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UV-SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF LORNOXICAM AND EPERISONE HYDROCHLORIDE IN BULK DRUG, FORMULATIONS AND AQUEOUS DISSOLUTION SAMPLES

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Keywords:

Two wavelength difference method, UV spectrophotometry, Lornoxicam, Eperisone Hydrochloride, Simultaneous estimation, Bulk drugs, Dissolution samples

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ABSTRACT: Lornoxicam has been found to be not interacted by eperisone hydrochloride at 377 nm. Therefore, it is estimated directly as a single component in the mixture, whereas eperisone hydrochloride is throughout interfered with by lornoxicam in UV region. So, it was estimated in the mixture using a two-wavelength difference method. Lornoxicam was found to have same absorbance at 262 nm and 283 nm but not eperisone hydrochloride. So, a difference in absorbance of the mixture at 262 nm and 283 nm was directly proportional to the concentration of eperisone hydrochloride. The calibration curves were validated according to ICH guidelines and were linear over the concentration range tested (10-20 µg/ml for lonoxicam and 3-24 µg/ml for eperisone hydrochloride). The curves were found to be precise and accurate as shown by acceptable limits of %RSD (0.37%-0.66%) and percent recoveries (98.73% ± 1.02%-102.44% ± 0.90%) respectively for both the drugs in mixture as well as in pure solutions.

INTRODUCTION: Central Drugs Standard Control Organization (CDSCO) has approved a combination of lornoxicam 4 mg and eperisone 50 mg tablet for improvement of myotonic conditions caused by neck shoulder arm syndrome, scapulohumeral periarteritis and low back pain in adult patients only [1]. Lornoxicam, an oxicam derivative, is a non-steroidal anti-inflammatory drug (NSAID).

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It is used in musculoskeletal and joint disorders like osteoarthritis and rheumatoid arthritis; it is also used in the treatment of other painful conditions including postoperative pain [2]. Lornoxicam is given in oral doses of 8 mg to 16 mg daily for the treatment of pain. It is available in oral and parental dosage forms.

Eperisone is a centrally acting skeletal muscle relaxant that has been used in the symptomatic treatment of muscle spasm and spasticity. It may also have a vasodilator action. Eperisone hydrochloride has been given by mouth in usual doses of 50 mg three times daily after food [3]. There is no official method reported for estimation of Lornoxicam in any of the pharmacopoeia. Eperisone hydrochloride is official in Japanese

Pharmacopoeia (XV) 2006 and the official method for assay is potentiometric method [4].

Various UV, HPTLC, and HPLC methods are reported for lornoxicam alone or in combination with other drugs [5-8]. Similarly, some chromatographic methods are found for evaluation of eperisone hydrochloride alone [9, 10] and in combination with lornoxicam [11, 12]. Various UV spectrophotometric methods are also found to be developed by various authors for simultaneous estimations of these two drugs. In this sequence, Javed Akhtar *et al.*, 2015 validated an absorbance ratio method for their simultaneous estimation of these drugs in synthetic mixture [13]. They used 0.1N methanolic sodium hydroxide as solvent. So, this method is not suitable for the estimation of aqueous dissolution samples. Similarly methods developed by Patel and Prajapati, 2013 [14], Parikh *et al.*, 2015 [15] and Javed Akhtar *et al.*, 2015 [16] cannot be used for quantitative simultaneous estimation of lornoxicam and eperisone hydrochloride in aqueous samples.

Some methods are also available for eperisone hydrochloride alone or in the combination of other drugs.

In this sequence, Andhale MM *et al.*, 2016 [17] estimated of eperisone hydrochloride in combination with paracetamol and cannot be used because the wavelengths of interaction are different from those of interest. In an HPLC method by Patil S *et al.*, 2018 [18] eperisone hydrochloride was alone estimated in non-aqueous medium and thus cannot be used for estimation of aqueous dissolution samples.

