RESEARCH ARTICLE

Spectrophotometric Determination of Esomepreazol in Pure form and in its Pharmaceutical Preparations

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ABSTRACT

Two simple, rapid, and sensitive spectrophotometric methods have been developed for the determination of Esomeprazol (ESO) in pure form and pharmaceutical preparations. The proposed methods are: (I) synthesis Schiff's base between ESO and Vanillin regent "4-hedroxy-3-methoxybenzaldehyde" in acidic medium to produce an intense yellow colored product, and (II) diazotization and coupling reaction between ESO and P-aminobenzoic acid", in an alkaline intermediate to from an intense brown colored product. A maximum absorption at 386 nm using reagent Vanillin and 412 nm on using reagent P-aminobenzoic acid. Beer's Law is obeyed in a concentrations range of 6-120 µg/mL and 25-240 µg/mL with a molar absorptivity 9.314 × 10^4 and 1.47×10^5 L/mol.cm for Vanillin and P-aminobenzoic acid, respectively.

The limit of detections (LOD) was found to be 0.048 and 0.023 µg/mL for Vanillin and P-aminobenzoic acid respectively. The suggested method was prosperity implement to the estimation of "This drug" in pure form and in the pharmaceutical formulations.

Keywords: Esomeprazol, P-aminobenzoic acid, Spectrophotometry, Vanillin.

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INTRODUCTION

Esomeprazol (ESO) (Figure 1), "A drug that is used to reduce the acids that are secreted inside the human stomach, as many people suffer from diseases and problems inside the stomach that make them much.[1] Molar mass is 767.2 gm/mol, m.p = 184-189°C, chemically know is magnesium; 5-methoxy-2-[-4-methoxy- 3,5- dimethylpriclin-2-yl] methylsal finally] benzimidazol-1-ide; trihydrate.[2,3] Several methods have been proposed for determination of this drug, such as HPLC,[4,5] TLC,[6] HPTLC,[7] Voltammetry,[8,9] UV-Spectrophotometry,[10,11] and UV-Vis. Spectrophotometry.[12,13]

AIM OF THE STUDY

This research aims to find a "uncomplicated, rapid, and cost-effective spectral methods for determination of Esomeprazole by using reagent Vanillin in the acidic medium, and reagent P-aminobenzoic acid in alkaline medium, and the success of the proposed methods for determination of ESO in its pharmaceutical preparations (like tablets).

Apparatus

Tqo UV-vis Spectrophotometer double beam from PG Instruments LTD, with 1cm quartz cell's, UV-Vis spectrophotometer single beam from genesys UV10, balance Kern 770 Gs\Gj from satorius BL 2105, Oven from memmert Schutzart DIN 40059-Ip20.

Materials

Esomeprazole 99% from SDI Samarra. Iraq. Vanillin 99% from Merck, P-aminobenzoic acid 99% from Merck, sodium nitrite 99% from merck, ammonium hydroxide 30–33% from Fulka, etanol 99.9% from Scharlan.

Solutions

- Esomeprazol magnesium trihydrate stock solution (1000 µg/mL): an exactly 0.1000 gm of ESO "standard" were dissolved in (100 mL) ethanol.
- Vanillin (1 × 10^{-2} M): was prepared by dissolving 0.0761 gm of vanillin in 50 mL ethanol.

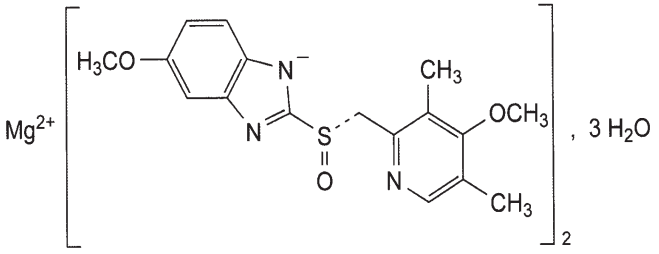

Figure 1: Esomeprazol magnesium trihydrate

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- P-aminobenzoic acid (1×10^{-3}M): was prepared by dissolving 0.0069 gm in 50 mL ethanol.
- $NaNO_2$ (1×10^{-3}M): was prepared by dissolving 0.0034 gm in 50 mL distilled water.
- Hydrochloric acid solution: prepared at an approximate concentration of (1.0 molar) by diluting 8.6 mL of concentrated acid (11.64 M) to (100 mL) distilled water.
- Ammonium hydroxide: was prepared by diluting (15.4 mL) of concentrated NH_4OH 13.36 M to 50 mL distilled water.

