedilol is reported to have no intrinsic sympathomimeticactivity and only weak membrane-stabilising activity [1]. Carvedilol is used in the management of hypertension and angina pectoris, and as an adjunct to standard therapy in symptomatic heart failure Action and us Beta-adrenoceptor antagonist; arteriolar vasodilator. Carvedilol occurs as white to pale yellowish white crystals or crystalline powder. Solubility Practically insoluble in water, slightly soluble in alcohol, practically insoluble in dilute acids and practically insoluble in water [2-5].



C24H26N2O4: 406.47
2-Propanol, 1-(9H-carbazol-4-yloxy)-3-[[2-(2-methoxyphenoxy) ethyl] amino]-, (±)-;
(±)-1-(Carbazol-4-yloxy)-3-[[2-(o-methoxyphenoxy) ethyl] amino]-2-propanol.

Figure 1: Carvedilol Chemical Structure

The literature survey reveals that various methods has been reported for estimation of Carvedilol by Titrimetric method. Spectrofluorometric methods Spectrophotometric methods, RP-HPLC methods, and HPTLC analysis method [6-13]. In the view of the need in the industry for routine analysis of Carvedilol, attempts are being made to develop simple and accurate instrumental methods for quantitative estimation of Carvedilol [14, 15]. Thus, there is need for the development of new, simple, sensitive and accurate analytical method for the quantitative estimation of Carvedilol as an active pharmaceutical ingredient. The present work describes simple and accurate Spectrophotometric methods for the estimation of Carvedilol hydrochloride in bulk and dosage form.

Experimental

Apparatus

Shimadzu UV- 1700 pharm spec (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurement.

Reagents

All chemical used were of analytical or pharmaceutical grade and Carvedilol standard material and tablets were provided from ALhokamaa company for pharmaceutical industries (HPI) Mosul-Iraq.

Carvedilol stock solution (100 ppm) was prepared by dissolving 0.01g of Carvedilol in 100 ml methanol in a volumetric flask. Carvedilol standard solution (10 ppm) was prepared by diluting10 ml of stock solution to 100 ml by methanol in a volumetric flask.

Determination of Absorption Maxima

The standard solution of Carvedilol (5µg/ml) was scanned in the range of 220-350 nm which shows maxima located at 242 nm Figure 2. Therefore ,242 nm wavelength was selected for the construction of calibration curve.

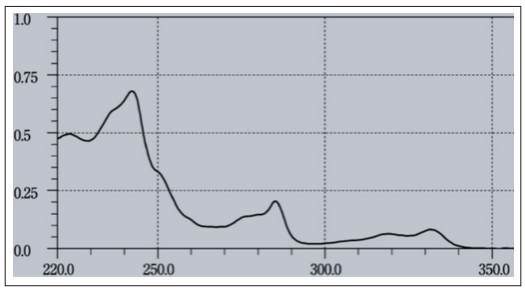


Figure 2: Absorption Spectra of 5 (µg/ml) Carvedilol Against Methanol

Recommended Procedure

From the absorption maxima, calibration curve was prepared in the concentration range of 0.5-10 µg/ml. The absorbance was measured at 242 nm against methanol as a blank. The concentration of the sample solution can be determined by using the calibration curve.

Procedure for Real Water Samples

To demonstrate the practical applicability of the proposed method, real water samples were analyzed by this method. Industrial waste water from the state company of drug industries and medical appliance (HPI) Mosul – Iraq, were fortified with the concentrations in the range of 1,5,10 µg/ml of Carvedilol. The fortified water samples were analyzed as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

Procedure for pharmaceutical preparations (tablets) Weight and powder 10 tablets [Tablets 25,50 mg]. Dissolve a quantity of the powdered tablets containing 0.01 gm. of Carvedilol in about 100 ml methanol and mixed for 20 mint and then filtered. The filtrate was take 10ml and mad up to 100 ml with methanol and aliquot of this solution was treated as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

Result and Discussion

UV visible spectrophotometry is still considered to be a convenient and low cost method for the determination of pharmaceuticals [16-26]. The method used for the determination of Carvedilol in pharmaceutical preparations and environmental wastewater samples was found to be sensitive, simple, accurate, and reproducible. Beer s law was obeyed in the concentration range of 0.5-10 µg/ml. Figure 3 with correlation coefficient of 0.9997, intercept of 0.002 and slope of 0.134. The molar absorptivity was found to be 5.4467×104 l/mol.cm.

