



## Research Article

# Analytical Method Development for Assay of Omeprazole in Bulk and Pharmaceutical preparations

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### ABSTRACT

A simple, rapid and accurate spectrophotometric method was developed for the determination of omeprazole in pure form and pharmaceutical formulations. The charge-transfer interaction between omeprazole as electron and 2,3-dichloro-5,6-dicyano-p-benzoquinone as pi-electron. In the present study omeprazole reacted with 2, 3-dichloro-5, 6-dicyano-1, 4-benzquinone to form an orange red colour charge-transfer complex which has maximum absorption at 460 nm against reagent blank. Beer's law is obeyed in the concentration range of 20-100 µg/ml. The proposed method was precise, accurate and reproducible and it was extended to the analysis of terazosin in the tablet formulations.

### INTRODUCTION

Omeprazole (Fig.1) is chemically 5-methoxy-2-[[[(4-methoxy-3, 5-dimethylpyridinyl)methyl]Sulfinyl]-1H-benzimidazole, a substituted benzimidazole that inhibits gastric secretion by altering the activity of H<sup>+</sup> /K<sup>+</sup> ATPase, which is the final common step of acid secretion in parietal cells<sup>2</sup>. It is employed in treatment of peptic ulcers, reflux esophagitis and Zollinger Ellison syndrome<sup>3-5</sup>. Omeprazole is a white to off-white crystalline powder that melts with decomposition at about 155°C. It is a weak base, freely soluble in ethanol and methanol, and slightly soluble in acetone and isopropanol and very slightly soluble

in water. The stability of omeprazole is a function of pH; it is rapidly degraded in acid media, but has acceptable stability under alkaline conditions. Its empirical formula is C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>3</sub>S, with a molecular weight of 345.42. Literature survey reveals different analytical techniques for the determination of omeprazole which includes Spectrophotometric method<sup>1-13</sup>, HPLC method<sup>14-16</sup>, Spectrofluorimetric method<sup>17</sup>, RPHPLC method<sup>18-19</sup>, HPTLC Method<sup>20</sup>, Capillary electrophoresis<sup>21</sup> Glassy carbon electrode<sup>22</sup>, Polarographic method<sup>23</sup>, Fluorometric Method<sup>24</sup>, Spectrophotometric and chromatographic method<sup>25</sup>, HPLC-UV

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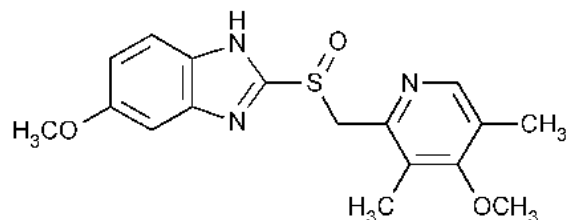
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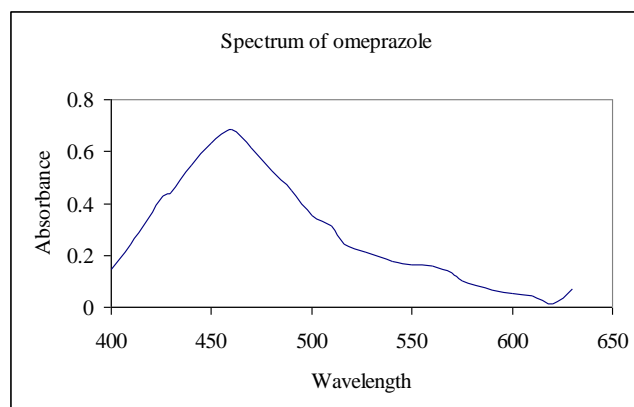
method<sup>26</sup>. The aim of present study is to estimate a simple, reliable, accurate, precise, and cost effective spectrophotometric method for estimation of omeprazole in its dosage and pharmaceutical formulations.



**Fig.1. Omeprazole**

### DETECTION OF WAVELENGTH FOR OMEPRAZOLE

The detection wavelength was determined by scanning the orange red solution in the range 400-630 nm using reagent blank. The overlain spectra were scanned and the wavelength was detected as 460 nm which was selected for analysis see figure 2.



**Fig.2: Spectrum of omeprazole treated DDQ solutions**

### MATERIALS AND METHODS

#### Instrumentation

Spectronic 1000 plus UV Visible Spectrophotometer with 1 cm matched quartz cells was used for all spectral and absorbance measurements.

#### Reagents

All the chemicals and reagents used were of analytical grade and solutions were prepared in

double distilled water. AR grade methanol was used in the present study.

