

NOTE**Simultaneous Estimation of Aceclofenac and Paracetamol in Tablet Dosage Form by UV Spectroscopy**

ANUREKHA JAIN*, AVIJEET JAIN, VIVEK VYAS,
NIHARIKA SUBEDAR and ARUN GUPTA

B.R. Nahata College of Pharmacy, Mhow-Neemuch Road, Mandaur-458 001, India
Tel: (91)9425108574 (M); E-mail: anurekha_jain@yahoo.com

A simple, precise, rapid and selective simultaneous equation and Q-analysis UV spectrophotometric method has been developed for the simultaneous determination of aceclofenac and paracetamol from combined tablet dosage form. The method involves solving of simultaneous equation value analysis based on measurement of absorptivity at 276, 249 and 270 nm, respectively. Linearity lies between 2-25 mcg/mL for aceclofenac and 1-30 mcg/mL for paracetamol. Results of analysis for both the method were validated statistically and by recovery studies.

Key Words: Aceclofenac, Paracetamol, UV spectroscopy, Simultaneous equation, Absorbance ratio method.

Paracetamol exhibit antiinflammatory analgesic and antipyretic activities, which are due to inhibition of cyclooxygenase-2. Dosage varies from 100-500 mg in single or divided dosage. It is official in BP¹, IP², USP³. Methods like UV and HPLC method for the estimation of paracetamol in pharmaceutical formulation are available⁴⁻¹¹. Aceclofenac is an orally administered nonsteroidal antiinflammatory drug^{12,13} which showing good effect of analgesic properties and good tolerability profile in a variety of painful conditions. Chemically, aceclofenac¹⁴ is [2-(2',6'-dichloro phenyl amino)phenyl] which is phenyl acetic acid derivative. The usual dose of aceclofenac is 100 mg given in twice daily by mouth. Several method¹⁵⁻¹⁷ have been reported for the assay of aceclofenac.

Spectral and absorbance were made on thermospectronic UV/Visible spectrophotometer (E-Merck) with 10 mm matched quartz cuvettes. Gift sample of aceclofenac and paracetamol were obtained from M/s Shree chemical Indore, methanol of analytical grade was used. Brands of tablet Acenac-P and Zerodol-P containing 100 mg of aceclofenac and 500 mg of paracetamol were procured from local pharmacy.

Method-I: Employing simultaneous equation¹⁸

The wavelength 276 nm for aceclofenac and 249 nm for paracetamol were selected as analytical wavelength. Calibration curve for both the drugs

obtained using concentration 1 to 30 mcg/mL, which was linear and obeyed Beer's law in concentration range of 0-25 mcg/mL for aceclofenac and 1-30 mcg/mL for paracetamol.

Molar absorptivity values determined for aceclofenac at 275 and 249 nm were 16.779×10^3 and $7.080 \times 10^3 \text{ cm}^{-1} \text{ mol}^{-1} \text{ L}$, while respective value for paracetamol were 15.598×10^3 and $3.291 \times 10^3 \text{ cm}^{-1} \text{ mol}^{-1} \text{ L}$. These values were the mean for four independent determinations. The method employs solving of simultaneous equation method.

The simultaneous equation formed here

$$A_1 = ax_1 \times c_1 + ay_1 \times c_2 \quad (1)$$

$$A_2 = ax_2 \times c_1 + ay_2 \times c_2 \quad (2)$$

where A_1 and A_2 are the absorbance of sample solution at 275 and 249 nm, respectively. c_1 and c_2 are the concentration of aceclofenac and paracetamol, respectively (g dm^{-3}) in the sample solution. ax_1 and ax_2 are the absorptivity in ($E_{1\text{cm}}^{1\%}$) are 478 and 200 of aceclofenac at 275 and 249 nm. Similarly, ay_1 and ay_2 are the absorptivity paracetamol is 218 and 1033 at 249 and 275 by substituting the value of c_1 from equation 1 into eqn. 2 the value of c_2 can be obtained.

Procedure for analysis of tablet formulation: 20 Tablets were weighed accurately and ground to a 100 mg of aceclofenac and 500 mg of paracetamol were transferred to a 100 mL volumetric flask separately. The contents were sonicated for 10 min with methanol, made to volume and filtered through Whatmann filter paper. The solution further diluted with methanol, to give concentration of 4 and 20 mcg/mL of aceclofenac and paracetamol, respectively. Absorbance of this solution was measured at 275 and 249 nm as a_1 and a_2 , respectively. Concentration of the two drugs in the sample were calculated using eqns. 1 and 2. Result of the analysis of the tablet formulation as shown in Table-1.

