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DEVELOPMENT OF AREA UNDER CURVE SPECTROPHOTOMETRIC METHOD FOR QUALITATIVE ANALYSIS OF ESOMEPRAZOLE

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ABSTRACT
The drugs Esomeprazole was dissolved in DMF using the Area under curve method in the simultaneous estimation spectrophotometric approach. 285–350 nm wavelength range. Esomeprazole is bound with Beer's law in the concentration range of 10, 15, 20 ,25, 30µg/ml. Using recovery studies, the proposed method's precision was verified, and the outcomes were validated in accordance with ICH recommendations. The findings of the analysis have been statistically corroborated by recovery studies. The technique worked well in evaluating Esomeprazole in tablet dose form without interfering with common excipients.

KEYWORDS:- *Esomeprazole, DMF,Area Under Curve method, Spectrophotometric method.*

INTRODUCTION

Isomeprazole is also known as nexium, often used as an duodenal and gastric ulcers, erosive eso-phagitis, gastro-esophageal reflux disease (GERD). It works by decreasing the amount of acid your stomach makes. t relieves symptoms such as heartburn, difficulty swallowing, and cough.

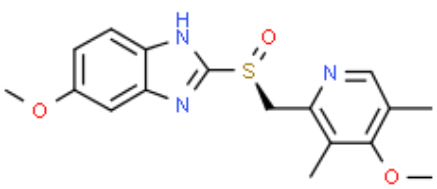
It works by decreasing the amount of acid your stomach makes.it relieves symptoms such as heartburn, difficulty swallowing, and cough Generally, HPLC has validated to be beneficial in diagnostic functions and the pharmaceutical industry. The purpose and goal of the present work were to develop and validate a simple, precise, sensitive spectroscopy approach for Esomeprazole in its bulk and tablet dosage form.

Cemically Ezomeprazole is a proton pump inhibitor (PPI) and its IUPAC Name, (S)-(−)-5-Methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl)methylsulfinyl]-3H-benzoimidazole. Esomeprazole is used to treat conditions where there is too much acid in the stomach. It has molecular formula C17H19N3O3S. and a molecular weight of 345.42 g/mo

To our notice, no UV- spectrophotometric method using area under curve method for the determination of esomeprazole in bulk and tablets form. Hence an attempt has been made to develop new are under curve spectrophotometric method for estimation of esomeprazole in bulk and tablet formulations with good accuracy, simplicity, precision and economy.

According to the literature survey, it was found that only few analytical methods like Spectrophotometry method and RP-HPLC methods was developed for the estimation of Esomeprazole in pharmaceutical dosage form.
There is no specific UV spectrophotometric method to develop and validate a area under curve method.

Chemical Structure of Esomeprazole :-



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MATERIALS AND METHODS

MATERIALS

Instrumentation

A Shimadzu model 1900 UV- Visible Spectrophotometer with 1cm matched quartz cells was used for the estimation and development of area under curve method.

Reagents and Chemicals

Esomeprazole was supplied by the Unichem laboratories limited Mumbai, Maharashtra as a gift sample for prepration of solution dimethylformamide was used.

METHODS

Selection of solvent

The primary considerations for choosing a media are solubility and stability. the drug was dissolved in verious solvent including water , methenol and dimethylformamide (DMF). Dimethyl formamide (DMF) has been choosen as the analytical media for the current experiment.drug shuld be soluble in choosen media and stable for long enough.

Preparation of Standard Stock Solution

Standard stock solution of Esomeprazole was prepared by dissolving accurately weighed quantities (10 mg) in 10ml of DMF (Dimethylformamide) and transferred it to 10ml volumetric flask. Volume was adjusted with DMF (Dimethylformamide) to obtain stock solution of 1000µg/ml concentration. 1ml aliquots was transferred in 10ml volumetric flask and was diluted upto DMF to get working standard solutions having concentration of esomeprazole 100µg/ml.

