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Research Article

Development of Two UV Spectrophotometric Methods for Estimation of Rabeprazole with Diclofenac Sodium Capsules and Rabeprazole with Domperidone Capsules

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Abstract

Development of UV spectrophotometric methods, Q- analysis method and first derivative method have been carried out and validated for estimation of Rabeprazole and Diclofenac sodium Capsules and Rabeprazole and Domperidone capsules which are used as proton pump inhibitor and antiemetic for the short-term treatment of nausea and vomiting, similarly Rabeprazole and Diclofenac sodium also used as relief of pain and inflammation in ulceric conditions in capsule dosage form. These Methods has been carried out by using 0.1N NaOH solution as solvent which is very economical as well easily available. The Q-analysis was based on the measurement of UV light absorbance of Rabeprazole, Domperidone at wavelength 291.2 nm, 240 nm and Rabeprazole, Diclofenac sodium at wavelength 275.6 nm, 245.2 nm respectively in freshly prepared dilute 0.1N NaoH solution. First derivative based on measurement of ratio of difference in wavelength and concentration dy/dx at wavelength of Rabeprazole, Domperidone at 265.1 nm, 244.6 nm and Rabeprazole, Diclofenac sodium at 275.2 nm, 252.2 nm respectively. The standard solutions obeyed Beer's law at the concentration range of 2 - 10 µg/ml for Rabeprazole, 3 - 18 µg/ml for Domperidone and 2 - 10 µg/ml Rabeprazole, 10 - 50 µg/ml Diclofenac sodium. The results of analysis and recovery studies had been carried out as per ICH Guidelines and validated which confirmed the accuracy of the proposed methods. These methods can be used for determination of different formulations.

Keywords: Rabeprazole; Domperidone; Diclofenac Sodium; Q-Analysis; First Derivative; UV Spectrophotometer

Introduction

Rabeprazole sodium RABE is chemically 2-({[4-(3-Metho xypropoxy)-3-methyl-2-pyridyl]methyl} sulfinyl)-1*H*-benzimidazole sodium [1]. It is a proton pump inhibitor. Diclofenic sodium DICLO is {2-[(2, 6-dichloroanilino), phenyl acetic acid derivative is an NSAID. The combination of RABE and DICLO is used for combined effect to relive post operated pain with antacid [1]. Domperidone is DOMP (5-chloro-1-{1-[3-(2, 3-dihydro-2-oxo-1H-benzimidazol-1-yl) propyl]-4- piperidinyl} benzimidazolin-2-one) [1]. DOMP is a dopamine antagonist and it is used in combination with RABE as an antiemetic. As per Literature review some methods have been reported for estimation of the effect of stability of rabeprazole sodium [2], HPLC method for the estimation of rabeprazole in human plasma using solid-phase extraction [3]. Spectrophotometric determination of Rabeprazole Sodium and Itopride Hydrochloride dosage form [4], Determination of rabeprazole enantiomers and their metabolites by HPLC with solid-phase extraction [5], Structural elucidation of rabeprazole sodium products [6], Spectrophotometric and chromatographic determination of rabeprazole in presence of its degradation products [7], Potentiometric and fluo-

rimetric determination of diclofenac in injection analysis system [8], HPLC Method for the determination of domperidone in human plasma [9] UV spectroscopic study analysis of Domperidone [10] Development and validation of a reversed-phase hplc method for determination of domperidone and pantoprazole in pharmaceutical dosage forms [11] individually as well as for the combination of each drug with other drugs were reported. This present study describes two different simple and accurate Uv-spectrophotometric methods for two different combinations, As RABE with DICLO and RABE with DOMP. As per review data, no study has been shown single Method is applicable for different two Formulations and carried out by two UV spectrophotometric methods. The validation of the methods carried out as per ICH guidelines. There was need of to develop simple and reproducible as well economical analytical methods for Laboratory use.

