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Research Article

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Stability Determination of Five Different Brands of Metformin 500 mg Available at Local Market of Nawabshah, Pakistan

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ABSTRACT

Worldwide, it was noticed that various brands are available for metformin with number of drug delivery system-same brands are also available and marketed in Nawabshah. The main theme of this study is to evaluate 05 different brands of metformin tablets marketed in nawab shah city for physico-chemical evaluation, various officials and un-official test were performed including weight variation, friability hardness, content uniformity and dissolution. All available brands of metformin come under official specification for friability and weight variation. The result indicates that 02 brands Met 02 & Met 05 passed the hardness test while Met 01, Met 03, Met 03 & Met 04 brands were failed for hardness, test, As for as content uniformity was concern Met 02, Met 03 and Met 05 satisfied the official results as mentioned in USP (United States Pharmacopeia). While met 01 and met 04 did not show the specified result, met 02, met 04 and met 05 brands released 70-80% of their drug content within 30 min except met 01 & met 04, which did not pass the acceptance criteria as mentioned in USP.

Keywords: Hardness; United States Pharmacopeia; Weight variation; Uniformity; Dissolution

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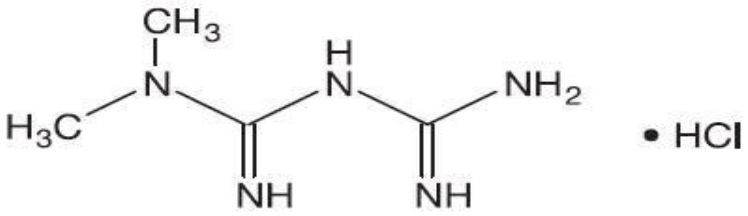
INTRODUCTION

Now a days society and government policies facing a lot of problems related to drugs [1] and pharmaceutical services as number of efficacious drugs [2] and developed for almost every disease related to human but the only factor that make them hazardous is quality because quality is only factor for market attraction along with legal and moral issues since bohemianism of quality standards [3,4]. Which are considered as essential because these standards can create serious outcomes such as toxic effect sub-therapeutic effect, therapeutic over dose [5]. All these subjects reduce the patient's adherence to wards treatment [6]. Assessment of physico-chemical evaluation of only drug is solid (tablet) dosage form is very much necessary as it can create a lot of issues that alter the dissolution rates

& bioequivalence [7]. So it is necessary to evaluate all standards of tablet formulation avoid from sub therapeutic effect during production [8] and these standards are responsible for claiming safety, efficacy & quality of the product during its entire shelf life till expiry date or consumption by consumer (patients) [9]. Scientific or IUPAC name of metformin hydrochloride is N, N dimethyl imido dicarbonimidic diamide hydrochloride or 1, 1-di methyl biguanide hydrochloride)and its mechanism of action is very clear, as it reduces absorption of glucose intestine, decreases gluconeogenesis in liver and enhance insulin sensitivity [10]. So that why it is considered as 1st line treatment therapy for use management of type-11 diabetes mellitus-it is also used in the management of obesity, metformin, actually activates adenosine monophosphate activated protein kinase (AMPK) [11,12]. AMPK is a liver enzyme that is responsible for insulin signaling, energy balance, Glucose & fat metabolism. (AMPK), is only enzymes, which is required to inhabit the glucose production within liver by inhabit the metformin effects [13,14].



Metformin Hydrochloride [15]

The main object of this study is to evaluate the physico-chemical properties of different brands of metformin tablets available in local market of Nawabshah.

MATERIALS AND METHODS

05 different brands of metformin available in the local market of Nawabshah were randomly selected with strength of 500 mg, and each brand was tagged with name (Met-01, Met-02, Met-03, Met-04 & Met-05) for there is identification-all physico-chemical tests were performed in all collected sample within product expiration dates. NaOH (sodium hydroxide), potassium dihydro orthophosphate and freshly prepared distilled water was used as Reagents for the entire work of evaluation.

Hardness test

10 tablets from each brand were taken and test was performed by using Monsanto hardness tester machine after applying pressure tablets were broken and uniformity was evaluated accordingly.

Friability Test

This test was performed by using the Friabilitator of Roche Company and instrument is adjusted at 25 rpm for 4 minutes after putting 20 tablets of each brand, before performing this test an average weight was calculated and after performing the weight was calculated again and it should not exceed 1% by USP.

Weight variation

This test was performed by using simple analytical balance. In which 20 tablets were taken from each brand and calculated individually after comparing with average weight according to USP-not move than 02 tablets should exceed the (± 5%).

Calibration curve of metformin Hcl in distilled

Water at 232nm: Pure drug powder of metformin HCL was distilled with 05 different known concentration. To establish a standard curve, and their curve were created to analyze pure drug.

Uniformity of content

This test was performed by using UV-Visible readings obtained from spectrophotometer at 232 nm, in this test, 10 tablets were taken from each brand and make various consent by using sonication techniques in 100 ml of distilled water, the test was repeated for number of times in order to achieve best outcomes, and USP standards were used to evaluate the uniformity.

