Original Article

UV Spectroscopic Method Development and Validation of Rabeprazole and Levosulpiride in its Bulk and Dosage Form

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Abstract

Logical strategy is the heart of drug investigation. The current work endeavored to foster precise, straightforward, and delicate techniques for concurrent assessment of rabeprazole and levosulpiride. The overlay range of levosulpiride and rabeprazole display λmax of 288 nm and 282 nm for LEVO and RABE. Standard adjustment bends for levosulpiride and rabeprazole were straight with connection coefficient (r) values in the scope of 0.9998-0.9997 at all chosen frequencies. The precision of the technique was affirmed by recuperation contemplated from the tablet at three distinct degrees of 80%, 100 percent, and 120% recuperation in the scope of 99.97-100 percent legitimizes the exactness of the strategy. Intraday and Interday accuracy was checked for UV strategy, and % RSD was viewed as under 2 for UV technique. The created strategy is a fast device for routine examination of rabeprazole and levosulpiride in the mass and the drug dose structure. Considering the possible general improvement of phony medication portions, the proposed strategy could be important for the quality control research offices in developing countries.

Keywords: UV spectroscopy, Rabeprazole, Levosulpiride, Simultaneous estimation, Method development

Introduction

During the most recent couple of years, logical science has seen broad improvement concerning refinement, quantitation, and instrumentation. Thus, more current scientific procedures (for example, joined strategies FT-IR, GC-MS, LC-MS, HPLC, HPTLC, and so on) and their areas of use have expanded impressively in light of the severe prerequisites for testing and observing the medications for endorsement. Interest in quality, approval information, and execution of logical techniques have acquired significance.

Presently a day the majority of the people groups are experiencing different kinds of sickness conditions. This can be happening because of the changing way of life. Implies inappropriate food admission and absence of activity can prompt the sickness. Because of this, numerous drug ventures present new medication particles or mixes annually to treat such sicknesses. In this, one of the overall sicknesses is gastric corrosiveness, which can additionally prompt Gastroesophageal Reflux Illness [GERD] or gastric/peptic ulcers.

Consequently, by taking a business sector overview and considering people groups' needs, we have attempted to advance the pursuit related to late medications and mixes. Numerous enterprises work on the medications used to treat Gastric Causticity, Gastroesophageal Reflux Sickness [GERD], or Gastric/Peptic Ulcers. Rather than a single medication, doctors lean toward a mix of medications. Consequently, by alluding to the articles on this mix at the lab level, we attempted to foster a technique for this blend of antiulcer drugs by keeping ICH rules.

UV is the quickest logical method for the examination of medications separately and in a blend as well. Its effortlessness makes it ideal for the investigation of many medications. Subsequently, it was thought to foster such techniques for examination, which can gauge the medications

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in the blend without earlier partition. Subsequently, the present work was endeavored to foster an exact, basic, and delicate strategy for concurrent assessment of rabeprazole and levosulpiride [1-6].

Materials and Methods

The method used was UV spectroscopy simultaneous estimation. **Table 1** shows the drugs and reagents used for the study.

Table 1. List of material for the work

	Material	Company
Drugs	Rabeprazole	Swapnroop Drugs & Pharmaceuticals, Aurangabad
	Levosulpiride	Swapnroop Drugs & Pharmaceuticals, Aurangabad
	Rabeprazole & Levosulpiride Tablet (Cyra-LS)	Local Retail Pharmacy
Reagents	Acetonitrile (UV grade)	Loba Chemicals
	Methanol (UV grade)	Loba Chemical
	Purified Water	Mili Q
	Potassium dihydrogen phosphate (A.R. grade)	Fisher Scientific
	O -phosphoric acid (A.R. grade)	Fisher Scientific

Major Instruments Used

The UV-spectrophotometer was Jasco V with 1cm matched pair quartz cell and spectral bandwidth of 1nm, PH meter used used was Global DBH-500, and sonicator was make of PCI, Mumbai.

Selection of Common Solvents [7]

Buffer: Acetonitrile (70:30) was chosen as a typical dissolvable for creating ghostly medication qualities. The determination was made subsequent to surveying the dissolvability of the two medications in various dissolvable.

Preparation of Standard Drug Solution [8]

The standard arrangement containing levsulpiride and rabeprazole was ready by dissolving 25 mg of levosulpiride and 25 mg rabeprazole independently in 100 ml of Cradle and Acetonitrile (70:30). This was sonicated for 15 min. Afterward, the last volume of every arrangement was made up to 250 ml with dissolvable to get the last stock arrangement containing 100 µg/ml of levosulpiride and rabeprazole in two different 250 ml volumetric flagons [6, 9-12].

