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Research Article

Development and Validation of UV Spectrometric and HPLC Method for Estimation of Escitalopram Oxalate and Flupentixol Dihydrochloride in Combined Dosage Form

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ABSTRACT

Reverse phase High-performance liquid chromatographic (HPLC) and UV spectrophotometric methods were developed and validated for the quantitative determination of Escitalopram oxalate and Flupentixol dihydrochloride in combined dosage form. Different analytical performance parameters such as linearity, precision, accuracy, specificity, limit of detection (LOD) and limit of quantification (LOQ) were determined according to ICH Q2R1 guidelines. The RP-HPLC method was developed by the isocratic technique on a column of Kromasil C8 (250×4.6 mm, 5 µm). The retention time for ESC and Flu was 3.6 min and 5.8 min respectively. The UV spectrophotometric determinations were performed at the zero crossing point (ZCP) of ESP was found to be 238 nm and ZCP of Flu was found to be 229 nm. The linearity of the calibration curves for each analyte in the desired concentration range was good ($r^2 > 0.999$) by both the HPLC and UV methods. The method showed good reproducibility and recovery with percent relative standard deviation less than 2%. Moreover, UV spectroscopy can be a cheap, reliable and less time consuming alternative for chromatographic analysis. The proposed methods are highly sensitive, precise and accurate and hence successfully applied for determining the assay of a Combined dosage form.

Key-words: Escitalopram oxalate (ESP), Flupentixol dihydrochloride (Flu.), UV spectrophotometric methods, RP-HPLC method.

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Introduction :[1-5]

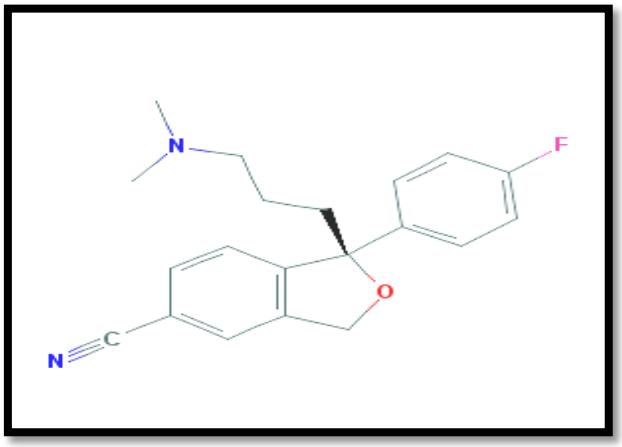
Escitalopram oxalate is a furancarbonitrile that is one of the SEROTONIN UPTAKE INHIBITORS used as an antidepressant. It is chemically designated 1S)-1-[3-(dimethylamino) Propyl]-1-(4-fluorophenyl)-3H-2-benzofuran-5-carbonitrile. It is an antidepressant agent for oral administration. Flupentixol is an antipsychotic neuroleptic drug. It is a thioxanthene, and therefore closely related to the phenothiazines. It is chemically designated as 2-(4-{3-[2-(Trifluoromethyl)-9, 9a-Dihydro-4ah-Thioxanthen-9-Ylidene] Propyl} Piperazin-1-Yl) Ethanol

A combined fixed dose formulation Rexipra FX 10 containing Escitalopram oxalate and Flupentixol dihydrochloride is available as tablet dosage form [6] for treatment of depression. A combination of both drugs reduces the dose of individual drugs. A pharmaceutical composition of Escitalopram oxalate 10 mg and Flupentixol Dihydrochloride 0.5 mg provided excellent effect on lowering depression.

