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REVIEW ARTICLE **OPEN ACCESS**

A review Paper on the Available Methods for the Analysis of an Anti-Diabetic Drug- "VOGLIBOSE"

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ABSTRACT
Diabetes Mellitus is an important concern in the health care division. The role of postprandial hyperglycemia (PPHG) in diabetes mellitus is significant. It is known that PPHG contributes to the increased risk of both micro- and macrovascular complications in patients with diabetes mellitus. Drugs are now available which specifically act to control PPHG of which can be Alpha-Glucosidase inhibitors like Acarbose, Miglitol and Voglibose. Voglibose has a preferential choice in the management of postprandial hyperglycaemia in treatment of type-2 diabetes mellitus. Voglibose is a research product of Takeda Pharma, a Japan based company. Voglibose is a highly reactive drug and the Recommended in low dosages of 0.2mg/0.3mg. The analysis of this drug is of great importance because of its reactivity and low concentration and also it is an anti- diabetic drug used for the treatment of type 2 diabetes which is one of the prevalent ailment in the society. Analysis is an important component in the formulation development of any drug molecule. A suitable and validated method has to be available for the analysis of drugs in the bulk, in drug delivery systems, from release dissolution studies and in biological samples. If a suitable method is not available then it becomes essential to develop and validate a simple, sensitive, accurate, precise, reproducible method for the estimation of drug samples. No spectrophotometric method were available for the estimation of Voglibose in bulk and formulations and thus various methods have been developed so far and this paper focuses on the review of the available methods of analysis of Voglibose.
Keywords: Voglibose, Post Derivatization, Assay, Uniformity of Content, Dissolution.

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INTRODUCTION

Diabetes Mellitus has emerged as an important concern in the health care division. Postprandial hyperglycemia is one of the earliest abnormalities of glucose homeostasis associated with type 2 diabetes and is markedly exaggerated in diabetic patients with fasting hyperglycemia. The role of postprandial hyperglycemia (PPHG) in diabetes mellitus is an important parameter. It is known that PPHG contributes to the increased risk of both micro- and macrovascular complications in patients with diabetes mellitus. Thus, the actual burden with this ailment is its associated complications. It appears in the literature that managing postprandial plasma glucose is more important in order to prevent the complications of type-2 diabetes [1].

Oral antihyperglycemic drugs and insulin are available that lower fasting and postprandial blood glucose levels. They can be classified based on their site of action. Alpha-Glucosidase inhibitors like Acarbose, Miglitol and Voglibose help to attenuate the rate of absorption of sucrose by acting as competitive inhibitors on the luminal enzymes. Apart from these there are newer insulin secretagogues which mimic the physiological release of insulin and thus improve PPHG.

The focus here is on Alpha Glucosidase inhibitors which play an important role in the control of PPHG and are comparatively inexpensive and can be taken orally for longer period, Lee, M.Y *et al.* [2]. Alpha Glucosidase enzyme which helps in the digestion of complex carbohydrates by cleaving oligosaccharides into monosaccharides. AGI compete with the oligosaccharides for the binding site and behave as classic competitive inhibitors. The mechanism of action of different AGIs is similar but not identical [1].

The literature reveals that Miglitol and Voglibose have equal efficacy in reducing PPHG as compared to Acarbose. The clinical benefit of Voglibose was its better safety profile as compared to Miglitol and Acarbose. Looking at the efficacy and safety profile amongst the available Alpha glucosidase inhibitors,

Voglibose has a preferential choice in the management of postprandial hyperglycaemia in treatment of type-2 diabetes mellitus [1].

Voglibose is a research product of Takeda Pharma, a Japan based company. Voglibose is a highly reactive drug and is recommended in small dosages of 0.2mg and sometimes with close observations 0.3mg is recommended. This drug concentration is supposed to be lowest in the pharmaceutical industry. The analysis of this drug is of great importance because of its reactivity and low concentration. Also as it is an anti- diabetic drug; which is used for the treatment of type 2 diabetes- one of the prevalent ailments in the society? Since, Voglibose absorbs UV in low wavelength region; it cannot be detected with high sensitivity with the normal processes. So special methods are necessary for the analysis of Voglibose.

Analysis is very important in the formulation development of any drug molecule. A suitable and validated method has to be available for the analysis of drugs in the bulk, in drug delivery systems, from release dissolution studies and in biological samples. If a suitable method is not available then it becomes essential to develop and validate a simple, sensitive, accurate, precise, reproducible method for the estimation of drug samples. No spectrophotometric method were available for the estimation of Voglibose in bulk and formulations and thus various spectroscopic methods have been developed so far, Rao, M. *et. al.* [3]. This paper focuses on the review of available methods for the analysis of Voglibose.

Available methods for the Analysis of Voglibose in Bulk and Tablet forms

JP, XVI Official Monograph, describes the Post Derivatization method with Fluorescent detectors for the estimation (assay) of Voglibose in its monographs. This describes about an LC_FD method with post column derivatization for the determination of Voglibose in pharmaceutical tablets. The sample was pre-treated by simple extraction and centrifugation without pre-column derivatization. For the post column derivatization, Sodium Periodate and Taurine dissolved in water was used as post column reagent. Voglibose was detected at an excitation wavelength of 350nm and an emission wavelength of 430nm.

