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UV- SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF DROTAVERINE HYDROCHLORIDE AND ACECLOFENAC IN BULK AND THEIR FORMULATION

***Sangram Kumar Rath, Rashmi Ranjan Sarangi, Susanta Kumar Panda,**

Arun Kumar Dash, Satyanarayana Rath, Srikant Nayak.

Department of Pharmaceutical Analysis and Quality Assurance Royal College of Pharmacy and Health Sciences, Berhampur, Odisha, India

ABSTRACT

A simple, accurate, validated and reproducible UV-spectrophotometric method has been developed for the simultaneous estimation of Drotaverine Hydrochloride and Aceclofenac in both bulk and tablet formulation. Drotaverine and Aceclofenac in combined tablet formulation were estimated by using the multicomponent mode at 357 nm for Drotaverine and 276 nm for Aceclofenac in their solution in methanol: double distilled water (50:50). The Beer's law obeyed the concentration range of 10-100µg/ml for both Drotaverine and Aceclofenac. Mean recovery of 99.54% for Drotaverine and 99.37% for Aceclofenac respectively signifies the accuracy of the method. This method can be used for the routine simultaneous estimation of Drotaverine Hydrochloride and Aceclofenac in industries and other analytical laboratories.

Key words: Drotaverine Hydrochloride, Aceclofenac, Multicomponent spectroscopy.

INTRODUCTION

Drotaverine (Fig.1) is chemically 1-[(3, 4-diethoxy phenyl) methylene]-6, 7-diethoxy-1, 2, 3, 4-tetrahydroisoquinolene and is an analogue of papaverine (Oneil M J *et al*., 2004). It is official in Polish Pharmacopoeia. It is used as an antispasmodic and smooth-muscle relaxant in pain associated with gastrointestinal colic, biliary colic, and postsurgical spasms. Literature study reveals UV spectroscopic (Dahivelkar PP *et al*., 2006; Metwally F H *et al*., 2008; Amina A *et al*., 2007), HPLC (Panigrahi D *et al*., 2008; Mezei J *et al*., 1984), HPTLC method (Dahivelkar PP *et al*., 2009), TLC (Metwally H *et al*., 2007) have been reported for the estimation of Drotaverine Hydrochloride.

Corresponding Author

Sangram Kumar Rath
Email: sangramrath02@gmail.com

Aceclofenac (Fig. 2), a NSAID is chemically 2-[(2',6-dichlorophenyl) amino] phenylacetoxyacectic acid, with potent analgesic and anti-inflammatory properties is used in the management of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. It is official in Indian Pharmacopoeia (IP, 2007). Several spectroscopic (Shah R *et al*., 2008; Nikam AD *et al*., 2008), HPLC (Shaikh K A *et al*., 2008; Momin MY *et al*., 2006), Voltammetric method (Posac J R *et al*., 1995) have been reported for the estimation of Aceclofenac individually and in combination with other drugs. However, there is no analytical method reported for the simultaneous estimation of Drotaverine Hydrochloride and Aceclofenac in a combined dosage formulation. Present work describes simple, accurate, reproducible, rapid and economical methods for simultaneous estimation of Drotaverine Hydrochloride and Aceclofenac in tablet formulation.

Figure 1. Structure of Drotaverine

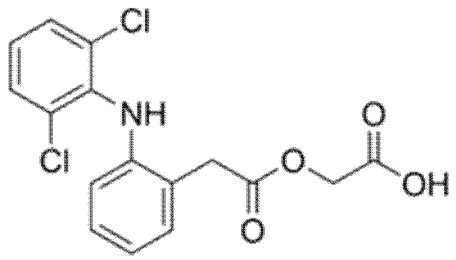
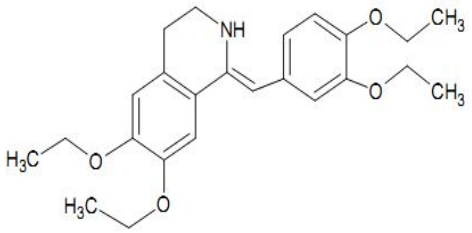


Figure 2. Structure of Aceclofenac



MATERIALS AND METHODS

Chemicals & Reagents: Analytically pure Drotaverine Hydrochloride and Aceclofenac were obtained as gift samples from M/s Akums Drugs & Pharmaceuticals Ltd., Haridwar (India). Commercial tablet formulations were purchased from the local market. All chemicals and reagents used were of Analytical Grade, obtained from Merck.

Instrument: A SHIMADZU double beam UV/Visible recording spectrophotometer (Model: 1700) with 2 nm spectral bandwidth was employed for all spectrophotometric measurement using 10mm matched quartz cell and Borosil glass wares were used for the study. Calibrated electronic single pan balances Sartorius CP 225 D, pH Meter (LABINDIA), Enertech Fast Clean Ultrasonicator were also used during the analysis.

Standard Stock Solution

The standard stock solutions of Drotaverine Hydrochloride and Aceclofenac were prepared by dissolving accurately weighed 100 mg of drug in 100 ml of a mixture of methanol and double distilled water (50:50) in two separate 100 ml volumetric flasks to get a concentration of 1000 µg/ml. Both were appropriately diluted with mixture of methanol and double distilled water (50:50) to get a concentration of 100µg/ml and were kept as the stock solutions.

