I.A.U. Karaj Branch

Journal of Applied Chemical Research, 6, 3, 35-45 (2012)

Journal of Applied Chemical Research

www.jacr.kiau.ac.ir

Determination of Sitagliptin Phosphate in Bulk Drugs by Extractive Spectrophotometric Method

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(Received 17 Dec. 2011; Final version received 22 May. 2012)

Abstract

An extractive spectrophotometric method is described for the assay of sitagliptin phosphate in bulk drug and in tablets. Sitagliptin phosphatewas extracted as an ion-pair complex from the solution containing Eriochrome black T and 0.1N HCl into chloroform and the absorbance of the complex was measured at 500nm.The working conditions of the method were investigated and optimized. Beer's law plot showed a good correlation in the concentration range of 1–25 μg ml^{-1}. Sensitivity indices such as molar absorptivity, Sandell's sensitivity, limits of detection and quantification are reported. Precision and accuracy of the methods were established. The method was successfully applied to the assay of sitagliptin phosphate in tablet dosage forms with recoveries varying from 99.70 to 101.23% and standard deviation from 0.428 to 0.983. The results were statistically compared with those of the reference method.

Keywords. *Sitagliptin phosphate, Eriochrome black T, Spectrophotometric Assay, Beer's law, Molar absorbtivity.*

Introduction

Sitagliptin phosphate(STP) [1-4] is an oral antihyperglycemicdrug of the dipeptidyl peptidase-4 inhibitor class. STP is used either alone or in combination with other oral antihyperglycemic agents(such as metformin or thiazolidinedione) for the treatment of diabetes mellitus type 2. The therapeutic importance of STP has necessitated the development of analytical methods for its determination in dosage forms in compliance with good manufacturing standards and biological fluids. Chromatographic techniques such as liquid chromatography-mass spectrophotometer (LC-MS) [5-8] and reverse phase-high performance liquid chromatography

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