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Uv Spectrophotometric Method For Simultaneous Estimation Of Lansoprazole (Lsp) And Domperidone (Dpd) In Combined Pharmaceutical Formulation

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ABSTRACT

The scope of developing and validating a method is to ensure a suitable strategy for particular analysis which is more specific, reliable, accurate and precise. To develop and validate an accurate, precise, reliable and cost-effective stability indicating UV method for simultaneous estimation of Lansoprazole (LSP) and Domperidone (DPD) in combined pharmaceutical formulation. Lansoprazole (LSP) is used as management of acidity and nausea and vomiting. The wavelength of maximum absorbance for Lansoprazole (LSP) and Domperidone (DPD) was 287.2 nm and 301 nm respectively. The UV method used for analysis was Q-Absorption ratio method; overlain spectra show the isosbestic point at 253nm. The linear regression analysis data for the calibration plots showed good linear relationship with R2=0.9934 and 0.9919 for Lansoprazole (LSP) and Domperidone (DPD) respectively at the concentration range of 2–20 µg/mL for Lansoprazole (LSP) and 2–20 µg/mL µg/mL for Domperidone (DPD). The method was validated for accuracy, precision, specificity and robustness. The proposed developed stability indicating method can be applied for identification and quantitative determination of Lansoprazole (LSP) and Domperidone (DPD) in drug formulation.

Keywords: Method development; Validation; UV-Spectrophotometer; Simultaneous estimation method; Lansoprazole (LSP) and Domperidone (DPD).

1. INTRODUCTION

Lansoprazole (LSP) is chemically, 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl] sulfinyl] benzimidazole. Lansoprazole (LSP) is a proton pump inhibitor (PPI) used to reduce gastric acid secretion. It is commonly prescribed for conditions such as gastroesophageal reflux disease (GERD), peptic ulcers, and Zollinger-Ellison syndrome. Lansoprazole works by inhibiting the H^+/K^+-ATPase enzyme in the stomach lining, providing long-lasting relief from acid-related disorders. Its oral formulations offer rapid absorption and effective symptom control. It has prolonged duration of action up to 24 hrs. It is used when regular administration of a long acting proton pump inhibitor (PPI) is requiring for management of acidity [1, 2].

Domperidone (DPD) is chemically, 5-chloro-1-[1-[3-(2-oxo-2,3-dihydro-1H-benzimidazol-1-yl)propyl]piperidin-4-yl]-1,3-dihydro-2H-benzimidazol-2-one. It is Domperidone (DPD) is a dopamine D_2 receptor antagonist commonly used as a prokinetic and antiemetic agent. It enhances gastrointestinal motility and helps relieve nausea and vomiting [3, 4].

Literature survey on the analytical methods for Lansoprazole (LSP) revealed some reported spectrophotometric methods, some HPLC analysis methods, for the estimation of Lansoprazole (LSP) its dosage forms from human plasma, urine and from pharmaceutical dosage forms. Similarly, literature survey regarding quantitative analysis of Domperidone (DPD) revealed reports on analytical method development for using spectrophotometry, HPLC, HPTLC, HPLC-MS, etc. While, there is only few reports of a UV method for simultaneous estimation of Lansoprazole (LSP) and Domperidone (DPD) [5, 6]. Hence, the present work was a good attempt to develop and validate simple, precise, reliable and accurate UV-Spectrophotometric methods for the simultaneous estimation of the Lansoprazole (LSP) and Domperidone (DPD) as treatment of acidity, nausea, vomiting, gastroparesis, and gastroesophageal reflux

2. MATERIALS AND METHODS

Instrument

UV-visible double beam spectrophotometer, make: Shimadzu double-beam spectrophotometer, model UV-2401 with a pair of 10 mm matched quartz cells was used for experiments. The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 200-400 nm.

Reagents and Chemicals

Micro Labs in Bangalore provided us with complimentary samples of Domperidone and Lansoprazole. All chemicals and reagent used were of AR grade and were purchased from Merck Chemicals, Ltd, India.

Preparation of Standard Solution of Formoterol Fumarate Dihydrate (FFD) and Fluticasone Propionate (FP)

Lansoprazole (LSP): Accurately weigh 10 mg of Lansoprazole and dissolve it in methanol to make 100 mL (100 µg/mL).

