International Journal of Pharmaceutical Chemistry
ISSN: 2249-734X (Online)
Journal DOI:10.7439/ijpc
CODEN:IJPCI4 (American Chemical Society)

Research Article

Development of validated UV spectrophotometric method for the simultaneous estimation of rabeprazole sodium and levosulpiride in capsule dosage form

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Abstract

A simple precise reproducible U.V. Spectrophotometric methods have been developed and validated for the simultaneous estimation of RPS and LSP in capsule dosage form. This Paper describes 2 methods for the simultaneous estimation of both the drugs. The simultaneous equation method (SEM) which involves the measurement of absorbance of RPS and LSP at 231.8 nm and 284.0 nm respectively and the absorbance ratio method (ARM) which involves the measurement of absorbance of the mixture of both the drugs at 259.0 nm which is isobestic point and at 284 nm ƛ max of RPS respectively. The developed method obeys the beers law in the concentration range of 2-10µg/ml for RPS and 7.5-37.5 µg/ml for LSP. The recovery studies shows %RSD for LSP 1.58, 0.52, 0.45 and for RPS 1.79, 1.52, 0.63 by ARM method and the recovery studies shows % RSD for LSP 0.23, 0.53, 0.88 and for RPS 0.76, 1.71, 1.56 by SEM method. The results of analysis have been validated statistically for accuracy, Precision, Repeatability, Specificity, and Ruggedness. The method was successfully applied to the determination of these drugs in pharmaceutical dosage form.

Key words: RPS, LSP, UV Spectrophotometry, Assay method, SEM, ARM

1. Introduction

The U.V. Spectrophotometric assay of drugs rarely involves the measurement of absorbance of samples containing only one absorbing component. The pharmaceutical analyst frequently encounters the situation where the concentration of one or more substances is required in samples known to contain other absorbing substances, which potentially interfere in the assay. If the formula of the samples is known, the identity and concentration of the interfering substance are known and the extent of interference in the assay may be determined. The the U.V. Spectrophotometric techniques for multicomponent samples is the property that at all wavelengths The absorbance of a solution is the sum of absorbance of the individual components or the measured absorbance is the difference between the total absorbance of the solution in the sample cell and that of the solution in the reference cell. In SEM there is measurement of absorbance of both the drugs at ƛ max of each other. While in ARM absorbances are measured at two wavelengths, one is being wavelength (λ_1) of equal absorptivity of two components i.e. an isoabsorptive point and other being λ max of one of the component[7]. The literature survey showed that very few UV Spectrophotometric methods for the above combination has been reported[2-6,8,10-11,13] so the present study was undertaken to develop simple, precise, accurate and reproducible U.V. Spectrophotometric method for the estimation of these drugs in their combined dosage form. Rabeprazole sodium (RPS) [Figure1] chemically is 2-({[4-(3-methoxypropoxy) methyl2pyridinyl] methyl} sulphenyl)-1*H*-benzimidazole sodium. And it is used in the states of Gastro-oesophageal reflux disease, Peptic ulcer. It is white to light yellow, crystalline powder and hygroscopic. It is freely soluble in water, chloroform, ethyl acetate, Methanol. It is proton pump inhibitor. While the Levosulpiride (LSP) [Figure 2] chemically is *N*-[[(2*S*)-1-

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Ethylpyrrolidin-2-yl] methyl]-2-methoxy-5 sulfamoylbenzamide and it is used in anxiety, Depression, schizophrenia. It is almost white and it is practically insoluble in water and sparingly soluble in methanol. It is a D_2 Receptor agonist[9,12,14-15,].

Figure 1: Structure of RPS

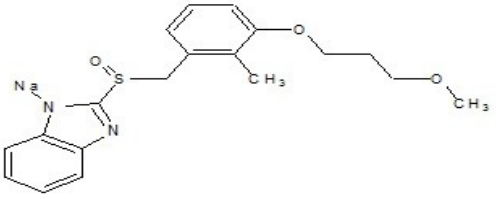
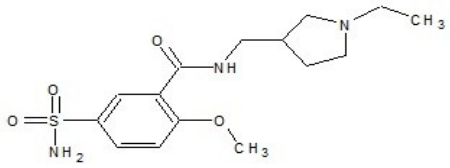


Figure 2: Structure of LSP.



