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RESEARCH ARTICLE

VALIDATED SPECTROPHOMETRIC METHOD FOR THE ESTIMATION OF PREGABALIN IN MARKETED FORMULATION

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Abstract

In present work a simple method was developed for the estimation of pregabalin in marketed formulation by spectrophotometer. Spectrophotometric methods are described for determination of pregebalin in bulk and pharmaceutical dosage forms using methyl orange as chromogenic agents. The methods were satisfactory applied for the determination of drugs in both bulk and pharmaceutical dosage forms.

Keywords: Pregabalin, Methyl orange, Spectrophotometric method.

INTRODUCTION

Modern medicines for human use are required to comply with specific standards and regulation set forth by the concerned authorities. The efficacy and safety of medicinal products can only be assured by analytical monitoring of its quality. Pharmaceutical analysis is an art and science of determining the concentration of drug constituents present in marketed formulation.[1]Pregabaline (PRG; (3S)-3-(aminomethyl)-5-methylhexanoic acid; figure 1a) is a widely used Anticonvulsant and Analgesic for Epilepsy.[2]

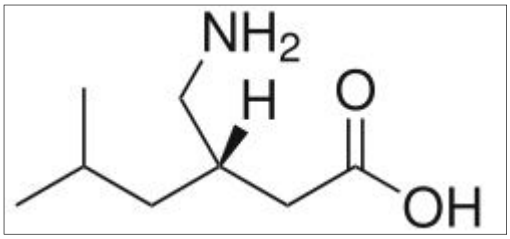

Figure 1: Chemical structure of pregabalin

In this study pregabalin have been determined spectrophotometrically by using methyl orange to determine and estimate the identity, strength, quality and purity of drug.

Materials and methods

Chemicals and reagents

All chemicals of analytical grade were used. Methyl orange dye solution: 2% dye solution was prepared by dissolving 2g of Methyl orange in100ml of distilled water.

Apparatus

The present work was carried out on UV visible spectrophotometer. The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 200-800nm.

Preparation of calibration curve

The absorption maxima of pregabalin were determined by running the spectrum of drug solution in double beam ultraviolet spectrophotometer. Accurately weighed 10 mg of Pregabalin separately and dissolved in 10 ml of 0.1N HCL in 10 ml of volumetric flask and prepared suitable dilution to make different concentration of standard with concentration range of 10-50µg/ml. 2 ml of standard drug solution and add 1 ml of methyl orange dye solution and 3 ml of chloroform, pipette out the coloured layer and analyzed for drug content by UV spectrophotometer at a λmax of 416.0 nm using of 0.1 N HCl as blank.

Assay of tablet formulation

Twenty tablets were taken and average weight of tablet was determined. The tablets were crushed in a mortar and the powder equivalent to 100mg of drug was transferred to 100ml standard flask.

The powder was dissolved in 50 ml of 0.1 N HCl and made up to volume with of 0.1 N HCL. The sample was mixed thoroughly and filtered through a 0.45µ membrane filter. The filtered solution was diluted suitably and add 1 ml of methyl orange dye solution and 3 ml of chloroform pipette out the coloured layer and analyzed for drug content by UV spectrophotometer at a λmax of 416.0 nm using of 0.1 N HCl as blank.

Validation of developed method

The developed methods were validated according to international conference on harmonization guidelines.[3]

Linearity

Linearity of both drugs was established by response ratios of drugs. Response ratio of drug calculated by dividing the absorbance with respective concentration. Then a graph was plotted between concentration and response ratio.

Accuracy

The accuracy of the proposed methods was assessed by recovery studies at three different levels i.e. 80%, 100%, 120%. The recovery studies were carried out by adding known amount of standard solution of pregabalin to pre analysed tablet solutions. The resulting solutions were then reanalyzed by proposed methods. Whole analysis procedure was repeated to find out the recovery of the added drug sample. This recovery analysis was repeated at 3 replicate of 5 concentrations levels.

