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RESEARCH ARTICLE
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ANALYSIS ON THE ANALYTICAL EVALUATION OF DRUG

Satyendra Singh[1*], Vivek Denial[2], Manmeet Singh[3]

[1*]Sunrise University, Alwarz Rajasthan
[2]Sunrise University, Alwarz Rajasthan
[3]Sunrise University, Alwarz Rajasthan

***Corresponding Author:** Satyendra Singh
*Sunrise University, Alwarz Rajasthan Email- satyendra29nov@gmail.com

Abstract
Type 2 diabetes (T2D), often known as adult-onset diabetes, is a type of diabetes marked by high blood sugar, insulin resistance, and insulin deficiency. **T**he main aim of the study is Analysis on The Analytical Evaluation of Drug**.** Identification test for Alogliptin Benzoate and MET Hydrochloride was carried out by using IR Spectroscopy and UV absorbance Spectra. The main aim of this research project was to develop and validate the analytical method for simultaneous estimation of MET and AGP by RP-HPLC.

Keywords: Diabetes, Simultaneous, Drug, Validation, Insulin, absorbance

1. INTRODUCTION

Type 2 diabetes (T2D), often known as adult-onset diabetes, is a type of diabetes marked by high blood sugar, insulin resistance, and insulin deficiency. Increased thirst, frequent urination, and unexplained weight loss are all common symptoms. Increased appetite, exhaustion, and unhealed wounds are also possible symptoms. Symptoms often appear gradually. Heart disease, strokes, diabetic retinopathy, which can lead to blindness, renal failure, and poor blood flow in the limbs, which can lead to amputations, are all long-term effects of high blood sugar. Ketoacidosis is uncommon, but abrupt start of hyperosmolar hyperglycemic condition is possible.[1]

Obesity and lack of exercise are the leading causes of type 2 diabetes. Some people have a genetic advantage. Type 2 diabetes accounts for 90% of diabetes cases, with type 1 diabetes and gestational diabetes accounting for the remaining 10%. Because of an autoimmune-induced loss of insulinproducing beta cells in the pancreas, type 1 diabetes requires a lower overall dose of insulin to manage blood glucose. Blood tests, such as fasting plasma glucose, oral glucose tolerance test, or glycated haemoglobin, are used to diagnose diabetes (A1C).

Type 2 diabetes can be mostly avoided by maintaining a healthy weight, exercising regularly, and eating a balanced diet (high in fruits and vegetables and low in sugar and saturated fats). Exercise and dietary adjustments are part of the treatment. MET is usually used if blood sugar levels are not sufficiently controlled. Many individuals' insulin injections may be required in the future. Regular blood sugar checks are recommended for insulin users; however, this may not be necessary for pill users. Obese people with diabetes often benefit from bariatric surgery.

Type 2 diabetes rates have risen dramatically in tandem with obesity rates since 1960. In 2015, nearly 392 million people have been diagnosed with the condition, up from around 30 million in 1985. Although incidence of type 2 diabetes is growing in young individuals, it usually occurs in middle or later life. Type 2 diabetes is linked to a ten-year reduction in life expectancy. Diabetes was one of the first diseases to be described, dating back to around 1500 BCE in an Egyptian book. Insulin's relevance in the condition was discovered in the 1920s.

Diabetes was one of the first disorders to be written about, with an Egyptian papyrus from around 1500 BCE stating "too much urine draining." The initial examples described are thought to be to have diabetes type 1 around the same time; Indian physicians noticed the condition and classified it as madhumeha, or honey pee, since the urine attracted ants. The Greek Apollonius Memphites coined the phrase "diabetes" or "to pass through" approximately 230 BCE. During the Roman empire, the sickness was uncommon, with Galen claiming to have only seen two cases during his career.

