Srikant Nayak. *et al*. / *International Journal of Biological & Pharmaceutical Research.* 2011; 2(2): 45-49.

ISSN 0976 - 3651
2229 - 7480

International Journal of Biological
&
Pharmaceutical Research
Journal homepage: www.ijbpr.com

IJBPR

UV- SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF PARACETAMOL AND ONDANCETRON IN BULK AND THEIR FORMULATION

***Srikant Nayak, Rashmi Ranjan Sarangi, Susanta Kumar Panda, Arun Kumar Dash Sangram Kumar Rath, Satyanarayana Rath.**

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

ABSTRACT

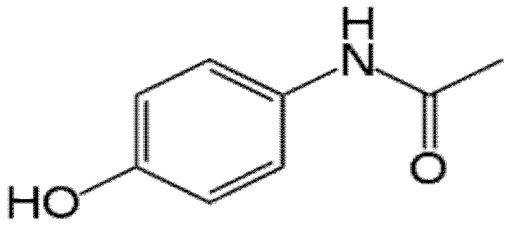
A simple, accurate, validated and reproducible UV-spectrophotometric method has been developed for the simultaneous estimation of Paracetamol and Ondancetron in both bulk and tablet formulation. Paracetamol and Ondancetron in combined tablet formulation were estimated by using the multicomponent mode at 248nm for Paracetamol and 267nm for Ondancetron in their solution in methanol: double distilled water (9:1). The Beer's law obeyed the concentration range of 2-20 µg/ml for Paracetamol and 0.1-1 µg/ml for Ondancetron. Mean recovery of 99.36% for Paracetamol and 99.99% for Ondancetron respectively signifies the accuracy of the method. This method can be used for the routine simultaneous estimation of Paracetamol and Ondancetron in industries and other analytical laboratories.

Key words: Paracetamol, Ondancetron, Multicomponent spectroscopy.

INTRODUCTION

Paracetamol (Fig.1) is a widely used OTC analgesic and antipyretic. It is official in IP (Indian Pharmacopoeia, 2007) and chemically it is N-(4-hydroxyphenyl) acetamide. Literature reveals UV Spectrosctroscopy (Gondalia. R *et al*., 2010) HPLC (Karthik mA. *et al*., 2007; Gopinath R *et al*., 2007), and HPTLC method (Khata *et al*., 2010), TLC (Sam Solomon *et al*., 2010) have been reported for the estimation of Paracetamol. Ondancetron (Fig. 2) is the prototype of the new class of selective 5-HT_3 receptor antagonist that have shown remarkable efficacy in controlling nausea and vomiting following administration of highly emetic anticancer drugs and radiotherapy. Chemically it is (*RS*)-9-methyl-3-[(2-methyl-1*H*-imidazol-1-yl) methyl]-2, 3-dihydro-1*H*-carbazol-4(9*H*)-one and is official is USP (USP, 2010). Several spectroscopic (Deport M *et al*., 1997), HPLC in human plasma (Colthup P *et al*., 1991; Sastry SP *et al*., 2002) have been reported for the

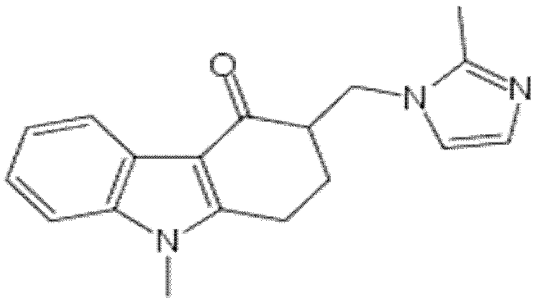
Figure 1: Structure of Paracetamol



Corresponding Author

Srikant Nayak
Email: srikanta4ever@gmail.com

Figure 2: Structure of Ondancetron



estimation of Ondancetron individually and in combination with other drugs. However, there is no analytical method reported for the simultaneous estimation of Paracetamol and Ondancetron in a combined dosage formulation. Present work describes simple, accurate, reproducible, rapid and economical methods for simultaneous estimation of Paracetamol and Ondancetron in tablet formulation.

MATERIALS AND METHODS

Chemicals & Reagents: Analytically pure Paracetamol and Ondancetron were obtained as gift samples from M/s Alembic Ltd., Baroda (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 Paracetamol and Ondancetron were prepared by dissolving accurately weighed 100 mg of drug in 100 ml of a mixture of methanol and double distilled water (9:1) 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 (9:1) to get a concentration of 100µg/ml and were kept as the stock solutions.

Determination of λmax

The standard solution of both Paracetamol and Ondancetron (10 µg /ml) were scanned in the wavelength region of 200-400nm and the λmax was found to be 248nm and 267nm 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 (9:1) to get set of solutions having concentration range 2-20µg/ml for Paracetamol and 0.1-1µg/ml for Ondancetron. Triplicate dilutions of each concentration of each drug were prepared separately. The prepared working solutions of Paracetamol and Ondancetron were scanned at 248nm and 267nm respectively. The respective absorbances were recorded and absorbances were plotted against the concentrations to obtain their respective calibration curves.

