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An Analysis on the UV-Visible Spectrophotometry Method

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Abstract— *In the pharmaceutical industry, quality control is a necessary process. Pharmaceutical medicinal products must be advertised as safe, therapeutically active formulations with predictable qualities and performance. The main aim of the study is an analysis on the UV-Visible Spectrophotometry Method. UV spectroscopy was performed on Shimadzu 1700 uv spectrometer, 1cm cell quartz cuvette. Mode was set as UV mode and Detector wavelength was kept at 231 nm and 276 nm. A simple, rapid, accurate, sensitive and cost economical methodology for simultaneous estimation and precise ultraviolet radiation methodology has been developed and valid as per ICH guidelines for simultaneous Estimation of MET and AGP in Their Combined dose form.*

Keywords— ***pharmaceutical, therapeutically, Spectrophotometry, economical, Estimation***

I. INTRODUCTION

In the pharmaceutical industry, quality control is a necessary process. Pharmaceutical medicinal products must be advertised as safe, therapeutically active formulations with predictable qualities and performance. As new and better therapeutic substances emerge, more exacting and complex analytical methodologies for their evaluation are being developed. The word quality control, according to the World Health Organization (WHO), refers to the sum of all methods used to assure the identification and purity of a medicine. The portion of good manufacturing practises (GMP) that deals with processes involving sampling, specifications, and testing, as well as the organisation, documentation, and release protocols, is known as quality control. This aid in ensuring that the essential and relevant tests are carried out, and that materials and products are not released for use, sale, or supply until their quality has been validated to meet international standards.

Because every stage of the production process impacts the qualities of the medicine, this attribute of a pharmaceutical preparation cannot be easily quantified and assured during in-process inspection and finished-product testing. This crucial fact highlights the importance of properly training all employees, starting with the fundamentals of quality assurance such as donning personal protective equipment (PPE) before starting work to entering production sites; up to the complex protocols of aseptic technique. Furthermore, a continuous yield of high-quality products is dependent not only on the operators, but also on the cleanroom materials and diverse equipment used to handle and prepare the final products. As a result, meticulous attention to detail is required.

1.1.2 Analytical Method Development

Combination products are pharmaceuticals that contain more than one medicine in one formulation. Analytical chemists responsible for the development and validation of analytical procedures may face formidable hurdles with these combination products. For drug products having many active ingredients, the development and validation of analytical procedures [spectrophotometry, high-performance

liquid chromatography (HPLC), and high-performance thin layer chromatography (HPTLC)]. Quality control laboratories use the official test procedures that result from these processes to assure the identification, purity, potency, and performance of medicinal items.

Every year, a greater number of medications are added to the market. These medications could be brand-new or structurally modified versions of existing ones. There is frequently a time lag between the release of a medicine to the market and its inclusion in pharmacopoeias. This is owing to the risk of ongoing and extended use of these medicines, reports of additional toxicities (leading to their removal from the market), the development of patient resistance, and the release of superior medications by rivals. In certain cases, pharmacopoeias may not have standards or analytical techniques for these compounds. As a result, newer analytical methodologies for such drugs are required.

The therapeutic advantage of complex medication combinations should take precedence above any potential analytical challenge, which is ultimately the responsibility of the analyst. As a result, novel analytical methodologies for such drugs are critical.

1.2.3 Some reasons for the development of newer methods of drugs analysis are:

• Existing analytical procedures may need expensive reagents and solvents. It could also entail time-consuming extraction and separation methods that aren't always reliable.

• Any pharmaceutical development programme must include the creation, validation, and transfer of analytical methods. Method development that works ensures that laboratory resources are optimized, while methods meet the objectives required at each stage of drug development.

II. LITERATURE REVIEW

Aravind A et al (2021) developed simultaneous measurement of Metformin Hydrochloride and Pioglitazone in tablet dose form, a UV Spectrophotometric approach was devised. Methanol was used to make the stock solutions. 231 nm and 269 nm were discovered to be the maximum wavelengths for Metformin Hydrochloride and Pioglitazone, respectively. In concentration ranges of 5-30g/ml and 2-12g/ml, Metformin Hydrochloride and Pioglitazone followed Beer's law. The accuracy, precision, linearity, robustness, LOD, and LOQ of the absorbance ratio method were evaluated and validated according to ICH guidelines for various parameters. Because the proposed method is extremely sensitive, exact, and accurate, it can be employed for the intended purpose.