Rao, M. *et al.* [3], cites UV spectroscopic methods for the analysis of Voglibose in pharmaceutical formulation. In this Voglibose was derivatized using Sodium Periodate and taurine in water and methanol. Voglibose was estimated at 282nm. This method was used for the estimation of Voglibose in bulk and tablet dosage forms.

Sai kishore *et al*. [4], affirms the reverse phase HPLC method for the analysis of Voglibose in tablet and bulk forms. In this method the exipients in the tablet form do not interfere for the quantification of the active drug. The instrument used is RP-18e,Hibar RT column. The mobile phase was composed of 0.025M Potassium Dihydrogen Phosphate with pH 2.5, Methanol and Acetonitrile in the ratio of 40:5:55 respectively in an isocratic mode and at a flow rate of 1ml/min. In this method Voglibose was derivatized with Sodium Periodate and Taurine as Voglibose cannot be directly detected. Voglibose was detected at 282nm.

Daswadkar, S.C. *et al.* [5], talks about two methods used for the analysis of Voglibose. The first method describes about an LC_FD method with post column derivatization for the determination of Voglibose in pharmaceutical tablets. The sample was pre-treated by simple extraction and centrifugation without pre-column derivatization. For the post column derivatization, Sodium Periodate and Taurine dissolved in water was used as post column reagent. Voglibose was detected at an excitation wavelength of 350nm and an emission wavelength of 430nm. The second method mentions about an LC_MS assay procedure for the analysis of Voglibose which is without derivatization. Voglibose was detected in an ESI mode with single ion recording (SIR,m/z 268.1). Both the methods could be successfully applied for the quantification of Voglibose in commercially available tablets.

Woo, J.S, Ryu, J.K. [6], refer to methods used for the analysis of Voglibose in bulk and tablet dosage forms using HPLC. The drug was separated using a mobile phase. The mobile phase used is acetonitrile: water, (20:80 v/υ). The instrument used is Agilent, TC C18 (250*4.6mm) with 5µm column and at a flow rate of 1.0ml/min at ambient temperature. Voglibose was detected at 272nm. The results have been validated and are found satisfactory with ICH guideline.

Kawamori, R *et al.* [7], deals with the statistics of how Voglibose used to prevent diabetes type 2 in Japanese patients. It is concluded in this paper that administration of Voglibose with certain lifestyle modifications can be used to reduce the development of Diabetes type 2.

Chatur, V.M. *et al*. [8], mentions of the comparison of the five different brands of Voglibose in terms of drug content, friability test, hardness test, wetting time, weight variation test, and disintegration and in-vitro dissolution studies.

Chen,X *et al*. [9], explains that Voglibose is an antidiabetic drug that acts as a competitive inhibitor of alpha glucosidase enzymes. It focuses on the properties of the Voglibose.

Deshpande, A.S. *et al*. [10], focuses on the method of derivative spectroscopy for the estimation of antidiabetic drugs: Metformin HCL, Glimepiride and Voglibose in multi ingredient tablet formulation. The

study of second order derivative spectroscopy method is used for the estimation of antidiabetic drugs using zero crossing method.
Floris, A. L. *et al*. [11], reviews the effects of monotherapy with -glucosidase inhibitors (AGIs) for patients with type 2 diabetes, with respect to mortality, morbidity, glycemic control, insulin levels, plasma lipids, body weight, and side effects. The AIGs used were Miglitol, Acarbose and Voglibose.

Motivation to find an alternative method of analysis of Voglibose

Currently, Voglibose, an antidiabetic drug which is used in very low concentration and has least absorbability.
Assay method of analysis:
Being a sugar type of molecular structure, Voglibose gives a very low response factor with UV detector. So the Japanese Pharmacopiea (JP) defines the Assay test procedure with the florescent detector with post derivatization method. Industries have developed suitable method by using UV detector which suffers with low response and needs highly skilled manpower to achieve precise results.
Test for Uniformity of Content:
As per the international guidelines, UoC or uniformity of content is an essential test for products with less than 10 mg strength. The hurdles mentioned for assay testing are applicable for this test parameter as well. Thus, for both Assay and Uniformity of Content the output obtained from the chromatogram suffers low response and the peak of the voglibose is either overlapped or is not significant. Some companies have developed an analysis method with the RI detector as RI is a suitable detector for Sugars. However RI is not a commonly used detector by all manufacturers as it is very expensive.
Dissolution is a test parameter used to evaluate the drug absorption rate in the body. Till date Voglibose dissolution test is not possible as dissolution test dilutes the drug concentration to 900 ml. Bioequivalence studies which helps to compare the developed formulation with innovator sample are not applicable to Voglibose due to same reason.
Hence, there is a scope for the development of alternative method to estimate the concentration of drug substance equal to or lesser than 0.2mg/ 0.3mg using much simpler techniques.

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