2. Experimental

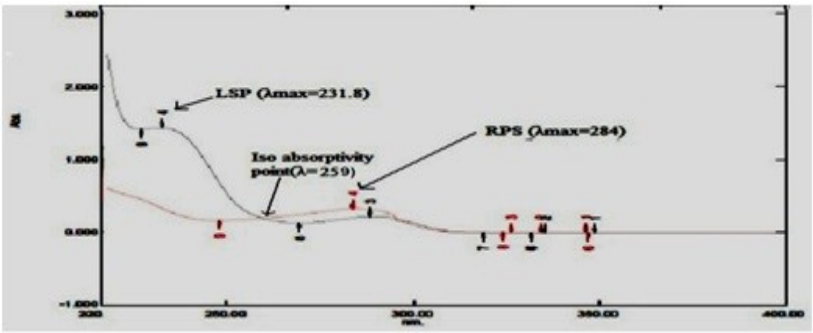
2.1 Reagents and Chemicals: Standard samples of RPS and LSP were received as a gift samples from Baroque Pharma, Khambhat (Gujarat) and Symed Labs Limited, Hyderabad (AP). The marketed formulation Neopride (INTAS Pharmaceutical) was purchased from the local market Containing RPS 20 mg and LSP 75 mg and all the chemicals used were are of analytical grade.

2.2 Instruments: A Shimadzu UV visible double beam spectrophotometer with model UV 1700 and software UV probe 2.33was used for spectral and absorbance measurement. Analytical balance of citizen model CY 104 (microanalytical balance) was used for weighing purpose also the ultrasonicator servewell instruments model RC-SYSTEM MU-1700 used for sonication purpose.

2.3 Preparation of Standard Stock Solutions of LSP and RPS: An accurately weight quantity 37.5 mg each of LSP and 10.0 mg of RPS were transferred to two separate 100.0 mL volumetric flasks containing 50.0 mL of methanol each sample, and volume was made up to mark with same solvent to the mark to obtained concentration 100.0 µg/mL each.

2.4 Determination of λ max and selection of Analytical Wavelength[7]: Appropriate aliquots from the stock solutions (3.75 mL of LSP and 1.0 mL of RPS) was transferred to two separate 10.0 mL volumetric flasks and the volume was adjusted to the mark with same solvent i.e. strength obtained was 37.5 µg/mL (LSP) and 10.0 µg/mL (RPS). Both the drug solutions were scanned separately between 400.0 nm to 200.0 nm. The overlain spectrum of both drugs was recorded from the overlain spectra analytical wavelengths 231.8 nm (λ max of LSP) and 284.0 nm (λ max of RPS) were selected for simultaneous equation Method (SEM), and 259.0 nm and 284.0 nm (λ max of RPS) were selected for estimation of drug using Absorption Ratio Method (ARM).

Figure 3: Overlain spectra of LSP & RPS



2.5 Study of linearity: A calibration curve was plotted over a concentration range of 2.0-10.0µg/ml for RPS and 7.5-37.5 µg/ml for LSP all the dilutions were made in methanol. A calibration curve was constructed by plotting absorbance VS concentration at both wavelengths.

2.6 Determination of E (1%, 1cm) of drugs at selected wavelengths[7]: Aliquot portions of LSP from stock solution were transferred to five 10.0 mL volumetric flaks, volume was adjusted up to mark to obtain the concentration of 18.75 µg/mL Similarly, aliquot portions from RPS stock solution were transferred to five10.0 mL volumetric flask 6.0 mL volumetric flask; volume was adjusted to mark to obtain concentration of 5.0 µg/mL Absorbances of these solutions were recorded at

wavelength 231.8 nm, 284.0 nm and 259.0 nm.E (1%, 1cm) values of drugs were calculated using following formula:

E (1%, 1cm) = Absorbance / Concentration (g / 100 mL)

2.7 Simultaneous Equation Method[7]: Concentrations $\mathbf{C_{LSP}}$ and $\mathbf{C_{RPS}}$ of LSP and RPS respectively in g/100 mL in the Physical Laboratory mixture and sample solution can be obtained by using simultaneous equation method as:

A set of two simultaneous equations were framed using these E(1%,1cm) values are given below

$$C_{LSP} = A2ay1\text{-}A1ay2/ax2ay1\text{-}ax1ay2 \quad \text{.....(1)}$$

$$C_{RPS} = A1ax2\text{-}A2ax1/ax2ay1\text{-}ax1ay2 \quad \text{.....(2)}$$

Where A1 and A2 are absorbance of mixture at 231.8 nm and 284.0 nm, ax1 and ax2, E (1%,1cm) of LSP at 231.8 nm and 284.0 nm respectively, ay1 and ay2, E (1%,1cm) of RPS at 231.8 nm and 284.0 nm respectively.