Habash IW et al (2020) reported that for analysing Alogliptin, Pioglitazone, and Metformin inside the bulk medication and tablet pharmaceutical dosage form, an RP-HPLC method has been developed and validated. The drug was separated using an ACE C18 (250 mm 4.6 mm), 5 m column with a flow rate of 1.0 mL/min at 25°C and detection at 230 nm. The detector's linearity was tested in concentrations ranging from 20 to 250 ppm, with a regression coefficient of 0.9998. When the API was stressed by acid, base, neutral, oxidation, and sunshine, the ICH guidelines were followed to determine stability. Linearity, precision, accuracy, the limit of detection, and the limit of quantification were all used in the validation process. According to ICH criteria, the results were satisfactory. The method's robustness was tested using variations in the mobile phase's pH, detector wavelength, mobile phase composition, and temperature. The method also yields a low relative standard deviation and a good recovery value, ensuring its suitability for regular analysis of tablets containing Alogliptin, Pioglitazone, and Metformin.

Godge RK, et al (2020) develop Simple, accurate, precise, and quick RP-HPLC technique validated according to ICH recommendations for the measurement of Alogliptin benzoate and Glibenclamide hydrochloride employing mobile phase [65:35 combination of Acetonitrile: Phosphate buffer pH-3.6 The suggested approach entails measuring Retention time at a certain analytical wavelength. 240.0 nm. Alogliptin benzoate (ALO) and Glibenclamide had retention times of 5.055 and 2.838, respectively. The suggested approach was tested for linearity in the ranges of 1-5 g/ml (r = 0.9998) for ALO and 10-50 g/ml (r = 0.9999) for MET. The method's linearity, accuracy, and precision were statistically confirmed. Inter-day and intra-day variance were found to have lower percent RSD (Relative Standard Deviation) values, indicating a high level of accuracy.

Mahrouse MA, et al (2019) approached in chromatographic separation performance with the least amount of labour and resources DOE was used in the development of an ion pair RP-HPLC method for the simultaneous determination of metformin hydrochloride (MET), alogliptin benzoate (ALO), and repaglinide (REP) in combined binary tablets because combination therapy of oral hypoglycemic drugs was generally recommended by Clinical Practice Guidelines on hypoglycemic agent therapy for the treatment of type 2 diabetes mellitus. Screening using the Plackett-Burman design followed by the face-centered composite design allowed for the calculation of optimal parameters that provide the best resolution and peak form within a reasonable amount of time. The constructed models were statistically examined, and the correlations between coefficients of the generated polynomial equations were interpreted using surface plots. The Models fit the data well and may be used to predict responses. The mobile phase was acetonitrile: phosphate buffer (0.01 M, adjusted to pH 2.5 with o-phosphoric acid): 0.3 percent sodium heptane sulfonate in water (60:20:20, v/v/v) at a flow rate of 1 mL min1. At 220 nm, UV detection was performed. The indicated medications produced sharp and clearly spaced peaks. The mean % recoveries of laboratoryprepared combinations comprising MET, ALO, and REP were 99.66 0.468, 99.98 0.398, and 99.70 0.988, respectively. The approach worked well for determining the medicines in binary pills, with recoveries of 99.75 0.6 and 99.74 0.982 for MET and ALO tablets, respectively. Q2 of the ICH guidelines were used to validate the method (R1). The constructed models were used to assess robustness. The analytical Eco-scale and the Green Analytical Procedure Index were used to analyse the developed method's greenness profile. The devised method for determining the mentioned pharmaceuticals in binary tablets proved to be an accurate, selective, precise, and environmentally friendly approach that may be used in quality control laboratories for regular drug analysis.

KB P, et al (2018) designed Two novel techniques for determining Alogliptin(ALG) and Metformin at the same time have been developed (MTF). Principal component regression (PCR) and partial least squares are two chemometrically aided spectrophotometric approaches (PLS). Alogliptin and Metformin spectra were acquired at various concentrations within their linear range, and the measurements were utilised to calculate the calibration mixture in methanol between wavelengths 200 and 400 nm at a 1 nm interval. Using the absorption spectra of acceptable solutions, the two approaches were effectively used to quantify each individual medication in the combination. The analytical responses of various chemometric techniques were measured and evaluated using relative prediction errors and recoveries (percent). The two methods were found to be satisfactory and successfully applied to a pharmaceutical dosage form and the results were compared.

III. METHODOLOGY

Instrument Parameters and Spectroscopic conditions

UV spectroscopy was performed on Shimadzu 1700 uv spectrometer, 1cm cell quartz cuvette. Mode was set as UV mode and Detector wavelength was kept at 231 nm and 276 nm.

Preparation of AGP (5 ppm) and MET (10 ppm) standard solution: 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.

Analysis of Pharmaceutical dosage form-Tablet by developed method Preparation of Sample solution: Tablet powder weighing 10 mg MET and 5 mg AGP was transferred to a 100 ml volumetric flask and diluent was added to make up the capacity. Pipette 1 mL from the above resolution into a 10 mL volumetrical flask and top up with diluent. Using a UV Spectrometer, examine the above solution.