Procedure for Determining the Sampling Wavelength for Simultaneous Estimation

Levosulpiride and rabeprazole (10µg/ml) each were checked independently in a frequency scope of 200-400 nm against dissolvable (Phosphate cushion and Acetonitrile 70:30) as clear to decide the frequency of greatest retention of medication. The concurrent condition strategy produced for the examination of levosulpiride and rabeprazole frequency was chosen for the assessment of levosulpiride and rabeprazole from overlain spectra [13]. The frequency was chosen for levosulpiride and rabeprazole from overlain spectra of the two medications at 288 nm, and 282nm, as displayed in **Figure 1**.

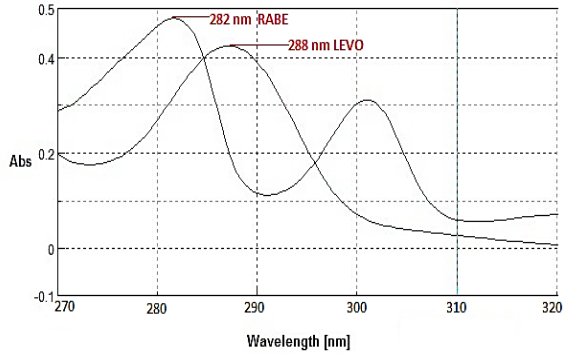

Figure 1. Overlay of rabeprazole and levosulpiride

Combined Stock Solution for Rabeprazole and Levosulpiride

The standard stock arrangement containing 100µg/ml of levosulpiride and rabeprazole weakenings of the two medications was ready to get the last focus 10 µg/ml arrangement of the two medications.

Procedure for Simultaneous Equation Method [14]

Two frequencies of the two medications were chosen in Cradle: Acetonitrile (70:30) dissolvable arrangement. The Standard stock arrangement was further weakened with a dissolvable answer for getting the stock arrangement of focus 10µg/ml. The absorbance of arrangement was estimated at a chosen frequency and not set in stone as a mean of five free conclusions. Convergence of the medication in the examples was acquired utilizing the following two conditions;

$$Cx = \frac{A_2 a_{y1} - A_1 a_{y2}}{a_{x2} a_{y1} - a_{x1} a_{y2}} \quad (1)$$

$$Cy = \frac{A_1 a_{x2} - A_2 a_{x1}}{a_{x2} a_{y1} - a_{x1} a_{y2}} \quad (2)$$

Where A_1 and A_2 are the absorbances of the mixture at λ1 and λ2, respectively.

a_{x1} and a_{x2} are the absorptivities of rabeprazole at λ1 and λ2, respectively

a_{y1} and a_{y2} are the absorptivities of levosulpiride at λ1 and λ2, respectively.

C_x and C_y are the concentrations of rabeprazole & levosulpiride in g/L, respectively.

Procedure for Plotting the Calibration Curve [15]

The weakening of the two medications was ready from the standard stock arrangement. Arrangements were examined in the chosen scientific frequency. Measure the absorbance of the two medications at the chosen frequency. The adjustment bend for the two medications was developed. The alignment bend for the two medications was built by plotting the absorbance against focus. Levosulpiride complied with Lager's regulation in the focus scope of 14-84 µg/ml, and rabeprazole complied in the fixation scope of 2-12µg/ml by utilizing quantitative methods of instrument slant, block, and connection coefficient values for alignment bend was acquired for the two medications. For levosulpiride, the fixation in the example arrangement was determined by utilizing the equation, Abs=A+B x C, C= grouping of levosulpiride where A=0.0022, B=0.0102, r2=0.9998. For rabeprazole, the fixation in the example arrangement was determined by utilizing the equation, Abs=A+B x C, C=concentration of rabeprazole where A= 0.0015, B =0.0592, r2=0.9997.

Analysis of Tablet Formulation

Advertised tablet definitions containing rabeprazole 20 mg and levosulpiride 75 mg were dissected utilizing this strategy. 20tablets were gauged, and their normal weight was determined. Then, at that point, the tablet is squashed into the powder. From 20 tablets, an identical load of 10 mg of the two medications was determined and afterward disintegrated in 50ml of dissolvable Cushion and Acetonitrile (70:30), sonicate for 20 min. At that point, the arrangement was separated through Whatman channel paper no. 41 and make up the conclusive volume with dissolvable to get the last grouping of the two medications to 100 µg/ml. After proper weakening, the absorbance was estimated, and centralization of each was still up in the air with the situation created by the adjustment bend of separate medications [16, 17].

Results and Discussion

Calibration Curve

The absorbance values calibration curve of levosulpiride and rabeprazole is shown in **Table 2**.