Methods by Mahrous GM *et al.*, 2019 [19] can also not be used for similar reasons for the evaluation of lornoxicam in aqueous samples. No dissolution media has been recommended in various official compendia. However, various writers have recommended fasting and fed state simulated intestinal fluid for lornoxicam [20] and phosphate buffer pH 6.8 for eperisone hydrochloride [21]. Therefore, the method is developed in phosphate buffer pH 6.8 as solvent along with appropriate cosolvent.

The aim of the present work was to develop a simple, precise and accurate UV spectrophotometric method for simultaneous assay of lornoxicam and eperisone hydrochloride in bulk drug, pharmaceutical dosage forms, physical mixture and dissolution samples. The method was validated according to ICH Q2 (R1) guidelines [22].

Overlay spectra of the two drugs showed that lonoxicam showed a peak maximum at 377 nm **Fig. 1** whereas eperisone hydrochloride shows zero absorption at the same wavelength. So lornoxicam was evaluated at 377 nm making a calibration curve of the mixture at 377 nm.

As far as the evaluation of eperisone hydrochloride is concerned, it is interfered by lornoxicam everywhere in its peak range **Fig. 1**. So, a two-wavelength difference method has been developed for estimation of eperisone hydrochloride. In this method two such wavelengths are selected for estimation of a component at both of which the absorbance of interacting component is the same. Two such wavelengths selected are 262 nm and 283 nm at both of which lornoxicam has same absorbance. Thus, the absorbance difference at these two wavelengths is directly proportional to the concentration of eperisone hydrochloride.

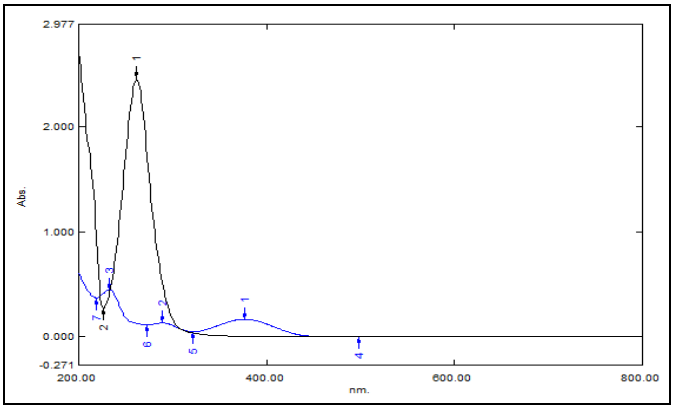

FIG. 1: OVERLAIN SPECTRA OF THE DRUGS IN LORNOXICAM AND EPERISONE HYDROCHLORIDE

MATERIALS AND METHODS:

Materials: Lornoxicam and eperisone hydrochloride are gift samples from sun pharmaceutical limited, Mumbai and Ranbaxy laboratories limited, Gurgaon, respectively. Other chemicals used were of analytical reagent grade.

Solvent System: Methanol: Phosphate buffer pH 6.8 in the ratio of 1: 2 as cosolvent or extraction medium and phosphate buffer pH 6.8 as solvent or diluent.

Methods:

Preparation of Stock Solutions of Lornoxicam and Eperisone Hydrochloride: 1000 µg/ml stock solutions of lornoxicam (A) and eperisone hydrochloride (B) were prepared by dissolving 50 mg of the two drugs each in 1: 2 ratio of methanol: phosphate buffer pH 6.8 in two separate 50 ml volumetric flasks, making the volume up to the mark with the same solvent.

Preparation of Mixed Standard Stock Solutions: The formulation was approved, having 4.0 mg lornoxicam and 50 mg eperisone hydrochloride. So, mixed standard solutions were prepared having both the drugs in the same ratio. One mixed standard solution (C) was prepared to have 30 µg/ml and 375 µg/ml concentrations of lornoxicam and eperisone hydrochloride respectively.

