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Research Article

VISIBLE SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF BISOPROLOL FROM ITS BULK AND TABLET FORMULATION

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ABSTRACT

The proposed method is new, simple, sensitive, reproducible, economical, accurate and precise and can be successfully applied in estimation of bisoprolol. This method can find applications in clinical studies and therapeutic drug monitoring. This method of colorimetric estimation of bisoprolol is based on the formation of blue colored chromogen when reacted with ferric chloride and pottasium ferricynide. The concentration of bisoprolol over range of 1- 13 µg/ml was found to obey Beer's law in the stated range. The blue colored complex has absorption maxmia at 770 nm with molar absorptivity and sandell's 2.2387 x 104 lit mol-1 cm-1 and0.0154 µg/cm2/0.001 absorbance units, reproducible, specific, and the reagent was not found to react with the soluble matters of the body fluids. The results analysis were validated as per ICH Q2B guidelines.

Keywords: Bisoprolol, visible spectroscopy, validation

INTRODUCTION

Bisoprolol or 2-Propanol, 1 - (4 - ((2 - (1 - methylethoxy)ethoxy)methyl)phenoxy) - 3 - ((1 - methylethyl)amino),(±),(E) - 2 - butenedioate (2:1) (salt) is a drug belonging to the group of beta blockers, a class of drugs used primarily in cardiovascular diseases[1-4]. More specifically, it is a selective type β1 adrenergic receptor blocker [5-7]. It is official drug in Indian pharmacopoeia. It is used for secondary prevention of myocardial infarction (MI), heart failure, angina pectoris and mild to moderate hypertension [8-9]. At lower doses (less than 20 mg daily), Bisoprololselectively blocks cardiac β1-adrenergic receptors with little activity against β2-adrenergic receptors of the lungs and vascular smooth muscle. It is small molecules white to off white crystalline powder, which is soluble in methanol [10].

Literature survey reveals that difference in spectrophotometry, spectrophotometry in combination with other drugs, colorimetric, liquid chromatography-tandem mass spectrophotometry, HPLC, micellar eletrokinetic chromatographic method, HPTLC are reported for estimation of Bisoprolol.

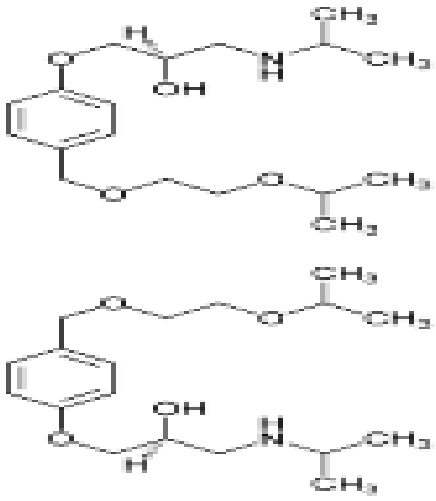

Figure 1: Structure of Bisoprolol

MATERIALS AND METHODS

Instrument

Spectrophotometric analysis was carried out on Systronic UV-VIS double beam spectrophotometer 2201 using a 1cm quartz cell. The instrument settings was zero order derivative mode and band width of 2.0 nm in the range of 200-800 nm.

Reagents and chemicals:

Bisoprolol supplied by Unichem Healthcare Company. All chemical were analytical grade obtained from SD fine chemicals. Water purified by glass distillation apparatus.

Methods

Spectroscopic Method Employing ColorimetricMethod:

Different aliquots of the standard drug solution were taken in series of 10ml volumetric flask to prepare the concentration ranging from 1-13 ug/ml to each flask 2ml of 0.3% w/v ferric chloride and 2ml of 0.02% w/v potassium ferricyanide was added and volume was made up to mark with water after 30 min the blue color stable complex was formed. These solutions were analyzed in 400- 800nm range and spectra were recorded. The absorbance of each concentration at 770 nm is plotted against concentration which gives calibration curve.

Procedure for tablet formulation:

Twenty tablets were weighed and ground to a fine power. Tablet powder equivalent to 10mg Bisoprolol was weighed and transferred to a 100ml volumetric flask to this 70 ml of solvent system methanol: water (40:60) was added. This solution was sonicated for 10 min and volume was made up to mark then solution was filtered through Whatmann fitter paper no 41 first few ml is rejected. This solution was further diluted to obtain the concentration of 10 µg/ml of Bisoprolol. To this solution 2ml of 0.3% w/v ferric chloride and 2ml of 0.02% w/v potassium ferricyanidewas added solution kept aside, after 30 minutes, stable blue colored complex was formed. Then solution was analyzed in 400-800 nm range from absorbance at 770 nm was recorded. Concentration of solution was calculated from the slope and intercept values obtained from calibration curve. Overlain spectra of drug reagent color complex are shown in Fig: 3 which shows that change in the color is observed by addition of drug to reagent. The fig. shows maximum absorbance at 770 nm which is selected as sampling wavelength.