Table 2. Absorbance values for calibration curves of rabeprazole and levosulpiride

Concentration LEVO (µg/ml)	Absorbance for LEVO	Concentration RABE (µg/ml)	Absorbance for RABE
14	0.140	2	0.128
28	0.282	4	0.232
42	0.416	6	0.357
56	0.570	8	0.472
70	0.712	10	0.593
84	0.849	12	0.715

Method Validation

The proposed strategy was approved by ICH Q2B rules for logical systems to decide exactness, accuracy, repeatability, heartiness, linearity, cutoff of discovery, the breaking point of quantitation, and vigor results, which were displayed in **Table 4**.

Table 3. Linear Regression analysis of calibration curve

Parameter	Levosulpiride	Rabeprazole
Wavelength Buffer & Acetonitrile (70:30)	288nm	282nm
Molar Absorptivity (lit/mol/cm)	0.9031	1.09
Beer's limit (µg/ml)	14-84 µg/ml	2-12 µg/ml
Slope (B)	0.0102	0.0592
Intercept(A)	0.0022	0.0015
Coefficient of Correlation	0.9998	0.9997

Y=A+B*+C, where C is the concentration in µg/ml, and Y is the absorbance unit

Accuracy (% Recovery)

It is the proportion of closeness between genuine worth and insightful worth that is determined by applying the test methodology at various times. Recuperation was finished at three distinct levels viz 80%, 100%, and 120%, inside as far as possible for both medications. Rate recuperation was determined involving the conditions for both techniques. Rate recuperation is given in **Table 5**.

Table 4. Linear Regression analysis of calibration curve

Parameter	Drugs		Std.Dev.*		% R.S.D.	
	LEVO	RABE	LEVO	RABE	LEVO	RABE
80%	99.97	100.01	0.00115	0.00091	0.51	0.28
100%	99.98	100.03	0.00115	0.00115	0.46	0.30
120%	100	99.94	0.00147	0.00176	0.53	0.42

*Average of six determinations, % R.S.D. Relative Standard Deviation, S. D. Standard Deviation

Linearity

The linearity of this technique was assessed by direct relapse examination and determined by the least square strategy. The medication shows linearity in the fixation range for levosulpiride 14-84 µg/ml and for rabeprazole 2-12 µg/ml. Standard weakenings were arranged utilizing the expected volume from the stock arrangement, and afterward, the volume was made up to 10 ml with Cradle and Acetonitrile (7:3) to yield the fixations. The absorbance of the subsequent

arrangements was estimated, and the adjustment bend was plotted among the absorbance and convergence of the medication. Results showed an amazing relationship among's absorbance and analyte focus. Adjustment bend for levosulpiride and rabeprazole was displayed in **Figures 2 and 3** separately.

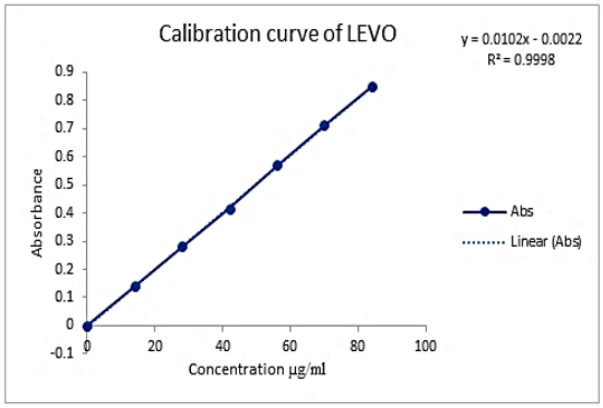

Figure 2. Calibration curve for levosulpiride

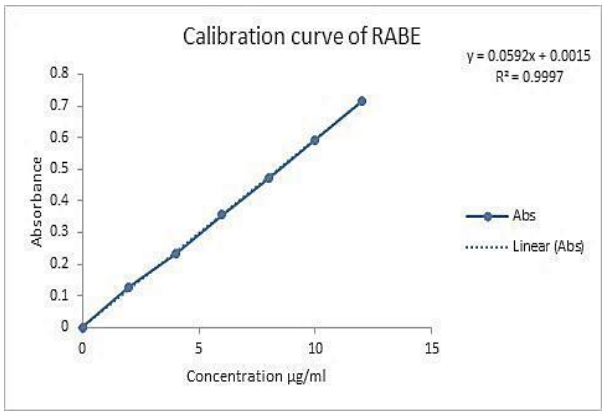

Figure 3. Calibration curve for rabeprazole

Interday and Intraday Precision & Accuracy

Accuracy was concentrated on utilizing the arrangement of fixation 10 µg/ml. The absorbance of the arrangement was estimated for three repeat tests. Intra-day accuracy studies were run three-fold around the same time and between days on three sequential days. The consequence of intraday accuracy was displayed in **Table 6**, and the aftereffect of interday accuracy and intraday accuracy were displayed in **Tables 6 and 7** separately.