2.8 Absorption Ratio Method[7]: Concentrations $\mathbf{C_{LSP}}$ and $\mathbf{C_{RPS}}$ of LSP and RPS respectively in g/100 mL in the physical laboratory mixture and sample solution can be obtained by using following equations:

$$C_{LSP} = \frac{Qm - Qy}{Qx - Qy} \times \frac{A}{ax} \quad \text{.....(3)}$$

$$C_{RPS} = \frac{Qm - Qx}{Qy - Qx} \times \frac{A}{ay} \quad \text{.....(4)}$$

Where,

$$Qm = \frac{\text{Absorbance of sample at 284.0 nm}}{\text{Absorbance of sample at 259.0 nm}}$$

$$Qx = \frac{\text{Absorptivity of LSP at 284.0 nm}}{\text{Absorptivity of LSP at 259.0 nm}}$$

$$Qy = \frac{\text{Absorptivity of RPS at 284.0 nm}}{\text{Absorptivity of RPS at 259.0 nm}}$$

A is the absorbance of mixture at 259.0 nm and ax, ax2 and ay, ay2 are absorptivities E (1%, 1 cm) of LSP and RPS at 259.0 nm and 284.0 nm and Qm= A2/A, Qy = ay2/ay and Qx = ax2/ax.

2.9 Analysis of Physical Laboratory Mixture

2.9.1 For SEM: Physical laboratory mixture of LSP and RPS was prepared by dissolving 37.5 mg of LSP and 10.0 mg of RPS in100 ml of volumetric flask with methanol. Appropriate volume 0.4 mL was transferred to 10.0 mL of volumetric flask and diluted up to mark with the same solvent to obtained the concentration 15.0 µg/mL of LSP and 4µg/ml of RPS respectively. the solution were scanned in the range 400-200nm and absorbances of the sample solutions were recorded at 231.8 nm and 284.0 nm i.e A1 & A2 respectively .

For SEM, the concentrations of the drugs in sample solution (C_{LSP} and C_{RPS}) were determined by using equation (1) and (2).

2.9.2 For ARM: Physical laboratory mixture of LSP and RPS was prepared by dissolving 37.5 mg of LSP and 10 mg of RPS in100.0 ml of volumetric flask with methanol .Appropriate volume 0.4 mL was transferred to 10.0 ml of volumetric flask and diluted up to mark with the same solvent to obtained the concentration 15.0 µg/ml of LSP and 4µg/ml of RPS respectively. The solution were scanned in the range 400-200nm and absorbances of the sample solutions were recorded at 259.0 nm and 284.0 nm i.e A & A2 respectively.

The concentrations of the drugs in sample solution (C_{LSP} and C_{RPS}) were determined by using equation (3) and (4).

2.10 Analysis of Marketed Formulation: Twenty capsules were opened, their content weighed accurately and grind into fine powder. An accurately weighed quantity equivalent to 37.5 mg of LSP and 10.0 mg of RPS was transferred to 100.0 mL

volumetric flask containing methanol, sonicated for 10 min and volume was made upto the mark with same solvent and filtered through Whatmann filter paper (no.41). Aliquot portion of stock solution was transferred to 10.0 mL volumetric flask and volume was adjusted to mark with the same solvent and final concentration for analysis was adjusted and further Quantification was done by using SEM and ARM method.

2.11. Method Validation[3]:

2.11.1 Accuracy: To the preanalysed sample solutions (15µg/mL of LSP and 4 µg/mL of RPS), a known amount of standard solutions of the pure drugs (LSP and RPS) were added at different level i.e. 80%, 100% and 120 %.

2.112 Precision: Precision was determined as intra-day and inter-day variations. Intra-day precision was determined by analyzing the 15.0, 22.5 and 30.0 µg/mL of LSP and 4.0, 6.0, and 8.0 µg/mL of RPS solutions for three times in the same day. Inter-day precision was determined by analyzing 15.0, 22.5 and 30.0 µg/mL of LSP and 4.0, 6.0, and 8.0 µg/mL of RPS of drug solutions daily for three consecutive days over a period of week.