Determination of Absorbance

The standard solution of Esomeprazole (10µg/ml) searched separately in the wavelength range of 285nm-350nm and the AUC was found to be 3.5168 in area between 300nm-310nm. The Area under curve of Esomeprazole in the solution of DMF is showing in fig. The experiment showed that the area under curve of Esomeprazole was simple and gave result with suitable precision.
Area under curve region of Esomeprazole is at 300nm-310nm



Fig.1: Area under curve of Esomeprazole conc.10µg/ml

Stability of drug in a selected solvent

The stability of the drugs in the selected solvent (DMF) was determinedby measuring the AUC of the drug solution 10µg/ml at different time interval.
The AUC was measured after 5min. the solution was found to be stable.
The stability data is given in table1.

Table 1: Area Under Curve Stability Data For Esomeprazole.

Sr. No.	Time (min)	Absorbance
1.	0	0.724
2.	05	0.645
3.	10	0.602
4.	15	0.514

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Selection of analytical Wavelength Ranges

Standard stock solutions having 1000µg/ml of Esomeprazole was prepared by dissolving in 10mg of drug in 10ml DMF. To gate the final conc. (10µg/ml) dilutions of standard stock solution were made using DMF. These were scanned in the **spectrum mode** of an instrument from **285nm- 350nm.** The **wavelength** was selected area between **300nm-310nm** for evaluation of Esomeprazole.

Linearity

Standard stock solution of Esomeprazole, relevant amount of solution were pipette out into 10ml volumetric flasks and dilutions were made with DMF to be working standard solutions of concentrations 10, 15, 20, 25, 30µg/ml. The differences in AUC of Esomeprazole were measured area between 300nm-310nm. The calibration curve of drugs was plotted.

The concentration range over which the drugs followed linearity was chosen as an analytical concentration range i.e.10-30µg/ml for Esomeprazole

Figure 1 Area under curve of Esomeprazole conc.10µg/ml



Figure 2 Area under curve of Esomeprazole conc.15µg/ml



Figure 3 Area under curve of Esomeprazole conc.20µg/ml



Figure 4 Area under curve of Esomeprazole conc.25µg/ml

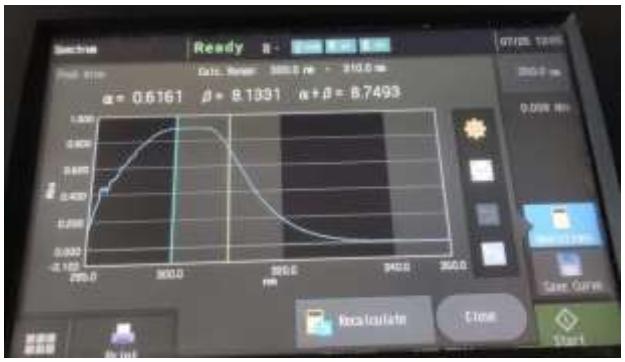


Figure 5 Area under curve of Esomeprazole conc.30µg/ml



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Table. 2: Standard Calibration Table for Esomeprazole by area under curve.

SR.NO	Concentration of Esomeprazole (drug) (µg/ml)	ABSORBANCE
1	10	3.5168
2	15	5.3134
3	20	7.0993
4	25	8.7493
5	30	10.312