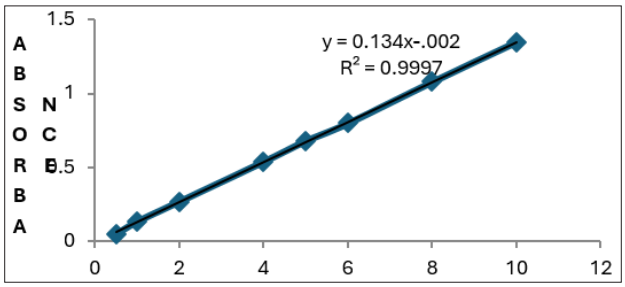


Figure 3: Calibration Curve

The accuracy and precision of the method, a pure drug solution was analyzed at three different concentrations, each determination being repeated ten times. The relative error (%) and relative standard deviation values are summarized in table1. From table 1 the values of standard deviation were satisfactory and the recovery studies were close to 100%, The RSD% value is less than1.6 indicative of accuracy of the method.

Table 1: Accuracy and Precision of the Proposed Method

Carvedilol taken (µg/ml)	Er (%) [a]	RSD (%)
0.5	1.1	1.4
5	1.1	1.5
10	1.2	1.5

* Average of Ten replicate determinations,

The optical characteristics and statistical data for regression equation of the proposed method. Data presented in Table 2

Table 2: Optical Characteristics and Statistical Data for Regression Equation of the Proposed Method

Parameter	Result
ג Max .nm	242
Beer`s law limits µg/ml	0.5-10
Molar extinction coefficient (l. mol^{-1}. cm^{-1})	5.4467×10^4 $L.mol^{-1}.cm^{-1}$,
Correlation coefficient (r^2)	0.9997
Regression equation (b+ ac)	
Slope(a)	0.134
Intercept(b)	0.002

Limit of detection. μg.ml^{-1}	1.5x10^{-3}
Limit of quantification. μg.ml^{-1}	4.9x10 $^{-3}$
Average recovery %	close to 100%.
RSD%	<1.6

Analytical Application

The proposed method was satisfactorily applied to the determination of Carvedilol in its pharmaceutical preparations tablets and wastewater samples, the results of the assay of the pharmaceutical preparations revels that there is close agreement between the results obtained by the proposed method and the label claim Table 3, and the results of water samples Table 4 show that the recovery values obtained were closed to 100%.

Table 3: Assay of Carvedilol in Pharmaceutical Formulations

Pharmaceutical formulation supplied by HPI	Amount of Carvedilol* Proposed method	Label claim	%Recovery
Tablet 25mg Tablet 50 mg	25.06mg 50.1mg	25 mg 50mg	100.24 100.2

*Mean of ten determinations.

Table 4: Determination of Carvedilol in Spiked Industrial Waste Water Sample

Water samples	Carvedilol (µg/ml) * Taken	Found	Recovery%
Industrial wastewater	1 5 10	1.001 5.004 10.01	100.1 100.08 100.1

*Mean of ten determinations.

Application of the Method to Content Uniformity [27-31].

The proposed method proved to be suitable for the content uniformity test, where a great number of assays on tablets are required. Data presented in Table 5 indicate that the proposed method can accurately and precisely quantitate Carvedilol in its commercially available tablets. The mean percentage (with RSD) of the labeled claim found in ten tablets was (0.518%) which fall within the content uniformity limits specified by the USP 33.

Table 5: Content Uniformity Testing of Carvedilol Tablets Using the Proposed Method

Parameter	% of the label claim
Tablet NO. 1	100. 28
Tablet NO. 2	100. 11
Tablet NO. 3	99. 56
Tablet NO. 4	100.71
Tablet NO. 5	99.38
Tablet NO. 6	99. 35
Tablet NO. 7	99.72
Tablet NO. 8	100. 55
Tablet NO. 9	100.66
Tablet NO. 10	99.76
Mean (x)	100.008
% RSD	0.518
Max. allowed unit [29]	±15%

Conclusion

In this work, a simple, rapid, precise and accurate spectrophotometric method was developed and validated for the determination of Carvedilol in pharmaceutical preparations and industrial waste water samples. The method free from such experimental variables as heating or solvent extraction step. The method rely on the use of simple and cheap chemicals and techniques and can be used for rapid routine determination and quality control of Carvedilol in pure form, bulk sample, pharmaceutical preparations and real industrial waste water sample.

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