IV. RESULTS

The spectrum of MET and AGP show no interference with the spectrum of MET and AGP blank, that the developed method is found to be specific.

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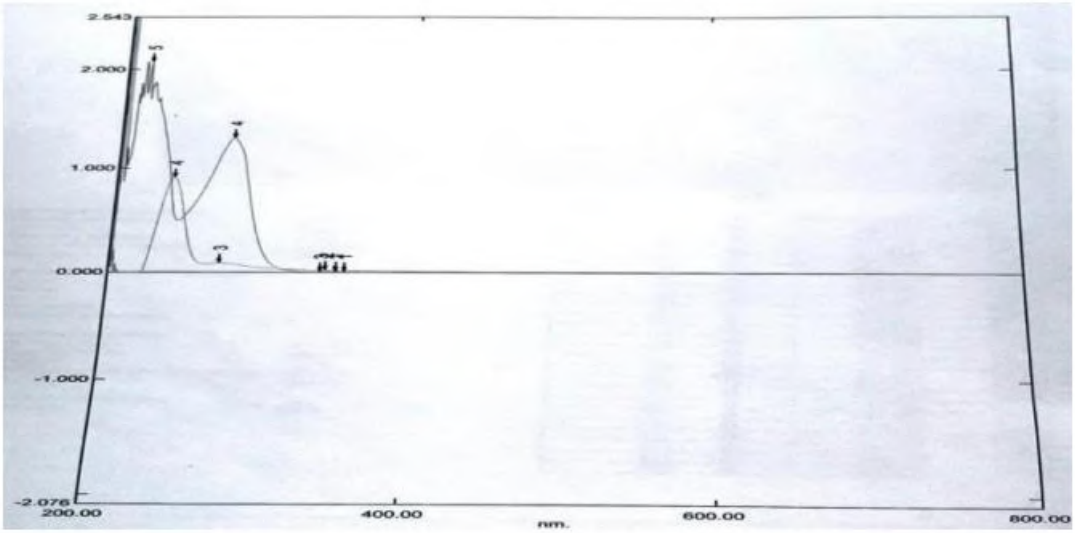

Fig.4.1 UV Spectra of MET and AGP

4.1.1 Linearity

Appropriate volume from AGP and MET hydrochloride standard solution was transferred to volumetrical flask of 10 ml unit} capacity. The volume was adjusted with mobile phase to allow a solution containing 5–25 µg/ml µg/ml AGP and 5–20 µg/ml MET hydrochloride. The correlation co-efficient of AGP and MET was achieved to be 0.998 and 0.999 severally.