Precision

Precision of the methods was studied at three level as at repeatability, intermediate precision (Day to Day and analyst to analyst) and reproducibility. Repeatability was performed by analyzing same concentration of drugs for five times. Day to Day was performed by analyzing 5 different concentration of the drug for three days in a week.

Results and discussion

The proposed spectrophotometric methods are indirect and based on the determination of the pregabalin in marketed tablet formulation using methyl orange as chromogenic agents.

Table 1: Readings for calibration curve of pregabalin

Replicate	10	20	30	40	50
1	0.121	0.258	0.388	0.535	0.756
2	0.110	0.282	0.394	0.551	0.736
3	0.114	0.268	0.396	0.551	0.766
Mean	0.112	0.284	0.396	0.552	0.765
S.D.	0.002	0.002	0.002	0.001	0.002
% RSD	1.360	0.536	0.500	0.208	0.260

Table 2: Statistical data for linearity

S. No.	Parameter	Remark
1	Linearity range	10-50 µg/ml
2	Regression equation	0.015x+0.023
3	Correlation coefficient	0.990

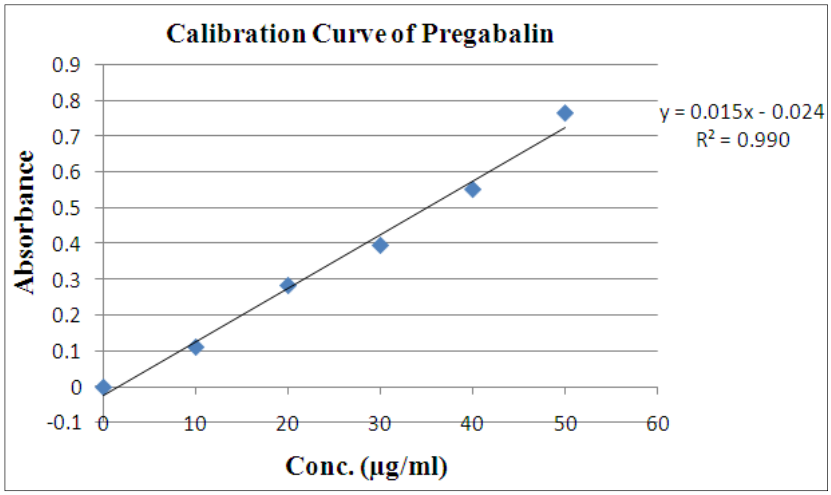

Figure 2: Calibration curve of pregabalin at 416nm

Table 3: Results of recovery studies on marketed formulations

Recovery level %	% Recovery (Mean±SD)*
80	99.12 ±0.146
100	99.22 ±0.282
120	99.12±0.144

*Average of five determination

Table 4: Results of validation (% R.S.D.)

	Parameters	Results
Precision	Repeatability	0.046
(% R.S.D.)	Day to Day	0.052
	Analyst to Analyst	0.048
	Reproducibility	0.088

*Average of five determination

Calibration curves have correlation coefficients (r) 0.990 indicating good linearity. The accuracy of the methods were determined by investigating the recovery of drugs at concentration levels covering the specified range (five replicates of each concentration).

Some Pharmaceutical formulations containing stated drugs have been successfully analyzed by the proposed methods. Results obtained were compared to those obtained by applying reported reference methods [4-7] which in turn indicate that there is no significant difference between proposed methods and reference ones relative to accuracy and precision.

Conclusion

The proposed spectrophotometric methods were accurate, precise and reliable for the Measurement of pregabalin in dosage form. The developed spectrophotometric method was validated for estimation of pregabalin using linearity, range, accuracy and precision. The RSD for all parameters was found to be less than one, which indicates the validity of method and assay results obtained by this method are in fair agreement. The developed method can be used for routine quantitative estimation of pregabalin in pharmaceutical preparation. The present methods are superior to the reference method with respect to both sensitivity and selectivity. The methods can be successfully applied for the analysis of marketed tablets and capsules.

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