For preparing this solution, 3 ml of the stock solution A and 37.5 ml of the stock solution B were transferred to a 100 ml volumetric flask and volume was made up to mark with phosphate buffer pH 6.8. Another mixed standard solution (D) was prepared to have 8 µg/ml and 100 µg/ml concentrations of lornoxicam and eperisone hydrochloride respectively. For preparing this solution, 0.8 ml of the stock solution A and 10 ml of the stock solution B were transferred to a 100 ml volumetric flask, and the volume was made up to the mark with phosphate buffer pH 6.8.

Preparation of Calibration Curve of Lornoxicam: Various aliquots of the mixed stock solution C were transferred to 10 ml volumetric flasks so as to prepare various working standard dilutions of 3, 6, 9, 12, 15, 18, 21 and 24 µg/ml with regard to lornoxicam and the volume was made up to mark with phosphate buffer pH 6.8. The calibration curve was prepared from these dilutions against phosphate buffer pH 6.8 between concentration and absorbance at 377 nm.

Preparation of Calibration Curve of Eperisone Hydrochloride: Various aliquots of the mixed stock solution D were transferred to 10 ml volumetric flasks so as to prepare various working standard dilutions of 10, 12, 14, 16, 18 and 20 µg/ml with regard to eperisone hydrochloride and the volume was made up to the mark with phosphate buffer pH 6.8. The calibration curve was prepared from these dilutions against phosphate buffer pH 6.8 between concentration and absorbance difference at 262 nm and 283 nm.

Method Validation: The method was validated according to ICH Q2 (R1) guidelines[22] for the following parameters.

Specificity: Mixed standard solutions of the drugs is known concentrations (10.8 µg/ml, 13.5 µg/ml and 16.2 µg/ml for lornoxicam containing eperisone hydrochloride at the level of 135 µg/ml, 168.75 µg/ml and 202.5 µg/ml respectively; and 12 µg/ml, 15 µg/ml and 18 µg/ml for eperisone hydrochloride containing lornoxicam at the level of 0.96 µg/ml, 1.2 µg/ml and 1.44 µg/ml respectively) were prepared separately in the given solvent system. Pure standard solutions in the same concentrations were also prepared. All solutions were scanned between 400 to 200 nm. All the spectra were observed for any difference in the wavelengths of study, and in absorbance/ corrected absorbance at wavelengths of study for pure and mixed standards.

Linearity: The linearity of the calibration curves prepared was determined using linear regression analysis. The linearity was also be proved by test for residuals [23].

Precision: Repeatability was determined by analyzing different levels of drug concentrations in mixed standards from independent stock solutions (n=6). Intraday and interday variations in estimation were determined to assess intermediate precision of the proposed method. Different levels 80%, 100%, and 120% of drug concentrations (in mixed standards) in 6 replicates were analyzed three times in a day for intraday variation. The same method was followed for three different days to study interday variation. The precision was determined as the percent relative standard deviation.

Accuracy: The accuracy studies were performed at three levels, *i.e.* 80%, 100%, and 120% by adding known amounts of the drug to a known concentration of the standard and analyzing the drug content (standard addition method).

Limit of Detection and Limit of Quantification: The limit of detection (LOD) and limit of quantification (LOQ) of the drugs by the proposed

method were determined using calibration standards. The LOD and LOQ were calculated as per equations 1 and 2 respectively, (ICH Guidelines Q2 (R1), 2005) [22].

$$LOD = 3.3 (SD_{Intercept} / Slope) \quad .....(1)$$

$$LOQ = 10 (SD_{Intercept} / Slope) \quad .....(2)$$

Where "$SD_{intercept}$" is the standard deviation of the intercept of regression line and "Slope" is the slope of the calibration curve.

RESULTS AND DISCUSSION: The spectrophotometric determination of lornoxicam and eperisone hydrochloride was studied using a UV spectrophotometer. This method was based on difference spectrophotometry.

