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*NOTE*

# Visible Spectrophotometric Determination of Aceclofenac in Tablet Formulation

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Two simple, economical, precise, convenient and reproducible visible spectrophotometric methods have been developed for the estimation of aceclofenac in tablet formulation. The developed methods are based on the formation of chloroform extractable complex of aceclofenac with orange G in acidic medium and naphthol green in aqueous medium. The extracted complex with orange G shows absorbance maxima at 481 nm and linearity in the concentration range of 10–80 mcg/mL. The extracted complex with naphthol green shows absorbance maxima at 633.6 nm and linearity in the concentration range of 0.2–1.0 mg/mL. Results of analysis for both the methods were validated statistically and by recovery studies.

Key Words: Aceclofenac, Colorimetry, Tablet formulation.

Aceclofenac, chemically [[2-[(2,6-dichlorophenyl) aminophenyl] acetyl] oxy] acetic acid, is a new analgesic and antiinflammatory drug used in the management of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis[1]. It is official in BP[2] which describes liquid chromatographic method for its quantification. Literature survey reveals spectrophotometric[3], HPLC[4–5], spectrofluorometric[6] and densitometric[7] methods for the estimation of aceclofenac from pharmaceutical formulation. The objective of the present investigations was to develop simple, accurate and economical spectrophotometric methods for the estimation of aceclofenac in tablet formulation.

Thermospectronic UV1, UV/Vis double beam spectrophotometer with spectral bandwidth of 2 nm, wavelength accuracy of ± 0.5 and 1 cm matched quartz cells were used for analytical method development. All the chemicals and reagents used were of analytical grade. Orange G reagent was prepared in acid phthalate buffer of pH 1.2. Naphthol green reagent was prepared in double distilled water. Both the reagents were extracted several times with chloroform so as to remove chloroform-soluble impurities. Tablet formulation of aceclofenac were procured from the local market.

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**Procedure for calibration curve:** For method I, in a series of 10 mL volumetric flasks, aliquots of standard drug solution (100 μg/mL) in chloroform were transferred and diluted with same so as to give several dilutions in the concentration range of 10–80 μg/mL of aceclofenac. To 5 mL of each dilution taken in a separating funnel, 5 mL of orange G reagent was added. Reaction mixture was shaken gently for 5 min and allowed to stand for 5 min so as to separate aqueous and chloroform layer. The chloroform layer was separated out and absorbance maxima measured at 481 nm against a reagent blank. A calibration curve was plotted between concentration of aceclofenac and measured absorbance.

For method II, in a series of 10 mL volumetric flasks, aliquots of standard drug solution (1 mg/mL) in chloroform were transferred and diluted with same so as to give several dilutions in the concentration range of 0.2–1.0 mg/mL of aceclofenac. To 5 mL of each dilution taken in a separating funnel, 5 mL of naphthol green reagent was added. The reaction mixture was shaken gently for 5 min and allowed to stand for 5 min so as to separate aqueous and chloroform layers. The chloroform layer was separated out and absorbance measured at 633.6 nm against a reagent blank. A calibration curve was plotted between concentrations of aceclofenac and measured absorbance.

**Procedure for analysis of tablet solution:** Twenty tablets (100 mg) of aceclofenac were weighed accurately and finely powdered. An accurately weighed portion of powdered sample, equivalent to 100 mg of aceclofenac was taken in a 100 mL volumetric flask containing 40 mL of chloroform and sonicated for 20 min. The resultant was filtered through Whatmann filter paper no. 41 into another 100 mL volumetric flask. The filter paper was washed several times with chloroform. The washings were added to the filtrate and the final volume was made up to the mark with chloroform.

For method I, 5 mL of filtrate was diluted to 50 mL with chloroform, 6 mL of this was further diluted to 10 mL with chloroform. This was treated as per the procedure of the calibration curve and the amount of drug present in the sample was computed from the respective calibration curve.

For method II, 6 mL of filtrate was further diluted to 10 mL with chloroform. This was treated as per the procedure of the calibration curve and the amount of drug present in the sample was computed from the respective calibration curve.

The procedure of analysis from tablet formulation for both the methods was repeated five times with two different strengths of tablet formulation. Results of analysis are reported in Table-1.

Recovery studies were carried out for both the methods by the addition of known amount of standard drug solution of aceclofenac to pre-analyzed tablet sample solution at three different concentration levels. The resulting solutions were analyzed by proposed methods. The results of recovery studies were found to be satisfactory and are reported in Table-1.

TABLE-1
RESULT OF ANALYSIS AND RECOVERY STUDIES

| Method | Label claim (aceclofenac) (mg/tab) | % of label claim estimated* | Recovery† (%) | Standard deviation | Relative standard deviation |
|---|---|---|---|---|---|
| Method I (orange G) | 100 | 99.37 | 99.63 | 0.7400 | 0.1699 |
| Method II (naphthol green) | 100 | 99.04 | 99.66 | 0.6253 | 0.5374 |

*Average of five determinations.
Average of recovery studies at three different concentration levels.

These proposed methods were found to be simple, accurate, economical and rapid. Recovery studies were found close to 100% that indicates accuracy and precision of the proposed methods. Statistical analysis was carried out the results of which were satisfactory. Standard deviation and relative standard deviation values were low that indicated reproducibility of the proposed methods. It was observed that excipients did not interfere in the determination of aceclofenac. Hence these developed methods could be used for routine estimation of aceclofenac in its tablet dosage forms.

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