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COMPARATIVE EVALUATION OF DIFFERENT BRANDS OF METFORMIN HCL TABLETS 500MG WITH DIABECON DS HIMALAYA TABLETS 500MG

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***Abstract*:** Metformin is an orally Anti Diabetic drug, which is available in various brands in local markets in Dehradun. The main purpose of this study is to compare and evaluate different brand of Metformin HCL tablets 500mg with Diabecon DS Himalaya. In this study we selected four different brand of Metformin Hydrochloride tablet 500mg and Diabecon DS Himalaya tablets from local market in Dehradun and evaluated various quality control parameters (physical and chemical parameters) as per official methods for comparison.
Weight variation for all four different brands of metformin hydrochloride tablets within ±5% of their average weight and when friability test was performed we found that the friability was not more than 1%, all the metformin hydrochloride tablet disintegrate within 15 minutes, percentage release of all brands of metformin hydrochloride tablets was found not less than 75% according IP specification limit within 45 minutes. Same procedure followed for Diabecon DS Himalaya tablets.

***IndexTerms* - Metformin Hydrochloride, Diabecon DS Himalaya, Dissolution, Quality control parameters**

I. INTRODUCTION

Metformin Hydrochloride is an orally anti hyper glycemic drug which is generally used in type 2 diabetes [1]. It is the first-line drug of choice for the treatment of type 2 diabetes, particularly in overweight and obese people and those with normal kidney function. [2]
Metformin belongs to the biguanide class of oral hypoglycemic agents. Chemically it is N, N- dimethyl imidodicarbonimidic diamide hydrochloride (1, 1-dimethylbiguanide hydrochloride) [3].

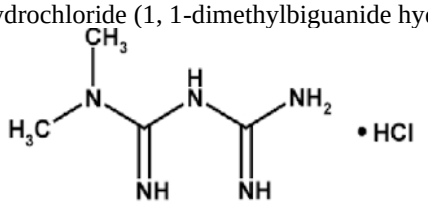

Figure 1. Chemical Structure of Metformin Hydrochloride
It is freely soluble in water & partially soluble in acetone, ether, chloroform, with 50-60% of Bioavailability, 4 - 8.7 hours of biological half-life hours [4]. ·
Metformin, an insulin sensitizer, not only improve hyper androgenism but also improves ovulation as well as pregnancy rates in patients with polycystic ovary syndrome, nonalcoholic fatty liver disease (NAFLD) and premature puberty [5]. Metformin Hydrochloride decrease intestinal absorption of glucose, suppresses glucose production, especially hepatic gluconeogenesis and improve peripheral tissue insulin sensitivity by increasing peripheral glucose uptake and utilization [6].
Metformin has no effect on plasma insulin concentration increases, and due to reduction in glucotoxicity it has an indirect effect on beta cell secretary function [7].
The recent studies on metformin show the drug having improvements in endothelial dis functioning, homeostasis and oxidative stress, insulin resistance, lipid profiles and fat redistribution. These properties give decreased adverse cardiovascular outcomes of metformin [8]. Diabecon DS Himalaya is a supplement composed of herbs used for centuries in Ayurvedic medicine, the action of which allows to increase the secretion of insulin in the body, which in turn allows a gentle and safe glycemic control. By increasing the level of glycohemoglobin, reducing micro-albuminuria and positively influencing the lipid profile, Diabecon minimizes late complications of diabetes.

II. MATERIAL AND METHODS

MATERIAL:

Chemicals: Four different brand of metformin tablets, Diabecon DS Himalaya tablets, pure metformin powder, sodium, hydroxide, potassium dihydrogen orthophosphate**.**

Glassware: Beaker, Volumetric flask, Measuring cylinder, Funnel, Test tube, Pipette etc.

Instruments: Weighing balance, Vernier caliper, Hardness tester, Friabilator, Disintegration machine, Dissolution machine, UV spectrophotometer.

METHODS -

Weight Variation Test: 20 tablets of each brand, were weighed using an electronic balance, average weight was calculated, and individual tablet weights were compared with the average weight [9]. Then % deviation was determined.

*% Deviation = individual weight of tablet – average weight of tablet / average weight of tablet***.**

Hardness Test: The hardness of the tablets were determined using Monsanto hardness tester. It is expressed in kg/cm^2. Five tablets were randomly picked from each batch and the hardness of the tablets were determined. The mean values were calculated for each batch [10].

