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Simultaneous estimation of simvastatin and labetalol in bulk and solid dosage form

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ABSTRACT

A simple, accurate, precise, sensitive, and highly selective ultra violet spectrometer method has been developed for the simultaneous estimation of simvastatin and labetalol in bulk and solid dosage form. The estimation of simvastatin was carried out at 239 nm while labetalol was estimated at 222.4 nm. The developed method was validated for linearity range, precision, recovery studies and interference study for mixture, all these parameter showed the adaptability of the method for the method quality analysis of the drug in bulk and combination formulation.

Keywords: Simvastatin, Labetalol, UV Spectrophotometric, Dosage form.

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INTRODUCTION

Simvastatin is chemically is 2,2-Dimethyl butanoic acid (1S,3R,7S,8S,8aR)-1,2,3,7,8,8ahexahydro- 3,7- dimethyl-8-[2-[(2R,4R)- tetrahydro-4-hydroxy-6 oxo2H pyran-2yl]ethyl]1-napthalenyl ester used as a HMGCoA reductase inhibitors. Simvastatin belongs to a class of drugs called HMG-CoA reductase inhibitors commonly called statins that derived synthetically from fermentation products of Aspergillus terreus. All statins act by inhibiting 3-hydroxy-3-methylglutarylcoenzyme (HMG-CoA).A HMG-CoA reductase, the rate limiting enzyme of the HMG-CoA reductase pathway, the metabolic pathway responsible for the endogenous production of cholesterol mainly used for the treatment of dyslipidemia and the prevention of cardiovascular diseases.Simvastatin is prodrug which is converted into its β- hydroxy which inhibits HMG CoA reductase (3-hydroxy-3-methyl glutarylCoenzyme A) enzyme, responsible for catalysing the conversion of HMG CoA to mevalonate a rate limiting step in the synthesis of cholesterol in liver.[7]

Labetalol HCl is a selective α1 and non-selective β adrenergic blocker used to treat high blood pressure.Chemically it is 2-hydroxy-5-{[1-hydroxy-2-(4 phenyl butane-2-lyl) amino] ethyl}benzamide. It has a molecular formula of C19H24N2O3.Hcl and a molecular weight of 328.40g/mol.[8]

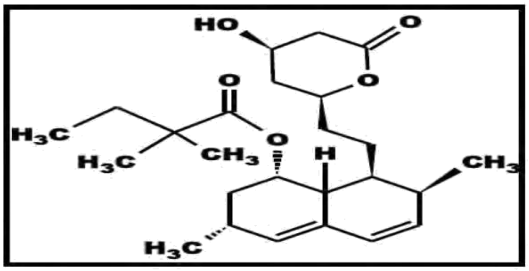

Figure 1 Chemical Structure of Simvastatin

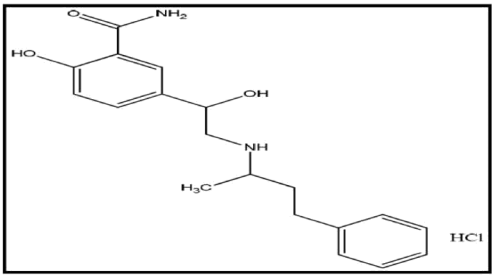

Figure 2 Chemical Structure of labetalol HCL

MATERIAL AND METHOD

A UV Visible double beam spectrophotometer (Shimadzu model UV 1800) attached to computer UV probe 2.33 with spectral width of 2 nm, wavelength accuracy 0.5 nm and pair of 1 cm matched quartz cell was employed.Kindly gifted reference standard of simvastatin and labetalol HCL (Flemigo pharmaceutical) were used for study.[1,2]

Preparation of standard stock solution

An accurately weighed quantity of about 100 mg of simvastatin was taken in 100 ml volumetric flask dissolved in sufficient quantity of 0.25 N NaOH then sonicated for 15 min and diluted to 100 ml with the same solvent so as to get the concentration of 100 µg/ml.s An accurately weighed quantity of about 100 mg of labetalol was taken in 100 ml volumetric flask dissolved in sufficient quantity of 0.25N NaOH then sonicated for 15 min and diluted up to 100 ml with the same solvent so as to get the concentration of 100µg/ml. This stock solution is used for making dilutions for calibration curve.1,2,5

Deternination of λ Max:

The standard solution of simvastatin and labetalol were separately scanned at different concentration in the range of 200-400 nm and the λ max was determined.[1]

Preparation of calibration curve:

For each drug appropriate aliquots were pipette out from standard stock solution into the series of 10 ml volumetric flask and the volume was made up to the mark with NaOH to get concentration of 2-10 µg/ml of simvastatin and 2-10 µg/ml of labetalol.Solutions of different concentrations for each drug were analysed at their respective wavelengths and absorbances were recorded.[1,7,8]

Preparation of mixed standard solution:

Accurately 20 mg of simvastatin and 50 mg labetalol were weighed into 100 ml clean and dry volumetric flask and 50 ml of 0.25 N NaOH was added.

