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Research

A New Validated UV-spectroscopic Method for Simultaneous Estimation of Tenegliptin and Metformin in Pharmaceutical Dosage Form

T. Gurumurthy[1*], P. Snehalatha, N. Sai Charitha, M. S. Tejaswini, M. Sangeetha, P. Jahnavi, K. Anetha, G. Thirumallesh Yadav

[1]Assistant Professor, Department of Pharmaceutical Analysis, Creative Educational Society's College of Pharmacy, chinatekur, Kurnool-518218 Andhra Pradesh, India
[1*]Research Scholar, Department of Pharmaceutical Analysis, Acharya Nagarjuna University College of Pharmaceutical Sciences, Guntur-522510, Andhra Pradesh, India

*Author for Correspondence: T. Gurumurthy
Email: gurumurthy.telugu@gmail.com

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Abstract

Simple, precise, economical, fast and reliable UV-Spectroscopic methods have been developed for the simultaneous estimation of Metformin HCl and Tenegliptin in bulk and pharmaceutical dosage form. The method which is based on measurement of absorption at maximum wavelength of 232 nm and 242 nm for Metformin HCl and Tenegliptin respectively. Linearity for detector response was observed in the concentration range of 2-10µg/ml for Metformin HCl and 2-10 µg/ml for Tenegliptin. The accuracy of the methods was assessed by recovery studies and was found to be 100.23 % and 99.36% for Metformin HCl and Tenegliptin respectively. The developed method was validated with respect to linearity, accuracy (recovery), precision and specificity. The results were validated statistically as per ICH Q2 R1 guideline and were found to be satisfactory. The proposed methods were successfully applied for the determination of for Metformin HCl and Tenegliptin in commercial pharmaceutical dosage form.

Keywords: Simultaneous equation method, UV-spectrophotometer, Validation, Tenegliptin, Metformin Hcl

INTRODUCTION

Teneligliptin
Teneligliptin is a pharmaceutical drug for the treatment of type 2 diabetes mellitus. It belongs to the class of anti-diabetic drugs known as dipeptidyl peptidase-4inhibitors or "gliptins"

IUPAC Name
1-(3-methyl-1-phenyl-1H-pyrazol-5-yl)-4-[(3S,5S)-5-(1,3-thiazolidine-3-carbonyl) pyrrolidin-3-yl]piperazines

Molecular Formula	:	$C_{22}H_{30}N_6OS$
Molecular Weight	:	426.5782g/mol
Brand name	:	Dynaglipt

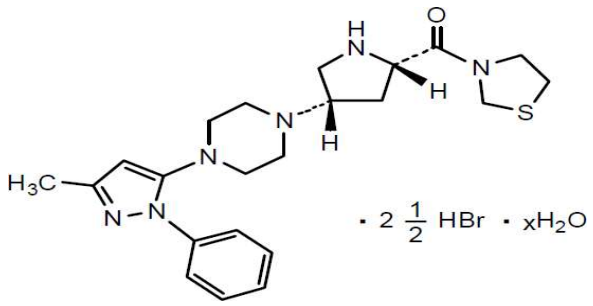

Fig 1: Chemical structure of Teneligliptin

Metformin

Metformin was discovered in 1922.French physician Jean Sterne began study in humans in the 1950s.It was introduced as a medication in France in 1957 and the United States in 1995.Metformin is on the World Health Organization's List of Essential Medicines, which lists the most effective and safe medicines needed in a health system Metformin is the most widely used medication for diabetes taken by mouth

Molecular Formula	:	$C_4H_{11}N_5$
Molecular Weight	:	129.1636 g/mol
Brand name	:	Dynaglipt-M
Category	:	Anti- hyperglycemic agents / Anti-diabetic drug

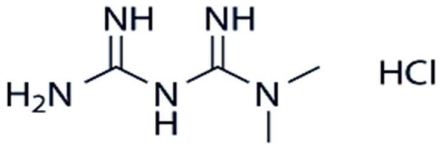

Fig 2: Chemical structure of Metformin

MATERIAL AND METHODOLOGY

Table 1: List of Instruments

S.NO	NAME OF THE INSTRUMENT	MODEL	MAKE
1	UV Vis Double Beam Spectrophotometer	UV3000+	Labindia
2	Analytical Balance	CA 234	Contech
3	PH Meter	361	Systronics

Materials: PURE SAMPLES: The pure standard samples of Tenegliptin and Metformin were supplied as gift samples of Mankind pharma ltd
Marketed Samples: Dynaglipt -M
Solvents: Methanol
All the reagents and chemicals used were of analytical grade and solvents were of spectroscopic grade.

METHODOLOGY

Preparation Of Standard Drug Solution: Weigh accurately 10 mg of pure Tenegliptin and Metformin separately into 10ml volumetric flasks and were dissolved in 10ml of methanol respectively obtain 1mg/ml concentration of each drug in methanol

Preparation Of Working Standard Solution: The working standard solutions were prepared by diluting the standard drug solutions to obtain different concentrations of Tenegliptin and Metformin in the ranges of 2, 4, 6, 8, 10µg/mL using methanol

Preparation Of Blank: methanol
Scanning Range: 200-400nm
Determination Of Λmax And Isobestic Point: The working standard solutions prepared by using solvents Methanol were scanned between 200-400nm against blank to determine –λmax and Isobestic point of Tenegliptin and Metformin.

