Global Journal of Nanomedicine
ISSN: 2573-2374

Juniper Publishers
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Research Article
Volume 4 Issue 3 - October 2018
DOI: 10.19080/GJN.2018.04.555638

Glob J Nanomed

Spectrophotometric Method Development for Simultaneous Estimation for Combination of Rosuvastatin and Curcumin

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Submission: August 14, 2018; **Published:** October 22, 2018

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Keywords: Rosuvastatin; Calcium salt; Hepatic; Inflammation; Cholesterol levels

Abbreviations: RSV: Rosuvastatin; VLDL: Very Low-Density Lipoprotein; LDL: Low Density Lipoprotein; LDL: Low-Density Lipoprotein-Cholesterol;HDL: High-Density Lipoprotein–Cholesterol

Introduction

Rosuvastatin (RSV) is the calcium salt of bis [(E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-methyl (methyl sulfonyl) amino] pyrimidin-5-yl] (3R,5S)-3,5- dihydroxyhept-6-enoic acid]. RSV is a selective and competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme-A (HMG-CoA) reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to Mevalonate, a precursor of cholesterol. RSV is a member of the class of statins, used to treat hypercholesterolemia and related conditions and to prevent cardiovascular disease. It increases the number of hepatic LDL (Low Density Lipoprotein) receptors on the cell surface to enhance uptake and catabolism of LDL. Secondly, RSV inhibits hepatic synthesis of VLDL (Very Low-Density Lipoprotein), which reduces the total number of VLDL and LDL particles4.whereas curcumin is bis-α -β-unsaturated β-diketone with molecular weight 368.37 used in the treatment of inflammation [1].

Similarly, Curcumin has been shown to have over 600 specific health related functions in the body. It is important to maintain healthy cholesterol levels. Bad (LDL) cholesterol is known to deposit cholesterol in blood vessels, which can cause blockages in blood flow. Preventing proper blood flow can lead to a number of serious health concerns. Curcumin has been shown to exhibit anti-atherosclerotic action through protection against inflammation and oxidation, modulation of cholesterol homeostasis and inhibition of platelet aggregation. Studies have reported that curcumin is beneficial in lowering low-density lipoprotein-cholesterol (LDL) and raising high-density lipoprotein–cholesterol (HDL) while reducing lipid per oxidation. Animal studies in high fat-fed atherosclerotic rabbit model have revealed that curcumin effectively inhibit LDL oxidation and decreases cholesterol and triglyceroids levels [2].The role of Curcumin in hypercholesterolemia is shown in Figure 1.

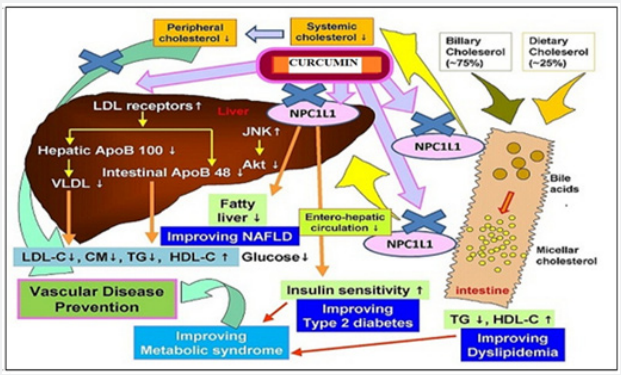

Figure 1: Role of curcumin in hypercholesterolemia.

In similar model, curcumin supplementation is also shown to significantly reduce early atherosclerotic lesions in thoracic and abdominal aorta, associated with reduced oxidative stress and decreased lipid peroxidation.Orally administered curcumin also decreases the formation of atherosclerotic lesions by 20% in apolipoprotein E and LDL receptor-Double knockout mice model of arthrosclerosis.

In human a study involving the administration of 500 mg of curcumin for 7 days to 10 healthy volunteers has shown a 29 %increases in HDL cholesterol, 12% decreases in total serum cholesterol and 33%decreases in total serum lipid peroxides. Administration of curcumin also reduces total and LDL cholesterol

levels in patients with acute coronary syndrome. Another study has shown that 10 mg of curcumin given twice daily for 30 days significantly lowers the serum LDL and increases the HDL levels in healthy patients.

