Research Article **CODEN: AJPAD7** **ISSN: 2321 - 0923**

Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry

Journal home page: www.ajpamc.com

https://doi.org/10.36673/AJPAMC.2023.v11.i01.A01

A COMPARATIVE STUDY OF METFORMIN BY UV SPECTROSCOPY

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ABSTRACT

In the present study, an attempt was made to evaluate the quality and pharmaceutical equivalence of five samples of Metformin available in Kanjirapally, Kerala India. Metformin HCl is an anti-diabetic drug from the biguanide class of oral hypoglycemic agents. The study was performed using in-vitro methods as per Indian Pharmacopoeia. Samples were assessed through both official and non-official tests like hardness, friability, weight variation, disintegration time, assay. All five samples met the prescribed limit and found to be of good quality, safe and effective. All samples were pharmaceutically equivalent and interchangeable.

KEYWORDS

Metformin HCl, Biguanide, Weight variation, Friability, Hardness and Indian pharmacopoeia.

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INTRODUCTION

Metformin (dimethylbiguanide) is an orally administered drug used to lower blood glucose concentrations in patients with non-insulin-dependent diabetes mellitus (NIDDM)[1]. Metformin received approval in 1994 by the US food and drug administration (FDA), as a drug that is prescribed for treating diabetes[2]. In addition to glucose lowering, metformin has anti-tumor effect, anti-aging effect, cardiovascular protective effect, neuroprotective effect or an optional treatment for poly cystic ovary syndrome[3]. They stimulate the peripheral utilization of glucose either directly or by facilitating insulin action. The biguanides are also anorexiant and may encourage loss in weight[4].

Diabetes mellitus (DM) is a chronic metabolic disorder of carbohydrate, fat and protein metabolism[5]. Diabetes is due to either the pancreas not producing enough insulin, or the cells of the body not responding properly to the insulin produced[6]. It is a metabolic disorder characterized by hyperglycemia, glycosuria, hyperlipidemia, negative nitrogen balance and sometimes ketonaemia[7]. The chronic hyper glycemia and attendant metabolic abnormalities of diabetes are often associated with secondary damage in multiple organ systems, especially the kidneys, eyes, nerves and blood vessels[8].

Metformin has been on the market for more than fifteen years and number of branded as well as generic forms of metformin are available. To detect the similarities and difference among them, a comparative study is essential by analyzing and evaluating the drugs with various qualitative and quantitative methods. Appropriate method of analysis is needed for the rational use of medicine. UV spectroscopy is a technique that measures the amount of light absorbed by a chemical substance within the range of 200-400nm[9].

MATERIAL AND METHODS

Reagents and chemicals

Glycomet 500mg, Glyciphage 500mg, Bigomet S R 500mg, Omnimet S R 500mg, Melmet 500mg and distilled water.

Apparatus and Equipment's

Double beam UV Visible spectrophotometer (Systronics Model No: 2202), Electronic weighing balance, Monsanto hardness tester, Roche friabilator, Disintegration apparatus, standard volumetric flask, measuring cylinder, beaker, pipette, funnel and mortar and pestle.

Methodology

Weight variation test

The purpose of this test is to verify the uniformity of each batch which ultimately reflect the drug content uniformity in all the formulation batches. Sample tablets (20) of each brand were weighed individually on a digital analytical balance. The average weight was determined and the percentage (%) deviation of the individual tablets from mean weight was determined. In order to pass weight variation test, the tablet should be within the limits of the percentage deviation allowed by IP[10].

Hardness test

The hardness of different brands of tablets was determined by 'Monsanto hardness tester' and measured in terms of Kg/cm2. Sample tablet of each brand was taken and placed between the spindle of the hardness tester machine until the tablet breaks and the pressure required to break the tablet was recorded[11]. The general limit for hardness is given as 4-10kg/cm2.

