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NOTE

Spectrophotometric Determination of Rabeprazole Sodium in Bulk and Tablet Formulation

S.A. GOSAVI, A.A. SHIRKHEDKAR* and S.J. SURANA
Department of Chemistry, R.C. Patel College of Pharmacy
Karwand Naka, Shirpur-425 405, India
E-mail: sandeep_pharma47@yahoo.com; atul_shirkhedkar@yahoo.com

Two simple accurate and sensitive UV spectrophotometric methods have been developed for the quantitative estimation of rabeprazole sodium in bulk and its pharmaceutical formulations. In method I, methanol was used as solvent. Rabeprazole sodium shows maximum absorbance at 284 nm and obeys linearity in the concentration range of 4-20 µg/mL. In method II, 10 % DMF was used as solvent. Rabeprazole sodium shows maximum absorbance at 284 nm and obeys linearity in the concentration range 5-25 µgmL. Rersults of the analysis were validated statistically and by recorvery studies.

Key Words: Rabeprazole sodium, Spectrophotometric method, Tablet.

Chemically, rabeprazole sodium is 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfonyl]-1*H*-benzimidazole sodium[1]. It is proton pump inhibitor and is used in the management of acid related disorders[2,3]. The literature survey reveals few HPLC[4], spectrophotometric[5] and super critical fluid chromatographic[6] methods for estimation of rabeprazole sodium from its formulations. The present paper describes two simple, reproducible and sensitive UV spectrophotometric methods for the determination of rabeprazole sodium. All spectral measurements were made on Shimadzu 1601 UV-visible spectrophotometer.

Preparation of standard solution: For method I, an accurately weighed 10 mg of rabeprazole sodium was transferred to 100 mL volumetric flask. It was dissolved in 25 mL of methanol and the volume was made up to the mark using same solvent to obtain concentration of 100 µg/mL. Different aliquots were taken from the stock solution and diluted with the same solvent to prepare a series of concentrations. The solutions were scanned on spectrophotometer in the UV range and their absorbances were measured at 284 nm using methanol as blank. The calibration curve was

found to be linear in the concentration range of 4-20 µg/mL. For method II, the similar procedure described in method I was followed using 10 % DMF as a solvent. The absorbances were measured at 284 nm using 10 % DMF as a blank. The calibration curve was found to be linear in the concentration range of 5-25 µg/mL. The slope, intercept, correlation coefficient and optical characteristics of both the methods are reported in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND STATISTICAL DATA OF THE REGRESSION EQUATION

Parameters	Method I	Method II
Solvent	Methanol	10 % DMF
Absorption maximum (nm)	284	284
Beer's law limit (µg/mL)	4-20	5-25
Molar absorptivity (l $mole^{-1}/cm^{-1}$)	1.35×10^4	1.71×10^4
Coefficient of correlation	0.9995	0.9996
Intercept (A)	-0.07	0.032
Slope(B)	0.049	0.036

Preparation of tablet sample solution: For method I, 20 tablets were weighed and crushed to fine powder. An accurately weighed powdered sample equivalent to 20 mg of rabeprazole sodium was transferred to 100 mL volumetric flask. The powder was dissolved in 50 mL of methanol by intermittent shaking and volume was made up to the mark with same solvent. The solution was filtered through Whatmann filter paper no. 41. After appropriate dilutions the absorbance of the sample solution was recorded at 284 nm and concentration of sample was determined. For method II, the similar procedure described in method I was followed using 10 % DMF as solvent and the absorbance was recorded at 284 nm. The results are reported in Table-2.

TABLE-2
RESULTS OF ANALYSIS

	Method I		Method II	
	Brand I	Brand II	Brand I	Brand II
Label claim (mg/tab)	20	20	20	20
*Amount found (mg/tab)	19.90	19.91	19.47	19.63
Standard deviation	0.049	0.142	0.135	0.062
RSD (%)	0.247	0.710	0.697	0.318

*Mean of five estimation.

Recovery studies were carried out for both the developed methods by addition of known quantity of pure drug solution to pre-analyzed tablet sample solution at three different concentration levels. The results of recovery studies are reported in Table-3.

TABLE-3
RECOVERY STUDIES

Method	Brand	Concentration added (µg/mL)	*Concentration recovered (µg/mL) ± SD	Recovery (%)
I	I	6.4	6.358 ± 0.030	99.35
		8.0	8.030 ± 0.072	100.43
		9.6	9.632 ± 0.096	100.34
	II	6.4	6.378 ± 0.012	99.66
		8.0	7.975 ± 0.060	99.69
		9.6	9.565 ± 0.066	99.64
II	I	8	8.017 ± 0.096	100.21
		10	10.109 ± 0.055	101.09
		12	12.027 ± 0.099	100.23
	II	8	7.922 ± 0.058	99.03
		10	9.988 ± 0.033	99.88
		12	12.056 ± 0.078	100.47

*Mean of three estimations.

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