Sushruta and Charaka, two Indian physicians, identified type 1 and type 2 diabetes for the first time in 400–500 AD, with type 1 being connected with youth and type 2 with obesity. The first effective treatment came in the early twentieth century, when Canadians Frederick Banting and Charles Best discovered insulin in 1921 and 1922, respectively. The discovery of the long-acting NPH insulin in the 1940s followed.

2. LITERATURE REVIEW

Tammam AS, *et al* (2022) reported a sensitive, affordable, easy, and precise spectrofluorimetric technique was devised and evaluated for alogliptin in pharmaceutical dosage forms and human plasma. The drug's pharmacokinetic behaviour in the blood of rats was also studied using this method. When the primary amine group in the tested medication combines with acetylacetone and formaldehyde, the Hantzsch reaction produces yellowish light products that may be detected spectrofluorometrically at 480 and 415 nm for emission and excitation, respectively. Several experimental parameters that affect the development and stability of the reaction product were investigated and improved. In the concentration range of 0.05–3.60 g ml1, the fluorescence and concentration curve for alogliptin was linear. The proposed method was verified using criteria established by the International Council for Harmonization. With good accuracy, the approach was used to evaluate the investigated medication in dosage formulations and spiked human plasma.

Magdy MA, *et al* (2022) reported the determination of alogliptin and metformin hydrochloride in the presence of metformin impurity "melamin" in pure form and pharmaceutical formulation, two simple, sensitive, and repeatable techniques were established. When these approaches were compared to the one reported, no significant differences were identified.

Anumolu PD *et al* (2022) demonstrated an integrated multivariate approach to quantify the constituent concentrations of alogliptin and metformin in combination using a simultaneous assessment method with three variables (flow rate, pH of the buffer, and percent of organic phase) at two levels (first order) and to observe the effectiveness of those variables on response as theoretical plates to optimise the critical method parameters. The analytical method conditions were checked for robustness and certified in accordance with industry standards. With retention durations of 11.68 and 4.98 min, respectively, the linear regression analysis results for calibration plots revealed a satisfactory linear relationship with r2 =0.999 for both medications in the working concentration ranges of 5-25 g/mL for alogliptin and 50-250 g/mL for metformin. The proposed approach was used to quantify the researched medications in tablets and spiked human plasma, with results showing 99-100 percent recovery for both alogliptin and metformin. Furthermore, the approach was used to investigate the in vitro dissolving profiles of marketed tablets using FDA data.

Rana K, *et al* (2021) developed methods for analysis using a variety of analytical techniques for estimating medicines in combinations For the simultaneous quantitative determination of (MET) and (ALO) in tablet dosage forms, an accurate, precise, and repeatable RP-HPLC method was devised. The procedure was found to be straightforward, precise, cost-effective, and repeatable. As a result, the proposed methodologies can be employed for routine MET and ALO quality control analysis in bulk drugs and formulations.

Patel HP, *et al* (2021) focuses on the optimization and validation of a sensitive reverse phase liquid chromatographic bioanalytical technique for the detection of metformin hydrochloride and alogliptin benzoate in plasma using a design-oriented approach. The optimal centrifugation speed, centrifugation time, and plasma volume selected as key technique parameters for optimising extraction recovery were 11 800 rpm, 15 minutes, and 100 l. In the percentage ranges of 0.022-2.2 g/ml for metformin hydrochloride and 0.0012-0.12 g/ml for alogliptin benzoate, this enhanced extraction procedure provided clear samples with high correlation. The mean percentage extract recovery for metformin hydrochloride and alogliptin benzoate were 90.83-95.87 % and 94.03-96.73 %, respectively, at three quality control levels. The plasma concentration time profile for formulation indicated a higher peak plasma concentration as compared to pure medications, showing that metformin and alogliptin hydrochloride absorption via formulation was superior. The devised liquid chromatographic technique shown strong quantitative capability, linearity, better extraction recovery, ease of operation, and quick analytical time at a reasonable cost.

3. METHODOLOGY

1. Identification test:

Identification test for Alogliptin Benzoate and MET Hydrochloride was carried out by using IR Spectroscopy and UV absorbance Spectra.