2.113 Repeatability: Repeatability was determined by analyzing LSP (15.0 µg/mL) and RPS (4.0 µg/mL) of drug solutions for six times.

2.114 Ruggedness: Ruggedness of the proposed method is determined by analysis of aliquots from homogenous slot by two analyst using same operational and environmental conditions.

2.115 Specificity: Accurately weighed quantities of Capsule powder equivalent to 37.5 mg of LSP and its equivalent RPS were taken in different volumetric flasks (50.0 ml) and were stored for 24 h under the following different conditions.

- At room temperature (normal)
- At 50°after addition of 1.0 ml of 0.1 M NaOH.
- At 50°after addition of 1.0 ml of 0.1 M HCl.
- At 50°after addition of 1.0 ml of 3% H_2O_2.

The samples were diluted with methanol and then volume was made up to the mark and filtered through whatman filters (No. 41). Aliquot of the filtrate was diluted with methanol so as to get concentration equivalent to 15.0 µg/ml of LSP and 4.0 µg/ml of RPS.

3. Results and Discussion

3.1 Selection of Analytical Wavelengths: It is based on the recording overlain spectra of both the drugs in the entire spectrum of 200-400 nm the overlain spectra is decipted in figure 3. The wavelengths selected are 231.8 nm (λ max of LSP) and 284.0 nm (λ max of RPS).

3.2 Determination of E(1%, 1cm) of drugs at selected wavelengths: Absorbances of the concentration of 18.75 µg/mL for LSP & 6.0 µg/mL for RSP were recorded at wavelength 231.8 nm, 284.0 nm and 259.0 nm and E (1%, 1cm) values of drugs were calculated.

Table No. 1: Absorptivity Values of LSP and RPS at 231.8 nm, 259.0nm and 284.0 nm

Sr. No.	E(1%1cm) at λmax 231.8 nm		E(1%1cm) at λmax 284.0 nm		E(1%1cm) at 259.0 nm	
	LSP	RPS	LSP	RPS	LSP	RPS
1	413.6	372.2	63.5	317.4	58.7	231.7
2	413.1	371.6	64.0	318.2	58.6	232.7
3	412.8	372.9	63.4	318.5	59.2	234.1
4	413.7	372.9	64.2	317.2	59.1	233.2
5	414.2	370.2	64.5	318.0	58.5	231.2
Avg.	413.5 (ax1)	372.0 (ay1)	63.9 (ax2)	318 (ay2)	58.8 (ax)	232.2 (ay)
±SD	0.54	1.11	0.47	0.54	0.63	1.01

3.3 Analysis of Physical Laboratory mixture:

3.3.1 For SEM: The concentrations of the drugs in sample solution (C_{LSP} and C_{RPS}) were determined and results are shown in Table No. 2

Table No.2: Analysis of Physical Laboratory mixture using SEM

Sr. No.	Amount Taken [µg/ml]		% Amount Found	
	LSP	RPS	LSP	RPS
1	15.0	4.0	99.42	102.16
2			100.18	98.13
3			99.55	100.49
4			99.15	101.43
5			99.17	100.94
6			99.25	100.49
AVG.			99.45	100.61
SD			0.39	1.37
%RSD			0.39	1.36

3.3.2 For ARM: The concentrations of the drugs in sample solution (C_{LSP} and C_{RPS}) were determined and results are shown in Table No. 3

Table No.3: Analysis of Physical Laboratory mixture using ARM

Sr. No.	Amount Taken [µg/ml]		% Amount Found	
	LSP	RPS	LSP	RPS
1	15	4	100.00	99.63
2	15	4	101.12	98.56
3	15	4	98.26	102.14
4	15	4	101.05	98.86
5	15	4	100.32	99.52
6	15	4	99.42	100.92
AVG.			100.03	99.94
SD			1.35	1.35
%RSD			1.35	1.35

3.4 Analysis of Marketed formulation: For SEM, The concentrations of two drugs in sample were determined, the percent label claim is calculated the % purity was found to be 99.48 for LSP and 100.59 for RPS.

