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A New Cost Effective First Derivative Spectrophotometric Method for Assay of Linagliptin in Combination with Selected Antidiabetics: Compared to Previously Reported Cost Effective Procedures

Lilian Shaker

Department of Pharmaceutical Sciences, Ain Shams University, Abbassia, Cairo 11566, Egypt

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ABSTRACT

A cost effective first derivative spectrophotometric method was developed to determine linagliptin in combination with empagliflozin and metformin either in bulk or in different marketed formulations, namely Tradjenta®, Jentadueto® and Glyxambi® tablets. Determination of linagliptin was performed by measuring the amplitude at 310 nm after applying first derivative to the measured zero order spectra. The obtained results proved that the method can be employed for the routine analysis of the drugs.

INTRODUCTION

Although many methods were developed for determination of Tradjenta® (linagliptin), Jentadueto® (linagliptin and metformin) and Glyxambi® (linagliptin and empagliflozin) tablets [1-18] but no spectrophotometric method was reported in the literature for determination linagliptin in its ternary mixture with empagliflozin and metformin. Thus, the aim of the present work was to develop a cost effective first derivative spectrophotometric method to determine linagliptin in its ternary mixture with empagliflozin and metformin. The importance of cost effective analysis has been increased recently in pharmaceutical analysis [19-56].

EXPERIMENTAL AND DISCUSSION

Aliquots from linagliptin methanolic stock solution (1 mg/mL) equivalent to 50-250 µg were transferred into a set of 10 mL volumetric flasks and completed to volume with methanol to prepare calibrators equivalent to 5-25 µg/ml. The zero order absorption of each solution was recorded against methanol as a blank at 296 nm, and then the first derivative spectra were computed using scaling factor equals to 10. The amplitude at 310 nm was measured for linagliptin then plotted against corresponding concentrations and the regression parameters were computed and found to be (Absorbance = 0.0431 Concentration - 0.0076 with r = 0.999). Also, the absorption spectrum was recorded for the laboratory prepared mixture containing 10 µg/ml of each drug, against methanol as a blank (figure 1). The amplitude of the first derivative spectra of the laboratory prepared mixture at 311 nm was used for linagliptin determination. The concentration of linagliptin was calculated from the regression equation. Accuracy results showed recovery percent between 98.22 % and 100.47 %. Also fifty milliliters of methanol were added to an accurately weighed amount of the finely powdered Tradjenta®, Jentadueto® and Glyxambi® tablets equivalent to 10 mg of each extract, sonicated for 15 min and then made up to 100 ml with methanol separately and then 1 ml of each diluted extract was further diluted with methanol in 10 ml volumetric flask separately. The solutions were filtered and the zero order absorption spectra were recorded. The amplitude of the first derivative spectra was recorded at 311 nm. The concentrations of linagliptin were calculated from the regression equation and the range of recovery was between 99.56 % and 102.33 %.

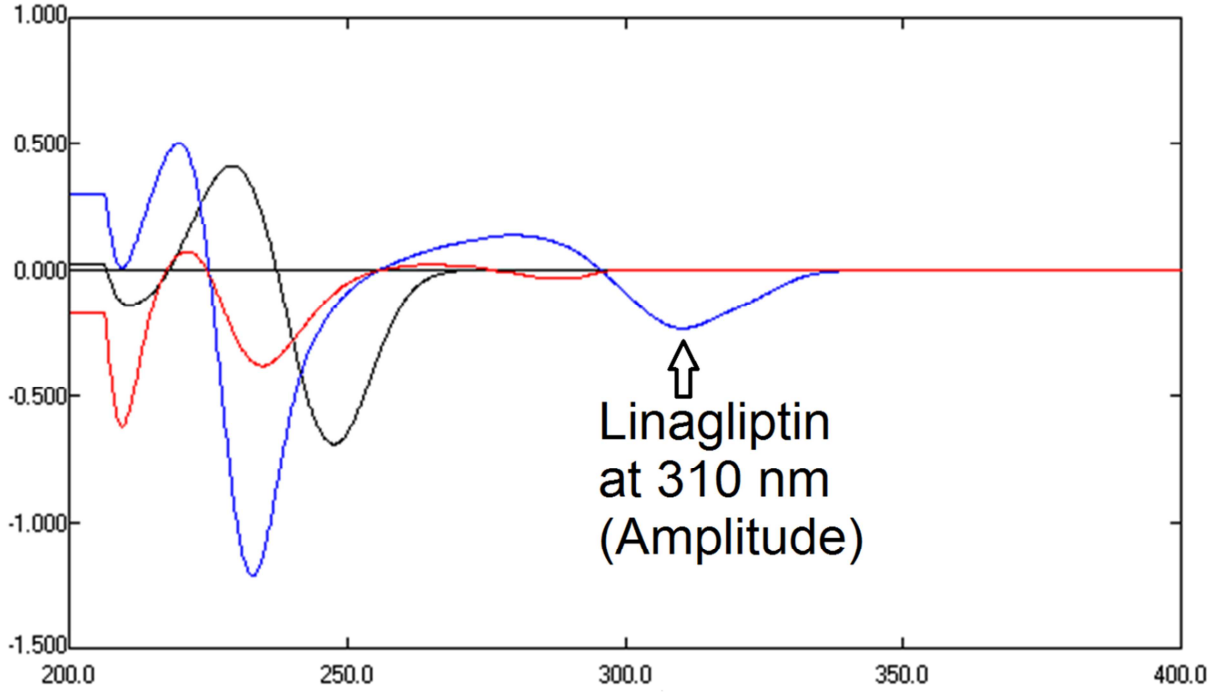

Figure 1: First derivative spectra of the laboratory prepared mixture showing amplitude of linagliptin at 310 nm without interference from metformin or empagliflozin

Cost-effectiveness is one of the major outcomes of the described analytical investigation in this article and the reported economic methods in literature [19-56] as the monetary cost of analyzing a sample with a given method and is commonly expressed as the price per analyte-sample pair. This property has two basic economic components, namely: the specific costs of using the required tools and the overhead costs of the laboratory performing the analyses. The fact that a laboratory in a developing country may not be equipped with the state-of-the-art instrumentation does not mean its chemical measurements are any less sophisticated. It may just mean that the measurements and techniques are cost-effective and sufficient for their intended purpose. Many laboratories in the developing countries depend on economic analysis rather than complex instrumentation techniques due to limitation in fund as a solution for the problem of counterfeit medicines. As validated analytical procedures, their economic applications on the accurate analysis of the reported drugs are possible. When patients receive a counterfeit medicine in the developing countries, they are subjected to multiple risks. They often suffer more than just an inconvenience; as they become victims of fraud medicines and are all put at risk of adverse effects. Developing countries should try their level best to establish good laboratories for monitoring and checking quality of all pharmaceuticals manufactured locally and those imported or donated to these countries. The Ministries of Health and all stakeholders involved in this issue must ensure that all drugs meet the set or established international standards and national standards using the described method in this article and the other proposed economic analytical procedures in the cited articles [19-56] as an example to follow.

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