2. Solubility:

Water and organic solvents were used to test the solubility of AGP Benzoate and MET Hydrochloride. 5 mL of solvent was used to dissolve the surplus medication. After that, the solution was ultrasonicated for 30 minutes. To achieve saturation equilibrium, it was left to stand for 24 hours at RT (room temperature) in a firmly covered vial. The solution was filtered via Whatman filter paper no. 41 after 24 hours. It was then diluted with the suitable solvent and the absorption was measured using a UV spectrophotometer.

3. Melting Point:

Melting point equipment was used to determine the melting points of AGP Benzoate and MET Hydrochloride. The medicine was placed in a tiny capillary tube on one side, which was attached to the thermometer's mercury bulb. The melting temperature was recorded once the thermometer was placed into the instrument.

4. Preparation of Standard Calibration Curve using UV-Visible Spectrophotometer:

Weighing 5 milligrammes of AGP and transferring it to a 100 mL volumetric flask with the diluent. Pipette 1 ml into a 10 ml volumetric flask and dilute with diluents to 10 ml. Weighing 10 milligrammes of MET and transferring it to a 100 mL volumetric flask with the diluent Pipette 1 ml into a 10 ml volumetric flask and dilute with diluents to 10 ml. UV spectroscopy was done on a Shimadzu 1700 uv spectrometer with a 1cm cell quartz cuvette using multiple dilutions of this stock solution. The detector wavelengths were retained at 231 nm and 276 nm, and the mode was adjusted to uv mode. Plotting concentration on the X-axis and absorbance on the Y-axis yielded the calibration curve. A suitable volume of AGP and MET hydrochloride standard solution was put to a volumetric flask with a capacity of 10 ml unit. A solution comprising 5–25 g/ml AGP and 5–20 g/ml MET hydrochloride was created by adjusting the volume with mobile phase.

4. RESULTS

Table 4.1 Solubility Study

Drug	Solubility
AGP Benzoate	It's soluble in dimethyl sulfoxide, water, and methanol; marginally soluble in ethanol; and very little soluble in octanol and isopropyl acetate.
MET Hydrochloride	It is water soluble but very marginally so in alcohol. Ether, chloroform, acetone, and methylene chloride are practically insoluble.

