RESEARCH ARTICLE

Spectrophotometric Methods for Estimation of Metformine HCl and Sitagliptin Phosphate Drugs in Bulk and Some Pharmaceutical Preparations

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ABSTRACT

The present study aimed to develop a method for detecting metformin hydrochloric (m.t.f) and sitagliptin (s.t.g) concentration. The method depended on estimation the absorbance of m.t.f and s.f.g wavelength 238 nm and 260 nm respectively concentration range was 1 to 24 ppm for (m.t. f) and (s.t.g). It was ranged from 12.5 to 600 ppm; the obtained results were analyzed statistically by using f-and t-test. The current methods were successfully applied to the analysis of pharmaceutical preparations. It is proven that the method is sensitive and precisely for determinations of (mt.f) and (s.t.g) a various pharmaceutical formulation.

Keywords: Metformin Hydrochloric, Pharmaceutical Preparations, Sitagliptin Phosphate.

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INTRODUCTION

Sitagliptin is [(2R)-1-(2,4,5-trifluorophenyl)-4-oxo-4-[3-(trifluoromethyl) -5,6dihydro [1,2,4] triazole [4,3-a] pyrazin -7(8H)-yl]butan-2-amine], (Figure 1).[1] It is an orally active and selective inhibitor of dipeptidyl peptidase-IV that is used for the treatment of Type 2 diabetes.[2] 1 Metformin hydrochloride is (N,N-dimethylimidodicarbon imidic diamide hydrochloride).[3] (Figure 2). It is prescribed as an oral hypoglycemic agent,[4] used in the management of non-insulin dependent diabetes mellitus.[5] Figure 1 shows chemical structure of sitagliptin phosphate (s.t.G) Figure 2 shows chemical structure of metformin hydrochloride (MTF).[6]

The literature survey reveals several analytical methods for qualitatively quantifying sitagliptin, metformin, and in other formulations.[7]

Infrequent analytical laboratories seeking the simultaneous detection of metformin and sitagliptin[8] in drug analysis, current research has been undertaken to develop accurate and simple spectrophotometry procedures for the qualitative selection[9] of metformin and pure sitagliptin of the same.[10] In the study, we have established a new and Simple method to determine sitagliptin and metformin.

Chemical materials and used devices:

- PH meter Hana following.
- Water bath (Germany).
- Sensitive balance(Thames side sensors).
- Ultrasonic cleaner(chaina).
- UV/visible spectrophotometer with double beam mode 1800 (SHimadzu- 1800).

Chemicals

Solvent: The solvent consists of the following components according to the following quantities, if placed in a 100 mL in a volumetric flask (45 mL of 0.025 m di-sodium hydrogen phosphate 35 methanol + 20 mL acetyl nitrile).

Pioneer Iraq sulmanya kindly donated sitagliptin phosphate standard its purity was found to be 98.87% .

Pioneer Iraq Sulmanya kindly donated metformine hydrochloric standard. Its purity was found to be 99.39%.

To prepare 0.025 M from Na_2HPO_4, we dissolve 0.750 g. in 250 mL of distilled water

Standard Stock Solution

A standard solution of sitagliptin and metformin 1000 ppm was prepared by dissolving 0.1 g of pure stg and mtf in solvent

Figure 1. Chemical structure of sitagliptin phosphate (STA)

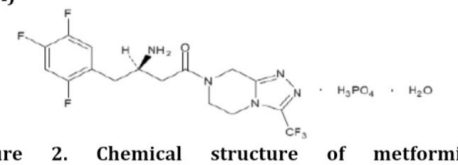
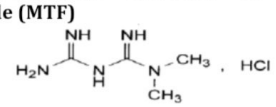


Figure 2. Chemical structure of metformin hydrochloride (MTF)



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separately in a 100 mL volumetric flask and an appropriate volume was taken and diluted to obtain 1000 ppm.

The Absorption Spectrum of STG and MTF Compounds

Figure 3 shows the UV-Vis spectrum of the sitagliptin compound. The spectrum was recorded in the range of 0–400 nm a sharp peak was observed to 250 nm the absorbance spectrum of metformin an absorption peak at short wavelength nearly 238 nm (Figure 4). Their statistical parameters can be studied from Table 1 and 2.

Calibration Curve of Compound

The calibration curves were determined according to the generalized method under the optimum state; a linear relating ship was acquired between absorption and concentration the Figure 5 display that m.t.f. is undergone Beer lambert law in the concentration incidence (1-24 ppm) the molar absorptivity and the sandal sensitive 0.015 µg. cm^{-2}.