Materials and Methods

Materials

Pharmaceutical grade RABE from Shreechem Pharmaceuticals, DICLO from Apex pharmaceuticals and DOMP from Apex pharmaceuticals, India was procured as gift sample and used. All analytical grade chemicals and solvents were obtained from Merck India Company.

Equipment

The UV-Visible Spectrophotometer- Shimadzu160A was used with data processing system. The scanning of standard and sample solution was carried out in 1cm quartz over the range 200-400 nm. The scan speed give good spectra at 60nm s^{-1} and slit width at 2 nm.

Procedure

Preparation of standard solutions and plotting calibration curves

Standard solutions of RABE, DICLO and DOMP in 0.1N NaoH were prepared to get 1 mg/ml concentration of each compound. The series of above solutions were prepared containing RABE 2,4,6,8,10,12 µg/ml, DICLO 10,20.30,40,50 µg/ml and DOMP 3,6,9,12,15,18 µg/ml by diluting the standard solution with 0.1N NaoH in standard volumetric flasks of 10ml for calibration Curve, Adjusted in first derivative mode and by first derivative method measured dy/dx at wavelength of RABE at 265.1 nm, DOMP 244.6 nm and RABE at 275.2 nm, DICLO 252.2 nm. The standard stock solution of all drugs having 10 µg/ml was scanned separately in the UV range 200-400 nm wavelength. Two wavelengths were selected for each formulation for the use of Q-analysis RABE, DOMP at 291.2 nm, 240 nm. As well RABE, DICLO at 275.6 nm, 245.2 nm respectively. Each standard drug's 1% solution absorbance measured at 1cm path length denoted as (A1%, 1 cm) to calculate Є Absorbtivity. Then mixed standard solutions were prepared for Q-analysis Method and first derivative method.

Rabeprazole		Diclofenac sodium	
Conc. in µg/ml	Absorbance	Conc. in µg/ml	Absorbance
2	0.002	10	0.007
4	0.003	20	0.012
6	0.005	30	0.018
8	0.007	40	0.023
10	0.009	50	0.029

Table 1: UV linearity range for Rabeprazole, Diclofenac sodium and Linearity Curve.

Rabeprazole		Domperidone	
Conc. in µg/ml	Absorbance	Conc. in µg/ml	Absorbance
2	0.002	3	0.004
4	0.003	6	0.008
6	0.004	9	0.012
8	0.005	12	0.015
10	0.006	15	0.020
12	0.007	18	0.023

Table 2: UV linearity range for Rabeprazole, Domperidone and Linearity Curve.

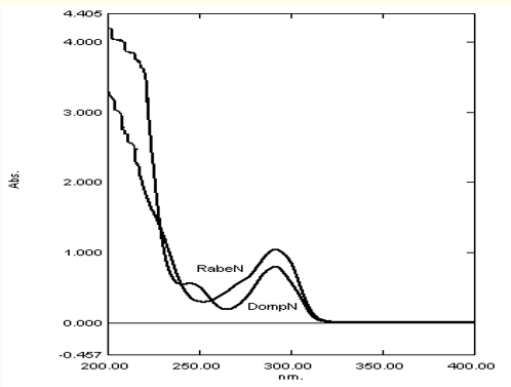

Figure 1: Overlay UV spectra of Domperidone and Rabeprazole.

Figure 2: Overlay UV spectra of Diclofenac and Rabeprazole

Q-value analysis

As shown in figure 1 overlain spectrum for RABE and DOMP two wavelengths were selected at 291.2 nm, 240 nm respectively, At the 240 nm both the spectrum intersect as iso-absorptive point for both drugs and another wavelength at 291.2 nm. Similarly from the overlain spectrum shown in figure 2 for RABE and DICLO two wavelengths were selected RABE and DICLO at 275.6 nm, 245.2 nm respectively, At 245.2 nm both the spectrum intersect as iso-absorptive point for both the drugs and at 275.6 nm. The absorbance of the standard and sample solutions was measured. The absorptivity values for both standard drugs at their the selected wavelength calculated by the equation

A= abc

Where A is Absorptivity a is Absorbance of 1% Solution b is cell width 1 and c is concentration (1%) solution, used for determination of Q values and another wavelength used was isoabsorptivite point for each combination. The concentrations of drugs C_1 and C_2 in sample solution calculated by using the following formula.

