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ORIGINAL ARTICLE **OPEN ACCESS**

UV-Spectrophotometric Method for Simultaneous Estimation of Simvastatin and Metformin 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 Metformin in bulk and solid dosage form. The estimation of simvastatin was carried out at 239 nm while metformin was estimated at 239 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, Metformin, 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 CoAreductase (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.[9]

Metformin is a biguanide oral hypoglycemic used primarily for treating type 2 diabetes mellitus (T2D.It has molecular formula C4H11N5 and molecular weight C4H11N5 , chemically it is a 1,1-Dimethylbiguanide.[8]

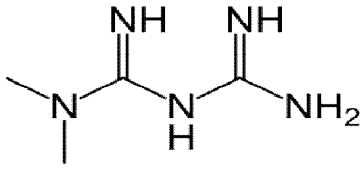

Figure1-Chemical structure of metformin

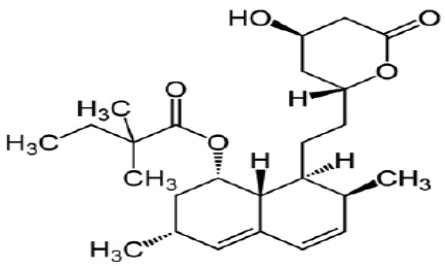

Figure2- Chemical structure of simvastatin

MATERIAL AND METHODS

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 metformin (Flemigo pharmaceutical) were used for study [2, 1].

Preparation of Standard Stock Solution:

An accurately weighed quantity of about 100 mg of simvastatin was taken in 100 ml volumetric flask dissolved n sufficient quantity of methanol then sonicated for 15 min and diluted to 100 ml with the same solvent so as to get the concentration of 1000µg/ml. An accurately weighed quantity of about 100 mg of metformin was taken in 100 ml volumetric flask dissolved in sufficient quantity of methanol then sonicated for 15 min and diluted up to 100 ml with the same solvent so as to get the concentration of 1000µg/ml. This stock solution is used for making dilutions for calibration curve [2, 8, 9].

Determination Of λ Max:

The standard solution of simvastatin and Metformin were separately scanned at different concentration in the range of 200-400 nm and the λ max was determined [1,2,8,9].

Preparation of Calibration Curve:

For 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 distilled water to get concentration of 2-10 µg/ml of simvastatin and 2-10 µg/ml of metformin. Solutions of different concentrations for each drug were analysed at their respective wavelengths and absorbance's were recorded [8, 9].

Preparation Of Mixed Standard Solution:

Accurately 50 metformin were weighed into 100 ml clean and dry volumetric flask and 50 ml of distilled water was added. This mixed standard solution was sonicated for 10 minutes and then volume made up with methanol and prepared solution was subjected to UV analysis [1].

Preparation of Stock Solution Of Tablet Formulation:

Bi layer Two tablets of simvastatin and metformin was prepared containing simvastatin and metformin were weighed and finely powdered sepsarately.50mg weight equivalent to simvastatin and metformin was weighed and transferred into 50ml volumetric flask and volume make up with methanol upto 50ml and transfer into 100ml volumetric flask and volume make up with 100ml distilled water then further dilution were make up with respective solvent such as 2-10ppm [1, 2].

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 [8, 9].

RESULTS AND DISCUSSION

The proposed method for determination of simvastatin and metformin showed molar absorptivity 2.038×104 L/mol.cm and 5.7×10^4L/mol.cm. The result of UV analysis has been shown in Table-1 indicates that the representative calibration curve of simvastatin and metformin were plotted at 239 nm and 233 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 metformin. Linear regression of absorbance on concentration gave the equation,

For, simvastatin

$y = 0.017x + 0.065$

Correlation coefficient (R2) = 0.998

For, metformin

y = 0.018x + 0.141

Correlation coefficient (R2) = 0.991.

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 metformin 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.