Stander Curve m.t.f

It has been explained in Figure 5.

Stander Curve (s.t.g)

The result is in Figure 6 shows that (s.t.g) obeys beer- Lambert law in the concentration it was ranged from (12.5–600 ppm) with an absorbance, the molar absorptivity $L.MoL^{-1}$ confirming that the cradle was accurate and sensitive see figure we additionally measured the LoD, LoQ detection limit.

$$E\,\% = \frac{0-T}{T} \times 100_{11}$$

$$SD = \sqrt{\frac{\sum(xi - x)^2}{n-1}}_{12}$$

SD: Standard deration

$$RSD\% = \frac{SD}{x} \times 100_{13}$$

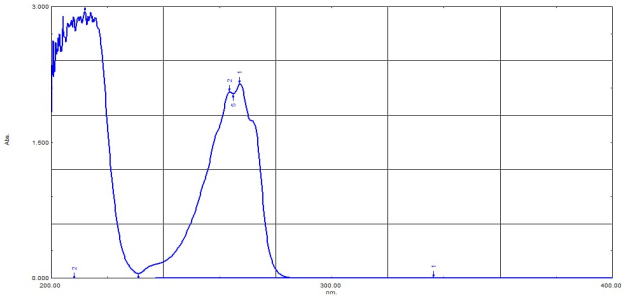

Figure 3: Spectrum of s.t.g (5 µg /ml (s.t.g), methanol acetyl nitril, Na_2 H PO_4)

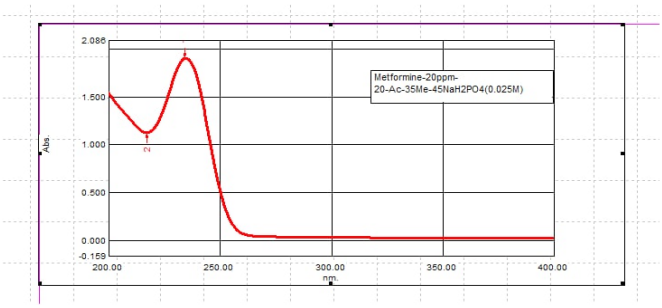

Figure 4: Spectrum of m.t.f (5 µg /mL) .m.t.f, methanol, actyl nitril, Na_2 H PO_4

Precision and Accuracy

Accuracy refers to the smallest value or the difference between the measured analytical value and the standard or known value. While precision refers to the smallest degree between the repeated measurements of the same lenity of materials, the accuracy, and precision of the method in this research was calculated by deration (RSD%), we calculate using the equations (Tables 1 and 2). Three different concentrations of drugs (m.t.f) and (s.t.g) we measured individually in the calibration curve (three solutions per consent and used five replicates of (m.t.f) and (s.t.g) under the best conditions and

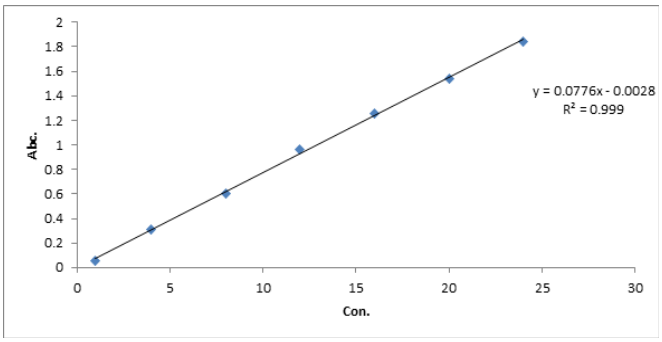

Figure 5: Calibration graph for metformin

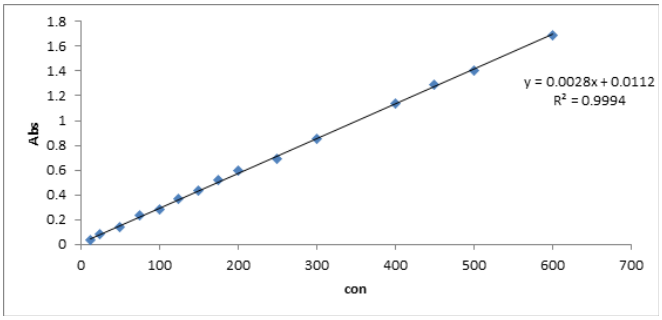

Figure 6: Calibration graph for sitagliptin

Table 1: Statistical parameters of the proposed method for (m.t.f.)