For estimation of RABE

$$C_1 = \frac{Q_0 - Q_2}{Q_1 - Q_2} \times \frac{A}{a_1} \qquad Q_0 = \frac{\text{Absorptivity of sample at 291.2 nm}}{\text{Absorptivity of sample at 240 nm}} \quad \text{Eq -----1}$$

For estimation of DOMP

A = Absorbance of sample at isoabsorptive point.

a_1 and a_2 = Absorptivities values of RABE and DOMP respectively at iso-absorptivite point.

For estimation of RABE

$$C_2 = \frac{Q_0 - Q_1}{Q_2 - Q_1} \times \frac{A}{a_2} \qquad Q_1 = \frac{\text{Absorptivity of RABE at 291.2nm}}{\text{Absorptivity of RABE at 240 nm}} \quad \text{Eq -----2}$$

$$Q_2 = \frac{\text{Absorptivity of DOMP at 291.2 nm}}{\text{Absorptivity of DOMP at 240 nm}} \quad \text{Eq ------3}$$

A = Absorbance of sample at isoabsorptive point.

a1 and a_2 = Absorptivities values of RABE and DOMP respectively at iso-absorptivite point.

For estimation of DICLO

$$C_2 = \frac{Q_0 - Q_1}{Q_2 - Q_1} \times \frac{A}{a_2} \qquad Q_1 = \text{Absorptivity of RABE at 275.6 nm} \qquad \text{Eq ---5}$$

Absorptivity of RABE at 245.2 nm

$$Q_2 = \frac{\text{Absorptivity of DICLO at 275.6 nm}}{\text{Absorptivity of DICLO at 245.2 nm}} \qquad \text{Eq ----6}$$

A = Absorbance of sample at isoabsorptive point.

a_1 and a_2 = Absorptivities values of RABE and DICLO respectively at iso-absorptivite point.

Derivative spectroscopy

The standard solutions were prepared by dissolving std drugs RABE 2 µg/ml to 12 µg/ml, interval of 2 microgram/ml. DICLO 10 µg/ml to 50 µg/ml interval of 10 microgram/ml. and DOMP 3 µg/ml to 18 µg/ml by interval of 3 microgram/ml, by diluting the standard solution with 0.1N NaoH in 10 ml volumetric flasks. The zero order spectrum was adjusted in first derivative mode and by first derivative method measured dy/dx at wavelength of RABE at 265.1 nm, DOMP 244.6 nm as shown in figure 3 and RABE at 275.2 nm, DICLO 252.2 nm as shown in figure 4. The linearity curve plotted concentration versus dy/dx at respective wavelength.

Figure 3: First order derivative overlay UV spectra of Domperidone and Rabeprazole.
A = Wavelength of RABE at 265.1 nm,
B = Wavelength of DOMP 244.6 nm.

Figure 4: First order derivative overlay UV spectra of Diclofenac and Rabeprazole.
A = Wavelength of RABE at 275.2 nm,
B = Wavelength of DOMP 252.2 nm.

Estimation of drugs in formulations

The estimation of the selected formulations by Spectrophotometric method was carried out using the optimized Spectrophotometric conditions. The absorbance of the standard and sample solution were measured at their respective fixed wavelength. This procedure was repeated three times and percentage of individual drugs calculated in that formulations, % recovery of formulations were calculated as presented in Table no 3 and table 4**.** The results shown in tables showed that the amount of label claim of the formulations found as per label claim.