Domperidone (DPD): Weigh 10 mg of Domperidone and dissolve it in methanol to prepare 100 mL (100 µg/mL).

Preparation of working Solution

From the above stock solution 1 mL each of LSP and DPD were taken and transferred to separate 10 mL volumetric flasks and the volume was made up to 10 mL with methanol so as to get the concentration of 2µg/mL and 20 µg/mL of LSP and DPD, respectively.

Selection of Detection Wavelength

By appropriate dilution of the standard stock solutions, working standard solutions of suitable concentrations, 10µg/mL, each of LSP and DPD were prepared separately. The standard solutions were then scanned in the spectrum mode of the instrument from 200 nm to 400 nm and their spectra were overlaid (Fig. 3).

Analysis of laboratory mixture

An amount of powder equivalent to 6 mg LSP and 100 mg DPD was transferred into a 100 mL volumetric flask containing 25 mL of methanol and mixed well. The solution was sonicated for 20 min, and then diluted to 100 ml with diluent. From this, 1 mL was pipetted out and transferred to a 10 mL volumetric flask and was diluted to 10 mL with the methanol to get solution containing 6 µg/mL and 100 µg/mL of LSP and DPD respectively. Absorbance of this sample solution was recorded for simultaneous equations at 301nm for LSP and 287.2nm respectively. The concentration was found out by using simultaneous equation [7].

Analysis of marketed formulation

Twenty capsules of marketed formulation of LSP and DPD corresponding to 2µg and 100 µg (Lans DX; Available Strength: 15mg + 10mg Rewine Pharmaceuticals) respectively were weighed; their average weights determined. The correct amount of drug powder equivalent to label claim was weighed and transferred to 10 mL volumetric flask and dissolved in methanol. The volume was then made up to the mark using same solvent. The solutions were filtered through the Whatman filter paper no.41. The filtrate was having concentration 2 µg/mL for LSP and 100 µg/mL for DPD. Absorbance of this sample solution was recorded for simultaneous equations at 301nm for LSP and 287.2nm respectively. Analysis procedure was repeated three times with capsule formulation.

Simultaneous equation method

A solution of LSP (2-20µg/mL) and DPD (2-20 µg/mL) were prepared separately in methanol and the solutions were scanned against blank in the entire UV range to determine the λ max values. Clear peaks were observed at 301 nm for LSP and 287.2nm for DPD. Hence these wavelengths were chosen as the λ max values for each drug respectively. For estimation of FFD the following equation 1 and 2 was used

$$C_x = \frac{A2ay1 - A1ay2}{ax2ay1 - axiay2} C_x = \frac{A2ay1 - A1ay2}{ax2ay1 - axiay2} \text{---------(1)}$$

For estimation of FP the following equation was used

$$C_y = \frac{A1ax2 - A2ax1}{ax2ay1 - ax1ay2} C_y = \frac{A1ax2 - A2ax1}{ax2ay1 - ax1ay2} \text{---------(2)}$$

A1 and A2 are absorbances of diluted mixture at 301nm for LSP and 287.2nm respectively. Cx and Cy concentrations of LSP and DPD respectively (µg/100mL). ax1, ax2, ay1, ay2 are absorptivity of LSP and DPD at 301 nm and 287.2 nm respectively. For the simultaneous equations were formed A1= Absorbance value × Cx + Intercept value Cx ×Cy and A 2= Absorbance value × Cx + Intercept value Cx ×Cy.

The concentration of Cx and Cy can be obtained.

$$\% \text{ Estimation of dru} = \frac{CXD}{W} X\ 100$$

Where C= Concentration of drug gm/100ml, D= Dilution factor, W= Weight of drug

Preparation of calibration curve

From the stock solution of Lansoprazole (LSP) and Domperidone (DPD) prepare series of dilutions in the concentration range of 2-20 µg/mL for LSP and 2-20 µg/mL for DPD. Absorbance of each dilution at their respective wavelengths (301nm for LSP and 287.2nm for DPD) were recorded. Linearity was obtained by plotting the graph of concentration vs. absorbance. Fig 4 and Fig 5.