Table 1: Representative calibration curve of simvastatin and metformin

Parameter	**Simvastatin**	**Metformin**
Detection Wavelength	239nm	233nm
Beer's law	2-10µg/ml	2-10µg/ml
Molar Absorptivity	2.038×10^4 L/mol.cm	5.7×10^4L/mol.cm
Regression Equation	Y= MX + C	Y= MX + C
Slope	0.017	0.018
Intercept	0.065	0.141

Table 2- Result of analysis of Tablet Formulation

Formulation	**Drug**	**Label claim(mg)**	**%Label Claim**
Tablet	Simvastatin	40mg	98.30%
	Metformin	500mg	99.10%

Table3-Result of Recovery Study

Formulation	**Drug**	**Label claim**	**%Recovery estimated**
	Simvastatin	40mg	98.30%
	Metformin	500mg	98.5%

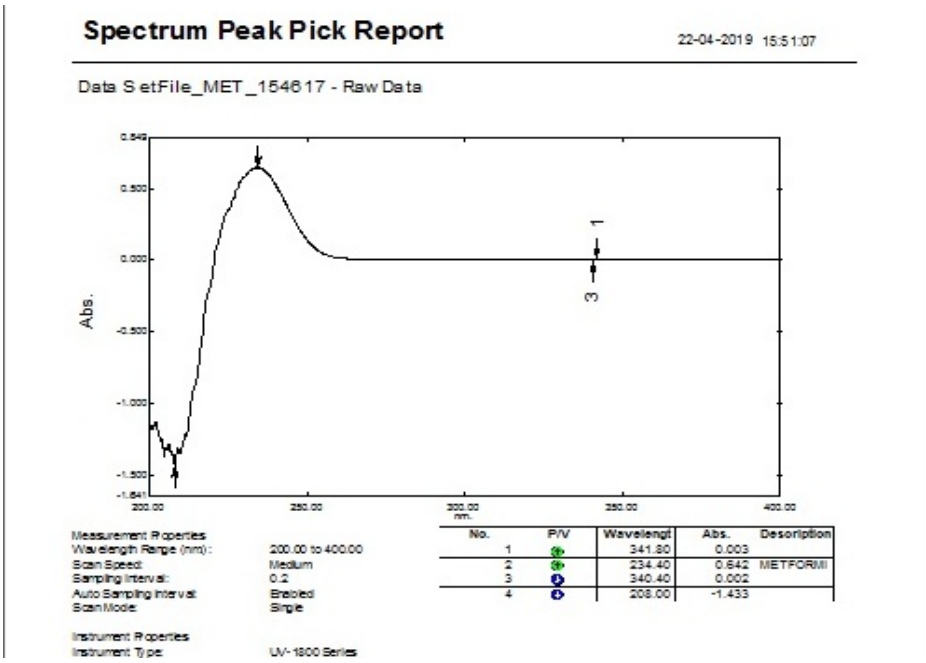

Figure3: λ max of Metformin

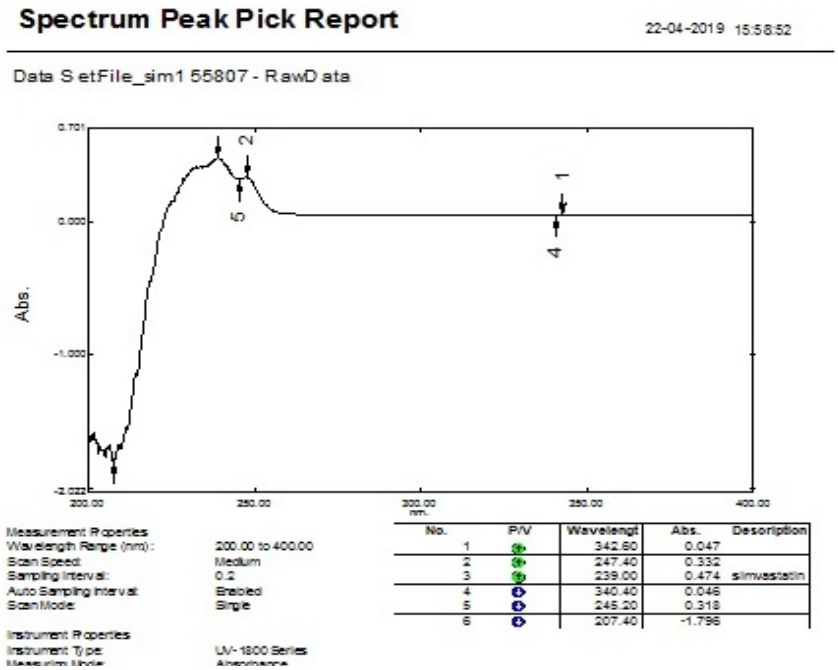

Figure4 - λ max of simvastatin

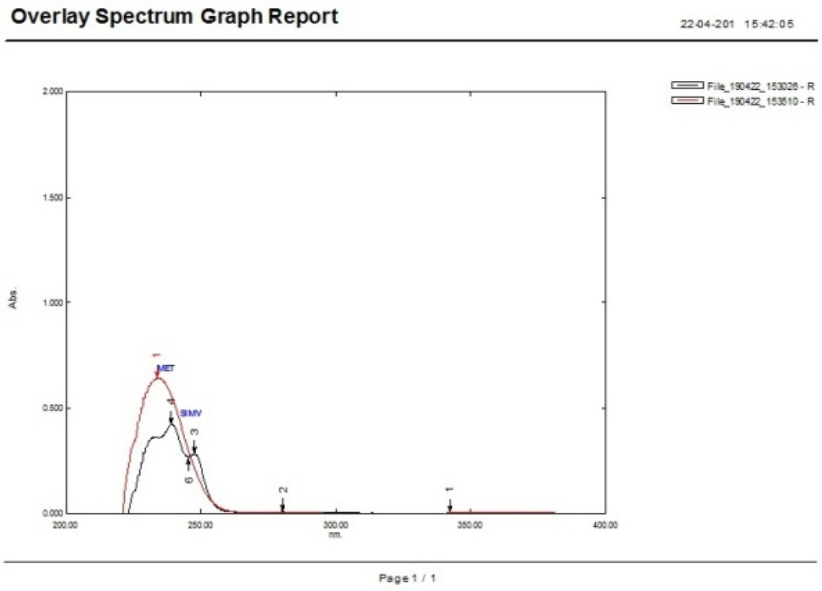

Figure5 – Combination of Simvastatin And Metformin

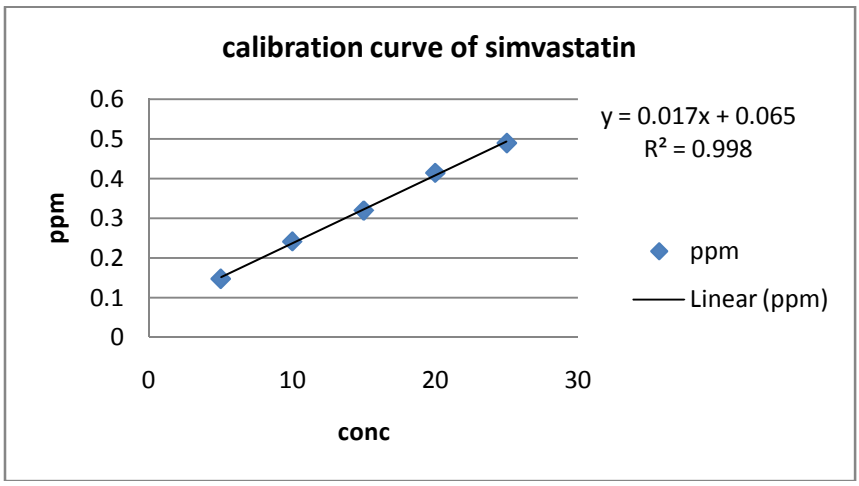

Figure 6 – Calibration curve of simvastatin

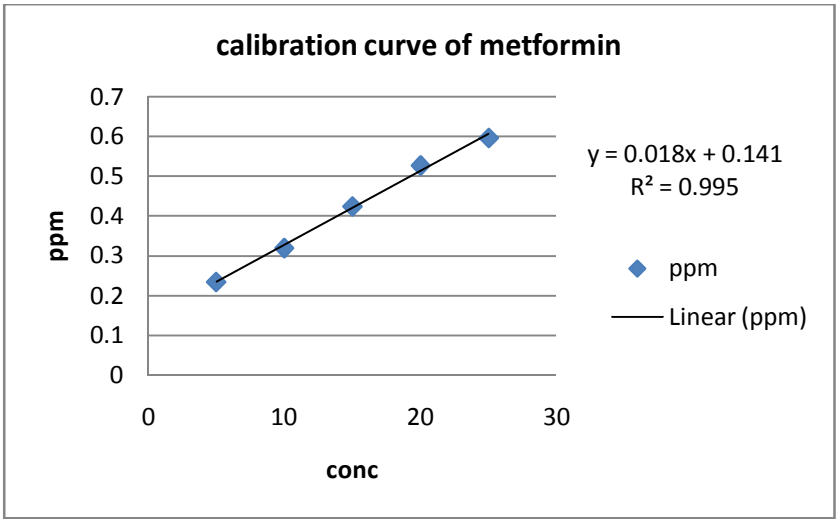

Figure7 - Calibration curve of Metformin

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 Metformin 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.

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