Validation Of The Developed Method

The developed methods by UV spectrophotometry were validated as per ICH guidelines of Q2R guidelines for the following parameters.

Preparation Of Working Standard Solutions For Linearity Curve: A series of 2, 4, 6, 8, 10 µg/mL were prepared from standard stock solutions of Tenegliptin and Metformin using methanol

Prepartion Of Solutions For Precision: The middle concentration 6 µg/ml has been selected for precision for the both drugs using methanol

Preparation Of Solutions For Accuracy: 50%, 100%, 150% concentrations were tested for recovery Tenegliptin and Metformin in methanol.

Determination Of Lod And Loq

Limit of determine and limit of quantification of the two Tenegliptin and Metformin were calculated by using the formulas:
LOD-3.3 σ/Slope
LOQ-10 σ/Slope

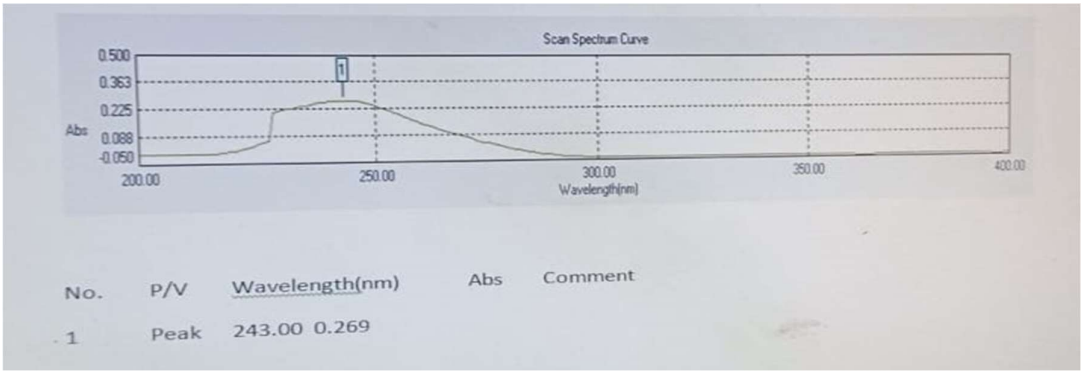

Fig 3: Determination of λ max of Tenegliptin in methanol.

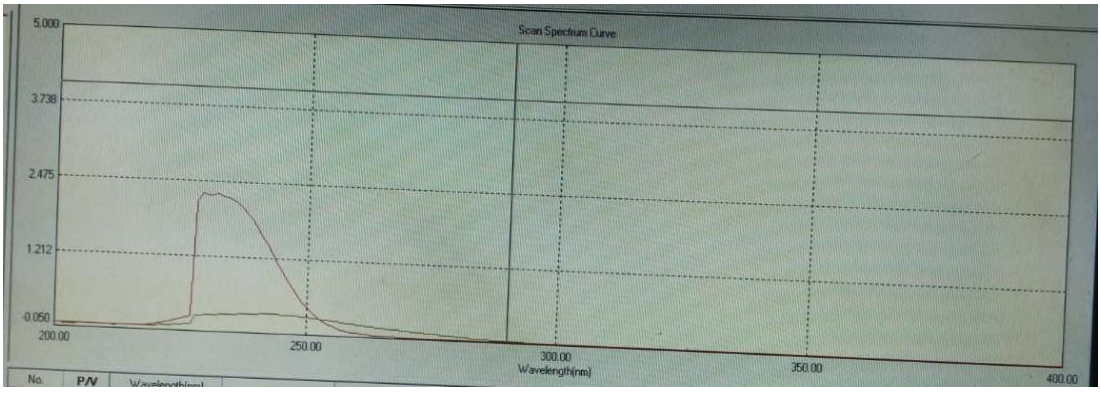

Fig 4: Determination of Isobestic point of Tenegliptin& Metformin in methanol

Table 2: Linearity results for Tenegliptin& Metformin

S.No	CONC	Absorbance of TEN at 242nm	Absorbance of MET at 232nm
1	2	0.095	0.011
2	4	0.148	0.190
3	6	0.212	0.266
4	8	0.267	0.358
5	10	0.315	0.437