Method validation

Validation was done as per ICH guidelines. The developed method was validated with respect to parameters such as linearity, limit of detection (LOD) and limit of quantitation (LOQ), precision, accuracy and robustness [8].

Linearity

For each drug, appropriate aliquots of 1mL, 2 mL 3 mL, 4 mL 5mL, and 6 mL standard working solutions were transferred to a series of 10 mL volumetric flasks. The volume was made up to the mark with methanol to obtain standard stock solutions for each drug of concentrations of 2-20 µg/mL for LSP and 2-20 µg/mL for DPD. The absorbance of each of these solutions were measured at the selected wavelengths and plotted against their concentrations (Fig. 1, Fig. 2).

Accuracy

To study the accuracy of the proposed method, recovery study was carried out by standard addition method at three different levels (80 %, 100 % and 120 %). Where known amount of pure drugs concentration for LSP 4.8 µg, 6 µg, and 7.2 µg and for DPD 80 µg, 100 µg and 120 µg was added to preanalysed formulation and percentage recoveries were calculated. The recovery experiments indicated the absence of interference from the commonly encountered pharmaceutical additives and excipients. Three determinations at each level were performed and % RSD was calculated.

Precision

The precision of the method was verified by intra-day and inter-day precision studies. Intra-day precision studies were performed by analysis of three different concentrations 12, 24, 36 µg/mL for LSP and 40, 80, 120 µg/mL for DPD three times on the same day. The inter-day precision of the method was checked by repeating studies on three different days.

Limit of detection and limit of quantitation

The LOD and LOQ were calculated by using the 3.3 σ/s and 10 σ/s criteria, respectively; where σ is the standard deviation of the absorbance and s is the slope of the corresponding calibration curve.

Robustness

Robustness was assessed by deliberately changing the spectrophotometric conditions and studying the effects on the results obtained. The proposed method was analysed by making deliberate changes in the detection wavelength ± 1 nm (301nm and 287.2nm). The absorbances were observed and % RSD was determined [9].

3. RESULTS AND DISCUSSION

Selection of analytical wavelength

In order to obtain accurate and reproducible results, the wavelength selected should be such that at each wavelength, the absorptivity difference between two drugs should be as large as possible. From the spectra wavelength were selected as 301nm for LSP and 287.2nm for DPD. The UV spectra of LSP and DPD are shown in Fig. 1 and Fig. 2.

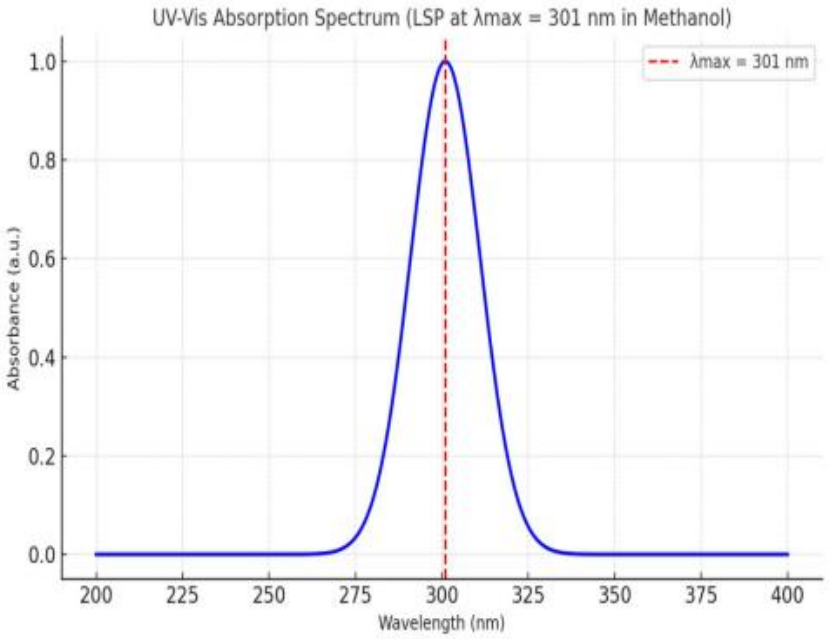

Fig. 1: UV absorption spectra of LSP.