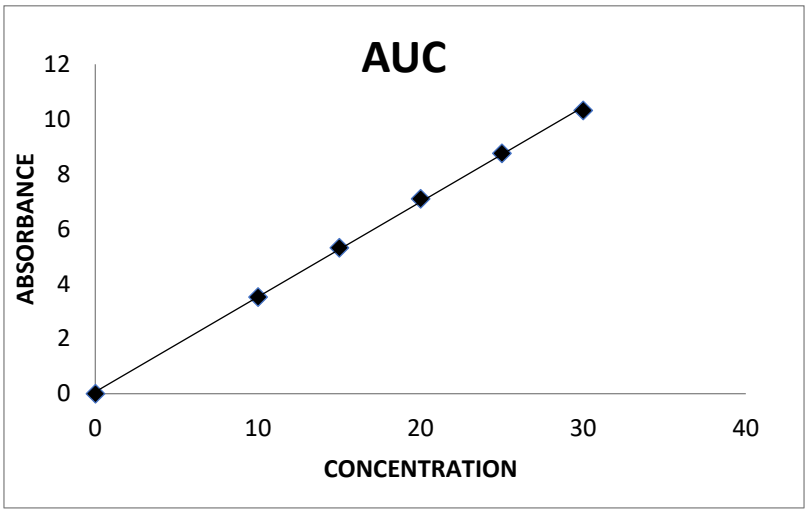


Fig.7: Area under curve Calibration curve for Esomeprazole.

Evaluation of Drug From Tablet Dosage Formulation (Tablet Assy Study)

Standard stock solution is prepared by adding the 20mg of drug into 20ml DMF it means 1mg/ml it is converted into concentration becomes 1000µg/ml. it converted into different conc.like 10 µg/ml,20 µg/ml,30 µg/ml,40 µg/ml,50µg/ml. 60 µg/ml 70 µg/ml and it is scanned under 318nm.

Sample

For commercial formulation analysis, brought the marketed one brands tablets strips of Esomeprazole brand name (20mg) which is belong to Unichem company, in this product each tablets contains 20mg.

Table3: Assay of Esomeprazole in tablet formulation 'ESOMEPRAZOLE 20' for area under curve method.

Sr. NO.	Concentration ofEsomeprazole. (Tablet)(µg/ml)	Absorbance
1	10	-0.0692
2	20	-0.1147
3	30	-0.1814
4	40	-0.2507
5	50	-0.2637
6	60	-0.3777
7	70	-0.4500

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Linearity graph of Assay Of Esomeprazole in tablet formulation.

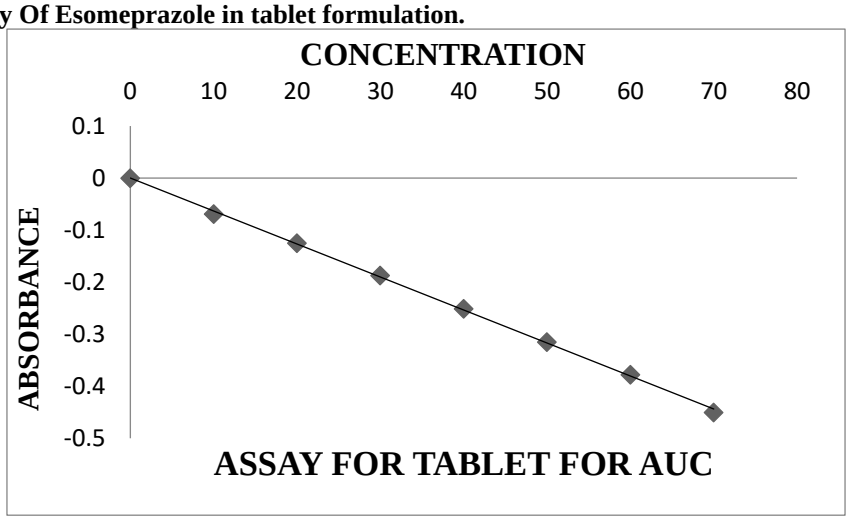


Fig:8 The linearity graph of Assy of Esomeprazole in tablet formulation for Area under curve method.

Table:4 Optical and regression Parameters of the Calibration Curve obtained by assy of Esomeprazole in tablet formulation for area under curve method.

Parameters	Esomeprazole
Linearity range (µg/ml)	10-70
Slope	-0.006347
Intercept	0.0001428
Regression coefficient(r^2)	0.9990

A. Accuracy (Recovery Study)

Recovery studies were used to evaluate accuracy. Experiments on recovery were carried out by adding predetermined amounts of powdered tablet to pure medication. Three concentrations of Esomeprazole were used for the recovery: 80%, 100%, and 120% of thereference concentration.