The overlain spectra of the two drugs are shown in **Fig. 1**. Lornoxicam showed absorbance maxima at 377 nm where eperisone hydrochloride was found to have nil absorbance indicating eperisone hydrochloride did not interfere with lornoxicam at 377 nm. Hence, the calibration curve of lornoxicam was prepared at its λmax, *i.e.* 377 nm. On the other hand eperisone hydrochloride was found to be interfered by lornoxicam throughout the scanning range. So, two such wavelengths were selected for estimation of eperisone hydrochloride at both of which the absorbance of lornoxicam was the same. Two such wavelengths observed were 262 nm and 283 nm, at both of which lornoxicam was found to have the same absorbance. Thus, the absorbance difference at these two wavelengths was directly proportional to the concentration of eperisone hydrochloride. So, the calibration curve of eperisone hydrochloride was prepared by plotting corrected absorbance (difference in absorbance at 262 nm (A_{262}) and that at 283 nm (A_{283})) on X-axis and concentration of eperisone hydrochloride on Y-axis. The calibration curves for lornoxicam and eperisone hydrochloride are presented in **Fig. 2** and **3** respectively.

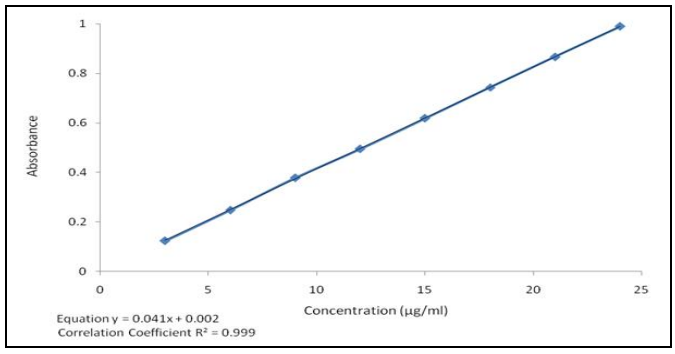

FIG. 2: CALIBRATION CURVE OF LORNOXICAM

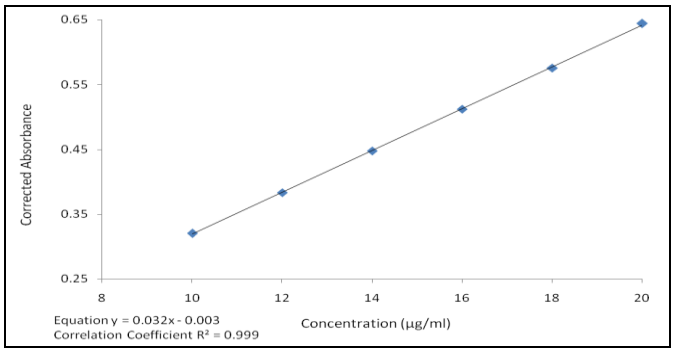

FIG. 3: CALIBRATION CURVE OF EPERISONE HYDROCHLORIDE

The Beer's law was obeyed and validated from 3 µg/ml-24 µg/ml for lornoxicam and 10 µg/ml-20 µg/ml for eperisone hydrochloride. The linear regression equations were found to be A=0.041C+0.002 (r=0.999, n=6) for lornoxicam and A=0.032C-0.003 (r=0.999, n=6) for eperisone hydrochloride **Table 1**, where C is the concentration in µg/ml, A is the absorbance/ corrected absorbance and r is the correlation coefficient.

TABLE 1: REGRESSION PARAMETERS FOR CALIBRATION CURVES

Parameter	Lornoxicam	Eperisone hydrochloride
Analytical wavelengths (nm)	λmax = 377	λ1= 262 and λ2 = 283
Linearity range (µg/ml)	10-20	03-24
Regression equation	a = 0.041	a = 0.032
(A = aC+b)[a]	b = 0.002	b = -0.003
$SD_{Intercept}$ (n=6)	1.10×10^{-3}	6.12×10^{-3}
Correlation coefficient (r)	0.999	0.999

[a]A= Absorbance, C = Concentration, a= Slope and b= Intercept

$SD_{Intercept}$ = Standard deviation of intercept,

λ_{max} = wavelength of maximum absorbance

λ1 and λ2 = wavelengths at which absorbance of lornoxicam was found to be equal

The linearity was also be proved by test for residuals. A linear relationship between predicted versus observed quantities and a random pattern of residuals supports the linearity for both curves [23] as shown in **Table 2-3** and **Fig. 4-7**.

