

# Spectrophotometric Method for the Estimation of Oxcarbazepine in Tablets

C. S. RAMAA\*, P. P. CHOTHE, A. A. NAIK AND V. J. KADAM

Department of Quality Assurance, Bharati Vidyapeeth's College of Pharmacy, Sector-8, CBD, Navi Mumbai- 400 614, India.

**The objective of this work was to develop a simple, accurate, rapid and sensitive method for the estimation of oxcarbazepine in tablets. The estimation is based on the reduction of ferric ions in its salt form to ferrous ions by the drug, which in presence of potassium ferricyanide produces green colored chromogen measured at 770 nm against reagent blank. The chromogen obeyed linearity over 4 to 28 µg/ml ( $r=0.9981$ ) with percent relative standard deviation (% RSD) of 0.4267. Recovery studies gave values ranging between 98.26 and 98.76. The proposed method is simple and suitable for routine determination of oxcarbazepine in tablets.**

Oxcarbazepine (OXC) is a novel antiepileptic drug, which was developed as a second generation and follow-up compound to carbamazepine (CBZ). OXC has similar therapeutic profile to CBZ but produces much less side effects on patients. It is not official in any pharmacopoeia. Chemically Oxcarbazepine is 10,11-dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide<sup>1</sup>. Clinically it has been used to treat several types of epilepsy<sup>2-4</sup>. Literature survey reveals determination of oxcarbazepine by chromatographic methods<sup>5-7</sup>.

UV/Vis Spectrophotometer 1601 (Shimadzu) with 1 cm

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**\*For correspondence**

E-mail: sinha\_ramaa@hotmail.com

matched cuvettes was used for spectrophotometric measurements. Gift sample of oxcarbazepine was received from Glenmark Pharmaceuticals, Mumbai. Tablets of oxcarbazepine were procured from local market. 0.5% ferric chloride and 0.15% potassium ferricyanide in 0.1 N hydrochloric acid solution were freshly prepared. The chemicals were from Loba Chemie.

The standard drug solution (100 µg/ml) was prepared by dissolving 10 mg in acetonitrile making the final volume up to 100 ml with the same solvent. Twenty tablets were powdered. Powder equivalent to 10 mg of oxcarbazepine was extracted with acetonitrile and filtered through Whatman filter paper no. 40. The residue was washed

**TABLE 1: ANALYSIS DATA OF TABLET FORMULATIONS**

Formulation	Label claim (mg/tab)	% Label claim*±S.D.	% Recovery* <sup>1</sup> ±S.D.
Tablet 1	150	98.62±0.873	98.97±0.496
(Oxecarb, Cipla)	300	99.31±0.996	98.78±0.318
Tablet 2	150	99.65±0.483	99.89±0.484
(Oxetol, Sun Pharma)	300	99.59±0.571	99.20±1.20

\*Mean of five determinations, <sup>1</sup>Reanalysis after adding known amount of drug to the analyzed formulation.

**TABLE 2: OPTICAL CHARACTERISTICS AND PRECISION**

Parameter	Observation
Absorption maxima (nm)	770
Beers law limit (µg/ml)	4-28
Co-relation coefficient	0.9981
Molar absorptivity (l/mole.cm)	$0.463 \times 10^4$
Sandell's sensitivity (µg/cm <sup>2</sup> /0.001)	$3.1 \times 10^{-2}$
Regression equation (y=mx+c)	0.0182
Slope (m) Intercept (c)	0.4297
Confidence limit with 95% level	0.0021

with small quantity of same solvent and the volume was made up to 100 ml.

Aliquots of standard solution, 0.4 to 2.8 ml were transferred to separate series of 10 ml volumetric flasks. 1.4 ml of ferric chloride and 1.2 ml of potassium ferricyanide were added to the respective flasks. The solutions were heated on boiling water bath for 2.0 min and cooled to ambient temperature. After 10 minutes the volume of each flask was adjusted to 10 ml with acetonitrile and the absorbance of solution was measured at 770 nm. Similarly the absorbance of sample solution was measured and the amount of oxcarbazepine was determined by using regression equation referring to the calibration curve.

To test the accuracy and reproducibility of the proposed method, recovery experiment was performed by adding known amount of drug to the reanalyzed formulation and reanalyzing the mixture (Table 1). The recovery was performed at 0%, 100%, 150% and 200% levels.

The proposed method determines oxcarbazepine in the concentration range of 4–28 µg/ml ( $r=0.9981$ ) with stability of 1 h. The stability of the colored complex was studied at a concentration of 16 µg/ml of standard solution and adding optimized quantities of ferric chloride (1.4 ml) and potassium ferricyanide (1.2 ml). The time scan analysis was carried out for 2 hrs. The absorbance of this solution was stable at 0.234 for a period of 1 h following which there was gradual decrease in absorbance. The optimum

spectrophotometric properties of the colored complex formed with ferric chloride, potassium ferricyanide reagents as well as different parameters affecting color development were extensively studied to determine optimum conditions for assay procedure. The other optical characteristics (Table 2) are as follows: Sandell's sensitivity is  $3.1 \times 10^{-2}$  µg/cm<sup>2</sup>/0.001, the absorptivity of complex is  $0.463 \times 10^4$  l/mole.cm, slope is 0.0182, y-intercept is 0.4297 and relative standard deviation is 0.4567.

The statistical parameters in method validation studies for precision, accuracy, specificity, stability of analytical solutions and ruggedness have justified the validity of the proposed method. The results of the assay (Table 1) and method validation studies show that the method is simple, accurate and precise with non-interference from tablet excipients.

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