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Spectrophotometric and chromatographic estimation of Telmisartan and Rosuvastatin in pharmaceutical dosage form

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ABSTRACT

A simple, accurate and rapid methods were developed for the simultaneous estimation of Telmisartan and Rosuvastatin in bulk and in combined tablet dosage form. In multicomponent mode of analysis, mixed standards of Telmisartan and Rosuvastatin and sample solution are subjected to scanning over the wavelength region of 400–200 nm in the multicomponent mode of UV-Visible spectrophotometer using sampling points (Absorption maxima), 295 nm and 247 nm of the two drugs. The drugs obeys Beer's law in the concentration range of 8-24µg/ ml and 2-6 µg/ ml for Telmisartan and Rosuvastatin respectively.The percentage purity values for Telmisartan and Rosuvastatin vary from 99.41–99.50% w/w and 98.73–100.94% w/w respectively. The quantitative results obtained are subjected to the statistical validation. The percentage recoveries vary from 99.32–100.11% w/w and 98.94–100.66% w/w for Telmisartan and Rosuvastatin respectively.

Keywords: Multicomponent mode; 0.1M Sodium Hydroxide; Validation.

1. INTRODUCTION

Telmisartan is chemically it is 4[(1, 4-dimethyl-2-pyl (2, 6-bi-1H-benzimidazol]-1-yl) methyl] [1, 1-biphenyl]-2-carboxylic acid[1]. Rosuvastatin is chemically (*E*)-(3*R*, 5*S*)-7-{4-(4-fluorophenyl)-6-isopropyl-2-{methyl(methyl sulphonyl amino)]pyrimidin-5- yl}- 3, 5-dihydroxy hepten-6-oic acid calcium[2]. Literature survey revealed that various methods such as UV [3-19], HPLC [10-16], HPTLC [17,18], are available in single and combination with other drugs. However, no spectrophotometric method has yet been reported for multicomponent mode of estimation of is Telmisartan and Rosuvastatin in tablet dosage forms.

2. METHODOLOGY

An Elico UV/Visible spectrophotometer SL 164 model with a Spectral band width of 10nm and wavelength accuracy of ±5nm with 1 cm matched quartz cells.The reference standards were obtained as gift sample from Nikon Laboratories, Villupuram, and the authenticity and purity of the sample was certified by the same.

2.1. Multicomponent Mode of Analysis

2.2. Preparation of Standard Drug Solution

An accurately weighed quantity of 50mg of Telmisartan and 125mg of Rosuvastatin were taken in 50ml standard flask and dissolved using 0.1M Sodium Hydroxide to give a standard stock solution having a concentration of 1000 µg/ml Telmisartan and 2500 µg/ml of Rosuvastatin. The standard stock solution was further diluted to give six mixed standard solutions having concentrations ranging from 8-24 µg/ml of Telmisartan and 2-6 µg/ml of Rosuvastatin. All the mixed standard solutions were scanned over the wavelength region of 400-200 nm in multicomponent mode using two sampling points (Absorption maxima of the two drugs), 295 nm and 247 nm.

The spectral data obtained from these scans was used to determine the concentration of the two drugs in the tablet sample solution.

2.3. Analysis of Tablet Formulation

Twenty tablets were weighed and ground to a fine powder. A quantity of the powder equivalent to 50mg of Telmisartan was accurately weighed and transferred to a 50ml volumetric

flask. The powder was dissolved in 0.1M Sodium Hydroxide and filtered through a Whatman filter paper. Then the volume was made upto 50ml using the same solvent. Then further dilutions were made to get the concentration of 20 µg/ml of Telmisartan and 8 µg/ml of Rosuvastatin and scanned over the range of 400-200 nm in the multi-component mode of spectrophotometer. The concentration of each component was obtained by analysis of the spectral data of sample solution with reference to that of the six mixed standards as a print out on the thermal paper attached to the instrument. The analysis of the two drugs was carried out six replicates using two different brands of tablets formulations.

2.4. VALIDATION OF METHODS

2.4.1. Linearity

Six mixed standard solutions were prepared and scanned over the range of 400 – 200nm in the multicomponent mode of spectrophotometer using two sampling points 295 nm and 247 nm for Telmisartan and Rosuvastatin. The data regarding the different concentrations used for preparing mixed standard solutions is shown in Table 1.

2.4.2. Precision

The precision of the method was confirmed by repeatability and intermediate precision. The repeatability was performed by the analysis of formulation was repeated for six times with the same concentration.The amount of each drug present in the tablet formulation was calculated. The % RSD was calculated.

2.4.3. Accuracy

To check the accuracy of the developed method and to study the interference of formulation excipients, analytical recovery experiments were carried out by using standard addition method in three different concentrations. From the total amount of drug found, the percentage recovery was calculated. This procedure was repeated for three times for each concentration. The % RSD was calculated.

3. RESULTS AND DISCUSSION

An attempt has been made to develop a fast, precise, reproducible and economical analytical method for Telmisartan and Rosuvastatin by using Multicomponent mode of analysis in their combined dosage form. The drugs obeys Beer's law in the concentration range of 8-24µg/ ml and 2-6 µg/ ml for Telmisartan and Rosuvastatin respectively. Sampling wavelengths based upon the direct UV spectroscopic data. There was no interference from tablet excipients was observed in these methods. The optical parameter values and correlation of coefficient for the method are reported in Table 2. The result of recovery studies for tablet is reported in Table 3. It indicates that there is no interference due to excipients present in the formulation. It can be easily and conveniently adopted for routine quality control analysis. Statistical analysis proves that, these methods are repeatable and selective for the analysis of Telmisartan and Rosuvastatin.

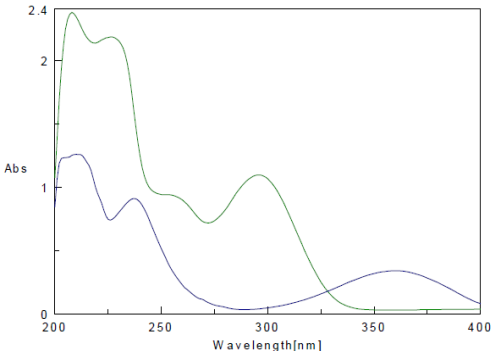

Figure - 1: Overlay UV Spectra

Table - 1: Concentrations of mixed standards used

Drugs	Mixed Standard Concentration (µg/ml)				
	1	**2**	**3**	**4**	**5**
Telmisartan	8	12	16	20	24
Rosuvastatin	2	3	4	5	6

Table - 2: Optical parameters

Parameters	Telmisartan	Rosuvastatin
λ_{max} (nm)	295	247
Beer's law limits (µg / ml)	8-24	2-6
Regression Slope (b)	0.047355	0.04501
Intercept (a)	-0.12496	-0.11392
Correlation	0.995425437	0.9968

Table - 3: Analysis of pharmaceutical formulation

Brand name	Compound	% Assay	% Recovery*
Telrose	Telmisartan	96.0	102.80
	Rosuvastatin	98.0	96.60

*Average for Three determinations at three different levels

4. CONCLUSION

A method was developed for the determination of tablets which is simple, quick, reliable, inexpensive and simple. The results indicate that the described method can be used for quantitative analysis of the compound.

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