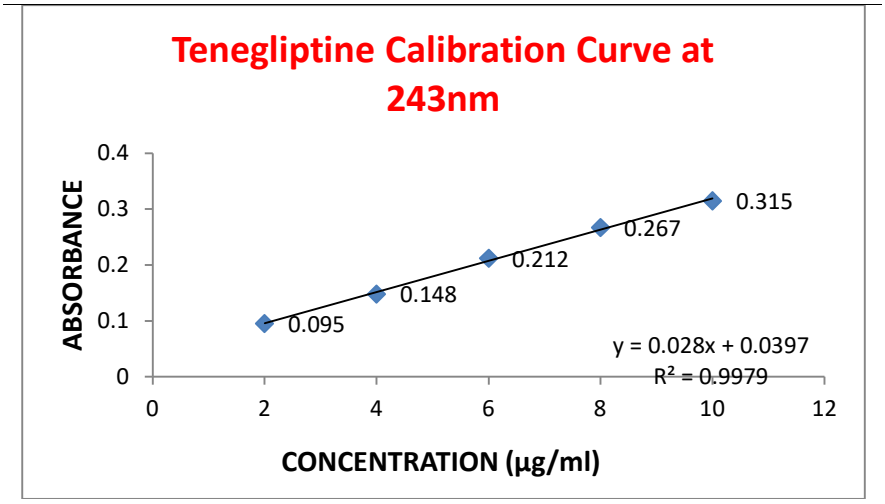

Fig 5: Calibration curve of Tenegliptine

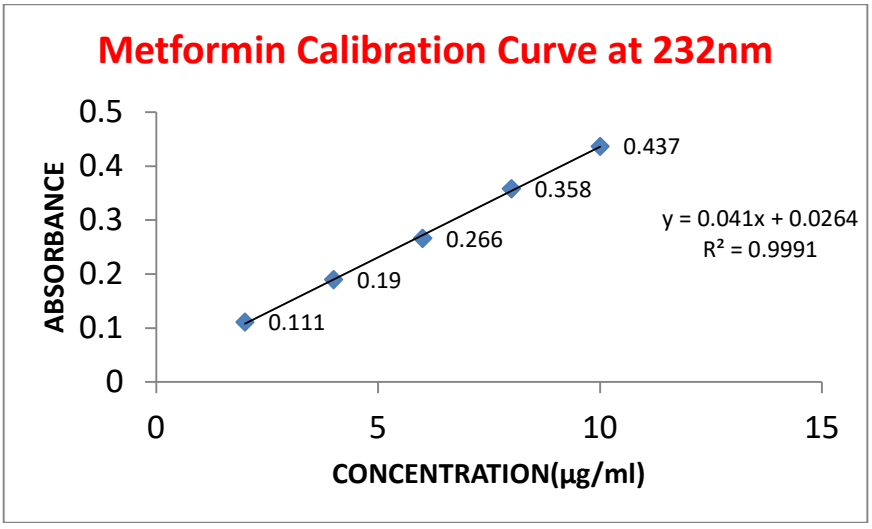

Fig 6: Calibration curve of Metformin

Table 3: Precision (Repeatability) results for Tenegliptin & Metformin

S.NO	Conc. (µg/ml)	Absorbance of TEN at 242nm	Absorbance of MET at 232nm
1	6	0.246	0.538
2	6	0.238	0.546
3	6	0.243	0.541
4	6	0.282	0.562
5	6	0.278	0.546
6	6	0.262	0.538

Mean	-	0.261	0.545
S.D	-	0.022	0.076
RSD	-	0.381	1.294

Table 4: Study of Accuracy

S.No	%Level	%Recovery TEN at 242nm	%Recovery MET at 232nm	%RSD of TEN	%RSD of MET
1	50	97.3	100.3	0.051	0.018
		99.0	98.2		
		97.3	98.2		
2	100	100.3	98.6	0.053	0.013
		98.3	101.0		
		98.3	98.6		
3	150	100.2	100.8	0.017	0.016
		99.1	99.7		
		98.4	99.7		

Table 5: Assay of Tenegliptin and Metformin in Tablets

S.NO	% RECOVERY	
	TEN	MET
1	97.0	102.0
2	99.8	99.6
3	99.5	99.8
Mean	98.8	100.4
SD	0.012	0.015
RSD	0.182	0.252

Table 6: Determination of LOD & LOQ OF TEN &MET

PARAMETER	TEN at 242nm	Met at 232nm
LOD (mcg/ml)	1.77	0.44
LOQ (mcg/ml)	5.36	1.32

RESULT AND DISCUSSION

The present work provides an accurate, reproducible, sensitive method for the simultaneous analysis of TEN & MET in bulk and Tablet formulation. Linear relationships between drug concentrations were obtained over the range of at 2-12 µg/ml & 3-18 µg/ml for TEN and MET respectively. Under experimental conditions described assay of capsule, linearity, accuracy studies and precision, LOD and LOQ were estimated. Correlation coefficient was found to be > 0.995. The results of commercial capsule formulation are presented in Table 1. The % assay was found to be 98.89- 100.90% for TEN and 99.43-100.30% for MET , and S.D. and R.S.D. for six determinations of sample, by this method, was found to be less than 2.0 indicating the precision of this method. No interference was observed from the pharmaceutical adjuvants or excipients

CONCLUSION

Simultaneous equation method was developed for the simultaneous estimation of TEN & MET in the bulk and tablet formulation. It was observed that simultaneous equation method provide a better recovery results. The method developed was validated according to ICH guidelines. The method was found to be simple, precise, accurate and cost-effective. Moreover, all the developed UV-Spectrophotometric methods require little sample preparation procedure with high sensitivity. Therefore, It can be used successfully for routine quality control analysis of TEN and MET in bulk drug and for determination of these drugs in commercial tablet formulation.

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