The objective of our study was to develop UV Spectroscopy method for the estimation of rosuvastatin and curcumin according to the ICH guidelines. Rosuvastatin and Curcumin were taken in combination in order to improve activity of therapeutic drug in adjacent to an herbal drug. There was no reported side effect or drug reaction on jointly administration of Rosuvastatin with curcumin administration. The standard was taken for both drugs at a concentration of 10µg/ml and was scanned between 200-400 nm. On ultraviolet–visible spectrophotometric investigation maximum light absorption of both drugs occurred at 237.4 nm and 430nm.respectively. The structure of rosuvastatin and Curcumin is shown in Figure 2.

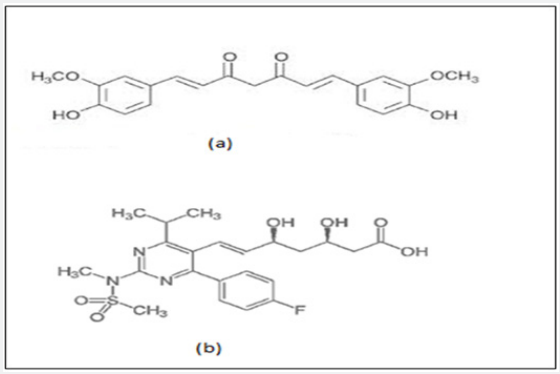

Figure 2: Structure of (a) curcumin and (b) rosuvastatin.

In fact, Curcumin could exert a synergistic effect when co-administration with Rosuvastatin. Hence a combined Drug delivery approaches was proposed for the development of a combination drug regimen[3].

Extensive literature has been done on study of rosuvastatin. Some of them are discussed as Reddy &Ashok etal.[4] in the year 2012 investigated the simultaneous determination of Rosuvastatin calcium and aspirin in tablets by Spectrophotometric method. Gajjr& Anuradha et al.[5]in the year 2010 explored the simultaneous estimation of Rosuvastatin and Ezetimibe by ratio spectra derivative Spectrophotometric method in their fixed dosage forms. In present work, simultaneous estimation of Rosuvastatin calcium with Curcumin is done by spectrophotometric method.

Materials and Methods

Materials

UV-visible double beam spectrophotometry (Shimadzu Model 1800) with matched quartz cell was used for all spectral measurements Reference standards of Rosuvastatin Calcium supplied by Torrent Research Center, Gandhi nagar, India with purity of 98.5% and 99.9% respectively. And curcumin was a gift sample obtained from RYM Exporters, New Delhi

Experimental methods

Selection of common solvent: After the solubility study of both drugs in different solvent, ethanol was confirmed as a common solvent for developing spectral characteristic [6].

Preparation of standard stock solution: Rosuvastatin (100mg) was transferred to a volumetric flask (100) having a reasonable quantity of ethanol and mixed properly. The volume was made up to 100ml with ethanol to have concentration of 1000 µg/ml of above solution was diluted to 1000 ml to give concentration of 10µg/ml .The same was designated as stock solution and was reserved for preparation of aliquots of various concentration 1,2,3,4,5,6,7,8,9,ml aliquots of stock solution was taken in a volumetric flask (10ml) and volume was madesolution was made up to10ml with ethanol to have concentration of 1,2,3,4,5,6,7,8,9, µg/ml. The absorbance was recorded for these concentrations at 237.4nm by using ethanol as a blank. The same done for curcumin [7]. The scan spectra and calibration curve of Rosuvastatin and Curcumin are shown in Figures 3a,b& 4a,b.

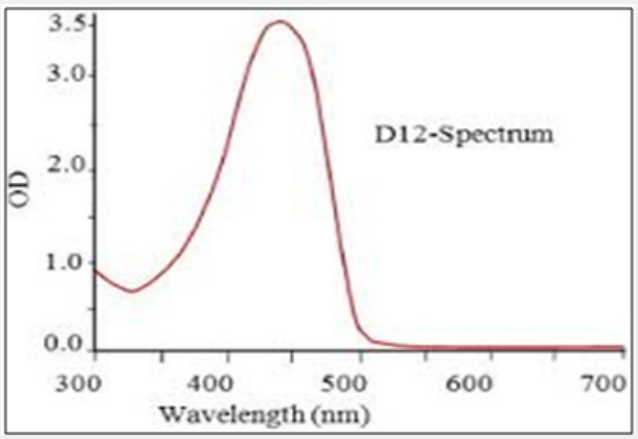

Figure 3a: Scan graph between wavelength v/s absorbance of pure curcumin.