This mixed standard solution was sonicated for 10 minutes and then volume made up to mark with 0.25 N NaOH and prepared solution was subjected to UV analysis.[1]

Preparation of stock solution of tablet formulation:

Bi layer Ten tablets of simvastatin and labetalol was prepared containing 20 mg of simvastatin and 50 mg of labetalol were weighed and finely powdered separately. Powder equivalent to 20 mg of simvastatin and 50mg of labetalol was weighed and transferred to a sintered glass crucible and drug was extracted with three 20 ml quantities of 0.25N NaOH, and then final volume of the solution was made up to 100 ml with 0.25N NaOH to get a stock solution containing 200 µg/ml of simvastatin and 500 µg/ml labetalol, and further dilutions were made to get a concentration of 2µgm/ml of simvastatin and 5 µg/ml of labetalol.[1,2,8]

Recovery:

To evaluate the accuracy, precision and reproducibility of the method, known amount of pure drug was added to the analyzed sample of tablet powder and the mixture was analyzed for the drug content using the proposed method. The percentage recovery was found to be within range. The recovery experiments indicated the absence of interference from the commonly encountered Pharmaceutical additives and excipients.[1,2]

RESULTS AND DISCUSSION

The proposed method for determination of simvastatin and labetalol showed molar absorptivity 2.038×10^4 L/mol.cm and 2.874×104 L /mol cm.The result of UV analysis has been shown in Table-1 indicates that the representative calibration curve of simvastatin and labetalol were plotted at 239 nm and 222.4 nm respectively. A linear relationship was obtained for both the drugs in the concentration range of 2-10µg/ml for simvastatin and 2-10µg/ml for labetalol. Linear regression of absorbance on concentration gave the equation, For, simvastatin

$y = 0.0507– 0.0156$

Correlation coefficient (R2) = 0.991

For, Labetalol $y =0.0675x + 0.0821$

Correlation coefficient (R2) = 0.997

The result of UV analysis for tablet formulation has been shown in Table-2 indicates that none of the pharmaceutical excipients interfered in the estimation of simvastatin and labetalol in the UV Spectrophotometric method. The calculation of concentration for tablet formulation done by simultaneous equation method. The result of recovery study shown in Table-3 clearly indicate that the percentage recovery was found to be within range.[1,2,6]

Table 1:

Parameter	simvastatin	labetalol
Detection Wavelength	239 nm	222.4 nm
Beers Law limit	2-10 µg/ml	2-10 µg/ml
Molar Absorptivity	2.038×10^4 L/mol.cm	2.874×10^4 L /mol cm
Regression Equation	Y= MX + C	Y= MX + C
Slope	0.0507	0.0675
Intercept	0.0156	0.0821
Correlation Coefficient	0.991	0.997

Table 2: Result of analysis of tablet formulation

Formulation	Drug	Label Claim (Mg)	% Label Claim
Tablet	simvastatin	20mg	98.20%
	labetalol	50 mg	99.1%

Table 3: Result of recovery study

Formulation	Drug	Label claim(mg)	% Recovery estimated
Tablet	simvastatin	20mg	98.3%
	labetalol	50 mg	98.2%