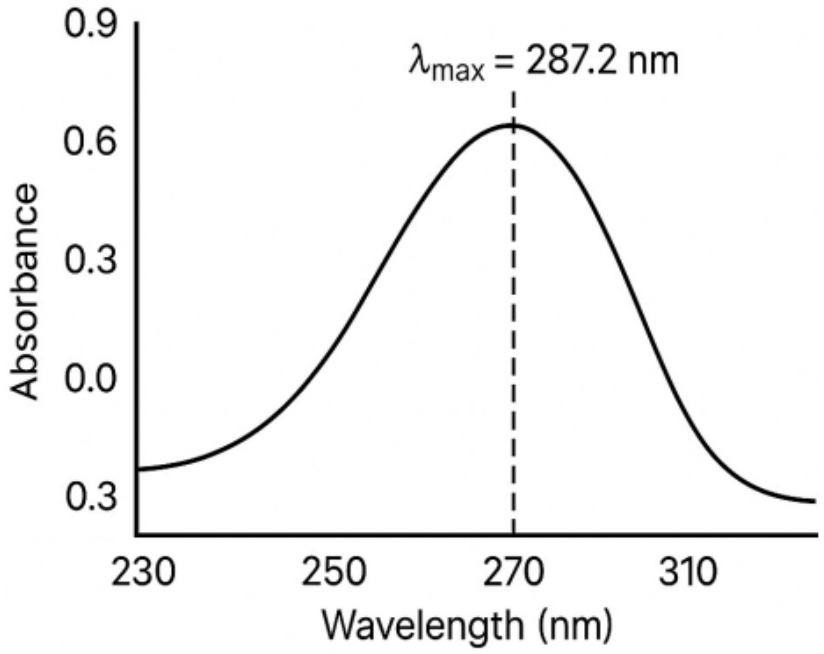

Fig. 2: UV absorption spectra of DPD.

Overlain spectra of LSP and DPD

The method was based on spectrophotometric simultaneous estimation of LSP and DPD in UV region. From the solubility point of view, attempt was made to dissolve both drugs in methanol. The absorbance spectral analysis shows the maximum absorbance (λ max) at 301 nm for LSP and 287.2nm for DPD. This method was based on simultaneous equation method which involves solving of simultaneous equations using absorptivity coefficient (A1, A2) values and absorbance at 287.2nm and 301 nm for estimation of LSP and DPD in standard and sample mixture. The overlain spectrum of LSP and DPD is shown in Fig. 3.

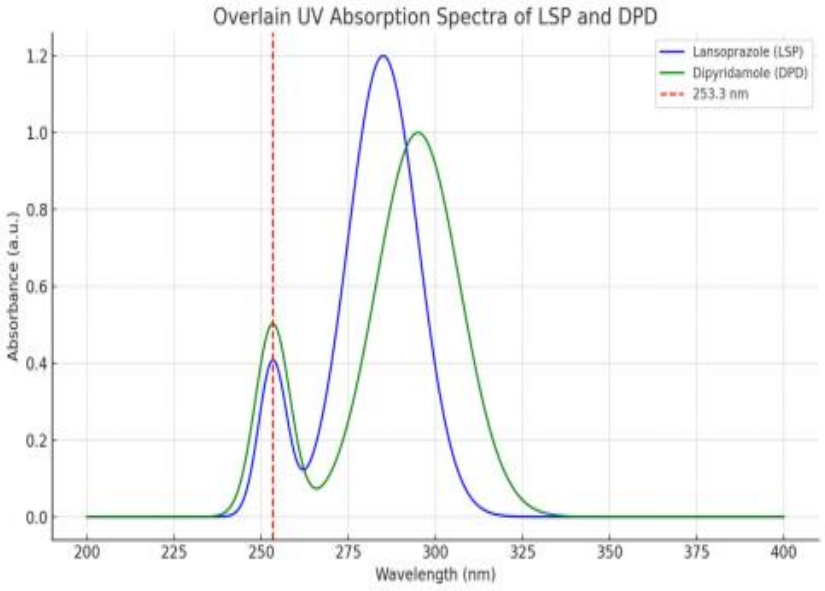

Fig. 3: Overlain UV absorption spectra of FFD and FP.

