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ORIGINAL ARTICLE **OPEN ACCESS**

Estimation of Pitavastatin Bulk by AUC Method Using UV-Visible Spectrophotometric Method

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ABSTRACT
As per ICH standards, latest work had been done to estimate Pitavastatin bulk by using the area under curve (AUC)method using UV-Visible spectroscopy. The wavelength range 220-250nm was selected for this purpose. Throughout the procedure, distilled water was used as a solvent. The method is seen to be linear in the concentration range from 2-10ug ml (R2 = 0.984). The current proposal is seen to be simple and accurate, and may be used for routine quality control analysis of Pitavastatin in bulk spectrophotometric estimation.
Keywords: Pitavastatin AUC, λ max, UV Spectrophotometric

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INTRODUCTION

Pitavastatin is a statin medicine, which means it belongs to the class of pharmaceuticals known as statins. 3-hydroxy-3-methylglutaryl reductase, the enzyme catalyzes the initial step in cholesterol production, is inhibited by it. Statins serve to enhance HDL (high density lipoproteins) by lowering LDL (low density lipoproteins), bad cholesterol, and triglycerides levels in the body (high density lipoproteins). Pitavastatin is a 3hydroxy,3methyl glutaryl Co A reductase inhibitor (statins) enzyme with a basic structure of 3hydroxy,3methyl glutaryl Co A reductase inhibitor (statins). Pitavastatin is a medication that is used to treat hyperlipidemia and dyslipidemia, as well as to avoid cardiovascular disease. (1) and (4) Their adult dose is 2mg orally once a day, with the possibility of increasing to 4mg per day in the future. It's a synthetic medicine that's taken by mouth. Abdominal discomfort, weariness, dyspepsia, nausea, dizziness, sleeplessness, and jaundice are some of the side effects. Pitavastatin, in contrary to other statins, was shown to improve insulin resistance in humans, as evaluated by the homeostatic model assessment (HOMA-IR) technique. (5) Pitavastatin is explained chemically in (Figure 1) (3R, 5S, 6E) -7-[2-cyclopropyl-4-(4-fluorophenyl) quinolin-3-yl] quinolin-3-yl] -3, 5-dihydroxyhept-6-enoic acid with Pitavastatin has the empirical formula C50H46CaF2N2O8 and a molecular weight of 880.98.

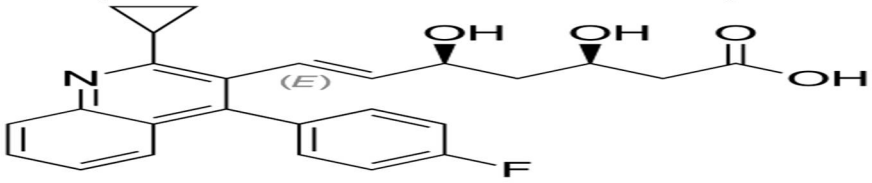

Fig 1: Structure of Pitavastatin.

AUC (area under curve):

When there is no abrupt peak or when vast spectra are obtained, the AUC (area under curve) method was used. It entails measuring the integrated absorbance value with respect to wavelength between the two wavelengths 1 and 2. The area bounded by the curve and the horizontal axis is created with this processing item (6).

Area calculation: (α+β) = $\int_{\lambda 2}^{\lambda 1} Ad\,\lambda$

MATERIAL AND METHODS

Chemicals:

Pitavastatin was obtained as gift sample from MacLeod's pharmaceuticals. Pvt. Ltd, Andheri , Mumbai. Ethanol Analytical reagent (AR) grade was used as solvent throughout the experimentation. All chemicals and reagents were of analytical reaget (AR) grade.

Instrumentation:

The absorbance of the obtained solution was determined to use a UV-1800 double beam UV-Visible spectrophotometer via Shimadzu (Kyoto, Japan) equipped with a computer-controlled software UV probe 2.33 with a spectral width of 2nm, wavelength precision of 0.5nm, and a pair of lcm matched quartz cells. For weighing operations, a Mettler Toledo (Model JL1503-C) analytical balance was utilized.

METHOD: -

EXPERIMENTAL WORK: -

A) To determine Pitavastatin solubility:

10 mg of the drug was weighed and the solubility was determined in double distilled water, ethanol, methanol, distilled Hydrochloric acid, acetonitrile, pyramiding, and chloroform.

B) To determine Pitavastatin's maximum concentration (Lambda max)

To prepare a standard stock solution of 1000ug/ml, weigh 50 mg of pure medication and dissolve it in a little amount of ethanol (5ml) before adding distilled water to make the volume up to 50 ml. To make the 100-ppm solution, 5 ml of standard solution was poured into a volumetric flask and diluted with 25 ml. To get standard solutions with concentrations of 2,4,6,8,10ug/ml, suitable dilutions were created using (prepared solvent 0.5ml ethanol-99.5ml distilled water) (ppm). [3,4] Fig 2 Spectral peak pick shows the intricacies of the spectrum peak.

