Simultaneous Spectrophotometric Estimation of Ciprofloxacin and Tinidazole from a Combined Dosage form

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Two simple, precise and economical procedures for simultaneous estimation of ciprofloxacin and tinidazole in two component tablet have been developed. The methods employ program in the Multicomponent Mode of analysis of the instrument used and absorbency ratios for the simultaneous estimation of the two drugs. In 0.01N acetic acid, ciprofloxacin has an absorbance maxima at 276 nm, tinidazole has an absorbance maxima at 317 nm and isobestic point at 297 nm. Both the drugs obey the Beer's Law in the concentration ranges employed for these methods. the results of analysis have been validated statistically and by recovery studies. The methods show on interference by the compound from each other or by excipients when applied to formulation by means of UV-VIS spectroscopy and can be applied for routine simultaneous estimation of both drugs.

THE literature describes spectrophotometric[1-4], HPLC[5,6] methods for the analysis of ciprofloxacin formulations where as spectrophotometric[7-10], IR[11], GC[12], HPLC[13-14] methods for the analysis of tinidazole formulations. No official/pharmacopoeial method is available for their simultaneous estimation. The objective of this investigation was to devise two simple, precise, rapid and economical spectrophotometric methods for the simultaneous estimation of ciprofloxacin and tinidazole from marketed combined pharmaceutical dosage form.

Shimadzu UV-VIS Recording Spectrophotometer (UV-160A) was used for the experimental purpose. Standard ciprofloxacin and tinidazole were procured from Khandelwal Labs. Mumbai and Emcure Pharmaceuticals, Pune. Ciprofloxacin and tinidazole (Ciprobiotic- Tz) tablets were procured from market.

Five mixed standard solutions with different concentrations of the two drugs were prepared in 0.01 N acetic acid. The concentrations of the two components in the five mixed standard solutions are given in Table-1. All the mixed standard solutions were scanned over the range of 400 nm to 240 nm in the Multicomponent Mode using two sampling points 276 nm and 317 nm. Overlain spectra of the five mixed standards is given in Fig. 1. The spectral data from these scans is used to determine the concentrations of two drugs in the tablet sample solutions.

Twenty tablets were weighed and average weight was calculated. They were crushed to a fine powder. Tablet powder equivalent to 3 mg of tinidazole was dissolved in about 75 ml of 0.01N acetic acid in a 100 ml volumetric flask. The flask was shaken for about 10 min, vigorously to dissolve the powder. Then the volume was made upto the mark with the same solvent. The solution was diluted to obtain 5 mcg/ml of ciprofloxacin and 6 mcg/ml of tinidazole. This sample was scanned over range of 400 nm to 240 nm in the Multicomponent Mode and the concentration of each component were obtained by analysis of the five standard. The analysis procedure was repeated five times with the same batch of tablets. The result of analysis is given in Table-2.

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Table 1: Composition of the mixed standards for method-1

Concentration in mcg/ml of	Standard solution number				
	1	2	3	4	5
Ciprofloxacin	10.0	0.0	5.0	7.5	10.0
Tinidazole	0.0	12.0	6.0	9.0	12.0

Table 2 : Results of analysis of commercial tablets

TABLET	Label Claim mg/tab		% of Label Claim estimated *			
			Method I		Method II	
	CF	TZ	CF	TZ	CF	TZ
Batch	250	300	102.17	100.27	98.98	101.28

*Mean of five estimations

Method	Standard deviation		Coeff. of Variation		Standard Error	
	CF	TZ	CF	TZ	CF	TZ
I	0.94416	0.40804	0.949	0.41	0.1888	0.0816
II	1.76864	1.18779	1.782	1.154	0.3537	0.2375

Table 3 : Recovery study data

Sr. No.	Conc. of added drug in final dilution in mcg/ml		% Recovery			
			Method I		Method II	
	CF	TZ	CF	TZ	CF	TZ
1	5	6	101.96	99.89	99.40	100.25
2	5	6	102.48	100.29	98.40	101.50
3	5	6	101.92	100.45	98.90	100.91
4	5	6	102.13	99.95	98.50	103.50
5	5	6	102.43	100.77	99.70	100.25

CF = Ciprofloxacin TZ = Tinidazole

The results of recovery studies carried out are stated in Table-3.

Following two equations have been derived which show the applicability of absorbency ratios to the analysis of ciprofloxacin and tinidazole.

