



International Journal of Pharmaceutics and Drug Analysis

Content Available at www.ijpda.org

ISSN: 2348:8948



SPECTROPHOTOMETRIC METHODS FOR SIMULTANEOUS ESTIMATION OF RABEPRAZOLE SODIUM AND ACECLOFENAC FROM THE COMBINED CAPSULE DOSAGE FORM

U Sri Venkatesh*, Suggu Divya¹*¹Sri Sivani College of Pharmacy, Chilakapalem, Srikakulam.

Received: 11 June 2025 Revised: 22 July 2025 Accepted: 04 Aug 2025

Abstract

Introduction: The present work aimed to develop and validate spectrophotometric methods for simultaneous estimation of rabeprazole sodium and aceclofenac in a pure and capsule dosage form.

Materials and Methods: Method 1 is based on solving a simultaneous equation. Absorbances of rabeprazole sodium and aceclofenac were measured at their respective absorbance maximas (λ_{max}) of 283 and 276 nm. Method 2 is the Q-analysis or absorption ratio method. Absorbances were measured at 256 nm (isosbestic point) and 276 nm (λ_{max} of aceclofenac). Methods are validated according to ICH guidelines.

Results: A linearity range for rabeprazole sodium and aceclofenac is 10–60 $\mu\text{g/ml}$ at respective selected wavelengths. The coefficient of correlation for rabeprazole at 283 nm and for aceclofenac at 276 nm is 0.9981 and 0.9997, respectively. A percentage estimation of rabeprazole sodium and aceclofenac from the capsule dosage form by method 1 is 100.22 and 99.96 and by method 2 is 99.99 and 100.05, respectively, with a standard deviation less than 2.

Conclusion: The proposed methods are simple, rapid, and validated and can be used successfully for routine simultaneous estimation of rabeprazole sodium and aceclofenac in a pure and capsule dosage form.

Keywords: Aceclofenac, absorbance ratio method, rabeprazole sodium, simultaneous equation method, spectrometric estimation

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*Corresponding Author

U Sri Venkatesh

DOI: <https://doi.org/10.47957/ijpda.v12i3.648>

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Introduction

Rabeprazole sodium, chemically known as 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridil]-methyl]sulfinyl]-1H-benzimidazole, is an anti-ulcerative drug. It belongs to the class of antisecretory compounds that neither exhibit anticholinergic nor histamine H-2 receptor antagonistic properties, but suppress gastric acid secretion by inhibiting gastric H⁺ K⁺ ATPase at the secretory surface of the gastric parietal cell.

Aceclofenac, chemically known as [[{2-[(2,6-dichlorophenyl) amino]phenyl} acetyl) oxy]acetic acid, is a non-steroidal anti-inflammatory drug. It inhibits prostaglandin (PG) synthesis by inhibiting cyclooxygenase enzyme.

Aceclofenac is official in IP, BP, and USP whereas rabeprazole sodium is not. Literature survey reveals that UV spectrophotometric methods are reported for determination of aceclofenac [1,2] and rabeprazole sodium [3,4] individually in different pharmaceutical dosage forms. There are also various UV spectrophotometric methods available for estimation of aceclofenac or rabeprazole in combination with other drugs [5-8], but the UV spectrophotometric method for simultaneous estimation of rabeprazole sodium and aceclofenac is not yet reported. In this work, we propose two simple and validated UV spectrophotometric methods for simultaneous estimation of rabeprazole sodium and aceclofenac in pure and capsule dosage forms.

Materials and Methods

Instruments

A double beam UV-visible spectrophotometer, model-Jasco-V 630, with a spectral band width of 1.5 nm and automatic wavelength corrections with a pair of 10 mm quartz cell was used for experimental work.

Reagents and chemicals

All reagents and chemicals used were of AR grade. The reference standard rabeprazole sodium and aceclofenac were obtained from Shreya Life Sciences Ltd., Aurangabad, as a gift sample. The commercially available capsule with brand name Altraday (Ranbaxy) containing rabeprazole-20 mg and aceclofenac-200 mg was purchased from a local market.

Procedures

Preparation of standard stock solution and calibration curve

The standard stock solutions of rabeprazole sodium [Figure 1] and aceclofenac [Figure 2] were prepared by dissolving 0.01 g of each drug in methanol, and the final volume was adjusted with the same solvent in 100 ml of a volumetric flask to get a solution containing 100 µg/ml of each drug. Working standard solutions of 10 µg/ml were scanned in the entire UV range of 400–200 nm to determine the λ_{max} . The λ_{max} of rabeprazole sodium and aceclofenac is 283 nm and 276 nm, respectively, and from overlain spectra [Figure 3] it is evident that the isosbestic point is at 256 nm. Six working standard solutions with a concentration of 10, 20, 30, 40, 50, and 60 µg/ml were prepared in methanol from stock solution. The absorbances of resulting solutions were measured at their respective λ_{max} and the isosbestic point and plotted a calibration curve to get the linearity and regression equation [Figure 4 and 5].

