



PHARMACOLOGY

A SINGLE BLIND IN VITRO UV SPECTROPHOTOMETRY QUANTITATIVE ASSAY OF DIFFERENT PHARMACEUTICAL ORAL PREPARATION OF 500MG METFORMIN

K.Latha^{1*}, Sheela D², Tharini C B³

¹Assistant Professor, Department of Pharmacology, Saveetha Medical College & Hospital, Saveetha University, Saveetha Nagar, Thandalam, CHENNAI – 602 105, T.N, India

²Post Graduate Student, Department of Pharmacology, Saveetha Medical College & Hospital, Saveetha University, Saveetha Nagar, Thandalam, CHENNAI – 602 105, T.N, India

³Professor & Head, Department of Pharmacology, Saveetha Medical College & Hospital, Saveetha University, Saveetha Nagar, Thandalam, CHENNAI – 602 105, T.N, India

Abstract

Aim: To find out the chemical equivalence of metformin 500mg of five different manufacturers. **Materials and methods:** Quantitative analysis of five different brand of metformin 500mg was done by spectrophotometry. The reproducibility was tested. Throughout the study quantitative analyst was kept blind of the product. **Results:** The results were analysed to find out the chemical equivalence of metformin 500mg. It was found to be chemically equivalent. **Conclusion:** The above study revealed the assay purity of metformin 500mg of five different brands, to that of Indian pharmacopoeia prescribed standards.

Keywords: Chemical equivalence, Metformin, Reproducibility, Spectrophotometry

Introduction

Chemically equivalent preparations are expected to elicit same therapeutic response. The prescribers have been encouraged to use non proprietary approved names. So that the least expensive brand can be supplied and cost is minimised. Metformin, the commonly used antidiabetic drug is taken up to find out chemical equivalence. The quantitative estimation of drugs or their active constituents can be done by 1. Bioassay, 2. Physicochemical methods, (like chromatographic, fluorimetric and mass spectrometric techniques), 3. Radio-immunological assay, 4. Microbiological methods¹. Metformin Hcl (N,N dimethyl imidodicarbonimidic diamide Hcl) is a biguanide prescribed for the treatment of type II diabetes and it is the drug of choice in obese patients^{2,3,4}. It increases glucose transport across the cell membrane in skeletal muscles and it can inhibit the formation of advanced glycosylation end product^{5,6,7,8,9}.

The proposed method is based on the direct determination of metformin with a high degree of accuracy and sensitivity. The method is easy, least expensive and is applicable to the quantitative determination of metformin Hcl in pharmaceutical formulation¹⁰. This was carried out since prescribers have been strongly encouraged to use non proprietary approved names in N. H. S prescription. So that the

least expensive brand can be supplied and N.H.S cost is minimised^{11,12}

The aim of the present study to find out the chemical equivalence of metformin 500mg of five different brands.

The objective of the present study is:

- To find out the assay purity of metformin commonly used
- To suggest the best brand of metformin tablets in quantification

Materials and Methods

Metformin active ingredient (standard) was supplied by A to Z pharmaceuticals. It was tested in the lab for the purity by measuring its melting point and IR spectrophotometry¹³ prior to testing. No further purification was carried out. De-ionized water was used for the preparation of different dilution. The commercial pharmaceutical formulation sample A, B, C, D, and E. They had an expiry of not less than one year at the time of study. The brand names were kept confidential. The tablets A, B, C, D, and E kept blind to the analyst.

Assay purity of metformin of different brands was carried out using UV spectrophotometer. This was done for reproducibility. UV spectrophotometric method we have as per Indian pharmacopoeia 10mcg dilution and specific absorbance as 798 at 232nm¹⁴.

* Corresponding Author, Email: drklatha@gmail.com



Since there may be chances of error, we confirmed with standard and sample comparison.

Result

Assay purity of five different brands of metformin performed. Assay purity was within the Indian Pharmacopoea limits. Reproducibility also obtained. Absorbance of metformin at 232 nm with 10mcg water dilution is

Metformin standard -0.8088
Sample A -0.7649
Sample B—0.7760
Sample C -0.7387
Sample D -0.7422
Sample E -0.6657
Assay purity limit is 95 – 105%
For this absorbance, assay purity calculated

S.No	Sample	Absorbance	Assay Purity %
1	A	0.7649	95.62
2	B	0.7760	96.94
3	C	0.7387	96.23
4	D	0.7422	96.76
5	E	0.6657	95.71

Discussion

This study conducted to identify the potency of a brand and to suggest the best brand of metformin tablets to the practitioners. Here, after doing the purity assay it showed that the five different brands are found to be chemically equivalent. Hence the drugs with all different brands showed equipotent. Metformin a commonly used oral anti diabetic drug can be estimated by UV spectrophotometry, HPLC and ion pair HPLC method^{15,16,17,18,19}. The HPLC method was found to be more simple, accurate, economic and rapidly acting for metformin identification¹⁹. Another study done by Tubino et al²⁰ reveals that metformin can also quantitatively estimated by UV visible diffuse reflectance spectrometry very simply. Here in our study we did the estimation by UV spectrophotometry. It proved that it also can easily and simply estimate metformin without any hindrance. The proposed method is simple, accurate, precise sensitive and can be successfully applied for routine quantitative estimation of metformin hydrochloride in bulk and solid dosage forms.

Conclusion

Chemically equivalent preparations are expected to elicit same therapeutic response. Here metformin 500mg in five different brands proved to have equal chemical equivalence. So we can interchange or replace the drugs if it is required.

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