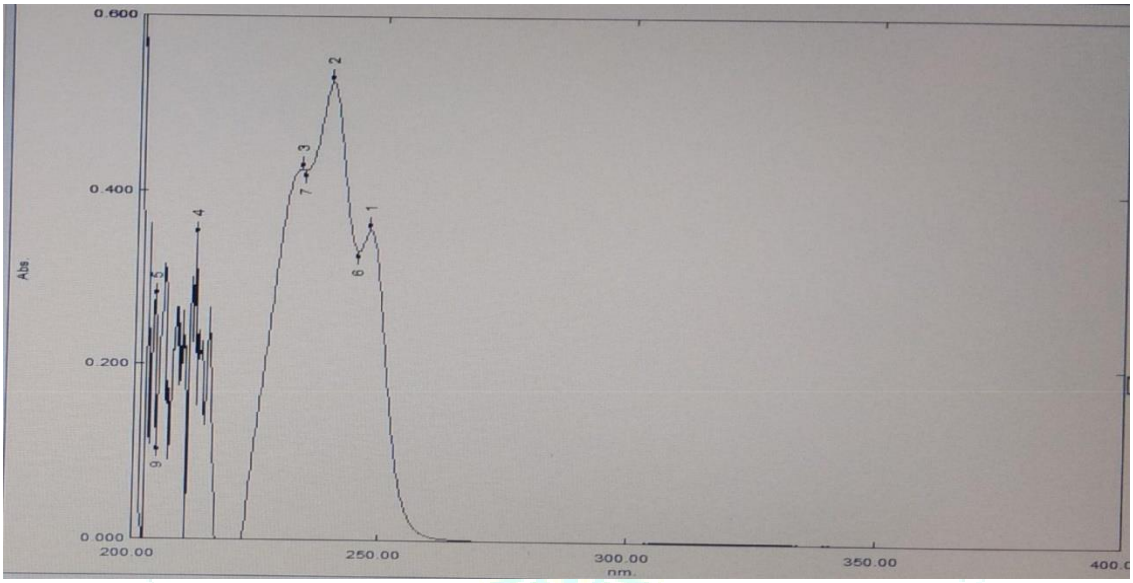

Figure 3: λ max of simvastatin

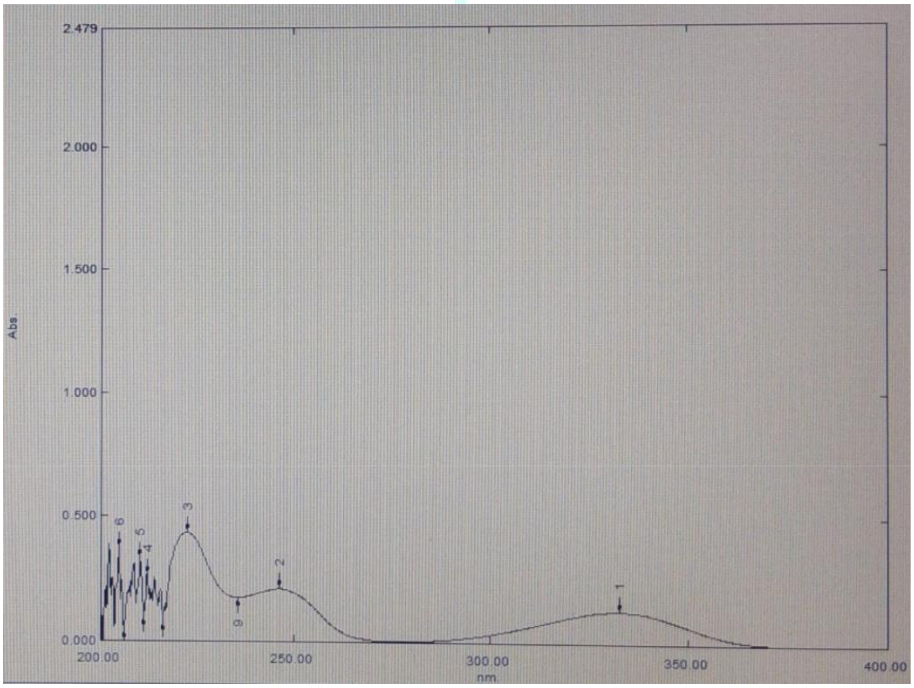

Figure 4: λ max of labetalol

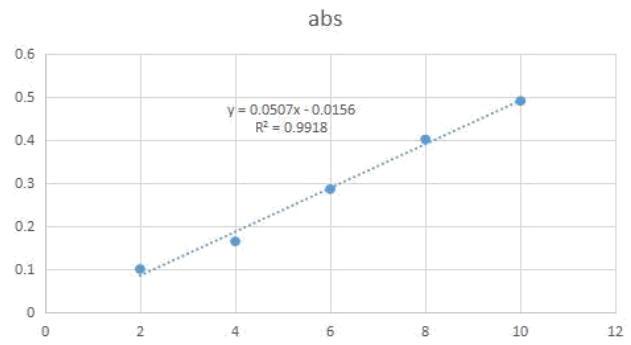

Figure 5: calibration curve for simvastatin

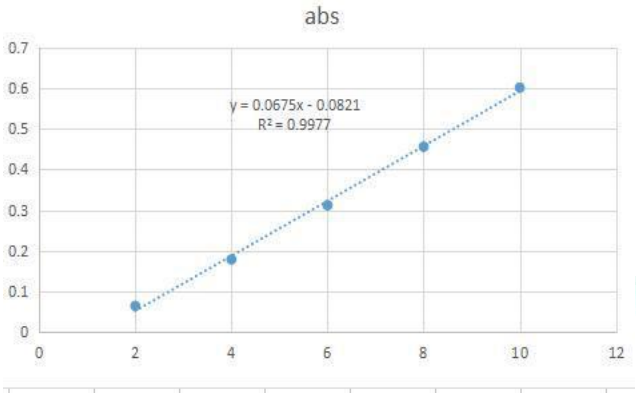

Figure 6: Calibration curve for labetalol

CONCLUSION

The Spectrophotometer provides versatile techniques for analyse drug in multicomponent pharmaceutical formulation in presence of various interferences. The present work describes simple, economical and non-interfering spectrophotometric method for the estimation of simvastatin and labetalol using simultaneous equation method. The method was found to be economic, simple, precise, accurate and reproducible during analysis of drug formulations containing the two drugs.[1,2,8]

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