Table 4.2 Melting Point

Drug	Melting Point
AGP Benzoate	186°C
MET Hy*d*rochloride	224°C

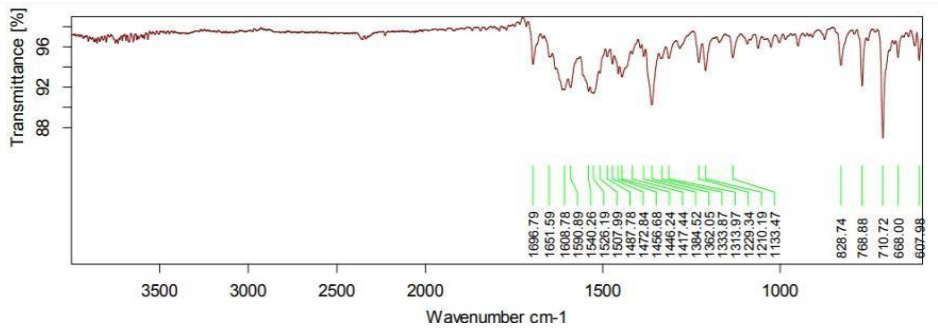

Figure 4.1 IR spectra of sample AGP

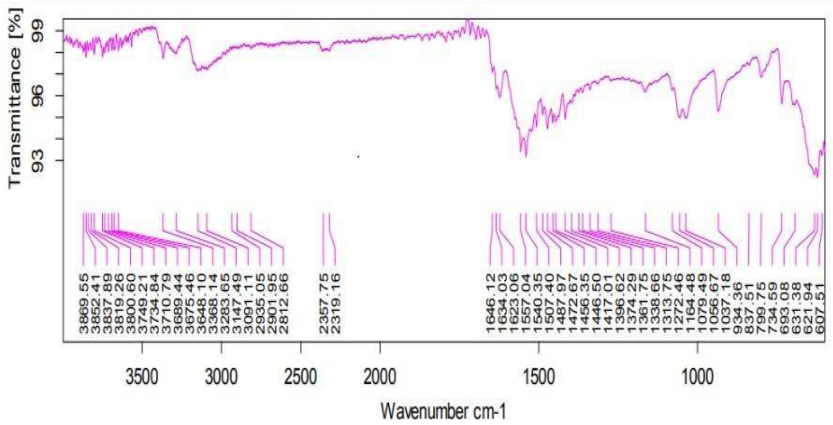

Figure 4.2 IR Spectra of sample MET

Determination of λ_{max}

The standard solution of AGP Benzoate was scanned between 200-400 nm on UV Spectrophotometer to determine the absorbance maxima.

The wavelength of maximum absorbance of drug was found to be 278 nm in diluent as shown in figure 4.3.

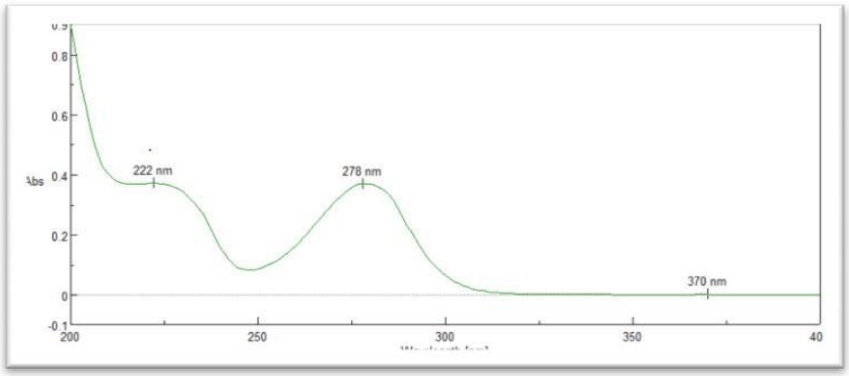

Figure 4.3 UV Spectra of AGP

The standard solution of MET was scanned between 200-400 nm on UV Spectrophotometer to determine the absorbance maxima. The wavelength of maximum absorbance of drug was found to be 233 nm in diluent as shown in figure 4.4.

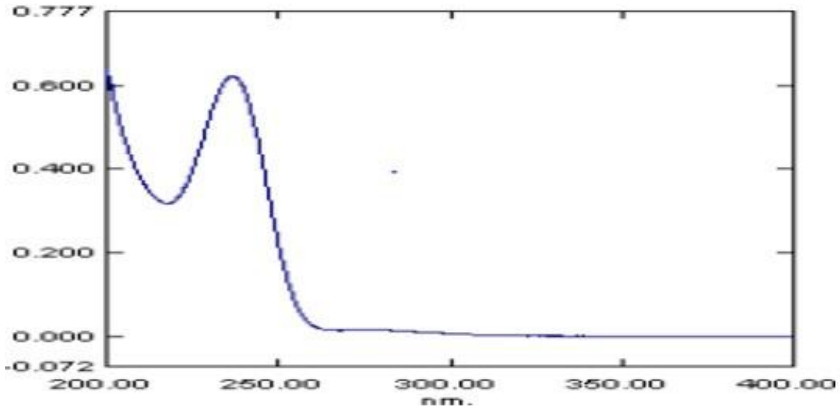

Figure 4.4 UV Spectra of MET

Calibration curve of AGP Benzoate:

The absorbance of the dilution was measured against diluent as a blank at λ_{max} 276 using double beam UV/visible spectrophotometer. The graph of absorbance versus conc. was plotted and data was subjected to linear regression analysis. The calibration curve of the drug is shown in Figure 4.5.