Friability Test: Friability of a tablet can determine in laboratory by Roche Friabilator. For this test twenty tablets are weighed and placed in the friabilator and then operated at 25 rpm for 4 minutes. The tablets are then dedusted and weighed. The difference in the two weights is used to calculate friability and the value of friability is expressed in percentage. It is calculated by the following formula -

$$\% \text{ Friability} = [(Iw - fw)/Iw] \times 100$$

Where, Iw = intial weight

fw = final weight

The official permissible limit for friability is 1% [11].

Disintegration Test: The invitro disintegration time of tablet was determined using disintegration test apparatus as per IP specification. Place one tablet in each of the 6 tubes of basket. Add a disc to each tube and run the apparatus by using water. And then time in second / minutes taken for complete disintegration of the tablet was recorded [12].

Dissolution Test: Medium. 900 ml of a 0.68 per cent w/v solution of potassium dihydrogen phosphate, adjusted to pH 6.8 by the addition of 1 M sodium hydroxide, speed and time. 100 rpm and 45 minutes. Withdraw a suitable volume of the medium and filter, dilute suitably with water and measure the absorbance of the resulting solution at the maximum at about 233 nm. Calculate the content of Metformin in the medium taking 806 as the specific absorbance at 233 nm [13].

Table 1 Four Different Brand of Metformin Hydrochloride Tablets

Brand name	Manufacture by	Batch number	Mfg date	Expiry date	Cost of pack of 20 tablets in Rs
Glyciphage	Franco Indian Pharmaceutical Pvt, Ltd	19120	06/2019	05/2022	32.82/-
Biciphage	German Remedies pharmaceutical Pvt. Ltd	IZD20080	07/2020	06/2022	27/-
Glycomet	USV Pvt, Ltd	28019770	09/2019	08/2022	32.92/-
Metfor	Cipla Pvt Ltd	E700054	01/2020	12/2022	30.18/-
Diabecon	Himalaya Drug company	722000292	04/2020	03/2022	53.33/-

III. RESULTS AND DISCUSSION.

Weight variation - According IP /BP the weigh variation limits ±5% for the tablets 250 mg or above 250 mg. In this study weight variation for all four different brands of metformin hydrochloride tablets and Diabecon DS Himalaya tablets within ±5% of their average weight.

Hardness test - Hardness is the amount of strength or resistance to withstand mechanical shocks. As we know that hardness is not an official test so there is no such a compendia limit for hardness but a force of about 4kg is considered minimum requirement for a satisfactory tablets. In this study the hardness result of all the different brand of metformin hydrochloride tablets and Diabecon DS Himalaya tablets were found satisfactory.

Friability test - Friability refers loss percent during transportation, handling, shipping, packaging, and this is closely related hardness of the tablet. The limit of friability is not more than 1% according IP/BP. In this study we found that friability of all the tablets of different brand of Diabecon DS Himalaya tablets and metformin hydrochloride less than 1%.

Disintegration - Disintegration time is time for dosage form in which solid dosage form completely disintegrate into their particles. In this study all the tablets of different brand of metformin hydrochloride and Diabecon DS Himalaya tablets were completely disintegrate within 15 minutes.

Dissolution – According the IP the % release of drug is not less than 75% and in this study we found that the % release all different brands of metformin hydrochloride and Diabecon DS Himalaya tablets above 75 % within 45 minutes. The result obtained satisfactory.

Table 2. Weight Variation, Hardness, Friability, Disintegration, % release of Metformin Hydrochloride

Brand	Weight in gm ±SD	Hardness in kg/cm^2	Friability %	Disintegration time	% of drug release in 45 minutes
Glyciphage	0.554±0.002	7.48±0.21	0.36	6minute21sec	86%
Biciphage	0.569±0.004	6.84±0.37	0.57	7minute15sec	92%
Glycomet	0.602±0.004	7.36±0.33	0.86	5minute51sec	91%
Metfor	0.524±0.003	4.94±0.43	0.67	6minute45sec	89%
Diabecon	0.503±0.002	4.00±0.53	0.47	6minute55sec	85%

IV. CONCLUSION

The test result of all the quality control parameters within limits of pharmacopoeia, from it has been concluded that all the different brands of metformin hydrochloride tablets and Diabecon DS Himalaya tablets was found standard quality, all the tablets are safe, effective for use. But difference in cost of all the brands is different. Cost wise Biciphage will be best suitable but if patient responding well with herbal drug Diabecon DS is also considered best.

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