TABLE 2: DATA FOR METHOD OF RESIDUALS FOR LORNOXICAM

Variable Concentration (µg/ml)	Predicted Concentration (C_P) (µg/ml)	Observed Concentration (C_O) (µg/ml)	Residual Concentration (C_P-C_O) (µg/ml)
3	3	2.97	-0.03
6	6	5.99	-0.01
9	9	9.17	0.17
12	12	12.03	0.03
15	15	15.03	0.03
18	18	18.07	0.07
21	21	21.09	0.09
24	24	24.07	0.07

TABLE 3: DATA FOR METHOD OF RESIDUALS FOR EPERISONE HYDROCHLORIDE

Variable Concentration (µg/ml)	Predicted Concentration (C_P) (µg/ml)	Observed Concentration (C_O) (µg/ml)	Residual Concentration (C_P-C_O) (µg/ml)
10	10	10.10	0.10
12	12	12.07	0.07
14	14	14.08	0.08
16	16	16.09	0.09
18	18	18.08	0.08
20	20	20.22	0.22

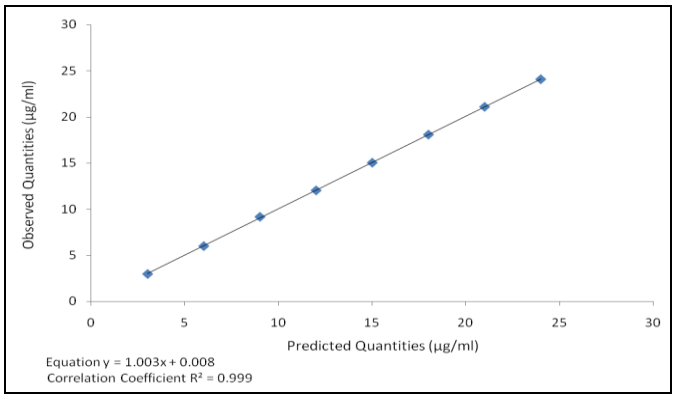

FIG. 4: PREDICTED QUANTITIES VERSUS OBSERVED QUANTITIES OF LORNOXICAM

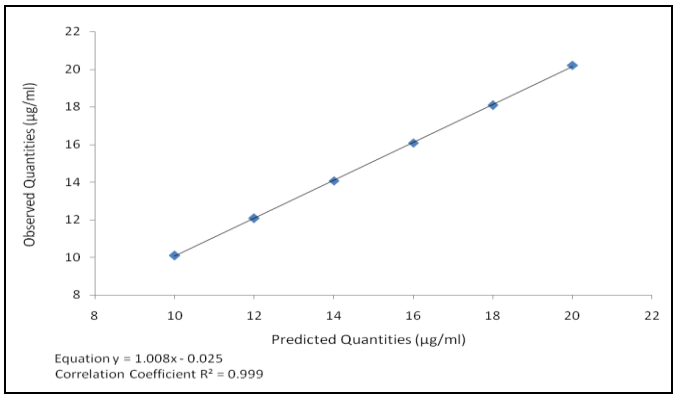

FIG. 5: PREDICTED QUANTITIES VERSUS OBSERVED QUANTITIES OF EPERISONE HYDROCHLORIDE

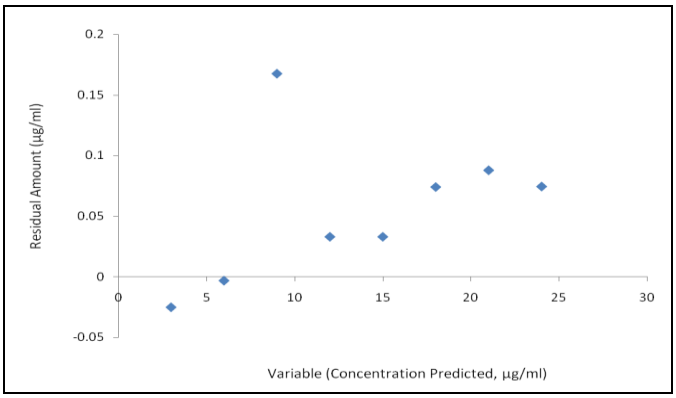

FIG. 6: RESIDUAL AMOUNT V/S VARIABLE CURVE FOR LORNOXICAM

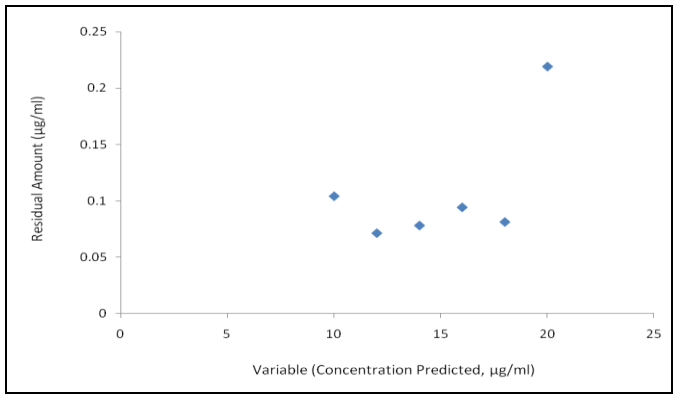

FIG. 7: RESIDUAL AMOUNT V/S VARIABLE CURVE FOR EPERISONE HYDROCHLORIDE

The validity of the method for specificity, repeatability, precision, and accuracy according to recommendations was tested (ICH Guidelines Q2 (R1), 2005) [22]. The method was validated for estimation of the drugs in pure as well as mixed standards. The results are presented in **Table 4-8**.