Here is the simulated overlain UV absorption spectrum of Lansoprazole (LSP) and Dipyridamole (DPD):

Blue curve: Lansoprazole, showing a primary peak around 285 nm and a shoulder at 253.3 nm.

Green curve: Dipyridamole, with a primary peak around 295 nm and a noticeable absorbance at 253.3 nm.

The red dashed line marks 253.3 nm, where both drugs exhibit some absorbance this wavelength can be suitable for simultaneous estimation if properly validated.

Study of Beer Lambert Law

To study the Beer Lambert law of LSP and DPD at the both wavelengths. The data is given in Table 3.

E (1% 1cm) of drugs calculated by using following formula and the result was shown in Table 1 & Table 2, respectively.

$$E(1\%\ 1cm) = \frac{\text{Absorbance}}{\text{Conc.}(gm/100ml)}$$

Table 1: E (1% 1cm) Data for LSP at 301 nm and 287.2 nm.

Concentration (µg/mL)	Absorbance at 215 nm	E 1 cm 1 %	Absorbance at 236 nm	E 1 cm 1 %
10	0.1510	151.15	0.1610	161.00
10	0.1430	143.07	0.1600	160.07
10	0.1402	140.22	0.1606	160.61
10	0.1421	142.10	0.1604	160.40
10	0.1380	138.022	0.1605	160.05
10	0.1372	137.25	0.1560	156.00
Mean		141.75		160.28
SD		1.51		1.67
RSD		0.83		1.04

Table 2: E (1% 1cm) Data for DPD at 301 nm and 287.2 nm.

Concentration (µg/mL)	Absorbance at 215 nm	E 1 cm 1 %	Absorbance at 236 nm	E 1 cm 1 %
40	0.2820	97.14	0.3044	147.24
40	0.2727	94.94	0.3007	101.6
40	0.2651	93.04	0.28313	96.45
40	0.2347	85.35	0.28957	90.81
40	0.2320	84.65	0.27825	86.23
40	0.23021	84.07	0.28817	81.71
Mean		90.81		104.22
SD		0.61		1.80
RSD		1.37		1.82

Validation of the method

Using optimised UV spectrophotometric conditions, the simultaneous equation method developed was validated in terms of linearity, LOD and LOQ, precision, accuracy and robustness.

Linearity

Linear regression data for the good correlation is observed between response and concentration over the ranges µg/mL for LSP and DPD, respectively. The calibration curves are given in Fig. 4 and Fig. 5 for LSP and DPD, respectively and the details of linearity is shown in Table 3.

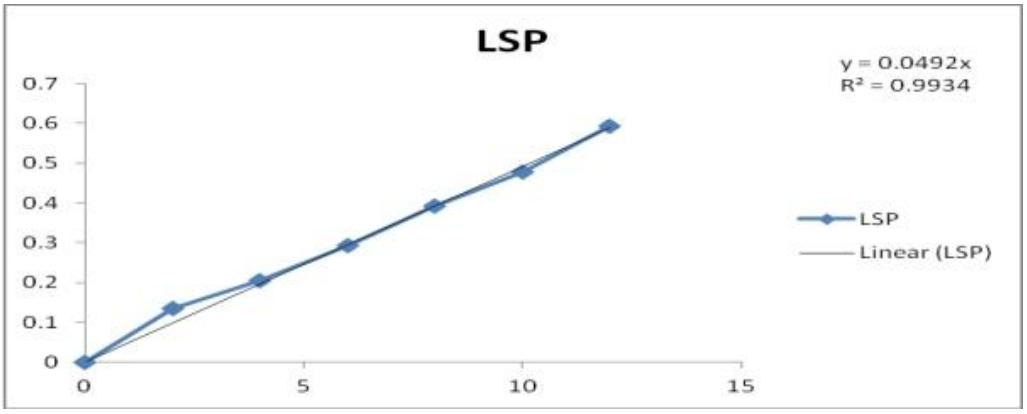

Fig. 4: Calibration curve for LSP.

