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Estimation of Labetalol Hydrochloride in bulk and formulation by UV-Spectrophotometric Area Under Curve.

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ABSTRACT

The current work was carried out for estimation of labetalol hydrochloride in bulk and pharmaceutical dosage form by utilizing area under curve method (AUC) method .For this purpose the wavelength range 200-400 nm was selected .Distilled Water was used as a solvent throughout the work. The linearity was observed in concentration range 5-25 µg/ml (r^2 =0.9788) for the method. The present was found which can be used for routine quality control analysis for spectrophotometric estimation of labetalol hydrochloride in bulk and dosage form.

Keywords: Labetalol hydrochloride, Area under curve (AUC), Distilled Water, UV Spectrophotometric.

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INTRODUCTION

Labetalol is used with or without other medications to treat high blood pressure (hypertension). Labetalol Hydrochloride is the hydrochloride form of labetalol, a third generation selective alpha-1-adrenergic antagonist and non-selective beta-adrenergic antagonist with vasodilatory and antihypertensive properties. Labetalol competitively binds to alpha-1-adrenergic receptors in vascular smooth muscle, thereby inhibiting the adrenergic stimulation of endothelial cell function and vasoconstriction in peripheral blood vessels. This agent also binds to beta-receptors in the bronchial and vascular smooth muscle, resulting in a decrease in adrenergic stimulation. The result is a decrease in resting and exercise heart rates, cardiac output, and in both systolic and diastolic blood pressure, thereby resulting in vasodilation, and negative chronotropic and inotropic cardiac effects. Chemically is 2-hydroxy-5-[1-hydroxy-2-(4-phenylbutan-2-ylamino)ethyl]benzamide;hydrochloride.[1,2]

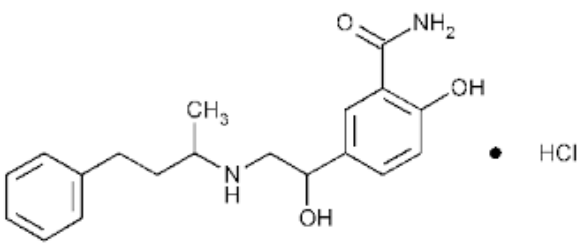

Figure 1 :Chemical Structure of labetalol hydrochloride.

MATERIALS AND METHOD

1.Chemicals : Labetalol hydrochloride was a gift sample from Flamingo Pharmaceutical, Taloja, Navi Mumbai, India. Labetalol Hydrochloride 100 mg MACLEODS. All chemicals and reagents were of analytical (AR) grade.

2.Instrumentation:

A Shimadzu (Kyoto , Japan)model UV – 1800 double beam UV – Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions . Analytical balance and mattler Toledo (Model JL1503–C).

3.METHOD:

A) UV-Spectroscopy Methods:

a)Area under curve method :

The AUC (area under curve) method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between the two selected wavelengths λ1 and λ2. Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which area has to be calculated. This wavelength range is selected on the basis of repeated

observation so as to get the linearity between area under curve and concentration. The above-mentioned spectrums were used to calculate AUC. [3]

4. Experimental Work:

a) To check the solubility of Labetalol Hydrochloride:

10 mg of Labetalol Hydrochloride was weighed and solubility of this sample was checked in distilled water, methanol, 1N NaOH.

b) To identify the λmax of Labetalol Hydrochloride:

Accurately weigh 100 mg of pure drug and dissolve it in a small portion of distilled water and makeup the final volume up to 100 ml using distilled water to give a standard stock solution of 1000 µg/ml. From above solution withdraw 10 ml solution and transfer it into a 100 ml volumetric flask and makeup final volume with distilled water to prepare 100 µg/ml solution. Suitable dilutions made with distilled water to get working standard solutions of 5, 10, 15, 20, 25µg/ml.[4] Spectrum peak details are shown in Fig 2 spectrum peak pick .

