UV Spectrophotometric Simultaneous Estimation of Valdecoxib and Paracetamol in Combined Tablet Dosage Form

VAISHALI NAGULWAR*, Y. R. DHURVEY, SHILPA DESHPANDE, KANCHAN UPADHYE, SUPARNA BAKHLE AND RITA WADETWAR
J. L. Chaturvedi College of Pharmacy, New Nandanvan, Nagpur-440 009, India.

The present work deals with the development of a simple, accurate and economical method for the simultaneous estimation of valdecoxib and paracetamol in combined tablet dosage form by Vierodt's UV spectrophotometric method. The λ_{max} values of valdecoxib and paracetamol in 0.1 N NaOH were 244 nm and 257 nm respectively. Both the drugs followed Beer's law in the concentration range of 1-6 µg/ml and 5-30 µg/ml respectively. The A1% 1 cm values for valdecoxib and paracetamol at 244 nm and 257 nm were 520 and 420, 510.8 and 636.8 respectively.

Valdecoxib, chemically 4,5,(5-methyl-3-phenylisoxazol-4-yl) benzene sulphonamide, is a new COX-2 inhibitor and an antiinflammatory drug[1,2]. It is yet not official in any pharmacopoeia. Paracetamol is an antipyretic and analgesic, official in Indian Pharmacopoeia[3] and in Martindale[4]. Chemically, it is N-(4-hydroxyphenyl) acetamide. Both the drugs in combination are used for the synergistic activity. Literature survey revealed various methods for the determination of paracetamol in combination with other drugs[5-9], but no method was found to be developed for its estimation with valdecoxib in combined dosage forms. The authors have hence developed Vierodt's method[10] for the simultaneous estimation of valdecoxib and paracetamol in pharmaceutical solid dosage form.

Pure drug paracetamol was obtained from Universal Medicaments Pvt. Ltd., Shanti Nagar, Nagpur, and valdecoxib was provided by Mepro Pharmaceuticals Pvt. Ltd., Surendranagar, Gujarat. Shimadzu 1601 spectrophotometer with 10 mm matched quartz cells was used for the spectral observations. Sodium hydroxide (analytical grade) and double-distilled water were used for the present study.

Stock solutions (1 mg/ml) of both the drugs were prepared in 0.1 N NaOH. For the verification of Beer's law, a series of diluted solutions of valdecoxib and paracetamol ranging from 1-6 µg/ml and 5-30 µg/ml respectively, and mixture of both the drugs were prepared in 0.1 N NaOH. It was observed that valdecoxib and paracetamol individually, as well as in their mixtures, gave a good linearity response.

For the estimation of pure drugs by the proposed method, solutions of 1 µg/ml valdecoxib and 25 µg/ml of paracetamol and a mixture containing 1 µg/ml and 25 µg/ml of both the drugs were selected for determination of absorbance values. The contents were calculated using the following equations. $C_X=(A_2ay_1-A_1ay_2)/(ax_2ay_1-ax_1ay_2)$, $C_Y=(A_1ax_2-A_2ax_1)/(ax_2ay_1-ax_1ay_2)$, where C_X and Cy are the concentrations of valdecoxib and paracetamol respectively, ax_1 and ax_2 are the absorptivity values of valdecoxib at 244 nm and at 257 nm respectively, ay_1 and ay_2 are the absorptivity values of paracetamol at 244 nm and at 257 nm respectively and A_1 and A_2 are the absorbances of the diluted sample at 244 nm and at 257 nm respectively.

For the estimation of drugs in the marketed preparations, 20 tablets containing 20 mg valdecoxib and 500 mg paracetamol (Valeron Plus and Coxval-P) were weighed and finely powdered. A quantity of powder equivalent to 10 mg valdecoxib and 250 mg paracetamol was accurately weighed and transferred to a 50 ml volumetric flask,

***For correspondence**
E-mail: vaishali614@yahoo.com

TABLE 1: RESULTS OF THE ANALYSIS OF COMMERCIAL FORMULATIONS AND RECOVERY STUDIES

Drug	Label claimed (mg/tab)	Amount found (mg/tab)	% of label claimed	Standard deviation	C.V	% recovery
Tablet 1						
Valdecoxib	20	19.78	98.94	± 0.055	0.278	100.01
Paracetamol	500	499.38	99.88	± 0.174	0.034	99.99
Tablet 2						
Valdecoxib	20	19.80	99.00	± 0.069	0.348	100.00
Paracetamol	500	499.21	99.84	± 0.061	0.012	99.93