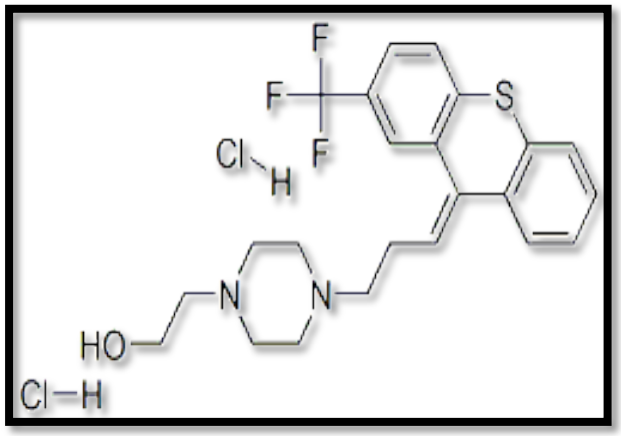
It is observed from literature review that there is no method available for simultaneous estimation of Escitalopram oxalate and Flupentixol dihydrochloride, so it was the area of interest to develop the method for estimation.

From the literature review, it has been found that analytical methods have been developed on individual drug of Escitalopram Oxalate and Flupentixol Dihydrochloride. But No analytical method have been reported for simultaneous estimation of Escitalopram Oxalate and Flupentixol Dihydrochloride combination. So this Combination is selected for following purpose.

In the present work we have developed a simple UV method for rapid simultaneous estimation of ESP and Flu using a First Derivative Method; obtained from absorbance maxima of both ESP and Flu. Both these methods are used to calculate drug content in combined dosage form.



Chemical structure of Escitalopram oxalate



Chemical structure of Flupentixol Dihydrochloride

Material and Method:

Reagent and chemicals

Escitalopram oxalate and Flupentixol Dihydrochloride were supplied by Intas Pharmaceuticals, Ahmedabad, India and B J Enterprise, Ahmedabad, India respectively. A combined fixed dose formulation Rexipra FX 10 containing Escitalopram oxalate 10 mg and Flupentixol dihydrochloride 0.5 mg is available as tablet dosage form for treatment of depression. HPLC grade acetonitrile, methanol, and purified grade Ortho Phosphoric Acid were from Avantor Performance Material India Ltd, Finar Ahmedabad, and Astron Chemical India, India respectively. All other reagents employed were of high purity analytical grade. All weighing was done on a calibrated analytical balance. Calibrated glass wares were used throughout the work. Double distilled water and Mili-Q water were used in the UV method and RP-HPLC method respectively.

RP-HPLC method

Instrumentation

The HPLC method was performed on a system equipped with prominence SPD-20A, UV/Vis detector and HPLC pump. The column used Kromasil C8 (250×4.6 mm, 5 µm). The mobile phase used was Acetonitrile: Buffer (60:40% v/v) and the final pH adjusted were 5.8 by using orthophosphoric acid. Injection volume was 20 µL. The flow rate was set to 1 ml/min and detection of both drugs was carried out at 235 nm by UV detector.

UV spectrophotometric method

Instrumentation

The UV method was performed on SHIMADZU double beam spectrophotometer (Model: UV-1800) with 2 nm spectral bandwidth using 10 mm matched quartz cuvettes. Data acqui-sition was done by using UV-probe software version 2.42. The absorption spectra of reference and test solution were carried out over the range of 200–400 nm.

Determination of wavelength of maximum absorbance (kmax) of ESP and Flu

Wavelength of maximum absorption was determined by scan-ning 10 µg /ml solution of ESP and Flu using UV–visible double beam spectrophotometer from 200 to 400 nm using methanol as blank.

➢ **First order Derivative Method**

Preparation of standard stock solution

- **Preparation of standard stock solution of Escitalopram Oxalate (100 µg/ml):** Accurately weigh 10 mg of Escitalopram Oxalate was transferred into a 100 ml volumetric flask and diluted with Methanol.
- **Preparation of standard stock solution of Flupentixol Dihydrochloride (100 µg/ml):** Accurately weigh 10 mg of Flupentixol Dihydrochloride was transferred into a 100 ml volumetric flask and diluted with Methanol.