PROCEDURES

(I) Determination of (ESO) by Vanillin

After initial testing, optimal conditions were obtained, transferring 2.0 mL of 500 µg/mL (ESO) to a 25 mL volumetric flask, then add 0.5 mL of 1.0 M HCl acid. After 10 minutes, with constant shaking, add 4.0 mL of 1×10^{-2}M from Vanillin, and after 15 minutes, the volume is supplemented with water to 25 mL, and was measured at 386 nm against distilled water as blank.

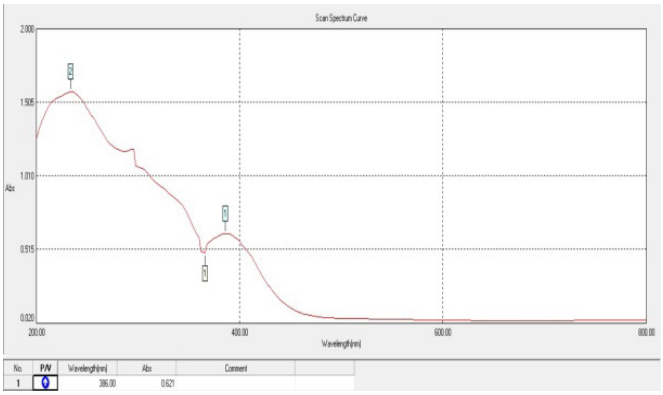

Figure 2: Absorption spectrum of (ESO) product against blank

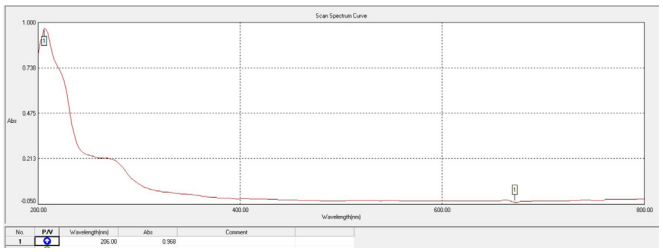

Figure 3: Absorption spectrum of blank against distilled water

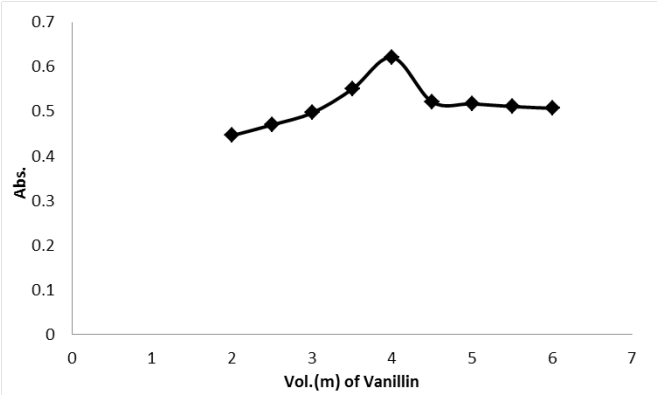

Figure 4: Effect Vol.(mL) of Vanillin (0.01M) on (ESO) product

Application of Proposed Methods

Average weight of ten tablets was computed and further to that, these tablets were grinded into exact powder. A precisely weighed amount of powder was transferred into a beaker and they were shaken with 50 mL solvent and filtered the filtrates, and the washings were collected in a 100 mL "volumetric flask" this filtrate and the washing was diluted up to the mark with solvent to obtain final concentration as 500 µg/mL. The identified methods were implemented for the determination of ESO in many available commercial tablets.

RESULTS AND DISCUSSION

Optimal Conditions

Effect of Reagent Concentration

The effect of reagent concentration on the reaction was studied at "room temperature" and the reaction of ESO with reagent depends on the concentration of Vanillin. So, its concentration was studied by different volumes of (0.01M) Vanillin, with the ESO concentration was maintained of Vanillin up to a particular concentration either decrease or remain steady, the highest absorption intensity was attained when the volume of Vanillin was 4.0 mL

Effect of the use Different Acids

The acids (HCl, H_2SO_4, HNO_3, CH_3COOH) were used, with a concentration of 1.0M for each and the same volume added 0.5mL, to know which acid the best absorption when product formation, that the best acid to form the product is HCl acid.

