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Simultaneous spectrophotometric estimation of telmisartan, amlodipine Besylate and hydrochlorthiazide in pharmaceutical dosage form

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ABSTRACT

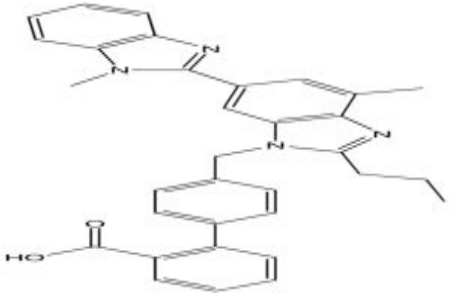
Two simple, accurate and rapid methods were developed for the simultaneous estimation of Amlodipine besylate, Telmesartan and hydrochlorothiazide in bulk and in combined tablet dosage form. The method is based on the simultaneous equation method. Telmesartan, amlodipine besylate and hydrochlorthiazide has absorbance maxima at 292.8 nm, 238.5 nm and 271.2 nm respectively.

Key words: Simultaneous equation method, UV spectrophototmeter, telmesartan, amilodipine besylate, hydrochlorothiazide.

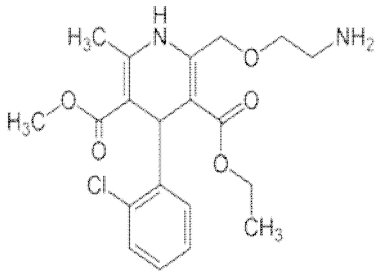
1. INTRODUCTION

Telmisartan is 4'-[(1, 4'-dimethyl-2'-propyl [2, 6'-bi-1H-benzimidazol]-1'-yl) methyl] [1,1'-biphenyl]- 2-carboxylicacid. Amlodipine besylate is chemically 3-Ethyl 5-methyl (4RS)-2-[(2-aminoethoxy) methyl] - 4-(2-chlorophenyl)-6- methyl-1, 4-dihydropyridine-3,5dicarboxylate benzene sulphonate .Hydrochlorothiazide is chemically 6-chloro-1, 1-dioxo-3, 4-dihydro-2H-enzo [e] [1,2,4] thiadiazine sulfonamide. Amlodipine besylate is official in IP [1] and Hydrochlorthiazide is official in IP [2].Literature survey revealed that various methods such as UV [3-10], HPLC [11], HPTLC [12], are available in single and combination with other drugs. However, no spectrophotometric method has yet been reported for simultaneous estimation of is Telmesartan,amlodipine besylate, and hydrochlorothiazide in tablet dosage forms.

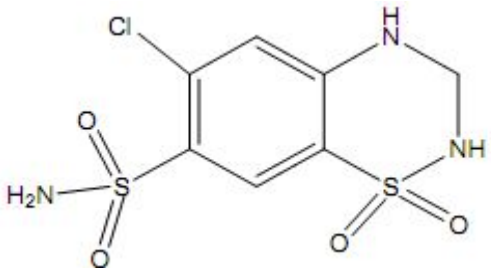
Figure 1: Structure of three drugs



Telmisartan



Amlodipine besylate



Hydrochlorothiazide

2. MATERIALS

2.1. Instumentation

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.

2.2. Preparation of Standard Drug Solution

The standard stock solution of Telmesartan, Amlodipine besylate and Hydrochlorthiazide were prepared by dissolving 25mg of each drug in 25ml of volumetric flask separately using methanol.The standard stock solutions were further diluted to get the concentration of 10 µg/ml of each and the solutions were scanned between the range 200 - 400 nm in 1 cm cell against blank and the overlain spectra was recorded (figure 2). The λmax of Telmesartan, amlodipine and hydrochlorothiazide were 292.8 nm, 238.5 nm and 271.2 nm respectively.

3. Methodology

3.1. Simultaneous Equation Method

Standard solutions having the concentrations ranges as Telmesartan (4-24 µg/ml), Amlodipine (4-24µg/ml) and Hydrochlorthiazide (4-24µg/ml) respectively for both were prepared in methanol.The absorbance of resulting solution was measured at 292.8 nm, 238.5 nm and 271.2 nm. calibrations were plotted at these wavelengths.The absorptivity co-efficients of these drugs were determined using calibration curve equations are

$$A_1 = ax_1\ bcx + ay_1\ bcy + az1bcz$$

$$A_2 = ax_2\ bcx + ay_2\ bcy + az2bcz$$

$$A_3 = ax_3\ bcx + ay_2\ bcy + az_3\ bcz$$

3.2 Analysis of Tablet Formulation

Twenty tablets were weighed and average weight was found. The tablets were triturated to a fine powder. An accurately weighed quantity of powder equivalent to 20 mg of Telmesartan was transferred in to 50 mL volumetric flask and added a minimum quantity of methanol to dissolve the substance and made up to the volume with the same. The solution was sonicated for 15 minutes, centrifuged for another 15 minutes at 100 rpm and filtered through Whatmann filter paper No. 41. From the clear solution, further dilutions were made and the absorbance of sample solutions were measured at all selected wavelengths. The content of AMB, TLM and HCT in sample solutions of tablet was calculated. This procedure was repeated for six times.

3.3 Validation of Methods

3.31 Linearity

For the linearity study, aliquots of the drug solutions were further diluted with methanol to get the final working standards of concentration ranges as Telmisartan (4-24 µg/ml), Amlodipine (4-24µg/ml) and Hydrochlorthiazide (4-24µg/ml) respectively. Calibration curves (n = 6) were plotted between concentration and absorbance of drugs. Optical parameters were calculated.

3.3.2. 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.

3.3.3. 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

4. RESULTS AND DISCUSSION

An attempt has been made to develop a fast, precise, reproducible and economical analytical method for simultaneous estimation of three drugs in their combined dosage form. The drugs obeys Beer's law in the concentration range of 4-24 µg/ ml for all the three drugs. Sampling wavelengths based upon the direct UV spectroscopic data. There was no interference from tablet excipients was observed in these methods.

Table- 1: Optical Parameters

Parameter	TLM	AMLO	HCTZ
λ_{max} (nm)	292.8	238.5	271.2
Beer's law limits (µg / ml)	4-24	4-24	4-24
Molar absorptivity (L. mole^{-1} cm^{-1})	5.23 x 10^2	1.04 x 10^3	1.46 x 10^4
Regression equation (Y = a+ bc):slope (b)	0.001105	0.002418	0.031167
Standard deviation of slope (Sb)	7.37 x 10^{-6}	4.35 x 10^{-5}	3.19 x 10^{-4}
Intercept (a)	0.0187	-0.0047	0.0135
Standard deviation of intercept (Sa)	2.44 x 10^{-3}	7.21 x 10^{-3}	3.17 x 10^{-3}
Standard error of estimation (S_e)	2.33 x 10^{-3}	6.87 x 10^{-3}	3 x 10^{-3}
Correlation coefficient (r)	0.9992	0.9994	0.9996
% Relative standard deviation*	0.4834	0.5011	0.5985

Table -2: Analysis of Pharmaceutical Formulation

Pharmaceutical Formulation	Labelled Amount (Mg)	Amount Found By Proposed Method (mg)	Recovery By Proposed Method (%)
Telact-Trio	40	39.8±0.4	99.85±0.41
	5	5.08±0.2	99.95±0.54
	12.5	12.47±0.4	99.47±0.29

The optical parameter values of % RSD and correlation of coefficient for simultaneous determination are reported in Table 1. The result of recovery studies for tablet is reported in Table 2. 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 three drugs.

5. 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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