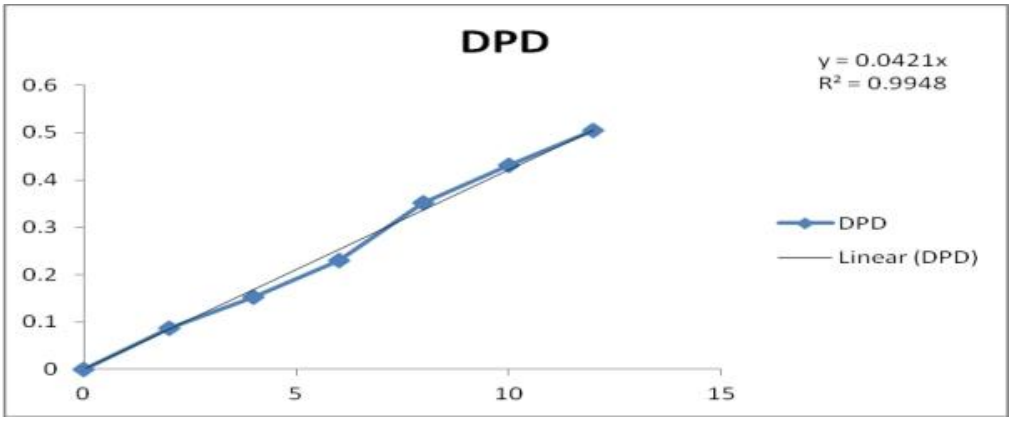

Fig. 5: Calibration curve for DPD.

Table 3: Data for LSP and DPD from linearity study.

S.N.	Concendration (µg/ml)	DPD	LSP
1	0	0	0
2	2	0.087	0.136
3	4	0.153	0.204
4	6	0.230	0.294
5	8	0.351	0.393
6	10	0.432	0.478
7	12	0.504	0.593
Slope		0.01546	0.03543
Intercept		0.004736	0.00279
Regression equation		y = 0.0422x + 0.00379	y = 0.0492x + 0.00168
Correlation Coefficient (r2)		R^2 = 0.9919	R^2 = 0.9934

Limits of Detection and Quantitation

The signal to noise ratios of 3:1 and 10:1 was considered as LOD and LOQ respectively. The LOD value was found to be 1.5µg/mL and 0.80µg/mL while LOQ value was found to be 0.47 µg/mL and 2.45 µg/mL for LSP and DPD respectively.

Precision

The mean % RSD of intraday and inter day precision values for FFD and FP were found to be 0.94 and 1.10 and 1.11 and 1.12 %, respectively. The RSD values were found to be <2 %, which indicates that the proposed method is precise. The precision studies data are shown in Table 4.

Table 4: Precision studies data for FFD & FP (*n=3).

S.N.	Time (Hours)	DPD	LSP
1	1	0.432	0.478
2	2	0.431	0.479
3	3	0.430	0.476
4	4	0.434	0.480
5	5	0.430	0.479
6	6	0.430	0.478
Mean		0.453	0.431
SD		0.001251	0.0015
%RSD		0.27	0.26

Accuracy

The accuracy of the proposed method was determined by recovery experiment using standard addition method. The proposed method when used for extraction and subsequent estimation of LSP and DPD from pharmaceutical dosage form after spiking with 80%, 100% and 120% of the additional drug afforded mean recovery of 99.05 % for LSP and 99.87 % for DPD. The mean recoveries indicate non-interference from excipients. The data of recovery studies are shown in Table 5.

Table 5: Recovery studies data.

Label claim (µg/capsule)	Total amount (µg)	Amount recovered (µg)	(%) Recovery	Mean (%) Recovery (±SD)
FFD 6	10.9	10.827	99.33	99.05 ± 0.0703
	13.0	12.821	98.62	
	14.2	14.089	99.21	
FP 100	190	189.91	99.95	99.87 ± 0.2243
	200	199.99	99.999	
	230	229.29	99.69	

Robustness

Robustness was performed by detection wavelength ± 1 nm. The result showed no statistical differences suggesting that the developed method was robust. Robustness values of LSP and DPD are mentioned in Table 6.

