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Spectrophotometric method for the determination of ezetimibe in pharmaceutical formulations

BH. CH. NARASIMHARAJU[1], G. DEVALARAO[2] and SIKHARAM RAMANJANEYULU[3]

[1]A.S.N.Pharmacy College, Burripalem Road, Tenali - 522 201 (India).
[2]KVSR Siddhartha College of Pharmaceutical Sciences, Vijayawada - 520 010 (India).
[3]St.Ann's College of Pharmacy, Chirala - 523 187 (India).

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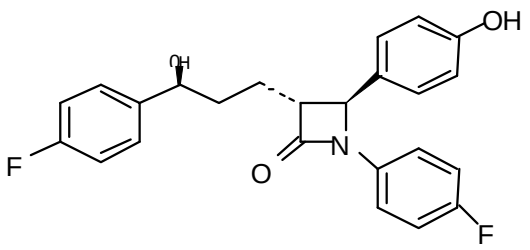
ABSTRACT

A Simple and reproducible spectrophotometric method has been developed for the determination of Ezetimibe in bulk and in dosage forms. The λ_{max} of Ezetimibe was found to be 234 nm. Linearity for this method lies in the range of 5-20 µg/ml. The proposed method is sensitive, accurate, reproducible and useful for the routine determination of Ezetimibe in tablet dosage form. No interference was observed from the excipients.

Key words: Ezetimibe, UV Spectrophotometer.

INTRODUCTION

Ezetimibe is a new Class of lipid lowering drug, which differs from other classes of cholesterol reducing compounds. It is chemically as (3R, 4S)-1-(4-Flourophenyl-3 Hydroxy propyl]-4-(Hydroxy pheny-2-azetidinone[1].



James E.Patrick *et al.,* studied the Ezetimibe pharmacokinetics[2]. Literature survey reveals the availability of few analytical methods such as HPCL[3-5], LC-MS[6], derivative spectrophotometry[7] and voltammetry[8] for determination of Ezetimibe in pharmaceutical Formulations. In the present investigation the authors propose a simple, sensitive and Reproducible spectrophotometric method for determination of Ezetimibe. The method is based on the measurement of light absorption in UV region in ethanol.

EXPERMENTAL

Instrument

Spectral and absorbance measurements were made

On Shimadzu UV/V is spectrophotometer 1601 with 1 cm matched quartz cells.

MATERIAL AND METHODS

Hetero Drug House private limited, Hyderabad, supplied Ezetimibe gratis. The tablets were obtained commercially. All other chemicals were of analytical grade.

Method

UV Spectrophotometer

The stock solution of Ezetimibe was prepared by dissolving 50 mg of pure drug in ethanol in a 50ml volumetric flask. It was diluted as and when required. The absorbance of 10-µg/ml was measured against a solvent blank between 200-400 nm. A graph was plotted and the absorption maximum was determined as 234 nm, which is shown in fig 1. A calibration curve was obtained at 234 nm for a series of concentrations in the range of 5-20 µg/ml. It was found to be linear and hence, suitable for the estimation of the drug. The slope, intercept correlation coefficient and optical characteristics[9] and summarized in Table 1.

Market sample analysis

Twenty tablets were weighed and finely powered. An accurately weighed portion of this equivalent to 50 mg of Ezetimibe was transferred in the 50 ml volumetric flasks containing about 25ml ethanol. The contents were sonicated for 30 min with intermittent shaking to ensure the complete solubility of the drug and then filtered through 0.45µm membrane filter. The volume was made to the mark with ethanol. The results are shown in table 2.

Recovery studies

To study the accuracy and reproducibility[10] of the proposed method, adding a known amount of drug to preanalysed sample at three levels and the percentage of recoveries were found out. The results are summarized in Table 3, which was found to be satisfactory.

RESULTS AND DISCUSSION

The λ_{max} of Ezetimibe in ethanol was found to be 234 nm. The amount of drug determined by the proposed method was in good agreement with label claimed providing the accuracy of the proposed method. The low percentage relative standard

Table1: Optical characteristic and precision data

Parameters	UV method value
Absorption Maximum (nm)	234
Beer's law limit (mcg/ml)	5-20
Sand ell's sensitivity	0.0217
(µg/cm2/0.001 abs. units)	188730
Molar Extinction Coefficient ($L.mol^{-1}cm^{-1}$)	
Correlation coefficient (r)	0.9998
Slope (m)	0.04
Intercept (c)	0.0059
% RSD	0.523
% Range of errors:	
0.05 significance level	0.0021
0.01 significance level	0.0028

* For five replicate analysis with in Beer's law limits

Table 2: Results of Assay

Sample	Label claim	UV-Method	
	(mg)	Amount found (mg)	(%) R.S.D
Tablet-1	10	9.95	0.661
Tablet-11	10	9.98	0.583

Table 3: Recovery studies of Ezetimibe

Sample concentration (µg/ml)	Fortified concentration (µg/ml)	Percentage Recovery	
		Tablet A	Tablet B
10	8	99.11	98.0
	10	97.10	98.70
	12	96.95	97.50

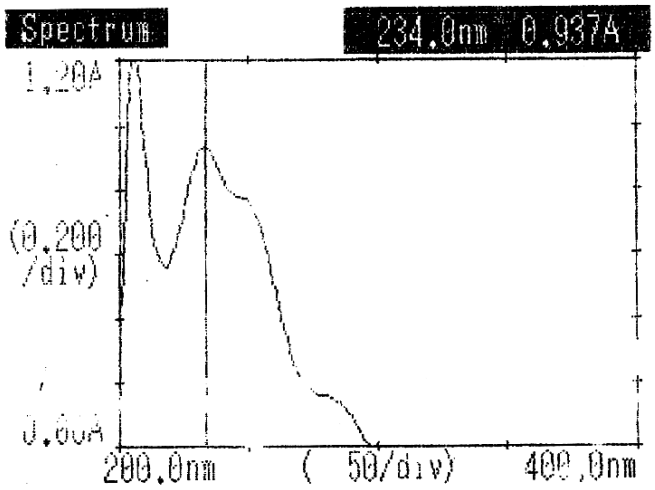


Fig. 1: λ_{max} of ezetimibe

deviation indicates the reproducibility of the method. The method is useful for tablet formulation where there is no interference of excipients in the absorbance of Ezetimibe.Thus the proposed method was simple, accurate and reproducible and can be used for the routine analysis of Ezetimibe in bulk and in pharmaceutical dosage forms.

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