Determination of λmax

The standard solution of both Drotaverine Hydrochloride and Aceclofenac (10 µg/ml) were scanned in the wavelength region of 200-400nm and the λmax was found to be 357nm and 276nm respectively.

Preparation of calibration curve

For each drug, appropriate aliquots were pipetted out from each standard stock solution into a series of 10 ml volumetric flasks. The volume was made up to mark with methanol and double distilled water (50:50) to get set of solutions having concentration range 10-100µg/ml for both Drotaverine Hydrochloride and Aceclofenac. Triplicate dilutions of each concentration of each drug were prepared separately. The prepared working solutions of Drotaverine Hydrochloride and Aceclofenac were scanned at 357 nm and 276 nm respectively. The respective absorbances were recorded and absorbances were plotted against the concentrations to obtain their respective calibration curves.

The absorbance maxima of Drotaverine Hydrochloride (357nm) and Aceclofenac (276nm) were used for the analysis of Drotaverine Hydrochloride and Aceclofenac respectively by multicomponent method. Seven different mixed standards of Aceclofenac and Drotaverine Hydrochloride (10:0.8) were prepared from their respective stock solutions. Before analyzing the selected tablet formulations the method was validated by analyzing the physical admixtures of Drotaverine Hydrochloride and Aceclofenac in the ratio of each component as in the formulation in consideration.

Assay of tablet dosage form

Two batches of tablet formulations containing 80 mg and 100mg of Drotaverine Hydrochloride and Aceclofenac respectively were used for analysis by the proposed method. The tablets were triturated with the help of mortar and pestle and made fine powder and the residue equivalent to average weight of a tablet was dissolved in a mixture of methanol and double distilled water (50:50) and sonicated for 10 minutes in the sonicator. This sonicated solution was filtered by using Whatmann filter paper and the volume was made to 100 ml by the solvent system. It was then sonicated, filtered and diluted accordingly such that the resulting solution was used as stock solution having concentration 80:100 µg/ml of Drotaverine Hydrochloride: Aceclofenac respectively. Then working solutions having concentration ratio 10:0.8, 20:1.6, 30:2.4, 40:3.2, 50:4.0, 60:4.8, 70:5.6 of Aceclofenac: Drotaverine Hydrochloride respectively were prepared and estimated by UV-Spectrophotometer at 276nm and 357nnm respectively by the proposed method.

RESULTS

The overlay spectra for absorbances of Drotaverine Hydrochloride and Aceclofenac are shown in figure 3 and 4 respectively. The calibration curve for Drotaverine Hydrochloride and Aceclofenac are shown in figure 5 and 6 respectively. The linearity data for Drotaverine Hydrochloride and Aceclofenac are shown in table 1 and 2 respectively. The overlay spectrum for the mixed samples of Drotaverine Hydrochloride and Aceclofenac is shown in figure 7 and the linearity for Drotaverine Hydrochloride and Aceclofenac in mixture is

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shown in table 3. The market formulations were analyzed by the proposed method and the results are shown in table 4 and the statistical analysis of the results is shown in table 5.