Table 6: Robustness evaluation of LSP and DPD.

Drugs Detection	Level (± 1 nm)	Absorbance	% RSD
LSP	- 1.0	0.1602	1.02
	0.0	0.1613	1.04
	+ 1.0	0.2738	1.07
FP	- 1.0	0.2687	1.05
	0.0	0.2627	1.09
	+ 1.0	0.2622	1.03

***Mean of the three determinations**

Analysis of laboratory mixture

The results of laboratory mixture are shown in Table 7. The results were found for the estimation of LSP and DPD is 99.80 % and 99.87 respectively. The satisfactory result was found; hence this method is applied for marketed formulation.

Table 7: Analysis of laboratory mixture.

Drugs	% Content found*	S.D.	% R.S.D.
LSP	99.80	1.89	1.9
DPD	99.97	1.43	1.46

*Mean of the three determinations

Analysis of Marketed formulation

Experimental results of the amount of formoterol fumarate dihydrate and fluticasone propionate in capsules, expressed as percentage of label claim were in good agreement with the label claims thereby suggesting that there is no interference from any excipients, which are normally present in capsules. The mean contents of LSP and DPD per capsule by proposed method results are summarized in Table 8.

$$\% \text{ Label Claim} = \frac{\text{Amount Estimated X W X D}}{\text{Wm X L}} X\ 100$$

Where W= Average weight of tablet, Wm= Weight of sample taken, D= Dilution factor, L= Label claim of drug.

Table 8: Analysis of marketed formulation.

Maxiflo-100 Rotacaps	Amount found (µg) %	% Content found*	S.D.	%R.S.D.
FFD	20	99.76	1.6968	1.6020
FP	10	99.60	1.3585	1.3459

*Mean of the three determinations

4. CONCLUSION

In the present study, simultaneous equation of UV spectrophotometric method was developed and validated as per ICH guidelines for some pharmaceutical formulation. The developed method has been validated for the linearity, accuracy, precision and robustness in order to ascertain the suitability of the analytical method. As the methods are found to be precise, robust and accurate, thus the newly developed analytical methods can be used for the simultaneous estimation of LSP and DPD in bulk as well as capsule formulation in research institutions, industries and testing laboratories for routine analysis.

5. ACKNOWLEDGEMENT

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6. CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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REFERENCES

1. Kennedy J H, Analytical Chemistry–Principals, 2nd ed. New York: Saunders College Publishing; 1990, p. 1-8.
2. A P Sherje, A V Kasture, K N Gujar, P G Yeole. Simultaneous spectrophotometric determination of lansoprazole and domperidone in capsule dosage form. Indian J Pharm Sci 2008 Jan;70(1):102-5. doi: 10.4103/0250-474X.40343.
3. Goodman & Gillman's, The Pharmacological Basis of Therapeutics, 2001, 10th Edition, 736-740.
4. Manish Kumar, Ajay Kumar Shukla, Ram Singh Bishnoi, C.P. Jain. Development of UV-spectrophotometric method for the determination of benidipine hydrochloride by using quality by design (QbD) approach. Int J App Pharm, 2018;10(4):92-97.
5. Parmar V K, Patel H N, Patel B K. "Sensitive and robust methods for simultaneous determination of beclomethasone dipropionate and formoterol fumarate dihydrate in rotacaps". Journal of Chromatographic Science. 2014; 52 (10):1255-66.
6. Malik K, Kumar D, Tomar V, Kaskhedikar S, Soni S. Simultaneous Quantitative Determination of Formoterol Fumarate and Fluticasone Propionate by Validated Reversed-Phase HPLC Method for Metered dose inhaler. Der Pharmacia Sinica. 2011; 2 (6): 77-84.
7. Kalsi P S, Spectroscopy of Organic Compounds, 6th ed. New Delhi: New Age International Publishers; 2007, p. 7-10.
8. Skoog D A, West D M, Holler F J, In: Fundamental of Analytical Chemistry, An Introduction, 7th ed. Landon: Saunders College Publication; 1996, p.973-992.
9. Sharma B K, Instrumental Methods of Chemical Analysis; 11th ed. Meerut: Goel Publishing House; 1991, p. 1-9...