Effect of acid volume:

Different and increasing volume of HCl were used at a concentration of 1.0 M, to know which volume gives the best absorption, the optimal added acid volume is 0.5 mL, and when the added volume increases, the color of the found product disappears gradually.

Effect of Time

The effect of stability of the product was studied for its importance in knowing the period in which it remains constant, the interaction which time was followed using optimum conditions in every ten minutes for total 60 minutes.

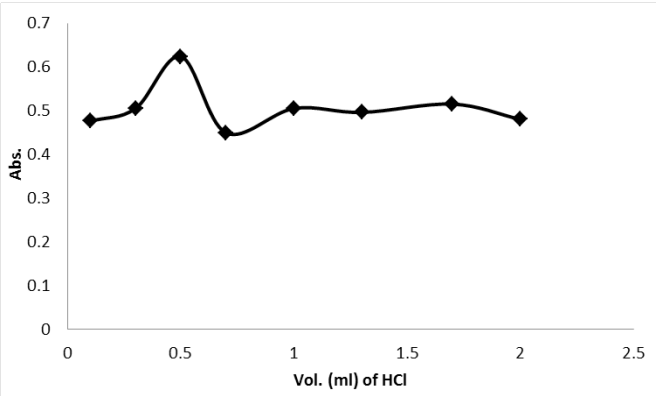

Figure 5: Effect of Vol. (ml) of HCl on the absorption values of the product

Effect of Additives

The effect of additives on the composition of the product was studied, and there is no effect of additives on absorption values.

Calibration Curve

The calibration curve for ESO with Vanillin showed the linearity at concentrations rang of 6–120 µg/mL, as show in Figure 6.

Application of the Proposed Methods

In Table 1, the result of determination of ESO in the pharmaceutical preparations as tablet.

(II) DETERMINATION OF (ESO) BY P-AMINOBENZOIC ACID

After initial testing, optimal conditions were obtained, transferring 0.5 mL of (1×10^{-3}M) P-aminobenzoic acid was transferred into series of (10 mL) volumetric flask, 0.5 mL of (1×10^{-3}M) Sodium nitrite solution. Then add (0.5 mL) of (1M) HCl acid, (4.5 mL) of (ESO) 500 µg/mL, and after 10 minutes, add 1 mL of 2M Ammonium hydroxide and diluted to 10 mL with ethanol and mixed well. After 15 minutes, the absorbance of colored "Azo" was measured at 412 nm against blank, absorption spectra of ESO-P-aminobenzoic acid against reagent blank in an alkaline medium at room temperature (25°C) producing a colored product in (Figure 7).

Optimal Condition

Effect of Acid Volume

Different and increasing volume of HCl were used at a concentration of 1.0 M to know which volume give the best absorption, the optimal added acid volume is 0.5 mL.

Effect of the Different Acids

The acid (HCl, H_2SO_4, HNO_3, CH_3COOH etc.) was used, with a concentration of 1.0 M for each, as well as, the same volume added 0.5 mL, to know which acid gives the best absorption to product formation, when adding HCl acid.

Effect of Base Volume

Different and increasing volume of NH_4OH were used at concentration of 2.0 M, to know which volume gives the best absorption, the optimal added base volume is 1.0 mL.

Table 1: Determination of ESO (as tablet)

Pharmaceutical preparations	*Content (mg) declared*	*Found (mg) by proposed method*	*%Recovery*
	80	79.77	99.71
ESOFAG	90	90.22	100.24
	100	99.23	99.23
	80	80.04	100.05
NEXIUM	90	89.97	99.97
	100	100.34	100.34
	80	80.05	100.06
PUMPIONX	90	89.06	98.96
	100	99.99	99.99

Effect of the used Different Bases

The base (NH_4OH, NaOH, KOH) were used, with a concentration of 2.0M for each, as well as, the same volume added 1-mL, to know which the best absorption when product formation, when adding NH_4OH base.

Effect of Reagent Volume

Figure 9, shows the Effect adding different volumes of the (P-aminobenzoic acid) on the absorption of product, the best added volume was 0.5 mL.

Effect of $NaNO_2$ Volumes

Figure 10, shows the effect of adding different volumes of sodium nitrite on the absorption of product, the best added volume was 0.5 mL.