Selection of Wavelength

- 3 ml standard stock solution of Escitalopram Oxalate (100 µg/ml) and 0.3 ml standard stock solution of Flupentixol Dihydrochloride (100 µg/ml) was transfer in separate 10 ml volumetric flask and dilute upto mark with methanol to get the 30 µg/ml of Escitalopram Oxalate and 3 µg/ml of Flupentixol Dihydrochloride. Each solution was scanned in the range of 200-400 nm.

  All zero order spectrums (D^0) were converted to first derivative spectrum (D^1). The overlain first derivative spectrums of Escitalopram Oxalate and Flupentixol Dihydrochloride at different concentration were recorded. The zero crossing point (ZCP) of Escitalopram Oxalate was found to be 238 nm and ZCP of Flupentixol Dihydrochloride was found to be 229 nm. At 238 nm (ZCP of ESP), Escitalopram oxalate shows zero absorbance but Flupentixol has considerable absorbance. Both this wavelength 238 nm and 229 nm were used for the determination of Escitalopram Oxalate and Flupentixol Dihydrochloride respectively.

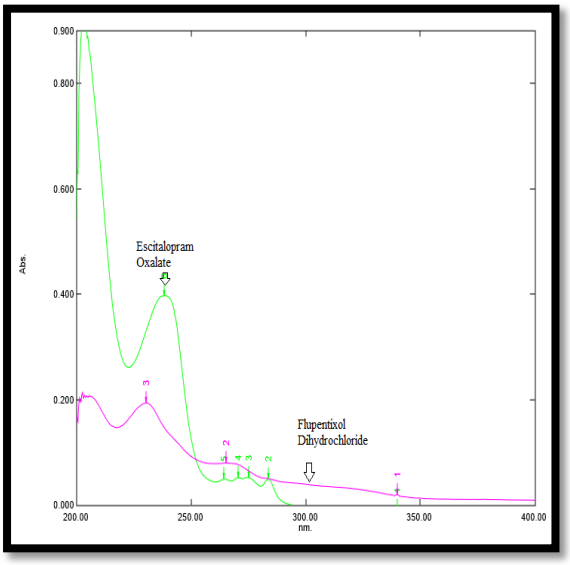


Figure 4.8: Overlain spectra of ESP (30 µg/ml) and Flu (3 µg/ml) in Methanol

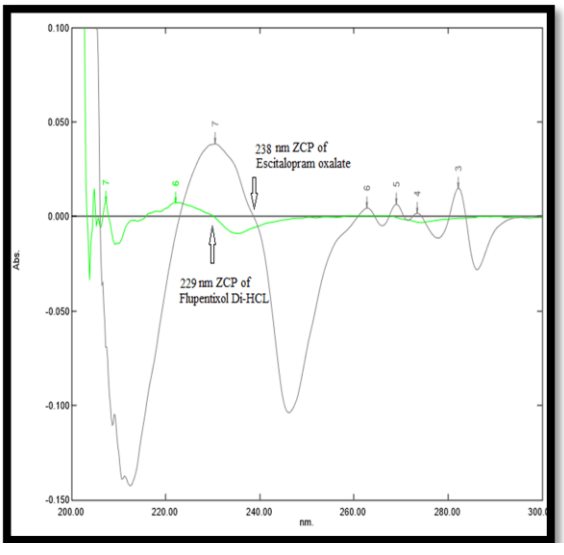


Figure 4.9: First Derivative Overlain spectra of ESP (30 µg/ml) and Flu (3 µg/ml) in

4.2.1.1.6 Preparation of Calibration Curve

- **Calibration Curve for Escitalopram Oxalate (10-50 µg/ml):**

Aliquots of stock solution of Escitalopram Oxalate (100 µg/ml) 1, 2, 3, 4 and 5 ml were pipette out in 10 ml volumetric flask separately and dilute upto the mark with Methanol which will give 10, 20, 30, 40 and 50 µg/ml

respectively. Absorbance of each solution was measured at 229 nm using methanol as blank. Graph of Absorbance Vs Concentration was plotted.