Table No. 4: Analysis of Marketed formulation using SEM

Sr. No.	Amount Taken [µg/ml]		% Amount Found	
	LSP	RPS	LSP	RPS
1	15	4	99.48	102.12
2	15	4	100.28	98.06
3	15	4	99.55	100.49
4	15	4	99.15	101.43
5	15	4	99.17	100.94
6	15	4	99.23	100.50
AVG.			99.48	100.59
SD			1.38	1.38
%RSD			1.39	1.38

For ARM, The concentrations of two drugs in sample were determined, the label claim is calculated the % purity was found to be 100.30 for LSP and 99.59 for RPS.

Table No. 5: Analysis of Marketed formulation using ARM

Sr. No.	Amount Taken [µg/ml]		% Amount Found	
	LSP	RPS	LSP	RPS
1	15	4	98.81	100.99
2	15	4	99.93	99.93
3	15	4	101.05	98.86
4	15	4	101.02	99.01
5	15	4	99.93	99.93
6	15	4	101.05	98.86
AVG.			100.30	99.59
SD			0.85	0.85
%RSD			0.85	0.85

3.5 Method Validation[3]

3.5.1 Accuracy: It is ascertained by the recovery studies at level of 80, 100 and 120 % were performed. The % RSD for LSP 1.58, 0.52, 0.45 and for RPS 1.79, 1.52, 0.63 by ARM method and the recovery studies shows % RSD for LSP 0.23, 0.53, 0.88 and for RPS 0.76, 1.71, 1.56 by SEM method.

Table No. 6: Recovery studies by SEM

Drug added (µg/mL) (n=3)				Amount found		% Recovery		% RSD	
LSP	RPS	LSP	RPS	LSP	RPS	LSP	RPS	LSP	RPS
15	4	12	3.2	12.00	3.22	100.01	100.58	0.23	0.56
				11.96	3.21	99.64	100.47		
				12.01	3.19	100.06	99.56		
15	4	15	4	15.10x	3.91	100.69	97.83	0.53	1.71
				14.97	4.02	99.78	100.56		
				14.96	4.04	99.76	100.97		
15	4	18	4.8	18.02	4.81	100.11	100.18	0.88	1.50
				17.73	4.93	98.53	102.71		
				18.00	4.80	99.99	100.05		

Table No. 7: Recovery studies by ARM

Pre-analysed sample solution (µg/mL)		Excess drug added (µg/mL) (n=3)		Amount found		% Recovery		% RSD	
LSP	RPS	LSP	RPS	LSP	RPS	LSP	RPS	LSP	RPS
15	4	12	3.2	12.17	3.13	101.40	97.92	1.58	1.79
				11.84	3.23	98.66	101.01		
				12.17	3.13	101.40	97.92		
15	4	15	4	14.80	4.04	98.66	101.01	0.52	1.52
				14.75	3.94	98.33	98.50		
				14.90	4.05	99.35	101.24		
15	4	18	4.8	17.76	4.85	98.66	101.01	0.45	0.63
				17.91	4.80	99.52	99.93		
				17.80	4.85	98.91	101.04		

3.5.2 Linearity: The developed method obeys the beers law in the concentration range of 2-10µg/ml for RPS and 7.5-37.5 µg/ml for LSP.

Table No. 8: Linearity Studies of LSP at 231.8 nm

Sr. No.	Concentration of LSP [µg/mL]	Absorbance (n=5)	STD	%RSD
1	7.5	0.3126	0.006	1.78
2	15	0.6209	0.005	0.81
3	22.5	0.9322	0.009	0.99
4	30	1.2443	0.020	1.61
5	37.5	1.5613	0.016	1.05

Table No. 9: Linearity studies of RPS at 284.0 nm

Sr. No.	Concentration of RPS [µg/mL]	Absorbance (n=6)	STD	%RSD
1	2.0	0.0640	0.001	1.08
2	4.0	0.1267	0.001	0.76
3	6.0	0.1922	0.002	0.89
4	8.0	0.2552	0.003	1.06
5	10.0	0.3200	0.004	1.34