Method I: Simultaneous equations

The simultaneous equation method of analysis is based on the absorption of the drugs rabeprazole sodium and aceclofenac at their wavelength maxims. Two wavelengths selected for the development of the simultaneous equations are 283 nm and 276 nm. The absorptivity values determined are for rabeprazole sodium are 0.02803 (a_{x1}), 0.02631 (a_{x2}) and for aceclofenac 0.03022 (a_{y1}), 0.03289 (a_{y2}) at 283 nm and 276 nm, respectively. These values are average of six estimations. The absorbances and absorptivity at these wavelengths were substituted in equations (1) and (2) to obtain the concentration of drugs.

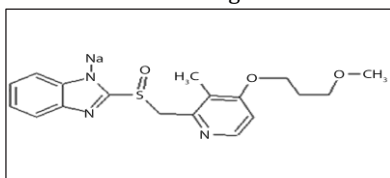


Figure 1: Structure of rabeprazole sodium

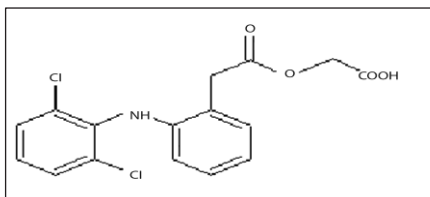


Figure 2: Structure of aceclofenac

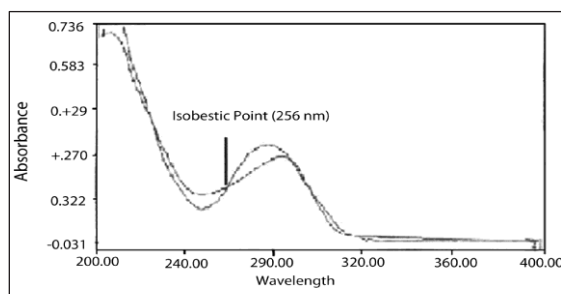


Figure 3: Overlaid spectra of rabeprazole sodium and aceclofenac

Method II: Absorption ratio method

The absorbance ratio method of analysis is based on the absorbance at two selected wavelengths, one is an isosbestic point and the other being the wavelength of maximum absorption of one of the two components. From overlain spectra [Figure 1], wavelength 256 nm (isosbestic point) and 276 nm (λ_{max} of aceclofenac) are selected for the formation of Q absorbance equation (equations 3 and 4). The absorptivity values determined for rabeprazole sodium are 0.01711 (a_{x1}), 0.02632 (a_{x2}) and for aceclofenac are 0.01876 (a_{y1}), 0.03289 (a_{y2}) at 283 nm and 256 nm, respectively. These values are average of six estimations. The absorbances and absorptivity at these wavelengths were substituted in equations (3) and (4) to obtain the concentration of drugs.

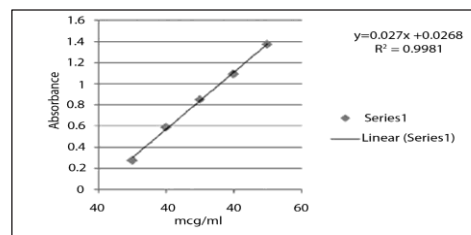


Figure 4: Calibration curve of rabeprazole

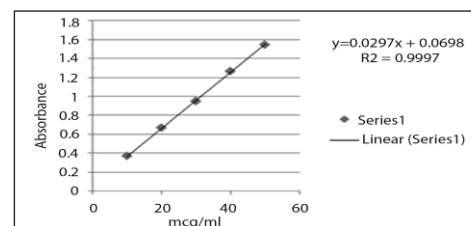


Figure 5: Calibration curve of aceclofenac

Procedure for capsule formulation

Twenty capsules were accurately weighed, and contents were removed. Average weight of the content per capsule was calculated. The contents of a capsule were reduced to fine powder and mixed thoroughly. A quantity of capsule powder equivalent to 10 mg of aceclofenac was transferred to a 100 ml volumetric flask and dissolved in methanol with vigorous shaking and the volume was made to 100 ml with the same solvent. The solution was filtered through the Whatmann filter paper no. 41. The aliquot portion of filtrate was further diluted to get a final concentration of about 1 µg/ml rabeprazole sodium and 10 µg/ml aceclofenac. The absorbance of sample solution

was measured at 283 nm and 276 nm in 1 cm cell against the blank. The content of rabeprazole sodium and aceclofenac in a capsule was calculated by the simultaneous equation method as well as absorbance ratio method.

Validation of the developed methods

The following parameters are considered under the ICH guidelines for the validation of the method [10].

Linearity

For each drug, appropriate dilutions of standard stock solutions were assayed as per the developed methods. The Beer-Lambert's concentration range was found to be 10–60 µg/ml. The linearity data for both methods are presented in Table 1.

Precision

Intermediate precision (inter-day and intra-day precision)

The inter-day and intra-day precision was determined by the assay of the sample solution on the same day and on different days at different time intervals, respectively. The results of the same are presented in Table 1.