Table 4.1 Linearity data for AGP

Concentration(µg/ml)	Abs.
5	0.31
10	0.65
15	0.92
20	1.27
25	1.61

Table 4.2 Linearity data for MET

Concentration(µg/ml)	Abs.
5	0.43
10	0.85
15	1.29

20	1.71
25	2.17

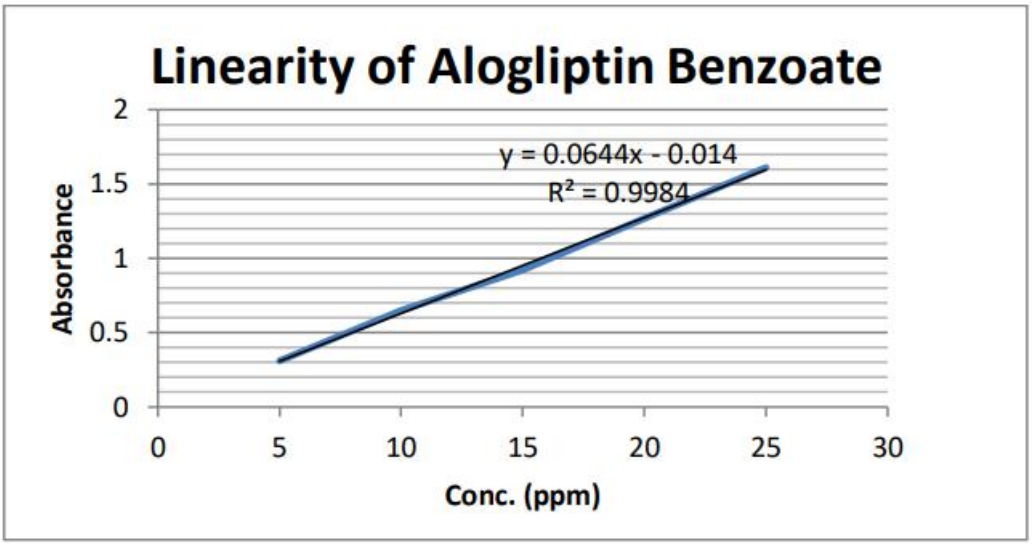

Fig. 4.2 Linearity of AGP

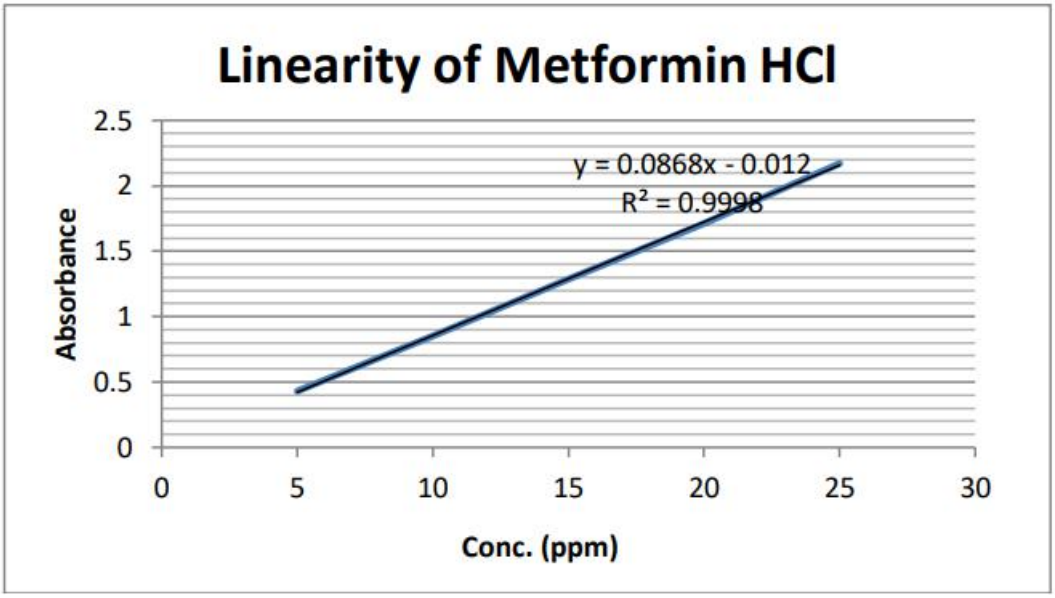

Fig. 4.3 Linearity of MET

4.1.2 Precision

Six measurements of the same solution of AGP (5 µg/ml) and MET (10 µg/ml) were supported by the results for technique precision of absorbance measurement for AGP (5 µg/ml) and MET (10 µg/ml). AGP and MET both had a percent RSD of 1.46 and 1.43, respectively.

Table 4.3 Method Precision data for AGP

Conc. (µg/ml)	Abs.	Mean	% R.S.D

5	0.35 0.35 0.36 0.35 0.37 0.35	0.3533	1.46

Table 4.4 Method Precision data for MET

Conc. (µg/ml)	Area Response	Average	% R.S.D
10	0.84 0.84 0.85 0.85 0.85 0.85	0.8466	1.43

Intraday and Interday precision

Intraday precision was assessed by analysing a standard solution containing (5, 10, 15 µg/ml) of MET and (5, 10, 15 µg/ml) of AGP three times on the same day and calculating two R.S.D. Interday precision was determined by analysing a reference solution containing (5, 10, 15 µg/ml) MET and (5, 10, 15 µg/ml) AGP three times on separate days and calculating two R.S.D.

Table 4.5 Intraday precision data for estimation of AGP

	AGP	
Conc. (µg/ml)	**Average Abs.**	**% R.S.D**
5	0.33	0.10
10	0.65	0.25
15	0.94	0.25

Table 4.6 Intraday precision data for estimation of MET

MET		
Conc. (µg/ml)	**Average Abs.**	**% R.S.D**
5	0.44	0.25
10	0.82	1.03
15	1.23	0.25

Table 4.7 Interday precision data for estimation of AGP

Conc. (µg/ml)	**Average Abs.**	**% R.S.D**
5	0.34	0.59
10	0.66	0.30
15	0.96	0.35

Table 4.8 Interday precision data for estimation of MET

Conc. (µg/ml)	**Average Abs.**	**% R.S.D**
5	0.43	1.32
10	0.84	0.96
15	1.25	0.54

V. CONCLUSION

A simple, rapid, accurate, sensitive and cost economical methodology for simultaneous estimation and precise ultraviolet radiation methodology has been developed and valid as per ICH guidelines for simultaneous Estimation of MET and AGP in Their Combined dose form. Validation concludes that developed UV methodology is linear, accurate, precise, specific and sturdy. It may be successfully acquired for routine quality control analysis of MET and AGP in Combined dose form. This methodology can currently transfer to utilize for routine laboratory analysis and assay of MET and AGP in their combined dose form.

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