Figure No. 4: Calibration curve of LSP at 231.8 nm

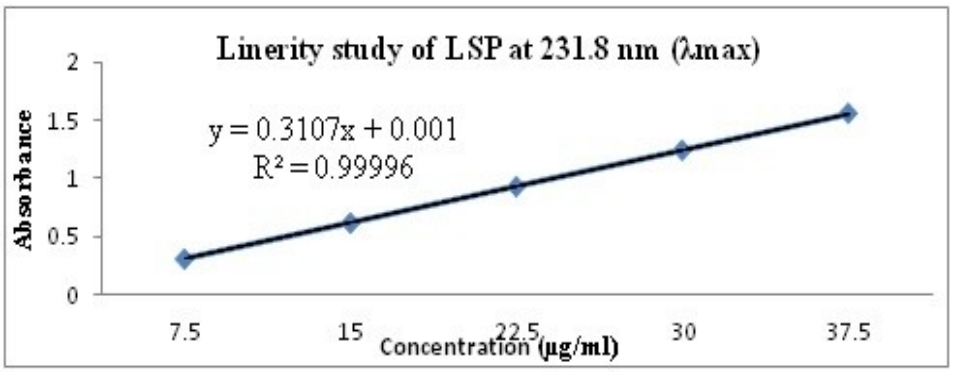
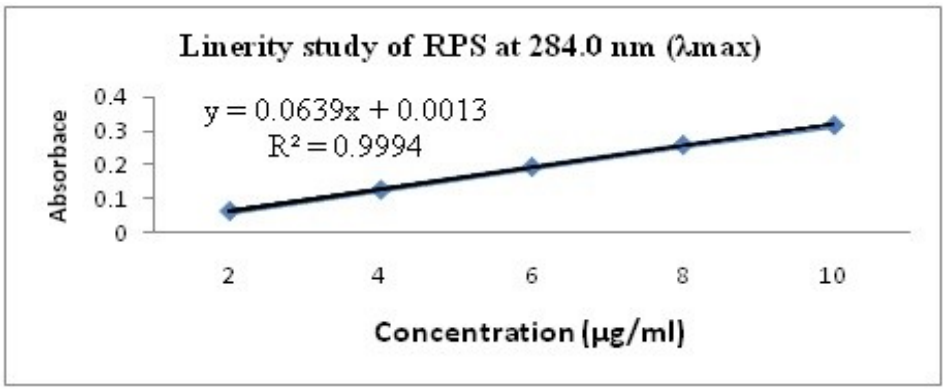


Figure No. 5: Calibration curve of RPS at 284.0 nm



3.5.3 Precision: Precision was determined as intra-day and inter-day variations. The results expressed as %RSD.

Table No. 10: Results of Precision Studies (Intra-day and Inter-day) for SEM

Actual amount (µg/mL)		Amount found (µg/mL)		% Amount found		% RSD	
Intra Day(n=3)							
LSP	**RPS**	**LSP**	**RPS**	**LSP**	**RPS**	**LSP**	**RPS**
15.00	4.00	14.75	3.96	98.32	98.91	0.98	1.03
		14.81	3.91	98.75	97.80		
		15.03	3.99	100.19	99.86		
22.50	6.00	22.50	6.08	100.02	101.38	0.91	1.59
		22.91	5.90	101.84	98.35		
		22.70	5.94	100.91	99.05		
30.00	8.00	30.03	7.96	100.11	99.52	0.80	1.28
		29.80	7.98	99.33	99.75		
		29.55	8.15	98.51	101.85		
Inter Day(n=3)							
15.00	4.00	14.72	3.99	98.14	99.67	1.33	0.49
		14.70	4.02	98.02	100.54		
		15.06	3.99	100.38	99.71		
22.50	6.00	22.65	5.96	100.68	99.33	0.62	1.35
		22.76	6.00	101.14	99.93		
		22.48	6.11	99.91	101.90		
30.00	8.00	30.22	7.86	100.73	98.27	0.82	1.80
		29.86	8.00	99.53	99.96		
		29.75	8.15	99.15	101.86		