Friability test

The tablets of each brand were taken and weighed. These tablets are subjected to abrasion using a Roche friabilatorat 100 revolutions for 4 minutes. The tablets were deducted carefully and weighed accurately again, then percentage weight loss was recorded. The % friability of the tablets was calculated using the formula[12].

$$\% \text{ Friability} = \frac{\text{Initial weight - final weight}}{\cdot 100 \text{ Initial weight}}$$

Disintegration Test

Tablet disintegration time of randomly selected six tablets of each brand was determined at 37^{o}C using disintegration apparatus employing distilled water as test fluid. The disintegration time was taken to be the time no granule of any tablet was left on the mesh[13].

Assay of Metformin Hydrochloride tablet

The assay was done to find out the % purity of the given five brand of metformin tablets. The test for assay was carried out using UV spectrophotometer method at specific absorbance (232nm) as per Indian pharmacopoeia.

Weighed and powdered 20 tablets. Weighed quantity of the powder containing about 0.1g of metformin HCl, shake with 70ml of water for 15 min, diluted to 100ml with water and filtered. Diluted 10ml of the filtrate to 100ml with water. Further diluted 10ml to 100ml with water and measure the absorbance of resulting solution at the maximum ATA bout 232nm[14,15].

RESULTS AND DISCUSSION

A comparative evaluation of five different brands of metformin tablets; Glycomet 500mg (USV), Glyciphage 500mg (Franco Indian), Omnimet SR 500mg (Elmex), Bigomet SR 500mg (Aristo) and Melmet 500mg (Micro) was done. The study was performed to calculate the % labelled claim, weight variation, hardness, friability, disintegration time and quantity difference among the different branded drugs of Metformin.

As per IP, the labelled claim should be within range of 95-105 %w/w. All the tablets are within this range. The uniformity of weight for the five brands of Metformin hydrochloride tablet gave values that compiled with I.P specification. Hardness of the tablets was in the range of 4.5 - 8.5kg/cm2 with all five brands. Friability values ranging0.019% to 0.208% w/w. The observed disintegration times for all the brands of Metformin hydrochloride investigated was less than 15 min limit as prescribed by official compendium.

Table No.1: Weight variation- Max % deviation allowed

S.No	Max % deviation allowed	As per IP standards
1	±10%	80mg or less
2	±7.5%	80-250mg
3	±5%	More than 250mg

Table No.2: Weight variation, %friability, hardness, disintegration, %labelled claim of different brands of metformin hydrochloride tablets

S.No	Brands	Weight variation	% Friability	Hardness (kg/cm2)	Disintegration Time (minutes)	% labelled claim (%w/w)
1	Glycomet	0.0299	0.112	5	5.06	97.49
2	Glyciphage	0.0285	0.030	4.5	8.06	97.99
3	Bigomet SR	0.0427	0.019	8	9.64	102.25
4	Omnimet SR	0.0385	0.208	8.5	9.94	102.74
5	Melmet	0.0322	0.028	6	6.64	98.54

S.No	Brands	Absorbance
1	Glycomet	0.778
2	Glyciphage	0.782
3	Bigomet SR	0.822
4	Omnimet SR	0.816
5	Melmet	0.782