- **Calibration Curve for Flupentixol Dihydrochloride (1-5 µg/ml):**

Aliquots of stock solution of Flupentixol Di-HCL(100 µg/ml) 0.1, 0.2, 0.3, 0.4, and 0.5 ml were pipette out in volumetric flask separately and dilute upto the mark with Methanol which will give 1, 2, 3, 4 and 5 µg/ml respectively. Absorbance of each solution was measured at 238 nm using methanol as blank. Graph of Absorbance Vs Concentration was plotted.

Preparation of Sample Solution

For analysis of drug in tablet, twenty tablets (Rexipra FX 10 containing 10mg of Escitalopram Oxalate and 0.5mg of Flupentixol Dihydrochloride) were accurately weighed and their average weight was determined.The tablets were then finely powdered. Powder weight equivalent to 10mg of Escitalopram Oxalate and Flupentixol Dihydrochloride were dissolved in a 100ml volumetric flask with methanol. It was sonicated followed by filtration through whatmann filter paper. The filtrate was diluted to the mark with Methanol. The mixture contains 100 µg/ml of Escitalopram Oxalate and 5 µg/ml of Flupentixol Dihydrochloride.

From above mixture solutions pipette out 1.0 ml and transferred in to a 10 ml volumetric flask and the volume was adjusted up to the mark with Methanol to make final concentration of Escitalopram oxalate 10 µg/ml and Flupentixol Dihydrochloride 0.5 µg/ml.

Method Validation [7-14]

The developed method was validated with respect to linearity, accuracy, precision, limit of detection and limit of quantification in accordance with the ICH guideline.

- **Specificity**

Specificity is the ability to assess unequivocally the analyte in the presence of components which may be expected to be present. Typically these might include impurities, degradants, matrix, etc.

- **Linearity & Range**

The linearity of Escitalopram Oxalate and Flupentixol Dihydrochloride was found to be in the range of 10-50 µg/ml and 1-5 µg/ml respectively. Calibration curve of Absorbance Vs Concentration was plotted and from that slope, intercept, correlation coefficient and regression line equation for Escitalopram oxalate and Flupentixol Dihydrochloride was constructed.

- **Precision**

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements o.btained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: Intermediate (Intraday) precision, reproducibility (Interday precision), repeatability.

1) Intraday Precision:

Solutions containing 20, 30, 40 µg/ml of Escitalopram Oxalate and 2, 3, 4 µg/ml of Flupentixol Dihydrochloride were analyzed three times on the same day and %R.S.D was calculated.

2) Interday Precision:

Solutions containing 20, 30, 40 µg/ml of Escitalopram Oxalate and 2, 3, 4 µg/ml of Flupentixol Dihydrochloride were analyzed on three different successive days and %R.S.D was calculated.

3) Repeatability: Solutions containing 30 µg/ml of Escitalopram Oxalate and 3 µg/ml of Flupentixol Dihydrochloride were analyzed for six times and %R.S.D. was calculated. R.S.D was not more than 2%.

- **Limit of Detection (LOD):**

Limit of detection can be calculated using following equation as per ICH guidelines.

$$LOD = 3.3 \times (\sigma / S)$$

Where, σ = standard deviation of the Y intercept of calibration curve

S = Mean slope of the corresponding calibration curve.

- **Limit of Quantification (LOQ):**

Limit of quantification can be calculated using following equation as per ICH guidelines.

LOQ = 10 x (σ/ S)

Where, σ = standard deviation of the Y intercept of calibration curve

S = Mean slope of the corresponding calibration curve.

