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Assay Determination of Rabeprazole Pellets Dosage forms by HPLC

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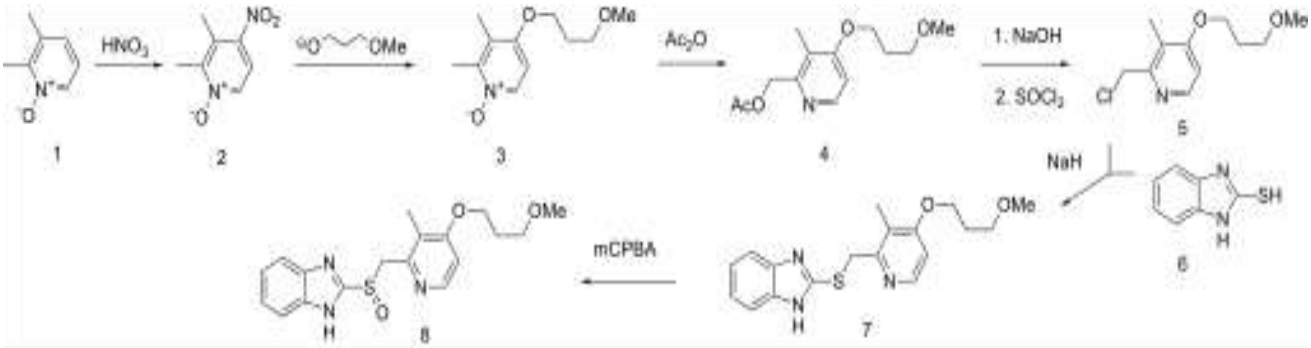
Abstract: ***Rabeprazole is a Bezimadazole derivative. It works as proton pump inhibitor, an anti-ulcerative drug used against peptic ulcer syndrome to suppress excess acid discharge in the stomach. . A simple, accurate, sensitive and precise High performance liquid chromate graphy method was proposed for the determination of Rabeprazole. The solutions of sample and standard were prepared in 0.1 N NaOH. In the High performance liquid chromatography method, the quantitative determination of the drug was carried at 280 nm. and the linearity range was found to be 14-26 µg/ml. The calibration graphs were constructed at their wavelength, and were found to be linear for HPLC methods. The proposed methods have been validated that included parameters such as linearity, accuracy, precision, LOD, LOQ, recovery and robustness, no significant difference between the performance of the proposed method concerning the mean values and normal deviations. The proposed methods can be utilized for analysis of pharmaceutical formulation.***

Keywords: Proton pump inhibitor, Peptic ulcer, High performance liquid chromatography, calibration graphs, validation, Rabeprazole

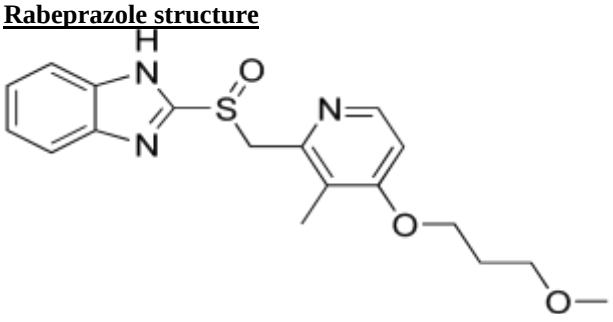
Rabeprazole Sodium Synthesis Flow Chart



1. Introduction

Rabeprazole is a Bezimadazole derivative. It works as proton pump inhibitor, an anti-ulcerative drug used against peptic ulcer syndrome to suppress excess acid discharge in the stomach. . A simple, accurate, sensitive and precise high performance liquid chromate graphy method was proposed for the determination of Rabeprazole. The solutions of sample and standard were prepared in 0.1 N NaOH. Structure of Rabeprazole as shown below

Rabeprazole structure



2. Chemicals and Instruments

Potassium di hydrogen orthophosphate, Sodium hydroxide, Rabeprazole sodium working standard, shimadzu L.C solutions 2010 software Double distilled water .

3. Method

Chromatographic conditions
Column: 4.6mm3D×25cm long, Packed with C18 with particle size 5µ
Flow rate: 1.0ml/min
Wave length: 280nm
Injection volume: 20µl

Buffer pH 7.4: Dissolve 6.8 grams of Potassium di hydrogen orthophosphate and 1.5 grams of sodium hydroxide in 1000 ml water adjust pH 7.4 with 0.1 M NaOH. Mobile phase: Prepare a suitable quantity of a filtered and degassed mixture of 65 volume of Phosphate buffer pH 7.4, 35 volume of acetonitrile

Standard Preparation: Transferred an accurately weighed quantity of about 20mg of Rabeprazole Sodium working standard to a 100 ml volumetric flask .Add 40ml of 0.1Msodium hydroxide and sonicate to dissolve .Make volume up to the mark with 0.1M sodium hydroxide and mix. Transfer 5 ml of the solution in to 50ml volumetric flask make up with mobile phase and mix.