Figure 3. Spectrum of Drotaverine Hydrochloride

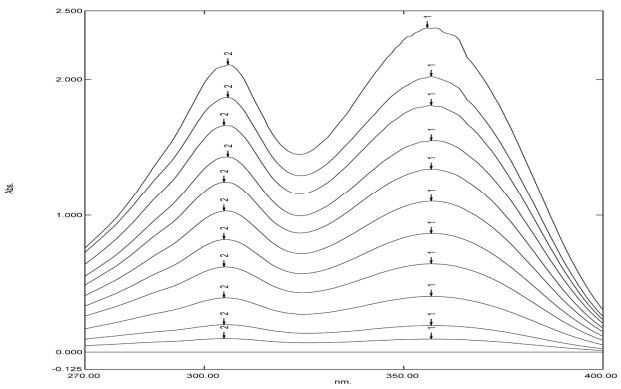

Figure 4. Spectrum of Aceclofenac

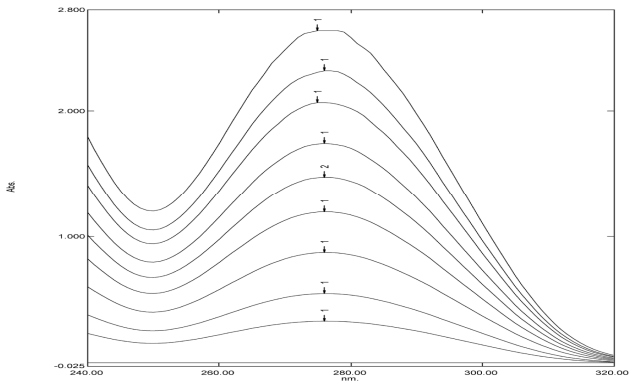

Figure 5. Calibration curve of Drotaverine Hydrochloride at 357 nm

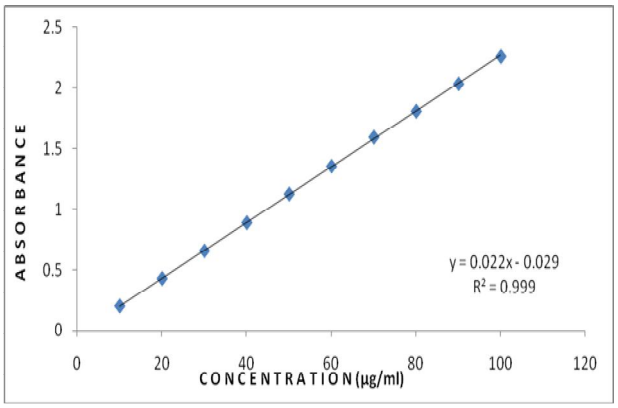

Figure 6. Calibration curve of Aceclofenac at 265 nm

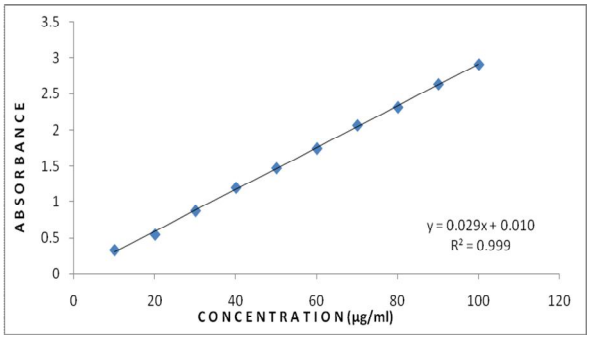

Figure 7. Overlay spectrum for the mixture of Drotaverine Hydrochloride and Aceclofenac

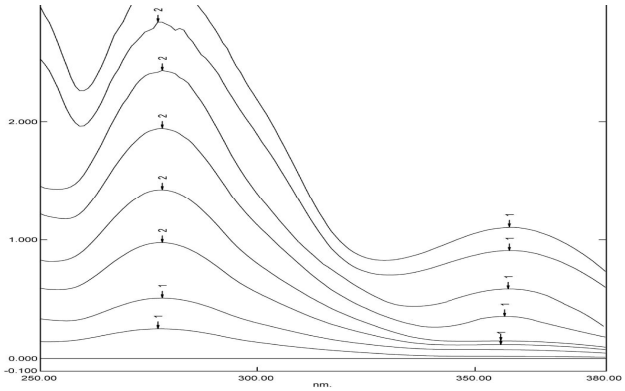

Table 1. Linearity table for Drotaverine Hydrochloride at 357 nm

Concentration (µg/ml)	Absorbance at 357nm
10	0.199
20	0.426
30	0.654
40	0.886
50	1.123
60	1.352
70	1.591
80	1.806
90	2.032
100	2.256

Table 2. Linearity table for Aceclofenac at 276 nm

Concentration (µg/ml)	Absorbance at 276 nm
10	0.329
20	0.549
30	0.873
40	1.196
50	1.474
60	1.744
70	2.066
80	2.317
90	2.635
100	2.914

Table 3. Linearity table for the mixture solution of Aceclofenac and Drotaverine Hydrochloride and (10:0.8)

Concentration (µg/ml) ACF:DRO	Absorbance at 357 nm	Absorbance at 278 nm
10 : 0.8	0.069	0.473
20: 1.6	0.225	0.866
30 : 2.4	0.389	1.339
40 : 3.2	0.571	1.751
50 : 4.0	0.749	2.214
60: 4.8	0.914	2.659
70: 5.6	1.096	3.175

Table 4. Assay results of formulations

Formulation	Formulation 1		Formulation 2	
	Aceclofenac	Drotaverine	Aceclofenac	Drotaverine
LABELED CLAIM (mg)	100	80	500	80
OBSERVED AMOUNT (mg) (±S.D) MG	99.62 ± 0.658	79.42±0.458	99.12±0.368	79.84±0.745
% RECOVERY	99.62	99.28	99.12	99.80
%R.S.D	0.821	1.062	0.953	1.471

Table 5. Statistical Analysis of results of Drotaverine Hydrochloride and Aceclofenac

	Formulation 1		Formulation 2	
Drug	Aceclofenac	Drotaverine	Aceclofenac	Drotaverine
% mean*	99.22	98.64	99.17	98.82
S.D.	0.984	1.256	0.657	0.978
% R.S.D	0.751	1.223	0.875	1.189

* Mean of six readings

CONCLUSION

The proposed method is simple for simultaneous analysis of Drotaverine Hydrochloride and Aceclofenac in tablet formulation. Two sampling wavelength 357nm and 276nm were used for analysis. The proposed method of analysis was validated by analyzing the laboratory prepared samples. The results were satisfactory. The mean recovery was 99.54% for Drotaverine Hydrochloride and 99.37% for Aceclofenac respectively. Moreover the assay results of the formulations were within the claimed limits. The results confirm that proposed method is simple, accurate, precise, economical and efficient.

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