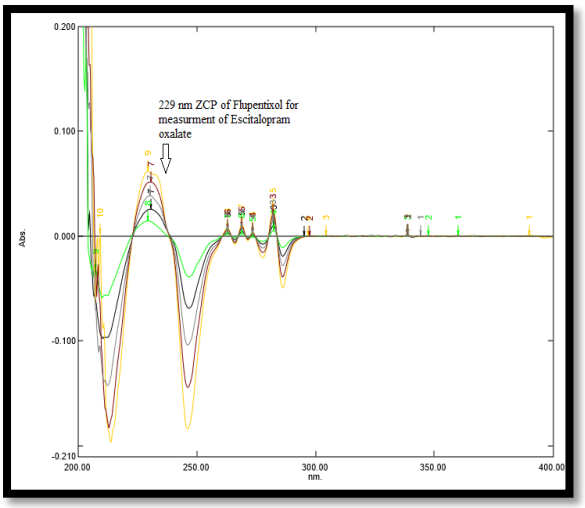
➢ **Accuracy:**

The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. Accuracy of the developed method was confirmed by doing recovery study as per ICH guideline at three different concentration levels 80%, 100%, 120% and the values were measured at all wavelengths for Escitalopram Oxalate and Flupentixol Dihydrochloride . This performance was done in triplicate.

Result and Discussion

- **Selection of wavelength for Escitalopram Oxalate and Flupentixol di-HCL**

  To determine the wavelength for measurement, Escitalopram Oxalate (30 µg/ml) and Flupentixol Di-HCL (6 µg/ml) solutions were scanned between 400-200 nm. Absorbance maxima were obtained at their λmax 238 nm and 230 nm for Escitalopram Oxalate and Flupentixol Di-HCL, respectively.



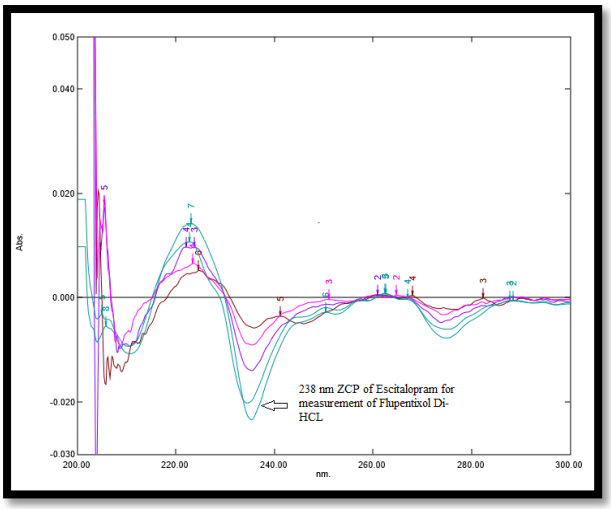


Figure 4.10: Overlain Spectra of Escitalopram Oxalate (10-50 µg/ml)

Figure 4.11: Overlain spectra of Flupentixol Di-HCl (1-5 µg/ml)

Table 4.6: Linearity Data of Escitalopram Oxalate

Escitalopram Oxalate(238 nm)		
Conc. (µg/ ml)	**Mean Absorbance ± SD (n=6)**	**% RSD**
10	0.0138±0.00024	1.7391
20	0.0251±0.00042	1.6733
30	0.0380±0.00063	1.6578
40	0.0515±0.00080	1.5533
50	0.0646±0.00081	1.2538

Table 4.7: Linearity Data of Flupentixol Di-HCl

Flupentixol Di-HCl (230 nm)		
Conc. (µg/ ml)	**Mean Absorbance ± SD (n=6)**	**% RSD**
1	|-0.0044|±0.00008	1.8181
2	|-0.0080|±0.00012	1.50
3	|-0.0121|±0.00018	1.4876
4	|-0.0160|±0.00023	1.4375
5	|-0.0190|±0.00026	1.3684