There was observed no difference in the wavelength/s of study. The method was found to be specific as indicated by less than 0.78% difference in absorbance and corrected absorbance of pure and mixed standard solutions (with common excipients) of lornoxicam (at 10.8 µg/ml, 13.5 µg/ml and 16.2 µg/ml) and eperisone hydrochloride (at 12 µg/ml, 15 µg/ml and 18 µg/ml) of the drugs **Table 4**.

TABLE 4: SPECIFICITY STUDIES FOR THE DEVELOPED ANALYTICAL METHOD

Pure Standards				
Conc. taken (µg/ml)	**Absorbance/ Corrected Absorbance****		**Absorbance/ Corrected Absorbance Diff. (A1-A2)**	**% Diff. w. r. t. A1**
	Drug (A1)	**Drug + Excipients (A2)**		
Lor Alone (Standard)				
10.8	0.446 ± 0.003	0.447 ± 0.003	0.001	0.22
13.5	0.557 ± 0.003	0.558 ± 0.003	0.001	0.18
16.2	0.664 ± 0.002	0.665 ± 0.003	0.001	0.15
Epr Alone (Standard)				
12.0	0.384 ± 0.002	0.383 ± 0.002	-0.001	-0.09
15.0	0.487 ± 0.002	0.488 ± 0.003	0.001	0.10
18.0	0.575 ± 0.003	0.577 ± 0.004	0.002	0.32
Mixed Standards				
Conc. taken (µg/ml)	**Absorbance/ Corrected Absorbance****		**Absorbance/ Corrected Absorbance Diff. (A3-A4)**	**% Diff. w. r. t. A3**
	Drug (A3)	**Drug + Excipients (A4)**		
Lor (Standard) : Epr mixture at 4:50 ratio				
10.8	0.447 ± 0.003	0.445 ± 0.002	-0.002	-0.45
13.5	0.557 ± 0.003	0.559 ± 0.003	0.002	0.36
16.2	0.666 ± 0.004	0.664 ± 0.003	-0.002	-0.30
Epr (Standard) : Lor mixture at 50:4 ratio				
12.0	0.383 ± 0.002	0.386 ± 0.002	0.003	0.78
15.0	0.486 ± 0.002	0.488 ± 0.003	0.002	0.34
18.0	0.573 ± 0.002	0.571 ± 0.001	-0.002	-0.32