C) Sample preparation for analysis of formulation:

Accurately weigh twenty tablets of metformin crush the tablets and measure the weight of powder equivalent to 100 mg of drug. Then transfer it into a 100ml volumetric flask dissolve it into distilled water properly and make up the final volume with same distilled water to prepare 1000 µg/ml solution. Then it filtered through whatman filter paper, pippetout 10ml filtrate transfer it into 100 ml volumetric flask and makeup the volume up to 100 ml with distilled water to prepare 100 µg/ml solution. Suitable dilutions made with distilled water to get working standards of 5, 10, 15, 20, 25 µg/ml.[5,6]

5. Analytical Method Development and Validation:

The developed method was validated as per ICH guidelines.

1) Linearity:

The linearity of an analytical procedure is the interval between the upper and lower concentration of an analyte in the sample.For which it has been demonstrated that the analytical procedure is of linearity. Standard solution of Labetalol hydrochloride (5,10,15,20,25µg/ml) was pipette out in to a separated series of 25ml volumetric flask. The volume was adjusted to the mark with distilled water and mixed well. [7,8] The absorbance maxima and area under curve for the solutions was measured at 219.20nm and range of 200-400nm for two methods respectively against distilled water as blank.

RESULTS AND DISCUSSION

1. λmax of Labetalol Hydrochloride

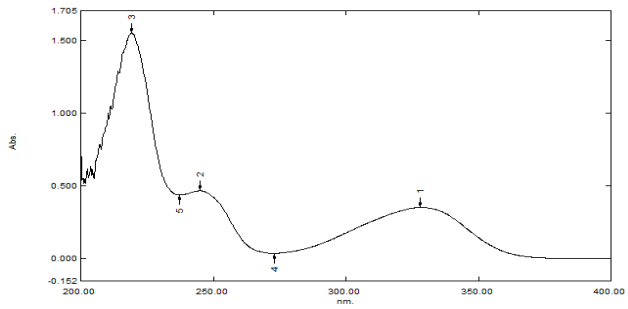

Figure 2: Spectrum Peak Report of Labetalol

2. Linearity & Range:

A] Calibration curve for pure drug:

a) Absorbance maxima method:

Under the experimental conditions described, the graph obtained for the absorbance maxima for pure drug showed linear relationship (Fig.2).Regression analysis was made for the slope, intercept and correlation-coefficient values. The regression equations of calibration curve were y=0.0517x +0.2567(R^2=0.9788) at 219.20 nm for absorption maxima the range was found to be 5-25µg/ml for the UV spectrometry.

Table 1: Calibration curve of Labetalol hydrochloride.

CONC.	ABS
5	0.444
10	0.868
15	1.039
20	1.279
25	1.531

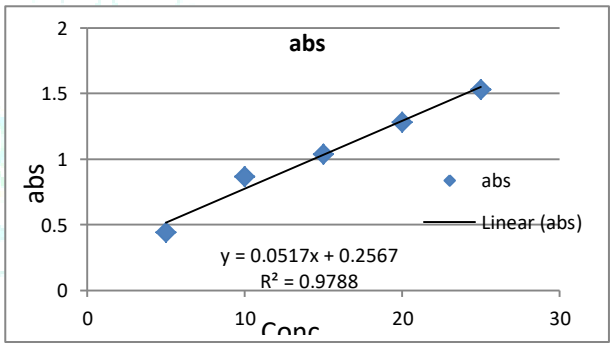

Figure 3: Calibration of Labetalol Hydrochoride (Pure Drug).

Table.2:Calibration curve of Labetamac.

Conc.	Abs.
5	0.389
10	0.871
15	1.225
20	1.55
25	1.796

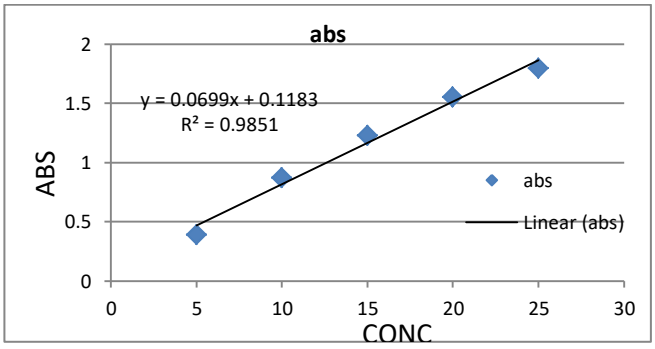

Figure 4: Calibration of formulation of Labetalol hydrochoride (Labetamac).