Limit of detection and limit of quantitation

The limit of detection (LOD) and limit of quantitation (LOQ) of rabeprazole sodium and aceclofenac by proposed methods were determined using calibration standards [Figures 2 and 3]. LOD and LOQ were calculated as $3.3s/S$ and $10s/S$, respectively, where S is the slope of the calibration curve and s is the standard

Table 1: Optical characteristics

Parameters	Method I		Method II	
	Rabeprazole	Aceclofenac	Rabeprazole	Aceclofenac
Wavelength λ_{max} (nm) Beer's law limit ($\mu\text{g/ml}$)	283	276	Isosbestic point at 256	
Correlation coefficient R^2	0.9981	0.9997	0.997	0.998
Slope	0.027	0.0297	0.016	0.016
Intercept	0.0268	0.0698	0.013	0.034
Intra-day (%RSD)	0.215	0.431	1.21	0.83
Inter-day (%RSD)	0.612	0.764	0.725	1.16
LOD ($\mu\text{g/ml}$)	0.194	0.352	0.742	0.486
LOQ ($\mu\text{g/ml}$)	0.832	2.386	1.48	3.27

Table 2: Results of the recovery study

Drug	Level of recovery (%)	Method I					Method II				
		Amt. added ($\mu\text{g/ml}$)	Amt. estimated ($\mu\text{g/ml}$)	Recovery (%)	SD*	% R.S.D.*	Amt. added ($\mu\text{g/ml}$)	Amt. estimated ($\mu\text{g/ml}$)	Recovery (%)	SD*	% RSD*
RAB	80	1.6	3.59	99.44	0.844	0.848	1.6	1.59	99.99	0.13	0.1330
	100	2.0	4.05	101.2	0.944	0.933	2.0	2.004	100.2	1.091	1.088
	120	2.4	4.38	100.7	0.578	0.5739	2.4	2.403	100.14	0.14	0.1398
ACE	80	16	35.84	99.95	0.622	0.624	16	35.95	99.36	0.538	0.5414
	100	20	40.34	100.8	0.576	0.571	20	40.08	100.2	0.703	0.698
	120	24	43.52	98.92	1.283	1.297	24	44.02	100.06	0.14	0.1399

*Mean \pm SD of three observations

Table 3: Results of analysis of capsule

Method	Label claim (mg/Cap) (n = 6)	Amount found (mg)	% of drug content	SD	% RSD	SE
I	Rabeprazole (20 mg)	20.044	100.22	0.3518	0.35101	0.143
	Aceclofenac (200 mg)	199.92	99.96	0.05508	0.05509	0.032
II	Rabeprazole (20 mg)	19.98	99.99	0.130	0.130	0.028
	Aceclofenac (200 mg)	200.12	100.05	0.1242	0.1241	0.132

Accuracy

To check the accuracy of the proposed methods, recovery studies were carried out at 80%, 100%, and 120% of the test concentration as per ICH guidelines. The recovery study was performed three times at each level. The results of the recovery studies are quoted in Table 2.

Results and Discussion

The linearity range for rabeprazole sodium and aceclofenac is 10–60 µg/ml and 10–60 µg/ml at respective selected wavelengths. The coefficient of correlation for rabeprazole at 283 nm and for aceclofenac at 276 nm is 0.9981 and 0.9997, respectively. Both drugs showed good regression values at their respective wavelengths, and the results of a recovery study revealed that any small change in the drug concentration in the solution could be accurately determined by the proposed methods. Percentage estimation of rabeprazole sodium and aceclofenac from the capsule dosage form by method 1 is 100.22 and 99.96 and by method 2 is 99.99 and 100.05, respectively, with standard deviation less than 2 [Table 3].

The validity and reliability of proposed methods were assessed by recovery studies. Sample recovery for both the methods is in good agreement with their respective label claims, which suggest noninterference of formulation additives in estimation [Table 2].

Precision was determined by studying the repeatability and intermediate precision. Repeatability indicates the precision under the same operating conditions over a short interval of time and inter-assay precision. The % RSD was calculated for rabeprazole sodium and aceclofenac. The results are mentioned in Table 1. An intermediate precision study expresses within a laboratory variation in different days. In intra- and inter-day precision studies for both the methods % RSD are not more than 2.0% indicates good repeatability and intermediate precision [Table 1].

The LOD and LOQ values for rabeprazole sodium and aceclofenac are 0.194, 0.352 µg/ml, and 0.832, 2.386 µg/ml by method 1 while the same by method 2 are 0.742, 0.486 µg/ml and 1.48, 3.27 µg/ml, respectively. Low values of LOD and LOQ indicates good sensitivity of proposed methods shown in Table 1.

Conclusion

The proposed methods are simple, rapid and validated in terms of linearity, accuracy, precision, specificity and reproducibility, and can be used successfully for routine simultaneous estimation of rabeprazole sodium and aceclofenac in pure and capsule dosage forms.

Funding

Nil

Acknowledgement

Not Declared

Conflict of Interest

Not Declared

Informed Consent and Ethical Statement

Not Applicable

Author Contribution

All are contributed equally

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