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Recovery Studies on Metformin Hydrochloride and Gliclazide Combined Dosage Form (Tablets) Using Rp-Hplc Techniques

Dibyajyoti Saha*, Swati Paul

Department of Pharmacy, BGC Trust University Bangladesh, Chittagong.

Research Article

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Corresponding Author:

Dr. Dibyajyoti Saha
Associate Professor and Chairman,
Department of Pharmacy,
BGC Trust University Bangladesh, Chittagong.
Email:saha.dibyajyoti@gmail.com
Telephone No: (+88) 01755588624

Abstract

Metformin hydrochloride is 1, 1-dimethyl biguanide hydrochloride and is also a hypoglecaemic drug. Gliclazide, is a third generation sulphonyl urea class hypoglycaemic drug which acts via stimulating β- cells of the isleta of langerhans of pancreas to release insulin. Metformin HCL differs markedly from glicazide and do not stimulate pancreatic β- cells but improve lipid profile well in type 2 diabetes.The research pathways were aimed at carrying out recovery studies of metformin hydrochloride and glicazide in combined dosage form (tablets) using RP-HPLC Techniques.

Keywords: *Metformin HCL, Gliclazide, Tablets, RP-HPLC.*

Introduction

Metformin hydrochloride is 1,1-dimethyl biguanide hydrochloride[1] and metformin acts by improving hepatic and peripheral tissue sensitivity of insulin and thus it acts as an antihypoglycaemic agent.Gliclazide,chemically is 1-(3-azabicyclo [3.3.0] oct-3-yl)-3(p-tolysulphonyl) urea [2] is a third generation sulphonyl urea which reduces blood glucose levels by stimulating insulin secretions from the beta cells of pancreas. The tablets which were used for this study was indicated for Type II Diabetes Mellitus (NIIDDM) in adults, with or without obesity, not responding to diet restriction and exercise[3,4]. Several methods(UV and HPLC) have been reported for the simultaneous estimation of gliclazide
And metformin hydrochloride in pharmaceutical dosage form [5, 6] and in plasma [7, 8].

Materials and Methods

The tablets were purchased from local market.

Apparatus and Reagents: HPLC system (Merk-Hitachi); Column used-LC1, RP,C18, (125mm x 4mm): Particle size 5 micron; 0.02M KH_2PO_4 and acetonitrile in the ratio 37:63; P^H adjusted to 4±0.1 by adding 30% dilute orthophosphoric acid, wave length 270 mm for metformin hydrochloride and 238 mm for gliclazide ; double distilled water; Acetonitrile HPLC grade; KH_2PO_4 GR grade ; Orthophosphoric acid AR grade.

Experimental Methodology:

The validation of the proposed method was done as per USP [9] and ICH [10] guidelines. The recovery studies were carried out by adding known amount of standard drugs to the pre-analyzed samples and subjecting them to the proposed HPLC method of analysis.

Take four separate volumetric flask 100ml capacity and marked them No one, two, three, four to each flask take 712 mg powdered tablets.Take flask no. one add metformin hydrochloride WS(99.69%) 28 mg and gliclazide WS (98.92%) 8.46 mg; make the volume to 100 ml with mobile phase, transfer 3.5 ml of this solution to a 25ml volumetric flask and volume to the mark 25 ml with mobile phase, 1 ml of this solution and volume to make 10ml with mobile phase and then filter through 0.45 micron filter paper.Take flask no. two add metformin hydrochloride WS(99.69%) 85.22 mg and gliclazide WS (98.92%) 16.92 mg; make the volume to 100 ml with mobile phase, transfer 3.5 ml of this solution to a 25ml volumetric flask and volume to the mark 25 ml with mobile phase, 1 ml of this solution and volume to make 10ml with mobile phase and then filter through 0.45 micron filter paper. Take flask no. three add metformin hydrochloride WS (99.69%) 127.83 mg and gliclazide WS (98.92%) 25.38 mg; make the volume to 100 ml with mobile phase, transfer 3.5 ml of this solution to a 25ml volumetric flask and volume to the mark 25 ml with mobile

Amount label claimed mg/ tablet	Amount found mg/ tablet	Amount of standard added mg/tablet	Total amount mg/tablet	Total amount recovered mg/tablet	% Recovery	Mean Recovery%
500.00mg	500.39 mg	28.00mg	528.39mg	526.05mg	96.88%	99.405%
500.00mg	500.39 mg	85.22 mg	585.61mg	580.47 mg	99.12%	
500.00mg	500.39 mg	127.83 mg	628.22mg	636.17 mg	101.26%	
500.00mg	500.39 mg	170.44 mg	670.83mg	673.27mg	100.36%	