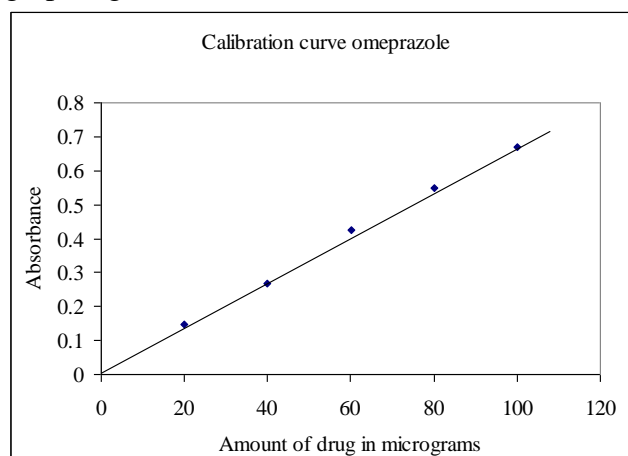
**DDQ solution(1% w/v):** 2,3-dichloro 5,6-dicyano-p-benzoquinone (Loba Chem., India) solution is prepared by dissolving 100 mg in 100 ml of distilled water.

#### Preparation of standard omeprazole solution:

50 mg of pure dissolved in methanol and the volume is adjusted to 50 ml with methanol. The stock solution is further diluted to get working concentration of 100 µg /mL.

#### Assay Procedure:

Various aliquots of the standard omeprazole solution ranging from 0.2-1.0 ml were transferred into a series of standard flasks. To each flask, 1.0 ml of 2, 3-dichloro-5, 6-dicyano-1, 4-benzquinon ewas added to produce an orange red colour. The final volume was brought to 10 ml with methanol. The reaction mixture in each flask was well shaken and allowed to stand for 5 min to complete the reaction. The absorbance of the orange red colour solution was measured at 450 nm, against the reagent blank prepared in similar manner omitting drug solution. Calibration graph is obtained by plotting absorbance values against the concentration of omeprazole solution. The calibration curve was found to be linear over a concentration range of 20 to 100 µg/ml of omeprazole. The amount of omeprazole present in the sample was read from the calibration graph(fig.2).



**Fig.3: Calibration curve of omeprazole****Pharmaceutical formulations**

Tablets are weighed and contents are powdered and well mixed. The powder equivalent to 50 mg of omeprazole dissolved in methanol, filtered, residue is washed with distilled water and the volume is made upto 50 ml with methanol. Further dilution is made as described in the preparation of standard solution of omeprazole. Further analysis is carried out as per procedure described above and results are summarized in the Table.2. The amount of drug present in the sample is estimated from calibration graph.

**Validation of Proposed Method**

**Linearity:** Validation was performed according to ICH guidelines. The linearity of the produced coloured product was investigated in the range of 20-100 µg/ml of omeprazole. Correlation coefficient found was 0.9994 which indicates that the proposed method was suitable for the quantitative analysis.

**Precision**

Precision of the method was studied by repeated measurements of drug solution and results showed lower %RSD values. The % RSD was calculated and was found to be in good terms with < 2 % indicating good repeatability of the proposed spectrophotometric method. Results are tabulated in Table 1.

**RESULTS AND DISCUSSIONS**

In the present study the omeprazole react with 2, 3-dichloro-5, 6-dicyano-1, 4-benzquinonesolution to form an orange red charge complex. The orange red coloured charge complex solution formed was

**Optical characteristics of the proposed methods****Table.1 Optical characteristics of the proposed methods**

Parameters	Proposed method
$\lambda_{\max}$ (nm)	460
Beer's law limit (µg/ml)	20-100

measured at 460 nm against reagent blank. The amount of drug read from calibration curve. The calibration curve was linear over the range of 20-100 µg/ml of omeprazole. The optical characteristics of the proposed method such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1. The molar absorptivity and Sandell's sensitivity values show sensitivity of the method. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized in the Table 1. The value of correlation coefficient (r) was 0.9994, which indicated the good linearity of calibration lines. The percent relative standard deviation calculated from the five measurements of terazosin hydrochloride shown in Table 1. The % RSD is less than 2, which indicates that the method has good reproducibility. The values of standard deviation values are low, indicates high accuracy and reproducibility of the method. The 't' calculated values are compares well with the theoretical value of 2.78 there by indicating that the precision of the method. The assay and validation results are satisfactory therefore the developed method can used for routine analysis of formulations without interference from excipients.

**CONCLUSION**

The proposed method is found to be simple, precise, accurate and time saving, reproducible and can be conveniently adopted for routine analysis of estimation of omeprazole in bulk drugs samples and pharmaceutical formulations.



Molar absorptivity (l mole <sup>-1</sup> cm <sup>-1</sup> )	1.89x10 <sup>2</sup>
Sandell's sensitivity(μg cm <sup>-2</sup> / 0.001 absorbance unit)	0.156
Regression equation (y = a + bc)	Y=0.085x+0.062
Slope (b)	0.004
Intercept (a)	0.002
Correlation coefficient (r)	0.999

\*Y = a+bx, where Y is the absorbance and x concentration in μg/ml

**Table No: 2 Assay of omeprazole in tablet formulations**

Tablets	Labeled amount(mg)	*Amount found (mg)±S.D*	% label claim	%RSD*	*t value
Tablet 1	20	20.02±0.15	100.1	0.7803	0.7242
Tablet 2	20	20.12±0.14	100.6	0.7152	0.3123
Tablet 3	20	19.94±0.07	99.7	0.3861	0.8776

\*Average of five determination based on label claim

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