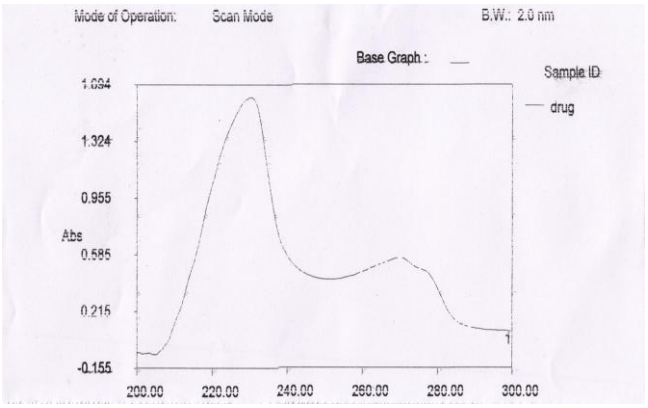

Figure 2: Spectra of 10 µg/ml of Bisoprolol, having maxat 230 nm

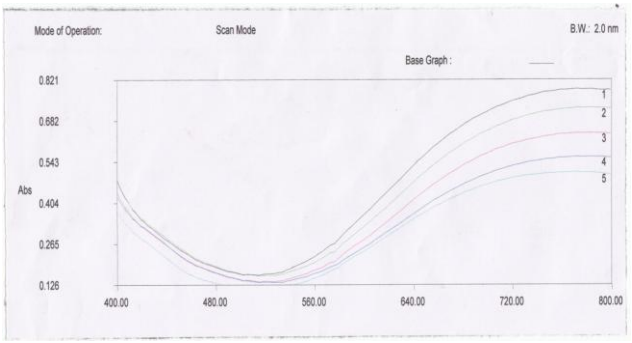

Figure 3: Overlain spectra of complex of Bisoprolol with Ferric Chloride and Potassium Ferricyanide, having max at 770 nm

RESULTS AND DISCUSSION

This method was validated according to ICH Q2B R1 guidelines for validation of analytical procedures in order to determine the linearity, sensitivity, precision, robustness and accuracy for the analyte. Accuracy and specificity of analysis was determined by performing recovery studies by spiking different concentration of pure drug in the preanalyzed tablet sample.

Table No. 1: Results of Linearity

Linearity	
Conc. (µg/ml)	**Abs.**
1	0.115
3	0.281
5	0.423
7	0.647
9	0.824
11	1.032
13	1.207

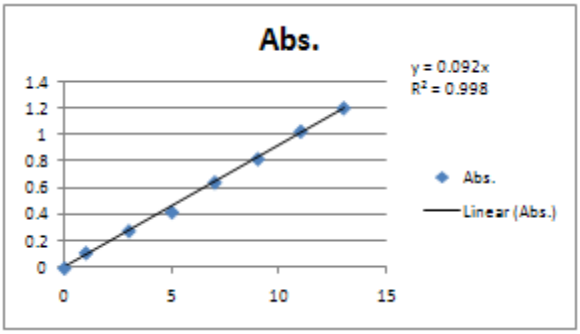

Table No 2: Results of Precision

Sr. No.	Concentration (µg/ml)	Intra-day absorbance mean			% RSD
		Absorbance1	Absorbance2	Absorbance3	
1	7	0.647	0.679	0.658	
2	7	0.649	0.675	0.660	
3	7	0.650	0.678	0.657	
4	7	0.649	0.681	0.663	
5	7	0.648	0.679	0.661	
6	7	0.652	0.679	0.661	
	%RSD	0.26%	0.30%	0.33%	0.30%
Sr. No.	**Concentration (µg/ml)**	**Inter-day absorbance mean**			**% RSD**
		Day1	**Day2**	**Day3**	
1	7	0.647	0.661	0.686	
2	7	0.649	0.659	0.679	
3	7	0.650	0.664	0.680	
4	7	0.649	0.66	0.679	
5	7	0.648	0.659	0.683	
6	7	0.652	0.654	0.683	
	%RSD	0.27%	0.50%	0.41%	0.39%

Table No. 3: Results of Sensitivity

	LOD	LOQ
	0.0617	0.1871
	0.0708	0.2147
	0.0786	0.2382
Avg	0.070367	0.213333
SD	0.070367	0.025577

Table No. 4: Results of Robustness

Temp.	30	25
Conc	7µg/ml	7µg/ml
Abs	0.647	0.674
	0.649	0.673
	0.650	0.669
	0.649	0.669
	0.648	0.671
	0.652	0.674
Avg	0.649167	0.671667
SD	0.001722	0.671667

Table No. 5: Results of Ruggedness

Conc.	Abs.	
	Analyst 1	Analyst 2
7 µg/ml	0.647	0.654
	0.649	0.661
	0.650	0.659
	0.649	0.658
	0.648	0.659
	0.652	0.660
Avg	0.649167	0.6585
SD	0.001722	0.002429

Table No. 6: Results of Specificity

Sr. No	Excipient conc.%	Drug conc (ug)	Drug Recovered(%)	Mean Recovered(%)	S.D	% R.D.S
1	50	7	100.71			
2	100	7	101.42			
3	150	7	101	101.04	0.357	0.353

Table No. 7: Method Validation Parameters.

Sr.No.	Parameters	Values
1	Beers's law limit (µg/ml)	13-Jan
2	Regression equation (y=mx+c)	y=0.092x
3	Correlation coefficient (r^2)	0.998
4	Slope (m)	0.092
5	Intercept (c)	0
6	Specificity	101.04%
7	Linearity (r^2)	0.998
8	Limit of Detection (µg/ml)	0.07±0.01
9	Limit of Quantitation (µg/ml)	0.021±0.025
10	Precision (%RSD)	
	-Intraday	0.296
	-Interday	0.392
	-Repeatability	0.26
11	Accuracy (% recovery)	99.06%

CONCLUSION

It is evident from results of validation studies that methods are accurate, sensitive, selective, precise and robust for spectroscopic estimation of Bisoprolol. More over the method is economic, simple and rapid, hence can be employed for routine analysis in quality control laboratory for estimation of Bisoprolol from marketed formulations after optimizing these methods to estimate Bisoprolol from biological fluids, these methods can be used in clinical and bioequivalence studies.

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