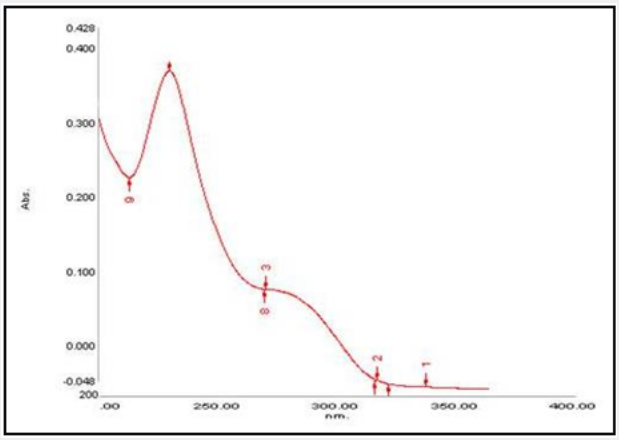

Figure 3b: Scan graph between wavelength v/s absorbance of rosuvastatin.

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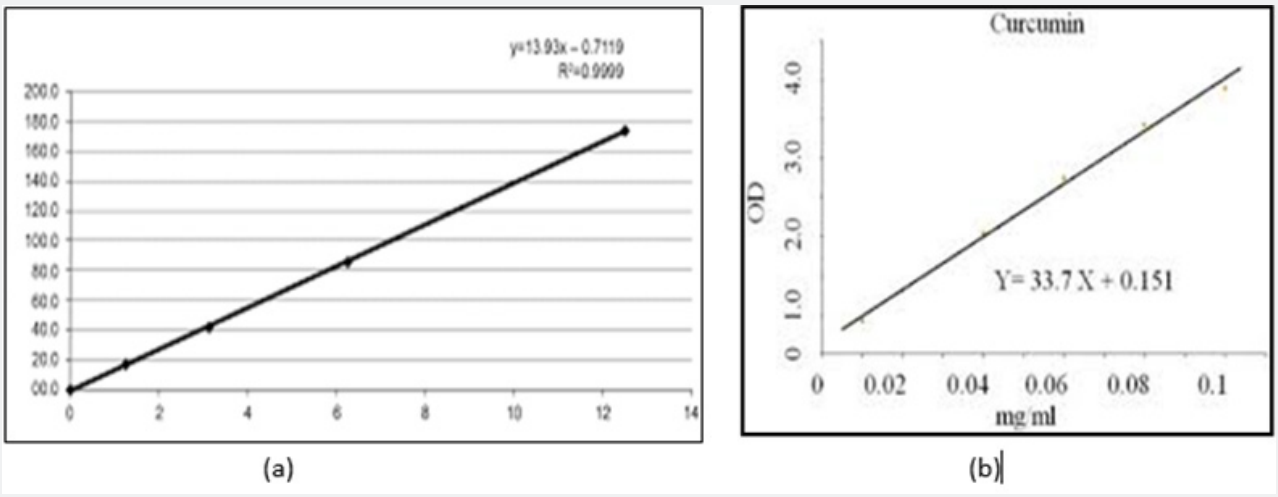

Figure 4a& 4b: a)Calibration curve of rosuvastatin and b) curcumin.

Method 1

Simultaneous equation method: From the standard stock solution,10ml of both the solution were taken and made it to final concentration of 10µg/ml. Absorbance was measured at both the wavelength (237.7nm and 430 nm) by using ethanol as blank. The readings were taken in triplicate. Absorbance of both the drugs was recorded at both the wavelength. The concentration was determined by using simultaneous equation method Kasture&Sharma et al.[8,9].

A1=ax1Cp+ay1Cs… (237.4nm)

A2=ax2Cp+ay2Cs… (430nm)

A1=Absorbance value of the sample solution at 237.4nm

A2=Absorbance value of the sample solution at 430nm

ax1 =Absorptivity of Rosuvastatin at 237.4nm

ax2=Absorptivity of Rosuvastatin at 237.4nm

ay1 =Absorptivity of curcumin at 430nm

ay2 =Absorptivity of curcumin at 430nm

Cp = Absorptivity of Rosuvastatin at 430nm

Cs=Absorptivity of Rosuvastatin at 237.4nm

Estimation of absorptivity (E1%, cm) values at selected wavelength: The Absorption (E1%, cm value) of Rosuvastatin and curcumin drugs was calculated at 237.4nm and 430 nm.