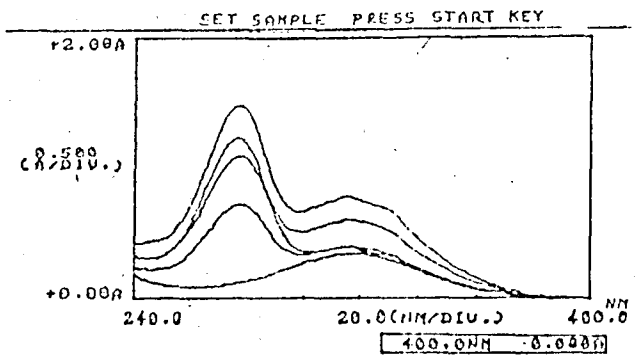

Fig.1 : Overlain spectra of mixed standards

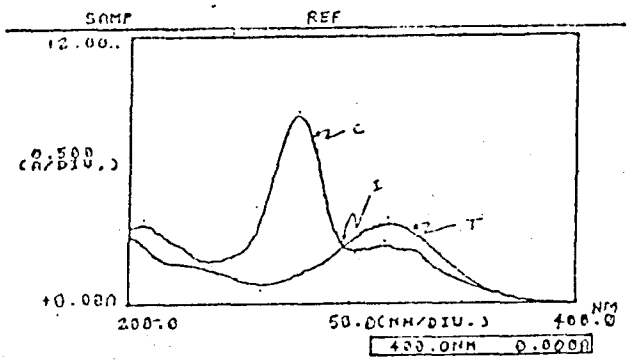

Fig.2 : Overlain spectra of Ciprofloxacin and Tinidazole

$$C_c = \frac{Q_O - Q_T}{Q_C - Q_T} \times \frac{A}{a_c} \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \quad >1$$

$$CT = \frac{Q_O - Q_C}{Q_T - Q_C} \times \frac{A}{a_T} \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \quad >2$$

C_c and C_T are concentrations of ciprofloxacin and tinidazole in g/L respectively in the sample solution. Q_o, Q_c and Q_T are the ratios of sample, ciprofloxacin and tinidazole solution absorbance at 276 nm to the absorbed at 297 nm (Isobestic point). A is the sample solution absorbance at 297 nm, a_c and a_T are molar absorptivities for ciprofloxacin and tinidazole at 297 nm (Isobesic point) respectively.

The standard Q_C, Q_T, a_c and a_T values were found to be

$$Q_C = 3.4352 \quad a_c = 40.9$$
$$Q_T = 0.4719 \quad a_T = 27.27$$

Tablet sample solutions were made as mentioned in method-I. Absorbance of these solutions at 276 nm and 297 nm were recorded and the concentration of two drugs in the sample were determined by substituting Q_c and A values of sample solution with the standard Q_c, Q_T, Q_c and Q_T values in Equation 1 & 2. The results of analysis of tablet formulation are stated in Table-2. Recovery studies gave satisfactory results which are stated in Table-3. The overlain spectra of ciprofloxacin (10 mcg/l) and tinidazole (15 mcg/ml) used for analysis is given as Fig. 2. The proposed methods were found to be accurate, simple and rapid for the routine simultaneous estimation of two drugs. Both methods are found to be economical as they require only 0.01N acetic acid as solvent. The values of standard deviation, coefficient of variation and standard error were satisfactorily low and recovery was close to 100% indicating the reproducibility and accuracy of methods.

The first method is specific for this instrument. It employs a programme for the simultaneous quantification of upto eight compounds from their mixtures. The instrument used for this analysis can store only one set of multicomponent mode data in its memory so every time different sample is to be analysed. This limitation is due to the large memory required to store the data obtained from scans of the standard solutions. The method requires no manual calculations and gives marginally better results than other methods.

The second method employing equation[15] based on absorbancy ratios is a very simple method and can be employed for routine analysis of these two drugs in combined dosage forms using a very simple instrument. It would only require determination of the absorbances of the sample solutions at the selected wavelengths as standard absorbancy values and molar absorptivities were determined and requires few simple calculations. The applicability of these method for estimation of both drugs doesn't require

the pure drug sample and analysis time required is only few min.

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Determination of Vitamin C Content of *Phyllanthus Emblica* and *Chyavanprash*

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Specific and sensitive O - Phenylene diamine fluorimetic method has been adopted for the determination of vitamin C content during various stages of *chyavanprash* preparation starting from major vitamin C containing fruit, *Phyllanthus emblica* (amla) and its dehydrated powder. The pericarp of both bigger and smaller varieties of amla fruit, and its freeze dried powder was found to contain 2.915 (± 0.1), 3.775 (±0.15) and 23.24 (±0.18) mg of vitamin C per gram of pulp/powder, respectively. Vitamin C was found to be exceptionally stable in fresh and dried Amla fruits. All the three market samples of Chyavanprash tested do not contain any vitamin C. It is probably destroyed during frying of amla pulp with ghee.

CHYAVANPRASH, a traditional polyherbal formulation, is widely used as tonic, rejuvanator, anabolic, immunomodulator and memory enhancer[1]., Amla, *Phyllanthus emblica*, one of the richest sources of vitamin C[2], constitutes the main ingredient (35%). Due to lack of suitable quality control standards of Ayurvedic drugs it is difficult to ensure uniformity of their composition and consequently