Effect of Time

Under the "optimum conditions" the effect of reaction time of ESO with reagent in alkaline medium was studied, the

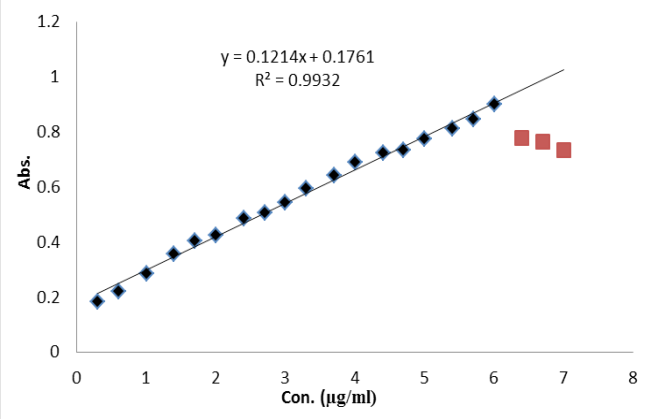

Figure 6: Calibration curve of ESO-Vanillin product

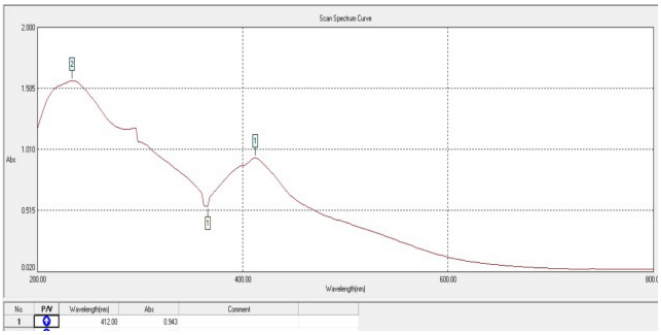

Figure 7: Absorption spectrum of ESO Product against blank

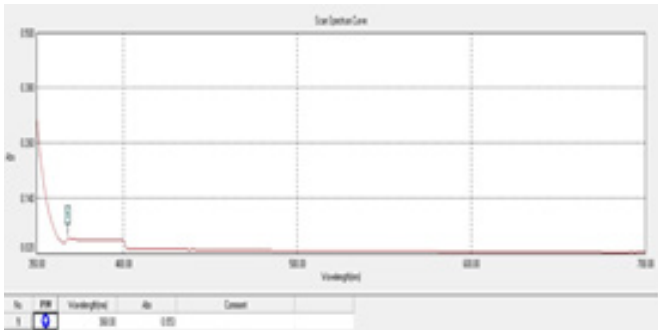

Figure 8: Absorption spectrum of blank against ethanol

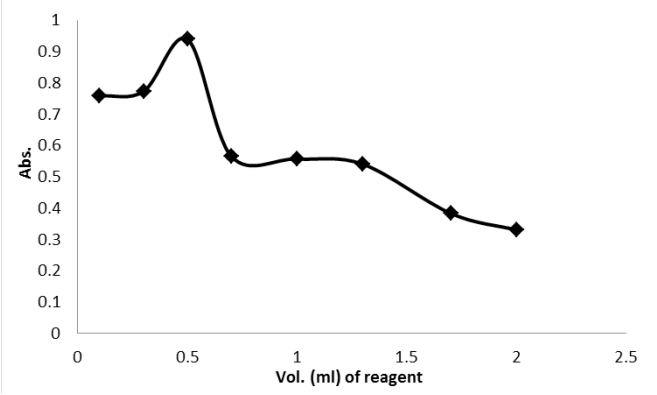

Figure 9: Effect of reagent volumes

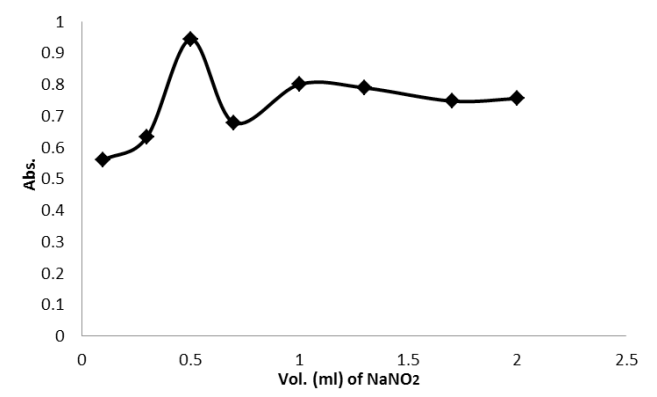

Figure 10: Effect of $NaNO_2$ volumes

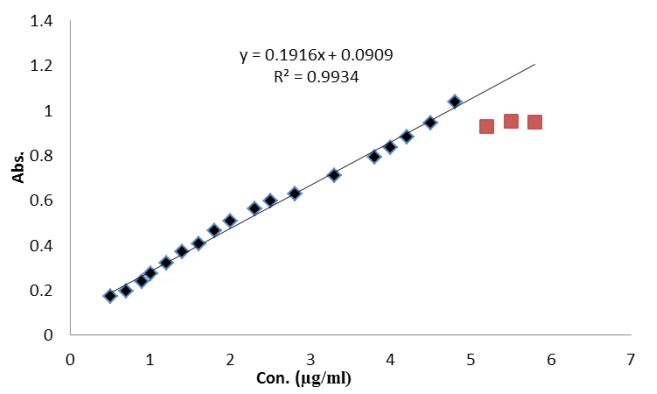

Figure 11: Calibration curve of (ESO-P-aminobenzoic acid) product

interaction which time was followed using optimum conditions every ten minutes for 50 minutes.

Effect of Additives

The effect of additives on the composition of the product between ESO with reagent was studied, and there is no effect of additives on absorption values.

Calibration curve

The calibration curve for ESO pure form with P-aminobenzoic acid showed the linearity at concentration rang of 25–240 µg/mL, as shown in Figure 11.

Application of the proposed method

In Table 2, the result of determination of (ESO) in the pharmaceutical preparations (as tablets).

Table 2: Determination of ESO as tablet

