Simultaneous Spectrophotometric Estimation of Aceclofenac and Paracetamol in Tablet Dosage Form

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Three simple, accurate and economic methods; multicomponent, two wavelength and simultaneous equations using area under curve have been described for the simultaneous estimation of aceclofenac and paracetamol in

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Aceclofenac (AC) and paracetamol (PC) are available in tablet dosage form in the ratio of 1:5. Aceclofenac is 2-[(2,6-dichlorophenyl) amino] benzene acetic acid carboxy methyl ester has analgesic and antiinflammatory activity. Paracetamol is N-(4-hydroxyphenyl) acetamide has analgesic and antipyretic activity. Aceclofenac is official in BP while paracetamol is official in BP, USP and IP. Literature survey reveals that HPLC method for AC and HPLC methods for analysis of PC as a single component system. There are no reported methods for analysis of both drugs in combination. Hence an attempt has been made to estimate them simultaneously by UV spectrophotometric analysis.

A Shimadzu UV/Vis double beam spectrophotometer, model 1601 was employed with spectral bandwidth of 2 nm and a pair of 1 cm quartz cell. Standard gift samples of AC and PC were obtained from Lupin Laboratories Ltd., Pune. Methanol AR grade was used as a solvent in the AC and PC were obtained from Lupin Laboratories Ltd., Mumbai. The instrument directly gives concentration of individual drug present in the mixture.

In the simultaneous equation using AUC method, the ‘X’ values of 5 µg/ml of AC and 25 µg/ml of PC were determined at the selected wavelength ranges, 224 to 260 nm and 254 to 294 nm. The ‘X’ values were determined as, X= Area under curve of component between the selected wavelength range/Concentration of the component in g/l ..l. A set of two simultaneous equations were framed using these ‘X’ values are given below, A1= 924.4 C1 + 1663.9 C2-2 and A2= 891.8 C1 + 685.0 C2-3, where C1 and C2 are the concentrations of AC and PC, respectively in g/l in the sample solution. A1 and A2 are the area under curve of sample solutions at the wavelength range, 224 to 260 nm and 254 to 294 nm, respectively. The ‘X’ values at 224 to 260 nm for AC and PC were found to be 924.4 and 1663.9, respectively, while at 254 to 294 nm for AC and PC were found to be 891.8 and 685.0, respectively. The ‘X’ values reported are the mean of six independent determinations. By applying Cramer’s rule and Matrices in Eqsns. 2 and 3, concentrations C1 and C2 can be obtained as, C1 = (A1× 685.0-A2 × 1663.9)/852.0-4 and C2 = (A2 × 924.4-A1 × 891.8)/852.0 (5). Area under curve (A1 and A2) of sample solution containing 5 µg/ml of AC and 25 µg/ml of PC
A, B and C are multicomponent, two-wavelength and simultaneous equation using area under curve methods respectively. AC and PC denote aceclofenac and paracetamol, respectively. *indicates average of six estimations.

were recorded between 224 to 260 nm and 254 to 294 nm, respectively. The concentrations of two drugs in the sample were determined by substituting $A_1$ and $A_2$ values of sample solution in Eqns. 4 and 5, respectively.

Average weight of twenty tablets (Aceclo Plus, Aristo Pharmaceuticals, Daman) were determined and crushed to fine powder. The powder sample equivalent to 5 mg of AC and 25 mg of PC was weighed and transferred in 100 ml volumetric flask and dissolved in 25 ml methanol. The content was kept in ultrasonicator for 20 min. Finally the volume was made up to the mark with double distilled water and filtered through Whatmann’s filter paper No. 41. The filtered solution was suitably diluted to obtain mixed sample solution containing 5 µg/ml of AC and 25 µg/ml of PC. This solution was scanned using different methods as discussed above. The results of tablet analysis were determined and recorded in Table 1. Recovery studies were carried out at 80%, 100% and 120% level of the label claim. The % recovery of AC and PC in the sample mixture was determined.

The results of tablet analysis and recovery studies obtained by proposed methods were validated by statistical evaluation and were recorded in Tables 1 and 2. All the developed methods were found to be simple, rapid and accurate for routine simultaneous estimation of AC and PC in tablet dosage form. The value of standard deviation was satisfactorily low and the recovery was close to 100% indicating the reproducibility and accuracy of the methods.

The multicomponent method is rapid and easy method because it does not require manual calculations and gives marginally better results than other two methods. However the method is specific for the instrument having multicomponent mode. Two wavelength method is based on the principle that the absorbance difference between two points on the mixture spectra is directly proportional to the concentration of the component of interest, independent of interfering component. The third method employing simultaneous equations using area under curve is a very simple method. Once the ‘X’ values are determined, then it requires only determination of area under curve of the sample solution at selected wavelength range and few simple calculations.

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Cleome rutidosperma (family: Capparidaceae) is a low growing herb, up to 70 cm tall, found in waste grounds and grassy places with trifoliate leaves and small, violet-blue flowers, which turn pink as they age. The elongated pods are green at first, later turning brown to whitish which are 5–6 cm long. The seeds are black, hard and smooth. The entire plant of Cleome rutidosperma is used medicinally for its diuretic and antibacterial activity.

**Material and Methods**

The dried powdered plant material (350 g) was refluxed with ethanol for 4 h. The whole plant including roots, leaves, and seeds of the plant of Cleome rutidosperma (C.R.-1) were collected from North Zaire and Angola. It has become naturalized in various parts of tropical America as well as Southeast Asia. The plant material (whole plant) was collected from North Zaire and Angola. The plant material was shade dried followed by rinsing with distilled water, dried in air and shade dried. A voucher specimen (C.R.-1) has been kept in our research laboratory for future reference. The fresh plant material was authenticated at Botanical Survey of India, 24-Pargana district of West Bengal, India during Aug 2003.

**Extraction**

An aqueous extract was prepared from the dried powdered plant material. This was filtered and stored at 4°C. The extract was then fractionated using the solvent mixture chloroform-methanol (1:1).

**Biological Studies**

**Diuretic Activity**

The diuretic activity and also effective against both gram-positive and gram-negative bacteria in a concentration dependent manner was investigated for diuretic activity and also effective against both gram-positive and gram-negative bacteria in a concentration dependent manner. The extract was used as the standard. The antibacterial activity was assessed by the disc diffusion method against Micrococcus luteus, Pseudomonas aeruginosa, Bacillus subtilis, Vibrio cholerae, Staphylococcus aureus, and Escherichia coli. A concentration of 100, 200 and 400 µg/disc was used.

**Antibacterial Activity**

The antibacterial activity was tested in rats at 400 and 600 mg/kg, orally and compared with furosemide (20 mg/kg, intraperitoneally). The extract was found to possess significant dose dependent antiplasmodial activity.

**Conclusion**

The dried powdered plant material was found to possess significant diuretic activity and also effective against both gram-positive and gram-negative bacteria in a concentration dependent manner.

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**References**