**Mean ± SD of 6 replicate determinations

TABLE 5: REPEATABILITY STUDIES FOR THE DEVELOPED ANALYTICAL METHOD

Solution	**Concentration of drug solution (µg/ml)**								**RSD**
	Prepared	**Found**							
		1	**2**	**3**	**4**	**5**	**6**	**Mean***	
Lor Alone	**13.5**	13.66	13.49	13.54	13.54	13.51	13.59	13.55 ± 0.06	0.45
Lor + Epr^	**13.5**	13.66	13.49	13.54	13.49	13.49	13.59	13.54 ± 0.07	0.51
Epr Alone	**15.0**	15.44	15.25	15.31	15.31	15.28	15.38	15.33 ± 0.07	0.44
Epr + Lor~	**15.0**	15.34	15.25	15.31	15.22	15.28	15.38	15.30 ± 0.06	0.38

*Mean ± SD; ^Lor (Standard): Epr mixture at 4:50 ratio; ~Epr (Standard): Lor mixture at 50:4 ratio

TABLE 6: INTRADAY PRECISION OF DEVELOPED ANALYTICAL METHOD

Solution	**Concentration of drug solution (µg/ml)**					**RSD**
	Prepared	**Found**				
		t1**	**t2****	**t3****	**Mean***	
Lor Alone	10.8	10.84±0.08	10.83±0.03	10.86±0.07	10.84±0.06	0.56
	13.5	13.55±0.06	13.48±0.11	13.57±0.06	13.54±0.08	0.61
	16.2	16.16±0.06	16.13±0.04	16.21±0.08	16.17±0.07	0.42
Lor + Epr^	10.8	10.87±0.07	10.87±0.06	10.87±0.08	10.87±0.07	0.60
	13.5	13.54±0.07	13.55±0.05	13.56±0.07	13.55±0.06	0.49
	16.2	16.19±0.07	16.18±0.05	16.17±0.07	16.18±0.06	0.46
Epr Alone	12.0	12.09±0.05	12.02±0.04	12.07±0.04	12.06±0.05	0.43
	15.0	15.33±0.07	15.26±0.09	15.26±0.10	15.28±0.09	0.59
	18.0	18.05±0.08	18.07±0.07	18.03±0.09	18.05±0.08	0.43
Epr + Lor~	12.0	12.06±0.06	12.07±0.05	12.09±0.03	12.07±0.05	0.42
	15.0	15.30±0.06	15.35±0.08	15.33±0.08	15.33±0.07	0.47
	18.0	17.99±0.06	18.03±0.08	18.04±0.07	18.02±0.07	0.37

*Mean ± SD of 18 determinations (6 replicate determinations every time for 3 points of time in a day), **Mean±SD of 6 replicate determinations; ^Lor (Standard): Epr mixture at 4:50 ratio; ~Epr (Standard): Lor mixture at 50:4 ratio

TABLE 7: INTERDAY PRECISION OF DEVELOPED ANALYTICAL METHOD

Solution	Concentration of drug solution (µg/ml)					RSD
	Prepared	Found				
		t1**	t2**	t3**	Mean*	
Lor Alone	10.8	10.84±0.08	10.85±0.07	10.86±0.08	10.85±0.07	0.66
	13.5	13.55±0.06	13.57±0.06	13.57±0.06	13.56±0.06	0.43
	16.2	16.16±0.06	16.17±0.08	16.17±0.09	16.17±0.07	0.45
Lor + Epr^	10.8	10.87±0.07	10.81±0.04	10.82±0.09	10.83±0.07	0.63
	13.5	13.54±0.07	13.58±0.07	13.54±0.06	13.55±0.07	0.49
	16.2	16.19±0.09	16.14±0.06	16.22±0.06	16.19±0.07	0.46
Epr Alone	12.0	12.09±0.05	12.08±0.05	12.18±0.10	12.12±0.08	0.66
	15.0	15.33±0.07	15.34±0.08	15.30±0.05	15.32±0.07	0.44
	18.0	18.05±0.08	18.11±0.11	18.13±0.08	18.10±0.09	0.52
Epr + Lor~	12.0	12.06±0.06	12.15±0.05	12.04±0.06	12.08±0.08	0.63
	15.0	15.30±0.06	15.35±0.11	15.28±0.07	15.31±0.08	0.54
	18.0	17.99±0.06	17.94±0.04	17.99±0.07	17.97±0.06	0.34