Sample preparation: Take around 5 grams of pellets in to a mortar and pestle and grind the pellets in to a uniform fine powder. Weigh accurately a bout a quantity equivalent to 20 mg of Rabeprazole sodium in to a dry 100 ml volumetric

flask add50 ml of 0.1 M sodium hydroxide and sonicate to dissolve. Make volume up to the mark with 0.1M sodium hydroxide and filter 20to 30ml of solution into dry test tube .Further dilute 5ml of the filtrate to 50ml with mobile phase .

Procedure: Inject sample preparation in duplicate in to the chromatograph and record the chromatograms. Measure the response for the major peaks. Calculate the quantity in percentage w/w of Rabeprazole sodium by using below formula.

$$\frac{AS}{SA} \times \frac{WS}{standard\ dilution} \times \frac{sample\ dilution}{sample\ weight} \times PS = Assay\%$$

$$\frac{AS}{SA} \times \frac{WS}{100} \times \frac{5}{50} \times \frac{100}{Aw} \times \frac{50}{5} \times PS = Assay\%$$

AS=Average peak area of sample preparation
SA= Average peak area of standard replicate injection
Ws=Weight of working standard in mg
Aw=Average weight of sample taken in mg
PS= Purity of working standard

The results are tabulated as follows

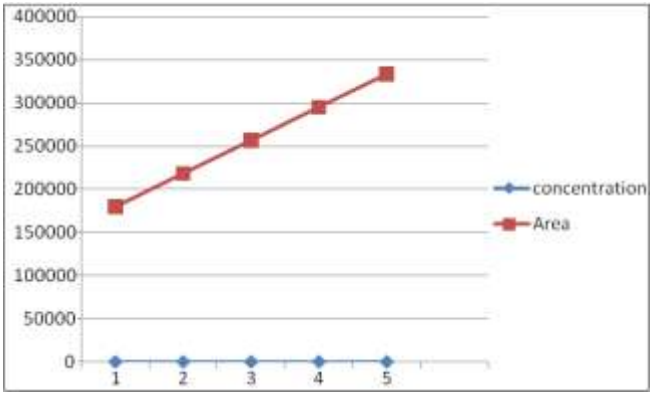
Semi formulation	S. No	Label claim	Amount estimated	%label claim	% Deviation	S.D	RSD
Pellets	1	8.5%	8.52	100.2353	0.2353	0.20265	0.5439
	2		8.56	100.7059	0.7059		
	3		8.53	100.3529	0.3529		
	4		8.51	100.1176	0.1176		
	5		8.54	100.4706	0.4706		
	6		8.53	100.3529	0.3529		

4. Method Validation

Above method is validated by considering the validation parameters such as linearity, accuracy, precision, LOD, LOQ, recovery and robustness, no significant difference between the performance of the proposed method concerning the mean values and normal deviations. The linearity range was found to be 14-26 µg/ml.

Linearity

	Concentration	Area
1	0.014	179501.7
2	0.017	217966.4
3	0.02	256431
4	0.023	294895.7
5	0.026	333360.3



5. Result and Discussion

System suitability test is applied to check the various parameters such as efficiency, resolution and asymmetry. The results obtained are shown in the table that is in concurrence with the USP requirement

S. No	Parameter	Rabeprazole
1	Theoretical plate	8250
2	Tailing factor	1.928
3	RSD for 6 injections	0.5439

Linearity: The linearity of Rabeprazole is established by plotting a graph of peak area of standard solution versus concentration. The linearity is found to be between 14-26 µg/ml.

Chromatography: The mobile phase of a degassed mixture of 65 volume of Phosphate buffer pH 7.4, 35 volume of acetonitrile found to be ideal for analysis of Rabeprazole. The RSD values are reasonably low, the concentration of Rabeprazole found to be with in the limits.

The precision of method is studied by making 6 injections of standard and very low RSD values indicating good precision. The reproducibility and reliability of the method has been tested by performing recovery studies which showed good results.

6. Conclusion

Proposed method is simple ,less expensive. High percentage of recovery shows that the method is free from interference of the excipients used in the semi formulations. It is use full for the routine quality control analysis.

7. Acknowledgement

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