Tablet 1 - Valeron Plus, Tablet 2 - Coxval-P. *All values are the mean of five readings

dissolved in 0.1 N NaOH, and the solution was filtered through Whatman filter paper no. 1 and the volume was made up to the mark with the same solvent. Aliquots of this tablet solution were diluted to get the concentrations ~ 1 µg/ml of valdecoxib and ~ 25 µg/ml of paracetamol. The sample solutions were scanned over the range of 190-400 nm. Absorbance of the sample solutions at 244 nm and 257 nm was measured and from the absorbance values, the concentration of drugs in the sample solution was determined by using Vierodt's formula. The amount and % claim calculated for both the drugs are shown in Table 1.

To study the accuracy and precision of the proposed method, recovery studies were carried out by adding a known quantity of standard to the preanalyzed sample. The procedure was repeated five times, and it was observed that the excipients present in the tablets did not interfere in the estimation of valdecoxib and paracetamol. The percent recovery calculated is shown in Table 2. The optical characteristics such as Beer's law limits, detection limit, molar absorptivities and Sandell's sensitivities are presented in Table 2.

Thus the proposed method is simple, accurate, precise and economical for routine analysis of two drugs without prior separation. The amount found was in good agreement with the labelled claim of the formulation. The value of standard deviation was satisfactorily low, indicating the reproducibility and accuracy of the method developed.

TABLE 2 : QUANTITATIVE PARAMETERS OF THE PROPOSED METHOD

Parameter	Valdecoxib	Paracetamol
A 1% 1 cm value	520	636
Beer's law limits (µg/ml)	1-6	5-30
ε-Molar absorptivity (1/mol/cm)	1.6399×10^4	0.9626×10^4
Limit of detection (µg/ml)	0.5	0.5
Limit of quantification (µg/ml)	1.0	1.0
Sandell's sensitivity (µg/cm^2)	0.01923	0.01570
Regression equation*		
Slope (B)	0.0525	0.0637
Intercept (A)	-0.00015	-0.00018
Correlation coefficient (r)	1.0	1.0

*y = A+Bx, where x is the concentration of the analyte and y is the absorbance value

ACKNOWLEDGEMENTS

The authors are thankful to Mepro Pharmaceutical Pvt. Ltd., Gujarat; and Universal Medicaments Pvt. Ltd., Nagpur, for providing the pure drugs. They are also grateful to Dr. V. D. Rangari, Principal, J. L. Chaturvedi College of Pharmacy, Nagpur, for his kind cooperation in the completion of this work.

REFERENCES

1. Shastry, C.S., Joshi, S.D., Veerapur, V.P. and Arvind, M.B., **Indian J. Pharm. Edu.**, 2003, 37, 154.
2. Sutariya, V.B., Mashru, R., Sankalia, M.G. and Parikh, P., **Indian J. Pharm. Sci.** 2004, 66, 360.
3. Indian Pharmacopoiea**,** 4th Edn., Vol. II, Controller of Publications, Delhi, 1996, 554.
4. Reynolds, J.E.F., In: Martindale. The Extra Pharmacopoeia**,** 31st Edn., The Royal Pharmaceutical Society, London, 1996, 81.
5. Vasudevan, M., Ravishankar, S., Ravibabu, T. and Nagarajan, J.S.K., **Indian J. Pharm. Sci.,** 2000, 62, 122.
6. Dhake, A.S., Sonaje, D.B., Kasture, V.S., Nikam, P.T. and Talekar, R. S., **Indian J. Pharm. Sci.,** 2001, 63, 55.
7. Zarapkar, S.S., Halkar, U.P. and Bhandari, N.P., **Indian Drugs**, 1999, 36, 710.
8. Gangwal, S. and Trivedi, P., **Indian Drugs**, 1999, 36, 683.
9. Kumar, A., Anroop, B. and Vijay, K.S., **Indian Drugs**, 2003, 40, 727.
10. Davidson, A.G., In: Beckett, A.H. and Stenlake, J.B., Eds., Practical Pharmaceutical Chemistry, 4th Edn., Vol.II, CBS publishers and Distributors, New Delhi, 2002, 284.

Accepted 1 October 2006
Revised 31 October 2005
Received 6 May 2005
Indian J. Pharm. Sci., 2006, 68 (5): 639-640