b) Area under curve method:

Under the experimental conditions described, the graph obtained for area under curve spectra showed linear relationship (Fig.3& Fig.4). The range was found to be 5-25µg/ml for area under curve spectrophotometric analysis.[9]

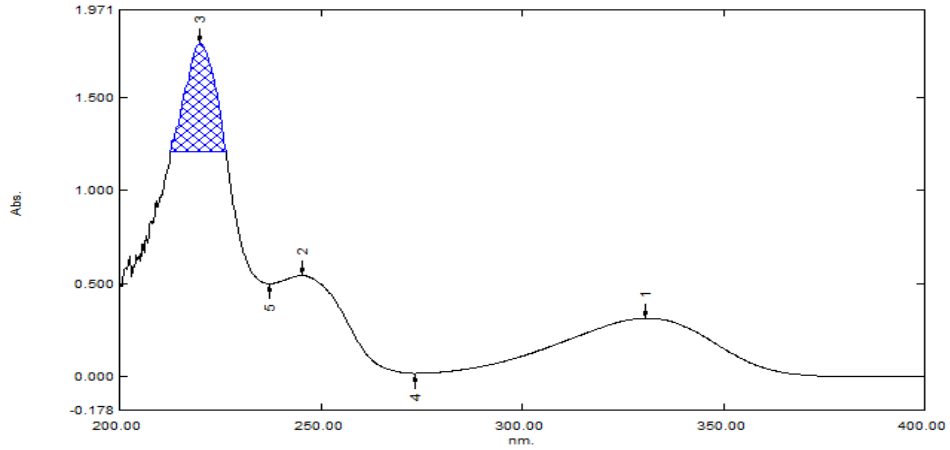

Fig 5 : Area between 212.60-226.40nm selected for Labetalol hydrochloride.

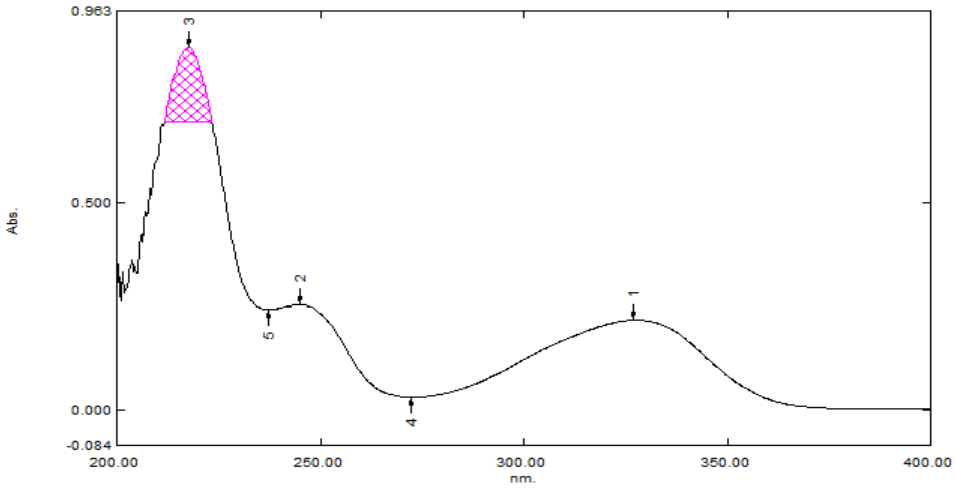

Fig 6: Area between 211.00-223.80nm selected for Labetamac.

CONCLUSION

Simple UV spectrophotometric methods have been developed and validated for the determination of Labetalol hydrochloride bulk and formulation. Because of cost-effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries and successfully applied and suggested for the quantitative analysis of labetalol hydrochloride in pharmaceutical formulations for QC, where economy and time are essential and to assure therapeutic efficacy.

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