Analysis of formulations by two methods

For each method taken twenty capsules, powdered the content of capsules and weighed accurately equivalent to 20 mg of RABE and DOMP 30 mg. For second formulation taken twenty capsules powdered its content and mix well and weighed equivalent to 20 mg RABE and 100 mg DICLO were dissolved 100 ml volumetric flask separately by using 50ml of 0.1N NaOH sonicated for 20 min. The solutions were diluted with0.1N NaOH solvent, filtered through Whatmann No. 41 filter paper. The filtrate was diluted with 0.1N NaOH to get final dilution 2.0 µg/ml of RABE, 3.0 µg/ml DOMP or 2.0 µg/ml RABE and DICLO 10 µg/ml separately.

The Q-analysis carried out by measuring absorption at respective wavelengths as for standard solutions. The results were obtained by calculating by equations given above Eq 1 to Eq 6. For first derivative method scanned diluted sample solutions at 200-

400 nm then converted in first order mode to get value of dy/dx for further calculation.

Results and Discussion

All the API RABE, DOMP and DICLO and were not completely soluble in water. But Completely soluble in 0.1N NaoH solution therefore it is used as solvent for all standard and sample solution preparation. The First derivative uv- absorption spectrum obtained for both the formulations dy/dx at different wavelengths respectively. Q-values calculated from above equations for each drugs then determine content of each drug C1 and C2 in each formulation. Results obtained were reported in Tables. Analysis of Rabeprazole and Diclofenac sodium formulation by UV method in table 3. And Analysis of Rabeprazole and Domperidone formulation by UV method in table 4. For recovery studies spiked each standard drug in it's powdered formulations 80%, 100%, 120% and carried out for both the methods. The results of the recovery analysis are reported in table 3 and table 4.

Method	λ Max (nm)	Formulations	Linearity and range µg/ml		Labeled amount (mg/dose)		Amount found (mg/dose)		% Recovery (mean ± S.D.) n = 3	
			Rabe	Diclo	Rabe	Diclo	Rabe	Diclo	Rabe	Diclo
First order derivative	275.2 and 252.2	Capsule	2-10 µg/ml	10-50 µg/ml	20 mg	100 mg	20.02 mg	99.55 mg	98.72 ± 0.056	99.96 ± 0.278
Q- Analysis method	275.6 and 245.2	Capsule	2-10 µg/ml	10-50 µg/ml	20 mg	100 mg	20.08 mg	99.48 mg	100.7 ± 0.045	100.2 ± 0.24

Table 3: Results of Analysis of Rabeprazole and Diclofenac sodium formulation by UV methods.

Method	λ Max (nm)	Formulations	Linearity and range µg/ml		Labeled amount (mg/dose)		Amount found (mg/dose)		% Recovery (mean ± S.D.) n = 3	
			Rabe	Domp	Rabe	Domp	Rabe	Domp	Rabe	Domp
First order derivative	265.1 and 244.6	capsule	2-12 µg/ml	3-18 µg/ml	20 mg	30 mg	20.06 mg	30.10 mg	98.85 ± 0.488	100 ± 0.022
Q- Analysis method	291.2 and 240	capsule	2-12 µg/ml	3-18 µg/ml	20 mg	30 mg	19.95 mg	29.90 mg	100.5 ± 0.567	99.98 ± 0.18

Table 4: Results of Analysis of Rabeprazole and Domperidone formulation by UV methods.

To carry out the stability study of standard and sample solutions during experiment, All solutions were analyzed over a period of 12 Hours with interval of 3 Hours at room temperature. The peak shape and peak area of RABE, DOMP and DICLO remained almost constant (% R.S.D. less than 2.0) and no significant degradation within the12 Hours, thus indicated that both solutions were stable for at least 12 Hours. One can complete the experiment in stipulated time period.

Conclusion

The proposed both spectrophotometeric methods for two different formulations are assured with required precision and accuracy. All the developed methods were easy, accurate and Precise, reproducible and economical. Therefore it can be used for laboratory as well institute level.

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