Method-2

Q-analysis (absorbance ratio method): Q-Absorbance method depends on the property that, for substances which obeys Beer's law at all wavelength, the ratio of Absorbance at any wavelength is a constant value independent of concentration or path length. In the quantitative assay of two components in a mixture by the absorbance ratio method, absorbance is measured at two wavelengths: once being the λmax of one of the equal absorptivities of the two components i.e an iso-absorptive point[10].

Determination of iso-absorptive point and selection of suitable wavelength: An iso-absorptive point (a wavelength of equal absorptivity of the components) was determined by taking overlain spectrum of the solutions rosuvastatin and Curcumin (20ug/ml) in ethanol (95%) in UV range against the solvent blank. From the overlain spectra of the two drugs, it was found that rosuvastatin showed λmax at 319 nm and curcumin showed max at 351 nm, as iso-absorptive point was selected for extermination of drug simultaneously [11].

Study of Beer's Lambert Law

The solution having concentration in range 1-10 for both rosuvastatin and curcumin were prepared in 0.1 N HCl using working standard solution. The absorbance of resulting solutions was measured at 275nm. Calibration curve were plotted at these wavelengths. Both the drugs obeyed linearity individually and combination within the concentration range of 1-10 µg/ml for both rosuvastatin andcurcumin [12].

Result and Discussion

The individual concentration range for Beer's Lambert Law was found 1-10µg/ml for both rosuvastatin and curcumin was found to be at 237.4 nm and 430nm. The overlay spectra of rosuvastatin and curcumin are shown in Figure 5. The coefficient correlations were 0.999 and 0.999 respectively. Table 1 enlists the details of parameters obtained in simultaneous estimation. UV-scan of 10 µg/ml solution of rosuvastatin and curcumin combination showed the absorption maxima at 237.4nm and 430 nm. The simultaneous estimation was done to check the interference between both the drugs at λmax of one another.

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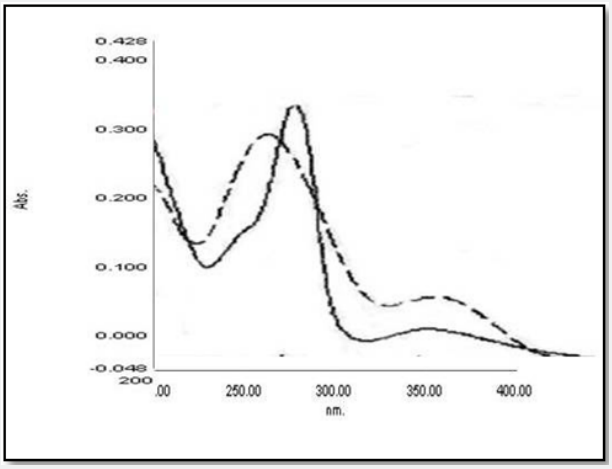

Figure 5: Overlay spectra of rosuvastatin and curcumin.

Table 1: Linearity data.

Parameters	Value for Rosuvastatin	Value for Curcumin
λmax	237.4nm	430nm
Linearity range(µg/ml)	1-10	1-10
Absorptivity	0.029	0.030
Regression coefficient(r^2)	0.999	0.999

By substituting absorbance and absorptivity values of table in simultaneous equation C_1 and C_2 were calculated C_1 = 9.78 µg/ml and C_2 = 10 µg/ml. The percentage of rosuvastatin and curcumin recovered after the combination was found to be 97.8% and 100% respectively and indicating no interference between both the drugs. The Linearity regression equation method for curcumin and rosuvastatin in different concentration range. The correlation coefficient of these drugs was found to be close to 1.00 indicating good linearity. Hence proposed method can be used for routine analysis of these two drugs in combined dosage form. It is validated as per ICH guidelines.

Conclusion

Rosuvastatin and curcumin both drugs are important for hypercholesterolemia and related conditions and to prevent cardiovascular diseases. This reduces the overall delivery of cholesterol to the liver, thereby promoting the synthesis of LDL receptors and the subsequent reduction in serum LDL-Cholesterol. UV-spectrophotometric method is selected for the analytical method development of Rosuvastatin and curcumin. The method is developed and validated. The proposed UV- spectrophotometric method was found very simple rapid and economical.However, the most important outcome of the simultaneous estimation is that we can formulate and analyze both drugs in combination for any suitable dosage form in a very safe and effective way. These methods can be used not only for above two combinations but also to a series of drugs having similar characteristic. This approach can be applied for the assay of the drugs in marketed formulation. Developed method can be used for routine analysis of these two drugs in combined dosage form.

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