Table 1: Recovery Study of Metformin Hydrochloride from Tablet

phase, 1 ml of this solution and volume to make 10ml with mobile phase and then filter through 0.45 micron filter paper. Take flask no. four add metformin hydrochloride WS (99.69%) 170.44 mg and gliclazide WS (98.92%) 33.84 mg; make the volume to 100 ml with mobile phase, transfer 3.5 ml of this solution to a 25ml volumetric flask and volume to the mark 25 ml with mobile phase, 1 ml of this solution and volume to make 10ml with mobile phase and then filter through 0.45 micron filter paper.

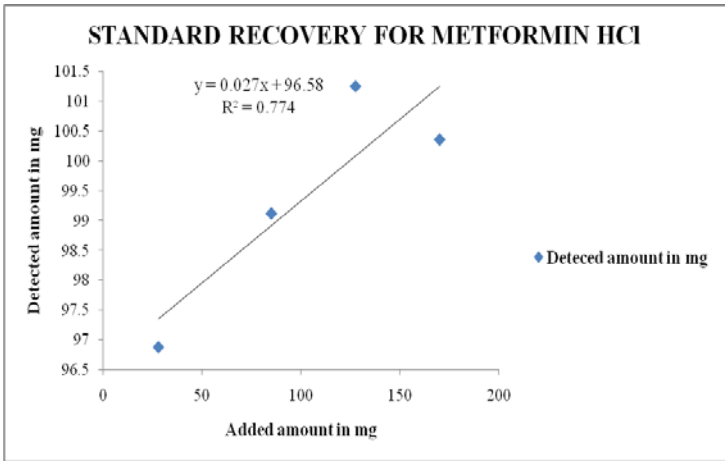

Figure 1: Graphical Representation of Standard Recovery for Metformin Hydrochloride

Table 2: Recovery Study of Gliclazide from Tablet

Amount label claimed mg/ tablet	Amount found mg/ tablet	Amount of standard added mg/tablet	Total amount mg/tablet	Total amount recovered mg/tablet	% Recovery	Mean Recovery%
80.00mg	79.78 mg	8.46mg	88.24mg	87.20mg	98.82%	101.625%
80.00mg	79.78 mg	16.92 mg	96.7mg	96.87mg	100.17%	
80.00mg	79.78 mg	25.38 mg	105.16mg	109.89mg	103.89%	
80.00mg	79.78 mg	33.84 mg	113.62mg	117.73mg	103.63%	

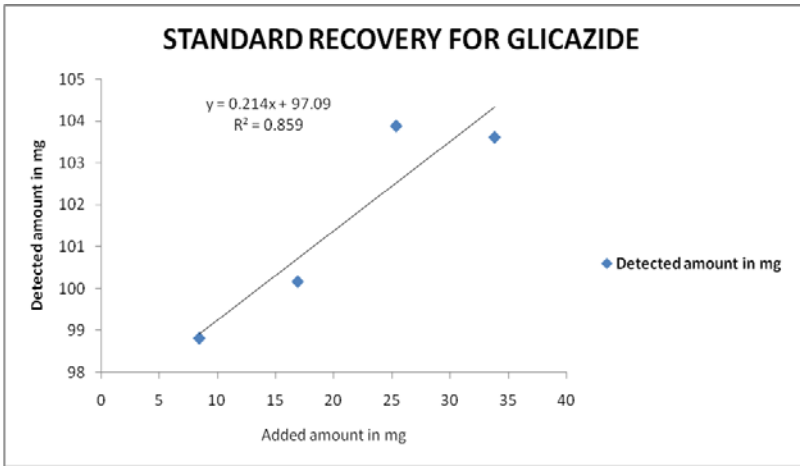

Figure 2: Graphical Representation of Standard Recovery for Glicazide

Conclusion

The recovery studies of Metformin Hydrochloride and Glicazide in tablets using RP- HPLC techniques were found to be simple, accurate, precise, linear, rapid and economical & can be used in routine quality control analysis.

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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

Not commissioned; externally peer reviewed

CONFLICTS OF INTEREST

The authors declare that they have no competing interests