The absorbance maxima of Paracetamol (248nm) and Ondancetron (267nm) were used for the analysis of Paracetamol and Ondancetron respectively by multicomponent method. Five different mixed standards of Paracetamol and Ondancetron (25:1) were prepared from stock solution of Paracetamol and Ondancetron. Before analyzing the selected tablet formulations the method was validated by analyzing the physical admixtures of Paracetamol and Ondancetron in the ratio of each component as in the formulation in consideration.

Assay of tablet dosage form

Two batches of tablet formulations containing 500 mg and 4mg of Paracetamol and Ondancetron respectively were used for analysis by the proposed method which follows a ratio of 125:1. When the method was tried with the ratio, the results showed wide variance. Hence, it was decided to adopt the standard addition method for the estimation of Ondancetron in the formulation whereby 16mg of pure Ondancetron was added before the tablet is analyzed. 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 weighed accurately. To this 16mg of Ondancetron was added. The resulting residue was then extracted with methanol: double distilled water (9:1). It was then sonicated, filtered and diluted twice to 10 ml and the resulting solution was used as stock solution having concentration 100:4 µg/ml of Paracetamol: Ondancetron respectively. Then standard solutions having concentration ratio 0.2:5, 0.4:10, 0.6:15, 0.8:20, 1.0:25 of Ondancetron: Paracetamol respectively were prepared and estimated by UV-Spectrophotometer at 267nm and 248nnm respectively by the proposed method.

RESULTS

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

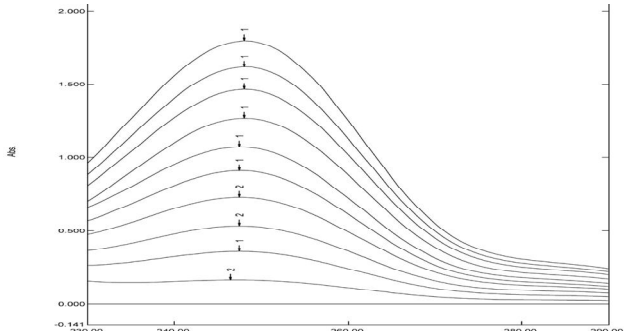


Figure 4: Spectrum of Ondancetron

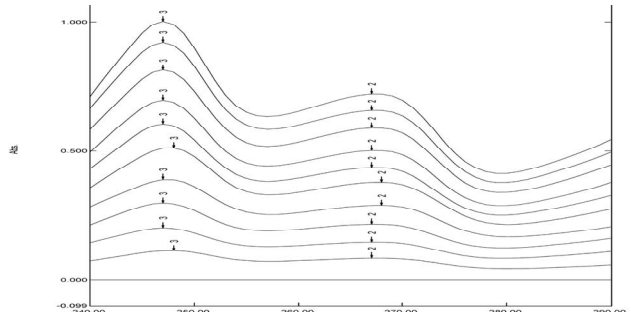


Figure 5: Calibration curve of Paracetamol at 248 nm

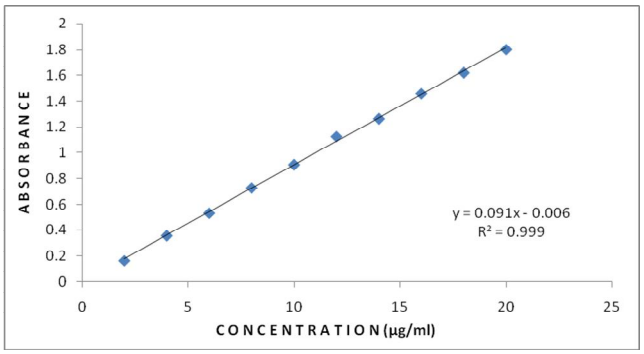


Figure 6: Calibration curve of Ondancetron at 265 nm

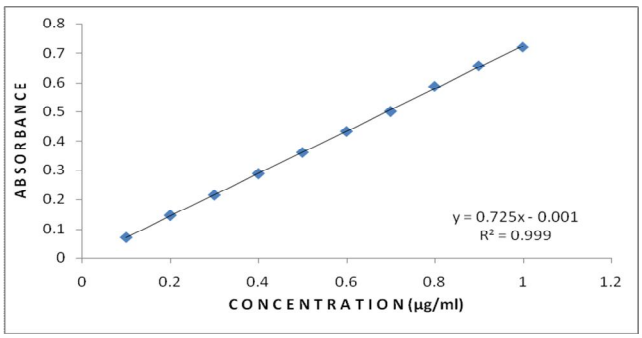


Figure 7: Overlay spectrum for the mixture of Paracetamol and Ondancetron

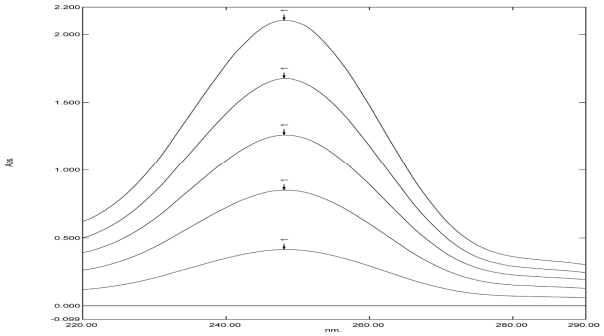


Table 1: Linearity table for Paracetamol at 248 nm

Concentration (µg/ml)	Absorbance at 248 nm
2	0.163
4	0.356
6	0.533
8	0.727
10	0.909
12	1.127
14	1.265
16	1.46
18	1.621
20	1.803