Parameters	*Values*
1- Maximum a absorption xmax [14]	238 nm
2- Extent of linearity [15]	(1–24) µg/mL
3- Molar absorptivity [16]	10.319 $L.mole^{-1}.cm^{-1}$
4- Sandal Sensitivity [17]	(0.042 $\mu g.cm^{-2}$
5- Mean recovery[18]	(98.55-99.75)%
6- Correlation of coefficient[19]	0.991
7- LoD	0.007 µg/mL
8- LoQ	0.032 µg/mL
9- %RSD [20]	0.021

Table 2: Statistical parameters of the proposed method for (s.t.g)

Parameters	*Values*
1- Maximum absorption	260 nm
2- Beer law (Extent of linearity)	(12.5–600) µg/mL
3- Molar absorptivity	1.46×10^3 $L.mole^{-1}.cm^{-1}$
4- sanded senility	0.358 µg.
5- Mean recovery	(98.44–100.5)%
6- Correlation coefficient	0.9994
7- LoD	0.008 µg/mL
8- LoQ	0.021 µg/mL
9-%RSD	0.666

Table 3: Precision and accuracy of suggest method of determination (mtf)

Concentration ppm				
Taken (ppm)	*Found*	*Error %*	*% Recovery*	*% RSD*
8	7.93	-0.8	98.75	0.0016
16	15.88	-0.7	99.25	0.0072
24	23.75	-1.0	98.95	0.0012

Table 4: Precision and accuracy of suggest method of determination (stg)

Concentration ppm				
Taken (ppm)	*Found*	*Error %*	*% Recovery*	*% RSD*
100	99.2	-0.8	99.2	0.015
400	400.2	0.05	100.5	0.022
600	590.64	-1.5	98.44	0.039

Table 5: As aresult of applying the proposed method to some pharmaceutical Preparations for (mtf)

	Concentration ppm				
Company	*Taken*	*Found*	*Error %*	*% Recovery*	*% RSD*
Merk 1000 mg	8	7.86	-1.75	98.25	0.0163
	16	15.85	-0.93	99.06	0.025
	24	24.02	0.08	100.0	0.0163
M .b c 500 mg	8	8.1	1.75	101.25	0.072
	16	15.65	-2.1	97.81	0.024
	24	23.42	-2.4	97.58	0.014
pioneer 500 mg	8	7.86	-1.75	98.25	0.039
	16	15.77	-1.43	98.56	0.035
	24	23.38	-2.58	97.41	0.013

Table 6: As aresult of applying the proposed method to some pharmaceutical Preparations for (stg)

	Concentration ppm				
Company	*Taken*	*Found*	*Error %*	*% Recovery*	*% RSD*
Pioneer 100 mg	100	98.14	-1.8	98.14	0.048
	400	401.1	0.27	100.2	0.006
	600	600.46	0.07	100.07	0.026
MSD100 mg	100	97.20	-2.8	97.2	0.061
	400	400.6	0.5	100.15	0.0048
	600	597.42	-0.5	99.5	0.0087
Getz 100 mg	100	97.40	-2.6	97.4	0.022
	400	401.6	0.25	100.4	0.0068
	600	597.42	0.37	99.5	0.0032

described in the procedure. The result obtained in Tables 3 and 4 is shown that the method is good accurate and precise.

Procedure for Pharmaceicel Preparations

The tablet is milled Ten of the form to be tasted, then the total weight is calculated, after finishing the grinding process. The average weight of the tablet is taken by dividing it by Ten; we dissolve the pharmaceutical substance in 100 mL of solvent so we get a concentration of 1000 ppm of the substance. We do the filtration process with a 45-micron filter paper. We re-filter with 100 uL glass micro-syringe. After completing the filtration, we prepare the required concentrations.

Analytic Application

As application The proposed method in (mtf) and (stg) spectroscopy was applied in some pharmaceutical preparations available in the local markets and various sources, as shown in Tables 5 and 6. Three solutions of one concentration and three different concentrations were prepared for each medicinal product. The accuracy and precision of the studied drug estimation methods were calculated in these for mutations. The result obtained in Tables 5 and 6 confirmed the possibility of applying the proposed analytical methods in estimating these drugs in pharmaceutical preparations.

CONCLUSION

It can be concluded that the proposals are simple and do not require sophisticated or immediate techniques. They are also selectively sensitive and can be for routine analysis of the mentioned drugs in their available forms. The methods are also suitable for application laboratories and procedures applied in each method that does not involve any critical interaction or boring sample preparation, as well as There is no need for derivation procedures; an optical spectroscopy aspect is a major group in analytical pharmacology as it provides a remote possibility to titrate stg and mtf in their pharmaceutical formulations.

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