Method-II: Absorbance ratio method¹⁸

From the overlain spectrum of aceclofenac and paracetamol, two wavelengths were selected one at 270 nm, which was isoabsorptive point for both the drug and other at 249 nm, the λ_{max} of paracetamol. The absorbance of the standard at and sample solution were measured as in the previous method. The $E_{1\text{cm}}^{1\%}$ value for both the drug at the isobestic point is 358 at the wavelength 270 nm. The method employ Q-value, concentration of drugs in sample solution was determined by using the following formula.

$$\text{For aceclofenac: } C_1 = Q_0 - Q_2/Q_1 - Q_1 \times A/a_1$$

$$\text{For paracetamol: } C_2 = Q_0 - Q_1/Q_2 - Q_1 \times A-a_2$$

where, Q_0 = Absorbance of sample at 249 nm/absorbance of sample at 270, Q_1 = Absorptivity of aceclofenac at 249 nm/absorptivity of aceclofenac at 270 nm, Q_2 = Absorptivity of paracetamol at 249 nm/absorptivity of paracetamol at 270 nm. A = absorbance of sample at isoabsorptive point, A_1 and a_1 - are the absorptivity of aceclofenac and paracetamol at isoabsorptive point.

Results of recovery studies were found to be satisfactory and presented in Table-1. Aceclofenac and paracetamol in combination is widely used in the treatment of inflammation. Both these drug have varying solubility in different solvents. However, they are freely soluble in methanol using this solvent and adopting spectrophotometer as instrument two methods have been developed. Both methods give reliable and accurate result and hence, can be adopted in routine analysis of this drug combination in marketed formulation.

TABLE-1
RECOVERY STUDY FOR ACECLOFENAC AND PARACETAMOL

Formulations	Drugs	Label claim (mg/tab)	Amount found (mg/tab)	Label (%)	SD	Recovery (%)
Method-A						
Acenac-P	Aceclofenac	100	99.86	99.86	0.46	99.07
	Paracetamol	500	499.81	99.96	0.50	99.44
Zerodol-P	Aceclofenac	100	100.17	100.17	0.44	99.13
	Paracetamol	500	499.79	99.95	0.52	99.42
Method-B						
Acenac-P	Aceclofenac	100	99.97	99.97	0.22	99.43
	Paracetamol	500	499.84	99.96	0.34	98.70
Zerodol-P	Aceclofenac	100	99.96	99.96	0.42	99.93
	Paracetamol	500	499.98	99.99	0.51	99.96

REFERENCES

1. The Indian Pharmacopoeia, Vol. 2, pp. 554-555 (1996).
2. The British Pharmacopoeia, Vol. 1, pp. 4-5 (2001).
3. The United States Pharmacopoeia, Vol. 23, pp. 38-40 (1995).
4. P. Parimoo, *Drug Dev. Ind. Pharm.*, **13**, 127 (1987).
5. N. Erk, Y. Ozkar, E. Banoglu, S.A. Ozkan and Z. Senturk, *J. Pharm. Biomed. Anal.*, **24**, 469 (2001).
6. M. Vasudevan, S. Ravisankar and T. Ravibabu, *Indian Drugs*, **7**, 386 (2000).
7. L. Manser and F. Darghouth, *J. Pharm. Biomed. Anal.*, **27**, 851 (2002).
8. A.S. Dhuke, D.B. Sonoje, V.S. Kasture and R.S. Takeru, *Indian J. Pharm. Sci.*, **63**, 55 (2001).
9. S.E. O'Connell, F.J. Zurzola, *J. Pharm. Sci.*, **71**, 1291 (1982).
10. M. Kartel, *J. Pharm. Biomed. Anal.*, **26**, 857 (2001).
11. H.C. Geicochea and A.C. Olivieri, *J. Pharm. Biomed. Anal.*, **20**, 255 (1999).
12. R.N. Brogden and L.R. Wiseman, *Drugs*, **52**, 113 (1996).
13. M. Grau, J.L. Grauch, A. Montero, A. Felipe and S. Julia, *Arzneim-Forsch*, **41**, 1265 (1991).
14. The British Pharmacopoeia, Vol. 1, pp. 4-5 (2001).
15. H.S. Lee, S.J. Choi and C.K. Jeong, *J. Pharm. Biomed. Anal.*, **23**, 775 (2000).
16. J.R. Posac, M.O. Vazquez, M.L. Tascon, J.A. Acuna, F. Dela, C. Fuente, E. Velasco and P.S. Balanero, *Talanta*, **42**, 293 (1995).
17. N.H. Zawilla, A.M.M. Abdul, N.M. El-Kousy, A.S.M. El-Moghazy, *J. Pharm. Biomed. Anal.*, **27**, 243 (2002).
18. A.H. Beckett and J.B. Stenlake, *Practical Pharmaceutical Chemistry*, CBS Publication & Distributors, Delhi, edn. 3, Part II, pp. 284-288.

(Received: 26 April 2006; Accepted: 4 May 2007) AJC-5645