Table No. 11: Results of Precision Studies (Intra-day and Inter-day) for ARM

Actual amount (µg/mL)		Amount found (µg/mL)		% Amount found		% RSD	
Intra Day							
LSP	**RPS**	**LSP**	**RPS**	**LSP**	**RPS**	**LSP**	**RPS**
15.00	4.00	14.68	4.06	97.86	101.55	1.48	1.26
		14.80	4.04	98.66	101.01		
		15.11	3.97	100.73	99.17		
22.50	6.00	22.19	6.06	98.66	101.01	1.28	1.5
		22.72	5.90	100.99	98.42		
		22.25	6.06	98.91	101.04		
30.00	8.00	30.3537	7.9252	101.18	99.0653	1.3	0.91
		30.01	7.9692	100.03	99.615		
		29.573	8.0668	98.577	100.835		
Inter Day							
15.00	4.00	14.8836	4.0153	99.224	100.383	1.55	1.41
		14.6465	4.0787	97.643	101.968		
		15.1102	3.9666	100.73	99.1648		
22.50	6.00	22.1973	6.0605	98.655	101.009	1.19	1.2
		22.728	5.9168	101.01	98.6136		
		22.5195	5.9996	100.09	99.994		
30.00	8.00	30.3537	7.9252	101.18	99.0653	0.89	0.59
		30.1151	7.9512	100.38	99.3899		
		29.8218	8.0168	99.406	100.21		

3.5.4 Repeatability: Repeatability was determined by analyzing LSP (15.0 µg/mL) and RPS (4.0 µg/mL) of drug solutions for six times.

Table No. 12: Repeatability studies for SEM

Sr. No.	Amount Taken [µg/ml]		% Amount Found [µg/ml]	
	LSP	RPS	LSP	RPS
1	15	4	99.42	102.16
2	15	4	100.18	98.13
3	15	4	99.55	100.49
4	15	4	99.15	101.43
5	15	4	99.17	100.94
6	15	4	99.25	100.49
AVG.			99.45	100.61
STD			1.37	1.37
%RSD			1.38	1.36

Table No.13: Repeatability studies for ARM

Sr. No.	Amount Taken [µg/ml]		% Amount Found [µg/ml]	
	LSP	RPS	LSP	RPS
1	15	4	100.77	98.82
2	15	4	97.98	102.10
3	15	4	98.68	101.58
4	15	4	98.13	102.73
5	15	4	97.27	102.50
6	15	4	97.63	102.35
AVG.			98.41	101.68
STD			1.46	1.46
%RSD			1.48	1.43

3.5.5 Ruggedness: Ruggedness of the proposed method is determined by analysis of aliquots from homogenous slot by two analyst using same operational and environmental conditions.

Table No. 14: Ruggedness studies for SEM

Sr. No.	Amount Taken [µg/ml]		Analyst-I		Analyst-II	
			% Amount Found		% Amount Found	
	LSP	RPS	LSP	RPS	LSP	RPS
1	15	4	102.12	99.62	99.42	102.16
2			99.02	101.67	102.67	99.00
3			100.49	99.76	99.55	100.49
AVG.			100.54	100.35	100.55	100.55
STD			1.55	1.15	1.84	1.58
%RSD			1.54	1.14	1.83	1.57

Table No. 15: Ruggedness studies for ARM

Sr. No.	Amount Taken [µg/ml]		Analyst-I		Analyst-II	
			% Amount Found [µg/ml]		% Amount Found [µg/ml]	
	LSP	RPS	LSP	RPS	LSP	RPS
1	15	4	98.81	100.99	99.63	100.00
2			99.93	99.93	100.99	98.81
3			101.05	98.86	99.93	99.93
AVG.			99.93	99.93	100.18	99.58
STD			1.12	1.07	0.72	0.67
%RSD			1.12	1.07	0.72	0.67

3.5.6 Specificity: The specificity studies are conducted in Normal, acidic, alkali, oxidative medium and the results of the specificity studies are as

Table No. 16: Results of Specificity study for SEM.

Sr. No.	Sample	% of label claim	
		LSP	RPS
1	Normal	97.38	96.02
2	Alkali	96.65	97.02
3	Acid	96.90	96.85
4	Oxide	95.42	96.01

Table No. 17: Results of Specificity study for ARM

Sr. No.	Sample	% of label claim	
		LSP	RPS
1	Normal	98.00	96.44
2	Alkali	97.12	95.76
3	Acid	94.19	95.08
4	Oxide	95.43	94.52

4. Conclusion

The proposed method was validated as per the ICH Guidelines. The proposed method shows good resolution between LSP and RPS. The method is very simple and rapid and no where involves the complicated sample preparation. The linearity and reproducibility data of the drugs carried out by this method showed that no major interference is caused in the estimation of the drugs. Therefore the method can be used for routine quality control of these drugs.

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