Dissolution test

This test was performed by using paddle method apparatus containing 900 ml of phosphate buffer and specified PH of 6.8 and temperature 37 ± 1 c° with 75 revolution per minutes. Single tablet from each brand was put in compartment, reading was noted, after intervals of 05, 10, 15, 30, 45 and 60 minutes. During the procedure after every interval of revolution, 5 ml of sample was withdrawn/discarded and fresh 5 ml of sample was then added in order to maintain the sink conditions-each discarded sample was filtered with syringe and absorbance sample was measured at 232 nm. Calibration curve was considered as standard to measure to the concentration of sample in phosphate buffer. Major theme of this study was to evaluate the dissolution profile of the product. All the drugs have specified dissolution specification as mentioned in the USP (United States Pharmacopeia and according to specification limit all the brands of metformin should release the drug content in systematic circulation about 75% within half an hour.

RESULTS & DISCUSSION

Hardness and friability

It is ability of tablets to strengthen during the handling, packaging and transportation showed the specification and it is quality of any tablet dosage form, which is assessed, in order to check the hindrance capability against deformation during shelf life. The results indicate that only 02 brands had pass the crushing test whereas remaining products were unable to pass, the results of friability (Table 1).

Table 1. Hardness and friability of metformin tablets.

BRANDS	HARDNESS (KP±SD); N=10	FRIABILITY (%); N=20
MET01	40 ± 0.76	0.05
MET02	5.57 ± 0.57	0.87
MET03	44.3 ± 0.94	0.04
MET04	37 ± 0.34	0.05
MET05	6.4 ± 0.35	0.79

Weight variation

Drug uniformity is measured in terms of weight variation as well as in terms of content uniformity, so all the brands of metformin successfully pass the test of weight variation.

Diameter variation

The diameter of all the available brands of metformin were accordance to specified limit given in USP and successfully all the brands pass this test (Table 2).

Table 2. Diameter variation of different brands of metformin tablets.

Name of Brand	Average Diameter of 10 Tablets	Allowed limit ± 5% & ± 3%	Upper control Limit	Lower control Limit	Results
MET01	11.4	0.57	12	10.8	Pass
MET02	12.7	0.38	13.1	12.3	Pass
MET03	11.9	0.59	12.5	11.3	Pass
MET04	10.9	0.54	11.4	10.4	Pass
MET05	11	0.55	11.5	10.4	Pass

Dissolution test

All oral dosage forms including tablets were freely available in systematic circulation after the process of absorption through Disintegration or Dissolution. Dissolution test was conducted to evaluate the impact of manufacturing techniques upon rate of dissolution. These variables may include binder effect, type of excipients, granulation process (Table 3 and Figure 1). In a study, dissolution test was mostly conducted to evaluate the *in-vitro* bioequivalence of various available dosage forms [15]. According to a study, numerous brands of metformin were evaluated, and their profiles were analyzed at different time intervals that are mentioned below [16].

Table 3. Dissolution results of various brands of Metformin at 45 minutes of interval.

S.NO	Name of Brands	Percentage of drug dissolved within 45 minutes
1	MET01	99%
2	MET02	100%
3	MET03	100%
4	MET04	87%
5	MET05	91%

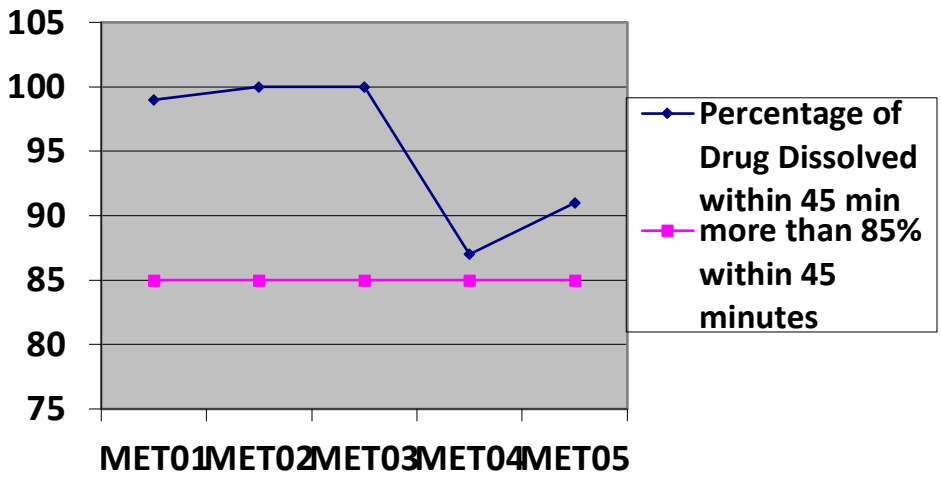


Figure 1. Dissolution results of various brands of Metformin at 45 minutes of interval.

CONCLUSION

Generally, it was noticed that a wide variation was observed in the selected brands of metformin during the study of Hardness whereas almost all brands pass the friability test and weight variation test. Three brands out of five successfully cleared the specified limit mentioned in USP while two brands did not get the desirable results.

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