Table 2: Linearity table for Ondancetron at 267 nm

Concentration (µg/ml)	Absorbance at 267 nm
0.1	0.072
0.2	0.146
0.3	0.216
0.4	0.288
0.5	0.361
0.6	0.434
0.7	0.501
0.8	0.587
0.9	0.656
1.0	0.721

Table 3: Linearity table for the mixture solution of Paracetamol and Ondancetron (25:1)

Concentration (µg/ml) OND:PAR	Absorbance at 248 nm	Absorbance at 267 nm
0.2 : 5	0.414	0.164
0.4 : 10	0.852	0.341
0.6 : 15	1.263	0.505
0.8 : 20	1.679	0.663
1.0 : 25	2.104	0.830

Table 4: Assay results of the marketed formulations

Formulation	Formulation 1		Formulation 2	
	PAR	OND	PAR	OND
LABELED CLAIM (mg)	500	4	500	4
OBSERVED AMOUNT (mg) (±S.D) MG	491 ± 0.087	3.86±0.748	489±0.658	4.05±0.458
% RECOVERY	99.10	99.80	99.62	99.18
%R.S.D	0.821	1.062	0.953	1.471

Table 5: Statistical Analysis of results of Paracetamol and Ondancetron

	Formulation 1		Formulation 2	
Drug	**PAR**	**OND**	**PAR**	**OND**
% mean*	99.22	98.54	99.17	98.82
S.D.	0.964	1.056	0.667	0.968
% R.S.D	0.510	1.189	0.751	1.223

* Mean of six readings

CONCLUSION

The proposed method is simple method developed for simultaneous analysis of Paracetamol and Ondancetron in tablet formulation. Two sampling wavelength 248nm and 267nm 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 99.36% for Paracetamol and 99.99% for Ondancetron respectively. Moreover the assay results of the marketed formulations were within the claimed limits. The results confirm that proposed method is simple, accurate, precise, economical and efficient.

ACKNOWLEDGEMENT

The authors extend their thankfulness to the authorities of Department of Pharmaceutical Analysis and Quality Assurance, Royal College of Pharmacy and Health Sciences, Berhampur for providing necessary requirements to carry out this research work and also to Alembic Ltd., Baroda (India) for providing gift samples of Paracetamol and Ondancetron.

REFERENCES

Colthup P, Felgat CC, Palmar J, Scully N. Determination of ondensetron in plasma and its pharmacokinetics in young and elderly. *J Pharm Sci*. 1991; 868: 71–4.

Deport M, Leroux S, High resolution liquid chromatographic method using ultraviolet detection for the determination of ondensetron in human plasma. *J Chromatogr B*. 1997; 693: 399–404.

Gondalia R and Mashru. R. Development and validation of spectrophotometric methods for simultaneous estimation of Ibuprofen and Paracetamol in soft gelatin capsule by simultaneous equation method.International *Journal of ChemTech Research.* 2010; 2(4): 1881-1885.

Gopinath R, Rajan S, Meyyanathan SN and Krishnaveni N. A RP-HPLC method for simultaneous estimation of paracetamol and aceclofenac in tablets. *Indian J Pharm Sci*. 2007; 69: 137-40.

Indian Pharmacopoeia,New Delhi: Government of India, *The Controller of Publication.* 2007; 2: 900.

Karthik mA, et al. Simuiltaneous Estimation of Paracetamol and Domperidone in tablets by RP- HPLC method. *Indian J Pharm Sci*. 2007; 69: 142-144.

Khatal LD, Kamble AY and MahadikMV. Validated HPTLC method for simultaneous quantitation of paracetamol, diclofenac potassium, and famotidine in tablet formulation. *Journal of AOAC International*. 2010; 93(3): 765-770.

Sam Solomon WD, Vijai Anand PR, Shukla R, Sivakumar R. Application of TLC- densitometry method for simultaneous estimation of Tramadol Hcl and Paracetamol in pharmaceutical dosage forms. *International Journal of Chem Tech Research.* 2010; 2(2): 110-115.

Sastry SP, Rao T. Spectophotometric determination of amiodarone and ondansetron in pharmaceutical dosage forms with citric acid-acetic acid anhydride reagent. *Indian J Pharm Sci.* 2002; 63: 482–5.

The United States Pharmacopoeia XXIV and National Formulary XIX. Asian ed. Rockville, MD: US Pharmacopoeial Convention. *Inc*; 2000; 1219.