Table 1: Calibration curve of Pitavastatin dose

Concentration (ppm)	Absorbance(nm)
Solvent (Blank)	0.000
2ppm	0.026
4ppm	0.050
6ppm	0.070
8ppm	0.083
10ppm	0.098

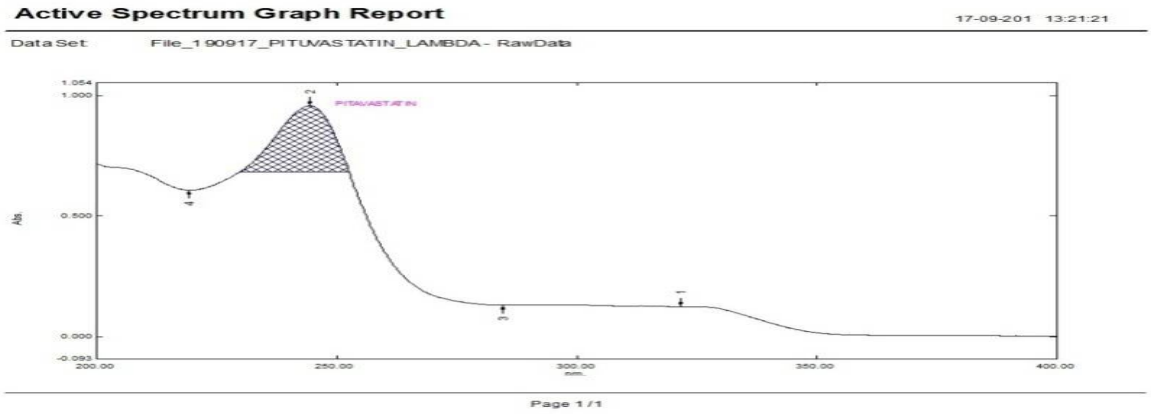

Fig 2: Spectrum peak pick

C) Area under curve method:

When there is no abrupt peak or when vast spectra are obtained, the AUC (area under curve) method was used. It entails measuring the integrated absorbance value with respect to wavelength between the two wavelengths 1 and 2. The area bounded by the curve and the horizontal axis is created with this processing item (6).

: Area calculation: (α+β) = $\int_{\lambda 2}^{\lambda 1} Ad\,\lambda$

Where is the area of the portion bounded by curve data and a straight-line connecting the start and end point, is the area of the portion bounded by a straight line connecting the start and end point on curve data and the horizontal axis, and λ1 &λ2 and are the wavelength range start and end point of the curve region By selecting the wavelength range across which area must be estimated, the horizontal axis is selected. This wavelength range was chosen based on repeated observations to ensure that the area under the curve and concentration are linear. The AUC was calculated using the spectrum obtained. The calibration curve was created by graphing the concentration (2-10 g/ml) against the AUC (6,7)

D)Development and Validation of Analytical Method:

Linearity: The gap between the highest and lower concentrations of an analyte in a sample is the linearity of an analytical method. (8) For which the linearity of the analytical technique has been shown. In a separate set of 25ml volumetric flasks, a 2-10g/ml standard solution of Pitavastatin was pipette out. Dilute ethanol solvent (0.5ethanol+99.5distilled water) was used to make up the final volume, which was thoroughly mixed. The wavelength maxima and area under curve for the sample was measured against distilled water as a blank at 244nm and 220-250nm with two methods, respectively.

Calibration curve table of pitavastatin is shown in Table.1. Calibration curve of pituvastatin.

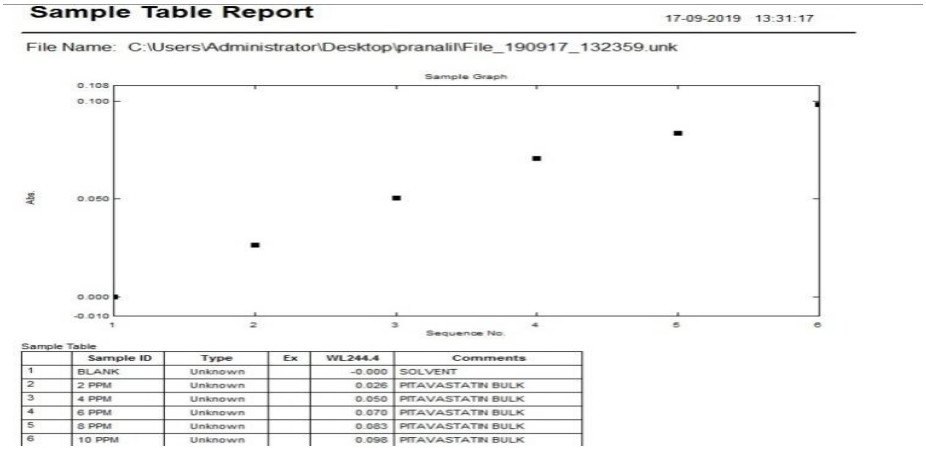

Fig 3:Linearity of Pitavastatin

RESULTS AND DISCUSSION:

A) Calibration curve for drug:

Methodof Absorbance maxima: The graph generated for the absorbance maxima for pure drug demonstrated a linear connection under the experimental circumstances indicated (Figure 3). The inclination, intercept, and correlation-coefficient values were all submitted to regression analysis. For the UV spectroscopic investigation, the regression equations for the calibration curve were y=0.0089x+0.0123(r2=0.984) at 244.40nm for absorption maxima. The range was determined to be 2-10g/ml. The Pitavastatin calibration curve is provided in Table.1. Pitavastatin Calibration Curve is illustrated in Figure 4. Pitavastatin Calibration Curve

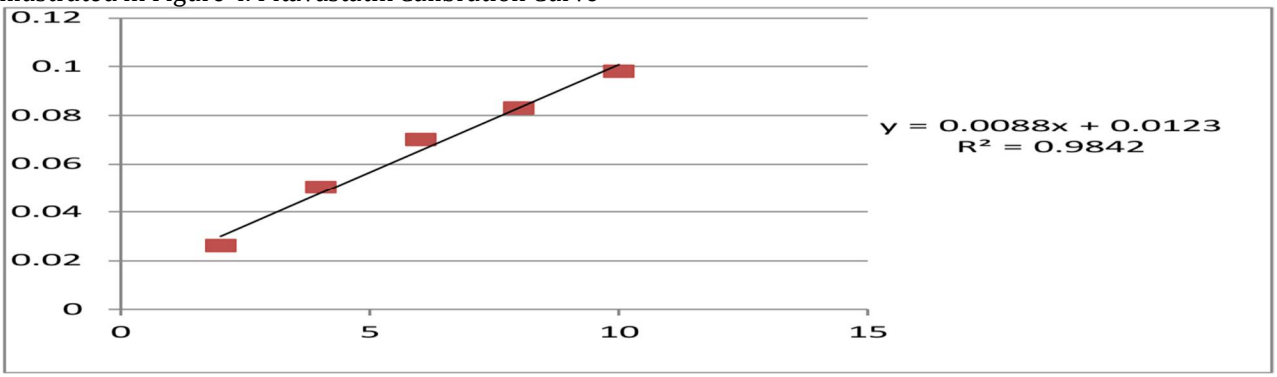

Fig 4: Calibration curve of Pitavastatin

B) Area under Curve method:

The graph derived for the AUC spectrum linear connection under the experimental conditions is described. The slope, intercept, and correlation data were all submitted to regression analysis. For the area under the curve spectrum, the equation is y=0.0089x+0.0123(R2=0.984) at 244.40nm. The range was discovered to be 2-10g/ml using spectrophotometric measurement of the area under the curve. Pitavastatin's area under the curve is seen in Figure 5. Pitavastatin Area Under Curve

Table 2:Area Under curve of Pitavastatin

Parameter	AUC
Wavelength Range (nm)	220-250nm
Concentration range(µg/ml)	2-10µg/ml
Slope (m)	0.0089
Intercept (c)	0.0123
Correction coefficient (R2)	0.984

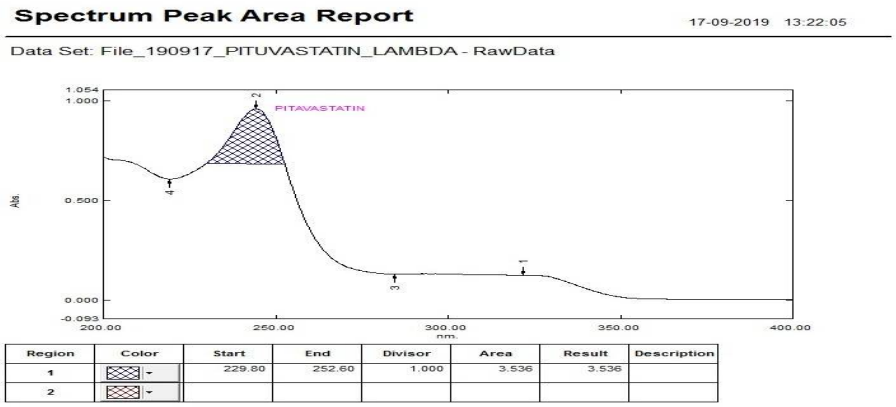

Fig 4: Area Under curve of Pitavastatin

CONCLUSION

Based on analytical method, an area under curve method for determining Pitavastatin was developed. The method was discovered to be simple, sensitive, accurate, and efficient when it was validated. As a result, this approach may be effectively employed for regular examination of Pitavastatin pharmaceutical dosage forms. The proposed Spectrophotometric approaches will not replace the already available methods for Pitavastatin analysis. It can, however, be used as a fallback if better equipment (such as HPLC) is not at all available for routine analysis.

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