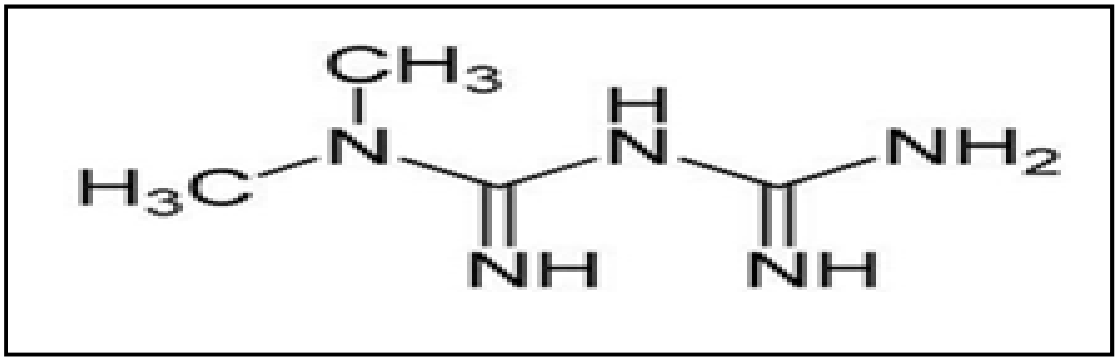
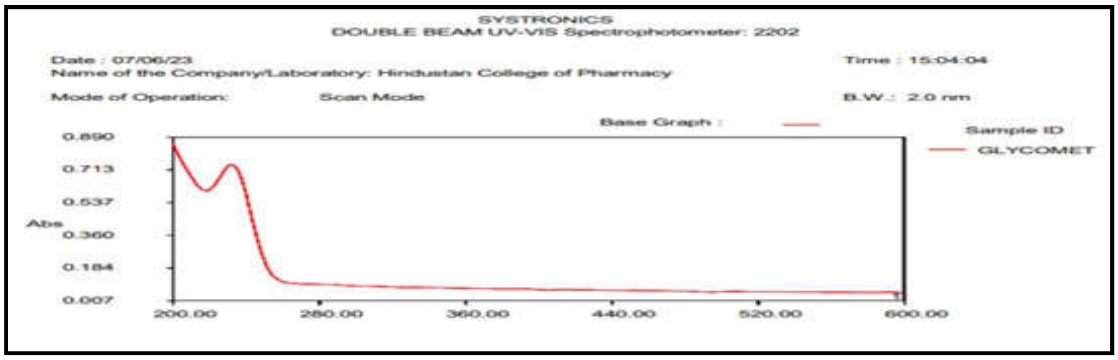
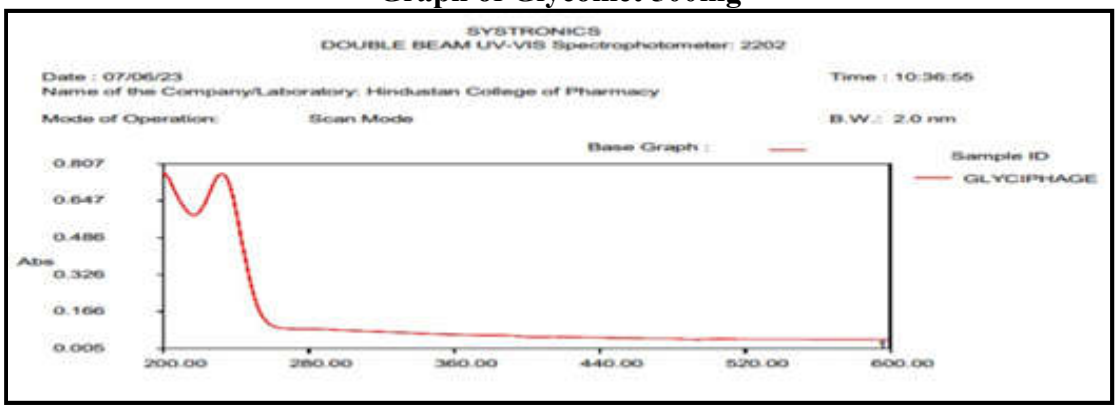