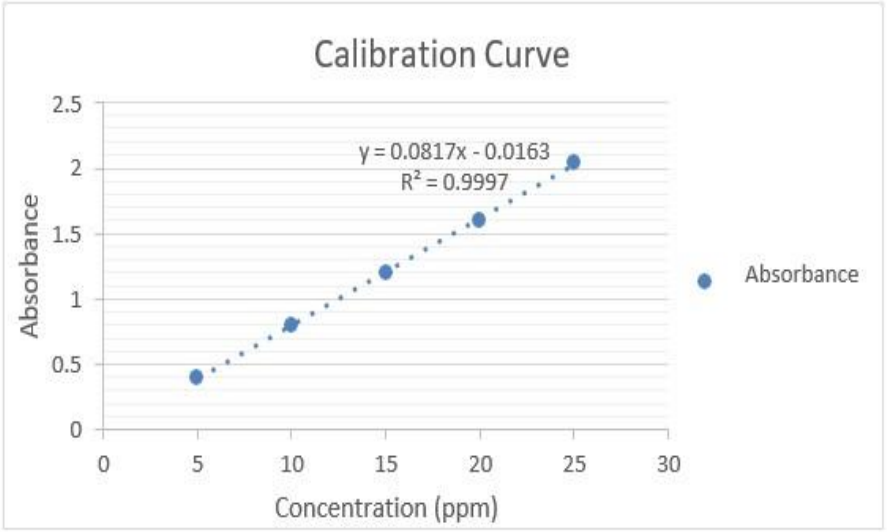

Figure 4.5 Calibration Curve of AGP Benzoate

Calibration curve of MET Hydrochloride:

The absorbance of the dilution was measured against diluent as a blank at λmax 233 nm using double beam UV/visible spectrophotometer. The graph of absorbance versus conc. was plotted and data was subjected to linear regression analysis. The calibration curve of the drug is shown in Figure 4.6.

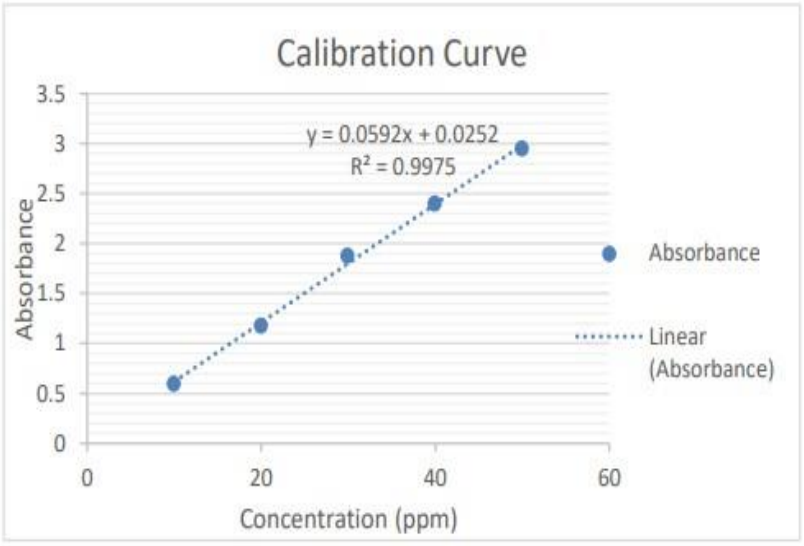

Figure 4.6 Calibration Curve of MET Hydrochloride

5. CONCLUSION

The main aim of this research project was to develop and validate the analytical method for simultaneous estimation of MET and AGP by RP-HPLC. A simple, specific, accurate, and precise RPHPLC method has been developed and validated as per ICH guideline for Simultaneous Estimation of MET and AGP In their Combined Dosage Form. Initially, the drug API were evaluated through identification test by IR, solubility, melting point and UV analysis in which the API's passed the analysis.

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