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Research Article

Novel UV Spectrophotometric Determination of Rabeprazole Sodium In Bulk and Pharmaceutical Dosage Forms

Sandeep Rajan Kolli, K.MohiniKalyani,B.Lakshmi,K.Vineela

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Corresponding Author:

***Sandeep Rajan Kolli,**

C.R.R. College of Pharmacy, Eluru-534007, West Godavari (DT), Andhra Pradesh

*Email Id-sndiprk@gmail.com

ABSTRACT

Rabeprazole (RBZ) sodium is a substituted benzimidazole that inhibits gastric acid secretion and used for the treatment of erosive or ulcerative GERD, DU and hypersecretory syndromes including ZES. In present work, a simple, sensitive, accurate and economical spectroscopic method has been developed for the estimation of Rabeprazole in Bulk and its pharmaceutical dosage forms. An absorption maximum was found to be at 292 nm with the solvent system 0.05N NaOH. The drug follows Beer law in the range of 2-18 µg/ml with correlation coefficient of 0.999. The percentage recovery of Rabeprazole ranged from 99.8 to 100.2 % in pharmaceuticaldosage form. Results of the analysis were validated for accuracy, precision, LOD, LOQ and were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis.

Key-words: Rabeprazole, UV spectrophotometry, Tablets, estimation.

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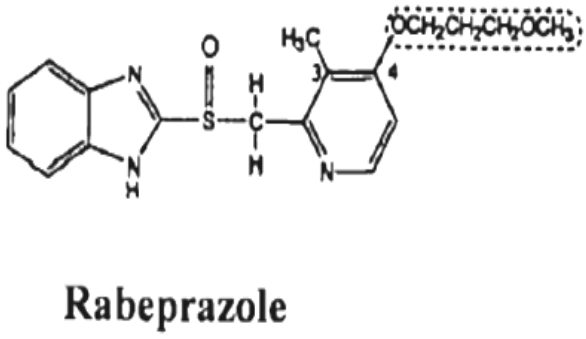
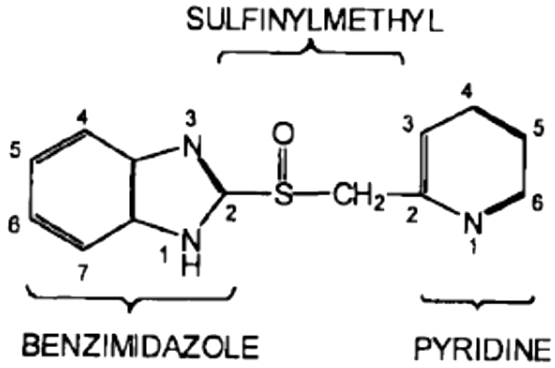
C.R.R. College of Pharmacy, Eluru-534007, West Godavari (DT), Andhra Pradesh

INTRODUCTION

Rabeprazole sodium, chemically Benzimidazolederivative 2-[[[4-(3- methoxypropoxy)-3-methyl2-pyridinyl] methyl] sulfinyl] - 1H- benzimidazolesodium and it is a proton pump inhibitor thatsuppress gastric acid secretion by specificinhibition of the enzyme system of Hydrogen/potassium adenosine triphosphatase (H+/ K+ATPase) at the secretory surface of the gastricparietal cell and is used in the treatment of variousgastric disorders such as gastric and duodenalulcers, gastro esophageal reflux disease and inpathological hypersecretory conditions[1-4].Molecular basis of Rabeprazole (RBZ) reveals thatit is a complex for the estimation by UV methodand the $-OCH_3$, Benzimidazole, pyridine are theresponsible for its therapeutic activity and qualitycontrol parameters [5, 6, 7]. A survey of literaturealso states that there was no specified reported dataon UV method for the estimation of Rabeprazole.An absorbance was found to be 292 nm and thespectrum was scanned for the drug dissolved in 0.05N NaOH.



Rabeprazole



MATERIALS AND METHODS

Rabeprazole sodium, tablets were purchased fromGlaxosmithkline pharmaceuticals Ltd. Mumbai.All the reagents and chemicals used were ARgrade. Spectrophotometer used was Double beamUV- Visible spectrophotometer with 10mmmatched quartz cell Model- UV-1700 PHARMASPEC**.** Make – shimadzu, Japan andAnalytical balance: shimadzu, Japan AX 200.Tablets REPRAL TM -20 (Elder pharmaceuticalsLtd. Mumbai), PARIT—20 (Glaxosmithkline
pharmaceuticals Ltd. Mumbai.

METHOD DEVELOPMENT

Preparation of standard stock solution

RBZ (10 mg) was accurately weighed andtransferred to a 100 ml volumetric flask. It was first
dissolved in 25 ml of 0.05N NaOH and sonicatedfor about 10-15 min., then finally made up to thevolume with 0. 05N NaOH(100µg / ml).

Preparation of calibration curve

From the standard stock solution fresh aliquotswere pipetted out and suitably diluted with 0.05NNaOH to get final concentration in the range of 2-18 µg /ml. The solutions were scanned underspectrum mode for 200-400 nm wavelength rangeand a sharp peak was obtained at 292 nm (Fig-1).A calibration curve was plotted taking anabsorbance on Y-axis against concentration ofstandard solution on X-axis (Fig-2). The methodwas applied for known sample solution and wasfound to be satisfactory for the analysis of tabletdosage forms.