*Mean ± SD of 18 determinations (6 replicate determinations every time for 3 points of time in a day), **Mean ± SD of 6 replicate determinations; ^Lor (Standard) : Epr mixture at 4:50 ratio; ~Epr (Standard): Lor mixture at 50:4 ratio

The low values of RSD (0.37%-0.66%, **Table 5-7**) indicated that the developed method was repeatable and precise. The accuracy was performed by recovery studies in **Table 8**. The percent recovery of the added known amounts of the drug to a known concentration of the sample was found to be 100.53% ± 0.78%-101.27% ± 0.62% and 99.67% ± 0.75%-101.88% ± 0.73% for pure and mixed standard solution of lornoxicam respectively; and 98.73% ± 1.02%-101.75% ± 0.78%, and 99.07% ± 1.08%-102.44% ± 0.90% for pure and mixed standard solution of eperisone hydrochloride respectively **Table 8**.

TABLE 8: ACCURACY STUDIES FOR THE DEVELOPED METHOD

Solution	C_s (µg/ml)	C_a (µg/ml) (% Spiking)	C_t* (µg/ml)	%Recovery*[#]
Lor Alone	6.75	4.05 (80%)	10.79±0.03	101.27±0.62
		6.75 (100%)	13.49±0.06	100.61±0.89
		9.45 (120%)	16.19±0.07	100.53±0.78
Lor + Epr^	6.75	4.05 (80%)	10.79±0.03	101.88±0.73
		6.75 (100%)	13.38±0.05	99.67±0.75
		9.45 (120%)	16.14±0.06	100.31±0.60
Epr Alone	7.5	4.5 (80%)	12.13±0.05	98.73±1.02
		7.5 (100%)	15.33±0.06	101.75±0.78
		10.5 (120%)	18.07±0.06	98.91±0.59
Epr + Lor~	7.5	4.5 (80%)	12.09±0.05	99.07±1.08
		7.5 (100%)	15.33±0.07	102.44±0.90
		10.5 (120%)	18.05±0.08	99.21±0.79

C_s= Concentration of standard solution, C_a= Concentration of sample solution added and C_t= Total concentration found, [#]% Recovery= $[(C_t-C_s)/C_a] \times 100$, *Mean ± SD of 6 replicate determinations; ^Lor (Standard): Epr mixture at 4:50 ratio; ~Epr (Standard): Lor mixture at 50:4 ratio

The limit of detection (LOD) and limit of quantification (LOQ) of the drugs by the proposed method were found to be respectively 0.09 µg/ml and 0.27 µg/ml for lornoxicam, and 0.63 µg/ml and 1.91 µg/ml respectively for eperisone hydrochloride. The developed method was also found to be robust as well as rugged.

CONCLUSION: The proposed method has been proved to be simple, precise, rapid, and reliable. The method was validated by evaluation of the validation parameters as described in the ICH Q2 (R1), 2005 guidelines for specificity, linearity, LOD values, LOQ values, inter- and intra-day precision, and accuracy which were obtained during the validation studies and were found to be within acceptable limits. Moreover, the method is fast with respect to analysis time as compared to sophisticated chromatographic techniques.

As the validation studies were performed in both pure as well as mixed standards, it can be concluded that the developed method can be successfully employed for quantification of

lornoxicam and eperisone hydrochloride in pure drug samples and in the mixture of the two drugs.

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