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Development and validation of UV-spectrophotometric determination of eplerenone in bulk and tablets

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Abstract

A simple, rapid, sensitive and accurate UV- Spectrophotometric method has been developed for estimation of eplerenone from pharmaceutical formulations. In (30% *v/v)* methanol, eplerenone showed absorbance maxima at 241 nm. Linearity was observed the concentration range of 4 - 24 µg/mL (r^2= 0.9996). The amount of drug estimated from the formulation was found to be in the good agreement with the label claim. The recovery studies were carried out at three different levels i.e. at 80%, 100%, and 120%. The mean percentage recovery was found to be in the range of 99.84 -100.39. The method was validated statistically.

Keywords: Spectrophotometry, Eplerenone

Introduction

Chemically, eplerenone is known as (Pregn-4-ene7, 21-dicarboxylic acid, 9, 11-epoxy-17- hydroxy-3-oxo, γ-lactone, methyl ester is an selective aldosterone blocker used in the treatment of hypertention. [1,2] Eplerenone binds to the mineralocorticoid receptor and blocks the binding of aldosterone, a component of rennin-angiotensin-aldosterone system [3] In literature few analytical methods such as liquid chromatography – tandem mass spectrometric [4], validated SPE-LC - MS [5] have been reported for the determination of eplerenone in biological fluids. RP-HPLC method has been found for determination of eplerinone in tablet formulation [6].

However, to our knowledge, no information related to the UV- Spectrophotometric method method for estimation of eplerenone in pharmaceutical dosage forms has ever been mentioned in literature. Therefore the aim of this work is to develop an accurate, specific and repeatable method for the determination of eplerenone in bulk and tablets.

Material and methods

All the reagents were used of analytical grades

Preparation of standard stock solution

Standard stock solution was prepared by dissolving 10 mg of eplerenone in 100 ml of (30% *v/v)* methanol to get concentration of 100 µg/ml. Different aliquots were taken from the stock solution and diluted to 10 ml mark with same solvent to obtain series of concentrations. The solutions were scanned on Spectrophotometer-2450 (Shimadzu) in the UV range 200 – 400 nm and absorbances were recorded at 241 nm against blank. The calibration curve was found to be linear in the concentration range 4 - 24 µg/ml.
(Y = **0.0433 X + 0.0183**; r2= 0.9996)

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Preparation of Sample Solution

For analysis of commercial formulation, twenty tablets were weighed and average weight determined and crushed into fine powder. A quantity of tablet powder equivalent to 10 mg
of eplerenone was transferred into 100 ml volumetric flask containing 30 ml methanol (30% v/v), shaken manually for 15 min., volume was adjusted to mark with same solvent and filtered through whatmann filter paper no. 41. After appropriate dilutions, absorbance of the sample solution was recorded at 241 nm and the concentration of the drug was calculated from linear regression equation; results are shown in **Table I.**

Recovery studies

To study the accuracy of the proposed method, recovery experiments were carried out by adding a known amount of drug to preanalysed sample at three levels and the percentage recoveries were calculated; the results are summarized in Table II

Table I: Results of assay

Label claim	*Amount found ±SD	Amount found [%]	%RSD
25 mg of eplerenone	25.01 ± 0.07	100.04	0.29

* mean of five estimations

Table II: Summary of validation

Parameters	Results
Linearity and range (µg/ml)	4 – 24
LOD	0.0914
LOQ	0.277
Accuracy (%Recovery *)	99.84 - 100.39 %
%RSD	0.56
Precision (%RSD)	
Intra-day (n=3)	0.20 – 0.17
Inter-day (n=3)	0.14 - 1.11
Repeatability (n=6)	0.56
Ruggedness	
Analyst –I	100.04 (%RSD = 0.52)
Analyst –II	100.02 (%RSD = 0.23)

* mean of three estimation at each levels

Results and Conclusion

The λ max of eplerenone in 30% *v/v* methanol was found to be 241 nm. The drug follows linearity in the concentration range of 4 - 24 µg/ml. The analysis of tablet formulation by proposed method was in good agreement with label claim. The recovery studies were carried out at three different levels i.e. 80%, 100% and 120%. The mean percentage recoveries were found to be in the range of 99.84 - 100.39%; the low values of %RSD are indicative of the accuracy of the method. The precision of the method was studied as an intra-day and inter-day precision and repeatability. The % RSD value less than 2 indicate that the method is precise. Ruggedness of the proposed method was studied with the help of two analysts. The %RSD value lies in the range of 0.23 and 0.52. The results from validation studies are shown in table II. The proposed method is simple, rapid, accurate and economical and useful for the routine analysis of eplerenone from marketed formulation.

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