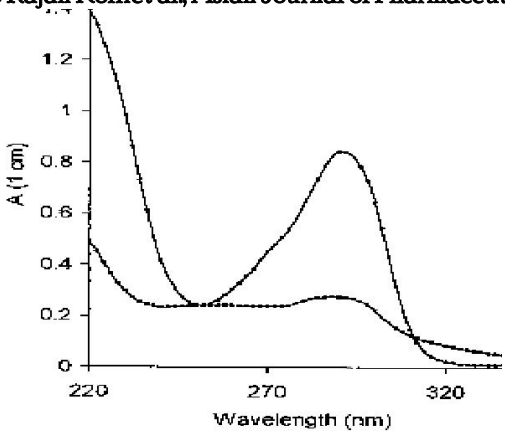


Fig. 1: Spectrum of Rabeprazole in 0.05N NaOH

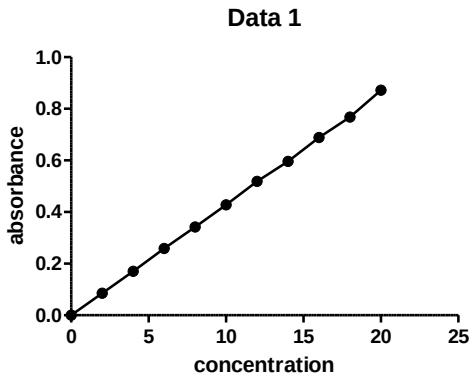


Fig. 2: calibration curve for Rabeprazole

Optical characteristics

The optical characteristics such as beer's law limit,molar extinction coefficient, % RSD were calculated. Regression characteristics like slope,intercept, correlation coefficient, LOD, LOQ, standard deviation were calculated in Table-1.

METHOD VALIDATION

The method was validated for different parameterslike Linearity, Accuracy and Precision.

Linearity

Fresh aliquots were prepared from the stocksolution (100 µg/ml) ranging from 2-20 µg/ml. The samples were scanned in UV-Visiblespectrophotometer using 0.05N NaOH as blank. It was found that the selected drug shows linearitybetween the 2-18 µg/ml.

Accuracy

Accuracy of the method confirmed by studyingrecovery at 3 different concentrations 80, 100, and120% of these expected, in accordance with ICHguidelines, by replicate analysis (n=6). Standarddrug solution was added to a pre analyzed samplesolution and percentage drug content wasmeasured. The results from study of accuracy werereported in table no.3. %Recovery = [(ct –cu)/ ca] ×100. Where ct is the total conc. of the analytefound; cu is the conc. of the analyte present informulation; and ca is the conc. of the pure analyteadded to the formulation.

Precision

Precision (intra-day precision) of the method wasevaluated by carrying out the six independent testsamples of Rabeprazole. The intermediateprecision (inter-day precision) of the method wasalso evaluated using two different analyst, anddifferent days in the same laboratory. The percent relative standard deviation (%RSD) and assayvalues obtained by two analysts were found to be Good.

RESULTS AND DISCUSSIONS

From the optical characteristics (Table-1) of theproposed method, Rabeprazole was shown its λ max at 292 nm in the solvent 0.05N NaOH with agood correlation coefficient 0.9999. The percentagepurity and relative standard deviation from theAssay of the tablet dosage forms (Table-2) werefound to be within the limits and from linearity data(Table-3) it was found to be that

Rabeprazoleobeys beer's law in the range of 2-18 µg / ml. Theaccuracy data of the drug (Table-4) was showngood percentage recovery and %RSD with therange of 99.4 -101.3 and 0.2-0.4 respectively. TheInter-day and Intra-day(Table-5) precision valueswere found to be 0.57 and 0.79 respectively, whichindicates that the proposed method is accurate andalso reveals that there is no interference of thecommonly used excipients and additives in theformulation.

Table 1: Optical characteristics and precisionof the proposed method

Parameter	Value
Absorption maximun	292 nm
Beer's law limit (µg/ml)	0.9999
Regression equation (Y= mX+c)	Y= 0.043x -0.002
Slope (m)	0.04318
Intercept (c)	0.00258
Standard Deviation	0.0075
LOD (µg / ml)	1.53
LOQ (µg / ml)	4.63

Table 2: Assay of Rabeprazole tablets

Dosage form	Label claim (mg/tab)	Amount found * ± SD	% Purity of the tablet ±%RSD
REPRAL	20	20.04 ± 0.07211	100.2 ± 0.36
PARIT	20	19.93 ± 0.055	99.85 ± 0.28

Table 3: Linearity of Rabeprazole in working standard

S.No	Concentration	Absorbance
1	0	0.
2	2	0.085
3	4	0.17
4	6	0.259
5	8	0.342
6	10	0.428
7	12	0.519
8	14	0. 596
9	16	0. 689
10	18	0. 768
11	20	0.872

Table 4: Accuracy data of the drug

Sample ID	Concentration µg /ml		(%) Recovery* ± S.D	RSD (%)
	Pure drug drug	Formulation		
80%	8	10	101.3±0.308	0.305
100%	10	10	99.4±0.397	0.40
120%	12	12	99.9±0.222	0.223

CONCLUSION

The proposed method for the estimation of Rabeprazole was found to be simple, sensitive and reliable with good precision and accuracy. The method is specific while estimating the commercial formulations

without interference of excipients and other additives. Hence this method can be used for the routine analysis of Rabeprazole in pure and pharmaceutical formulations.

Table 5: Precision of the Rabeprazole working standards

Assay of Rabeprazole as percent of labeled amount		
Sample no	**Analyst –I(Intra-day precision)**	**Analyst –II(Inter-day precision)**
1	100.32	99.78
2	101.32	101.52
3	99.88	100.36
4	100.22	101.24
5	99.98	99.87
Mean	100.34	100.54
%RSD	0.57	0.79

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