Pharmaceutical preparations	*Content (mg) declared*	*Found (mg) by proposed method*	*%Recovery*
	75	74.97	99.96
ESOFAG	125	125.04	100.03
	175	174.89	99.93
	75	75.01	100.01
NEXIUM	125	124.22	99.38
	175	175.67	100.38
	75	74.74	99.65
PUMPIONX	125	125.03	100.02
	175	174.54	99.74

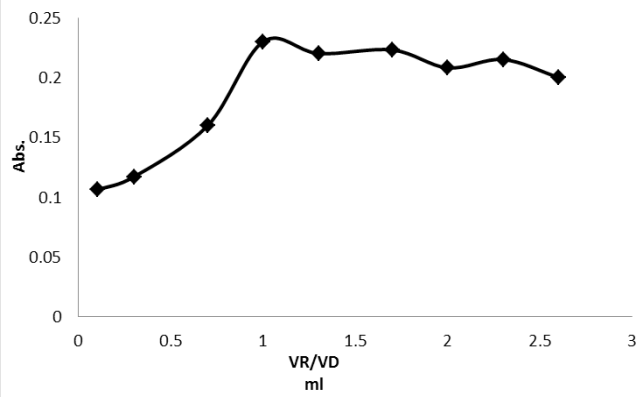

Figure 12: Mole-ratio method of ESO

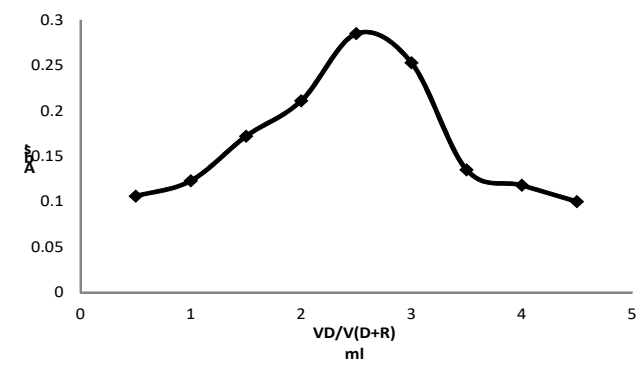

Figure 13: Continuous variation method of ESO

Equivalence of the Generated Product

Under the optimum conditions, "the stoichiometry" of the reactions between (ESO), with reagent were studied by mole–ratio (upon initial concentration 1×10^{-3}M), and continuous variation (upon initial concentration 8×10^{-4}M) methods. The equivalence between reagent and this drug was 2:1 (Figures 12, 13).

CONCLUSION

These methods described here are simple, rapid, convent and do not requires special working conditions unlike many other reported methods. The procedures showed shorter reaction time, stable colored species with inexpensive reagents. The determination can be performed at room temperature and do not require heating step. The proposed methods can be

applied to determination of ESO in pharmaceutical preparation (Tablet).

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