For each accuracy level, three accuracy samples were created using theabovementioned process. After analysing the solution, a formula was used to calculate the percentage recoveries.

$$\%\text{RECOVERY} = \frac{\text{OBSERVED AMOUNT OF COPMOUND IN SAMPLE}}{\text{AMOUNT OF ALL COMPOUND PRESENT IN SAMPLE}} \times 100$$

The recovery values are summarized in following table:-

Table9c.1: Accuracy parameter of Esomeprazole for Area Under Curve Method

Level of % Recovery	*Amount Present (mg/ml)	Amount Of Stand. Added (mg/ml)	Amount present + Amount of std added	Total Amount Recovered (mg/ml)	% Recovery	%mean Recovery	SD	CV
80	20	16	36	36.01	100.02	99.91	0.137	0.0014
80	20	16	36	35.9	99.72			
80	20	16	36	36.00	100			
100	20	20	40	40.02	100.05	100.02	0.0206	0.0002
100	20	20	40	40.01	100.02			
100	20	20	40	40.00	100			
120	20	24	44	44.00	100	99.93	0.1134	0.0011
120	20	24	44	43.90	99.77			
120	20	24	44	44.01	100.02			

a. Precision

The precision (inter-day) was evaluated by carrying four independent samples of Esomeprazole with four different analysts in the same laboratory. The precision values obtained by four analysts were summarized in table 10c.1.

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Table 10c.1: Determination of precision of Esomeprazole for Area under curve method.

Sample Number	Assay of Esomeprazole as %of labelled amount (Inter-Day Precision)			
	Analyst I	Analyst II	Analyst III	Analyst IV
1	99.90	99.85	100.01	100.25
2	98.65	99.01	99.78	99.99
3	100.1	99.99	100.15	98.99
4	99.99	99.88	99.05	100.1
Mean	99.66	99.68	99.77	99.83
S.D.	0.5874	0.3918	0.4393	0.4951
CV	0.0059	0.0039	0.0044	0.005

RESULT AND DISCUSSION

Method development and optimization:

The goal of the current study is to develop and validate an easy-to-use, reasonably priced UV spectrophotometric method for quantifying Esomeprazole in bulk and tablet dosage forms using the absorbance maximum approach.

The maximum absorbance of Esomeprazole was found to be 318 nm, and it demonstrated greater solubility in DMF than in distilled water. The current UV spectrophotometric techniques are low-maintenance and cost-effective in comparison to other techniques.

Linearity

The standard solutions of Esomeprazole in DMF (10µ g/ml each) subjected to scanning under area between 285nm to 350nm and the area was found to be 3.5168 for area under curve method using Shimadzu 1900i spectronic UV- Visible spectrophotometer .The calibration curve of Esomeprazole was found to be linear at conc. Range 10 to 30 µ g/ml at area between 300nm to 310nm. There for, it was clear that Esomeprazole can be determined in presence of DMF with no intervention of any irrelevant substance in pharmaceutical products

CONCLUSION

The results of the validation parameters showedIt may be concluded from the experimental research that a areaunder curve approach for estimating Esomeprazole in pure dose form have been devised.The proposed methods for certain drug was found to be precise and accurate. This procedure, on the other hand, is more repeatable. The results and statistical characteristics show that the suggested UV spectro-photometric approach is straightforward, quick, precise, and accurate. The simplicity and speed of the spectro photometric that these analytical processes are suitable for their intended purpose eand meet the ICH Q2/B standards. As a result of evaluating the parameters, UV spectro-photometric methods were discovered to be accurate, precise, and sensitive. Because of their low cost and low maintenance, the current UV spectro-photometric methods can be preferred in small-scale industries and successfully applied and suggested for the quantitative analysis of Esomeprazole in pharmaceutical formulations for QC, where economy and time are critical, as well as to ensure therapeutic efficacy.

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