Table 5. Results of interday precision

Time	%Label claim estimated (Mean± S.D.)		% R.S.D.	
	LEVO	RABE	LEVO	RABE
T-1	99.99±.0.00098	99.99 ±0.0007	0.48	0.24
T-2	99.98 ± 0.00175	100±0.00085	0.64	0.27
T-3	99.96 ± 0.00155	100.01±0.001	0.67	0.38

*Average of six determinations, % R.S.D. relative standard deviation, S.D. standard deviation

Table 6. Results of intraday precision

Day	%Label claim estimated (Mean± S.D.)		% R.S.D.	
	LEVO	RABE	LEVO	RABE
Day-1	100±0.00092	99.97±0.00115	0.47	0.32
Day-2	99.99 ± 0.0010	99.99 ±0.00142	0.56	0.44
Day-3	99.94±0.00136	99.98 ±0.00166	0.63	0.59

*Average of six determinations, R.S.D. relative standard deviation, S.D. standard deviation

Limit of Detection (LOD) & Limit of Quantitation (LOQ)

The limit of detection (LOD) is the base grouping of the analyte in the example which can be broken down by the instrument. The limit of quantitation (LOQ) is the base centralization of the analyte that can be dependably measured. The Limit of detection (LOD) and Limit of quantitation (LOQ) was estimated utilizing the recipe. Six clear conclusions were utilized. The result is displayed in **Table 8**.

Table 7. Results of LOD & LOQ

Drug Name	Limit of Detection	Limit of Quantitation
Levosulpiride	0.234	0.478
Rabeprazole	0.124	0.368

Robustness

The power of a scientific technique is a proportion of its ability to stay unaffected by little however conscious varieties in strategy boundaries and gives a sign of its unwavering quality during typical utilization. Not set in stone getting ready two experts of the two medications by changing the dissolvable focus. The result is displayed in **Table 9**.

Table 8. Results of robustness

Analyte	Label claim (mg)		% Label claim (Mean ±S.D.)		% R.S.D.	
	LEVO	RABE	LEVO	RABE	LEVO	RABE
1	75	20	99.83 ±0.0011	99.97±0.0011	0.73	0.44
2	75	20	99.97±0.0065	99.94 ±0.0015	0.43	0.58

*Average of six determinations, % R.S.D. Relative Standard Deviation, S.D. Standard Deviation

Analysis of Tablet Formulation

The overlay range of levosulpiride and rabeprazole shows λmax of 288 nm and 282 nm for LEVO and RABE. Standard alignment bends for levosulpiride and rabeprazole were straight with connection coefficient ® values in the scope of 0.9998-0.9997 at every chosen frequency. The precision of the technique was affirmed by recuperation examined from the tablet at three distinct degrees of 80%, 100 percent, and 120% recuperation in the scope of 99.97-100 percent

legitimizes the exactness of the strategy. Intraday and Interday accuracy was checked for UV strategy, and % RSD was viewed as under 2 for UV technique. The factual information acquired after the repeat decision is displayed in **Table 9**.

Table 9. Results of tablet analysis

Drug	Amount (mg)	S.D.	% R.S.D.	Drug
LEVO	74.92	0.000833	0.39	**LEVO**
RABE	19.96	0.000966	0.31	**RABE**

Conclusion

The proposed UV Spectrophotometric technique considers basic, dependable, exact, and precise estimation of rabeprazole and levosulpiride at the same time in a consolidated dose structure. Consequently, we effortlessly embraced routine quality control investigations. The created strategies were viewed as straightforward, quick, exact, and precise for the assurance of medications, in particular two-part tablet measurements type of rabeprazole and levosulpiride. The added substances typically present in the tested drug plans didn't slow down the assurance of rabeprazole and levosulpiride. The techniques were assessed with the best condition, for example, straight connection, including coefficient of relationship, vigor, exactness, and accuracy.

The % RSD for all boundaries was viewed as under 2, which shows the legitimacy of the strategy and measure results acquired by this technique in fair of arrangements. The interday and intraday accuracy was viewed as inside limits. The recuperation rate of the two medications for all strategies was considered as inside the reach.

These outcomes show that the proposed UV spectroscopic technique was straightforward, quick, monetary, exact, and precise consequently, they are reasonable for examining rabeprazole and levosulpiride in the mass and tablet measurement structure without the obstruction of excipients. These techniques can be applied effectively to ensure rabeprazole and levosulpiride in drug tablet measurement structure without obstruction and with excellent responsiveness.

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