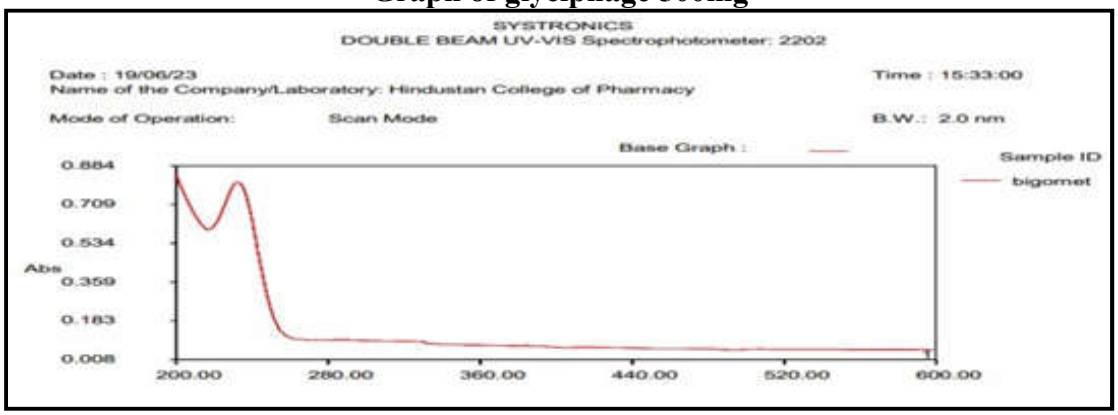
Figure No.1: Structure of metformin



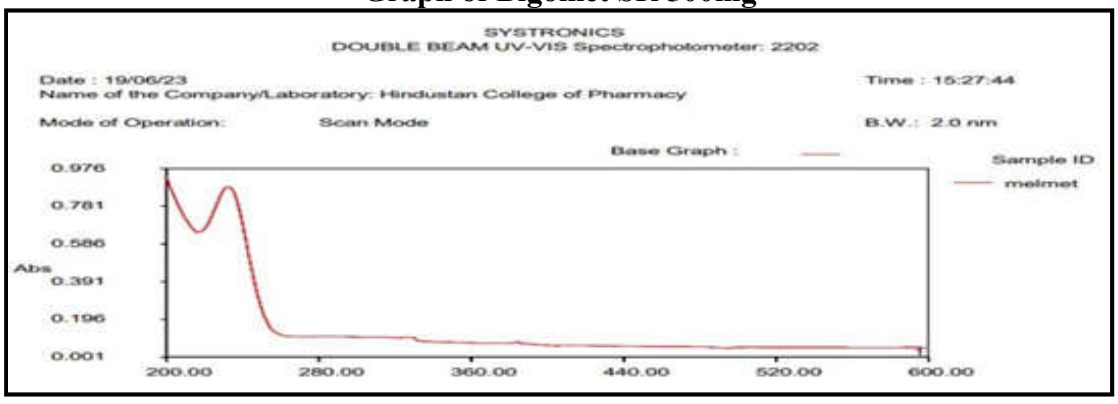
Graph of Glycomet 500mg



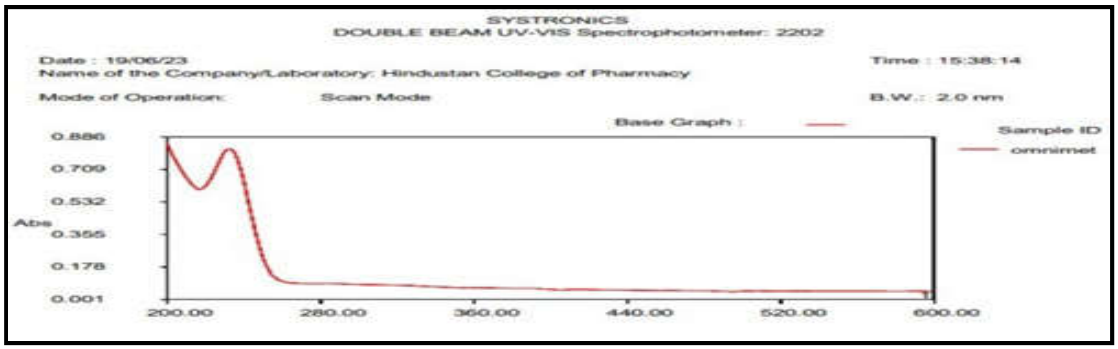
Graph of glyciphage 500mg



Graph of Bigomet SR 500mg



Graph of Melmet 500mg



Graph of omnimet 500mg

CONCLUSION

The study was aimed to assess the quality as well as physicochemical properties of five different brands of metformin hydrochloride. From this study it can be concluded that all the brands of metformin HCl tablets complied with the IP specifications for percentage labelled claim, weight variation, friability, hardness and disintegration test. By comparing and evaluating the results, safety and efficacy of these marketed products of metformin hydrochloride tablets can be determined.

ACKNOWLEDGEMENT

Authors are very thankful to Department of pharmaceutical chemistry and faculties of Hindustan College of Pharmacy, Kanjirapally, Kottayam. Authors are also thankful to the Management, for providing the necessary facilities to carryout this work.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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Please cite this article in press as: Prasanth A R *et al*. A comparative study of metformin by UV spectroscopy, *Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry,* 11(1), 2023, 1-6.