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DEVELOPMENT OF UV SPECTROPHOTOMETER METHOD OF CARVEDILOL IN BULK AND PHARMACEUTICAL TABLET DOSAGE FORMULATION

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Abstract

The simple, precise and economic UV methods have been developed for estimation of Carvedilol in single component. Carvedilol has the absorbance maxima in zero order spectra in 230 nm (method A). Method B applied was first order derivative for the analysis of Carvedilol at 238.5 nm .Method C applied was area under curve in the wavelength range of 234-228 nm. Drug followed Beer-Lamberts law in the concentration range of 503.5 µg/ml for zero order, 10-60 µg for area under curve methods and first order derivative spectrum. The percentage recovery of Carvedilol ranged from 98.05 to 101.075 in pharmaceutical dosage from result of analysis was validated statistically and by recovered study.

INTRODUCTION

Carvedilol are available in tablet dosage form in the ratio of 2:5.Chemically, carvedilol is (2RS)-(9H-Carvazol-4-yloxy)-3-[[2-(2-methoxyphenoxy) ethyl] amino] propan-2-ol]-acid has beta receptor activity. Carvedilol is official in BP and USP. It is first beta blocker labeled in United States especially for the treatment of heart failure of ischemic or cardiomyopathic origin with significant antioxidant activity.[1-3] Relative to other beta blocker, carvedilol (CAR) has minimal inverse agonist indicating a reduced negative chronotropic and inotropic effect, which decreases its potential to worsen symptoms of heart failure .[4]At high dosage ,it exerts Calcium channel blocking activity.[5] The benefit of using CAR in patient with CHF in both single –center and multicenter trial have been reported in the literature[6-8]. it prevent vitamin E, glutathione and SH protein depletion induced by oxidation stress, the main defense mechanism against tissue injury caused by free radical[9].

Several analytical methods such as spectrophotometry[10, 11], HPLX12[16] capillary electrophoresis, fluorometry[21], synchronous flurometry, HPLC-MS/MS[22], differential pulse Voltametry[23] GC-MS[24] have been widely used for the determination of CAR. Has also been reported. It is worthwhile to mention here that the thus are not a selective methods since excipient present in the dosage form to spectrophotometer methods reported recently[10, 11] are in the UV region and the dosage form to the drug can interfere with the estimation method. In view of the importance of CAR have been developed. The proposed method when compare with the reported spectrophotometric methods take the advantage over the UV spectrophotometric method in terms of selective (Table 1) the proposed method are simple, accurate and easy to apply in routine analysis of the drug.

MATERIAL AND METHODS

Accurately about 10mg of carvedilol was weighed and transferred to 100 ml volumetric flask, 25ml methanol added to dissolve drug then volume was made up with distilled water up to the mark to give the drug stock solution of concentration 100g/ml. Aliquots of standard stock solution were pipette out and suitable diluted with distilled water to get final concentration of standard solution. In zero order spectrum

method at n=6 showed a sharp peak at 230nm. (Figure 1) the absorbance difference at n=(d A/D) is calculated by the inbuilt source of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solution was diluted so as to get the final concentration in the range of 5-35 g/ml and scanned in zero order spectra. The calibration curve of dA/d against concentration of the drug showed linearity (Table 2).similarly for first order derivative same method was employed at n=6 showed a sharp peak at 238.5nm (Figure 2). The standard drug solution was diluted so as to get the final concentration in the range of 10-50microgram/ml and scanned in first order derivative spectra. The calibration curve of dA/d against concentration of the drug showed linearity (Table 3).

The AUC method involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelength lambda1 and lambda2 area calculation processing item calculation the area bound by the curve and the horizon axis (Figure 3). The horizons axis is selected by entering the wavelength range over which the area has to be calculated .the wavelength range is selected on the basis of repeated observation so as to get the linearity between area under curve and concentrated (Table 4). Suitable dilution of standard stock solution (100m/g) of the drug were prepared and scanned in the spectrum mode from the wavelength range 400-200nm and the calibration curve was plotted. All the three methods were checked by analyzing the sample with known concentration. All three methods were validated according to ICH guidelines by carrying out analysis of single component for estimation of carvedilol in tablet formulation twenty tablet of the brand were weighed and triturated to fine powder. The powder equivalent to 10mg of carvedilol was weighed and dissolved in 25ml alcohol and further dilute with quantity of sufficient with distilled water. It was kept for ultra sonification for 45min this was then filtered whatmann filter paper no 41 to get stock solution of concentration of 100microgram /ml various dilution of the tablet solution were prepared and analyzed for six times and concentration was calculate by using the calibration curve (Table-5). recovery study were carried out at three different level i.e. 80%,100% and

120% by adding the pure drug (8,10 and 12mg resp) to previsiously analyzed tablet powder sample from the amount drug founds, percentage recovery was calculate (Table 7)

RESULT AND DISCUSSION

all the three methods A, B and C for estimation of cravedilol in single component from were found to be simple , accurate and reproducible, beer lambert law was obeyed in the concentration range of 10-60mg/ml for first order and area under curve method and 5-35mg/ml for zero order in the derivative spectra(Table 1). The validation of the proposed method was further confirmed by recovery study data clearly indicate the reproducibility and accuracy of method. The value of standard deviation was satisfactory (Table 6). The recovery value for carvedilol ranged from 98.05 to 101.07% (Table 7).

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Table 1

Optical characteristic and other for carvedilol

Parameters	Method A	Method B	Method C
Max(nm)/wavelength range (nm)	230	238.5	234-228
Beer 'lamberts range (nm)	5-35(mg/ml)	10-60	10-60
Coefficient of correlation ($r^{2)}$	0.9994	0.9994	0.9995
Regression equation's=mx+c	0.0259x-0.0038 0.0025+.004		0.1893x-0.0684
A-slope (m)	0.0259	-0.0025	0.1893
b- Intercept (c)	-0.0038	0.0004	-0.0684
LOD	0.0229	0.33	0.0038
LOQ	0.694 0.0118	1	
Molar absorptive	$5.2*10^2$ $3.94*1^2$		$1.18*10^3$

Table 2

Statistical validation by zero order spectrum method

Parameter	Means	S.D	C.O.V	S.E
r^2	0.9994	0.00018	.018	0.000073
Slope	0.026	.00049	1.88	0.0002
Intercept	0.0	0.0	0.0	0.0

Table 3

Statistically validation by first order spectrum method

Parameter	Means	S.D	C.O.V	S.E
r^2	0.9994	0.00025	0.025	0.0001
Slope	0.0027	0.09	3333	0.036
Intercept	0.0	0.0	0.0	0.0

Table 4

Statistically validation by first order under curve method

Parameter	Means	S.D	C.O.V	S.E
r^2	0.9995	0.00023	0.023	0.0009
Slope	0.1893	0.00000007	0.000037	$02.9*10^{-18}$
Intercept	0.0	0.0	0.0	0.0

Table 5

Analysis of tablet formulation

Sr. no	Tablet sample	Amount %(mg/tab	Amount found(mg/Tab)	%of tablet claim
1	T1	10	10.05	100.5
2		10	9.85	98.5
3		10	10.14	101.5

Table 6

Analysis of tablet formulation

Sr. no	Tablet sample	%mean	S.D	C.O.V	S.E
1	T1	100.16	1.2	1.243	0.716

Table 7

Statistical evaluation of tablet formulation

ingredient	Level of Addition	Tablet amount	Amount added	Amount recovered	%recovery	Average recovery
Meclizine	80	10	8	17.65	98.05	99.43
	100	10	10	20.34	101.7	
	120	10	12	21.68	98.54	

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