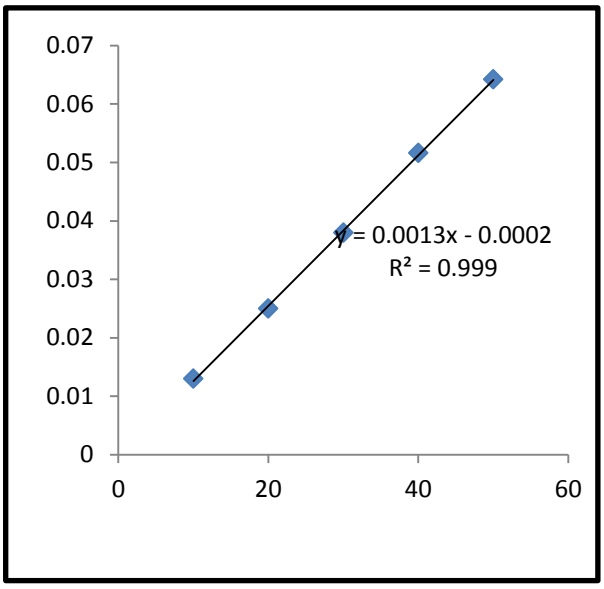


Figure 4.12: Calibration Curve of ESP (10-50 µg/ml) at 238 nm

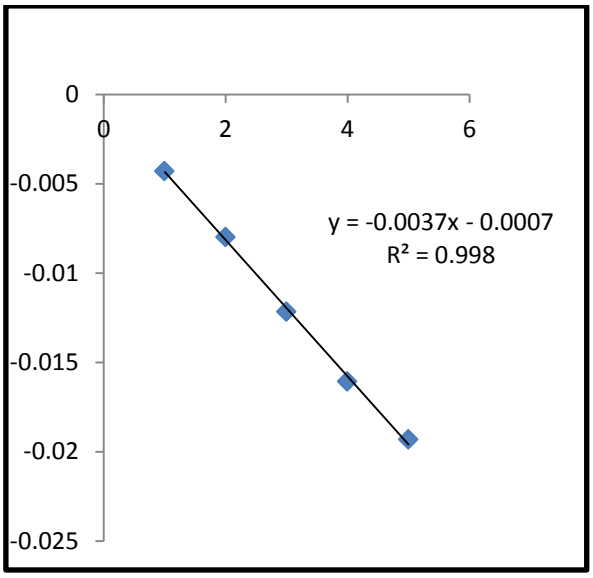


Figure 4.13: Calibration Curve of Flu (1-5 µg/ml) at 230 nm

Table 4.8: Intraday Precision of Escitalopram Oxalate & Flupentixol Di-HCl

Drug name	Conc. (µg/ml)	Mean Absorbance ±SD (n=3)	% RSD
ESP	20	0.0251±0.00042	1.6733
	30	0.0380±0.00063	1.6578
	40	0.0515±0.00080	1.5533
Flu	2	|-0.0080|±0.00012	1.50
	3	|-0.0121|±0.00018	1.4876
	4	|-0.0160|±0.00023	1.4375

Table 4.9 Interday precision of Escitalopram Oxalate and Flupentixol Di-HCl

Drug name	Conc. (µg/ml)	Mean Absorbance ±SD (n=3)	% RSD
ESP	20	0.0280±0.00050	1.7857
	30	0.0394±0.00068	1.7258
	40	0.0562±0.00094	1.6725
Flu	2	|-0.0092|±0.00014	1.5217
	3	|-0.0132|±0.00020	1.515
	4	|-0.0173|±0.00025	1.4425

Table 4.10: Repeatability of Escitalopram Oxalate and Flupentixol Di-HCl

Drug name	Conc. (µg/ml)	Mean Absorbance ±SD (n=3)	% RSD
ESP	30	0.03950±0.00060	1.5189
Flu	3	|-0.0133|±0.00025	1.8796

Table 4.11: LOD and LOQ Data

Parameter	ESP	Flu
LOD (µg/ml)	0.8148	0.891
LOQ (µg/ml)	2.4692	0.2702

Table 4.12: Recovery Study

Name of Drug	% Level of recovery	Test Amount (µg/ml)	Amount of drug taken (µg/ml)	Total Std Amt (µg/ml)	Total Amount Recovered (µg/ml)	% Recovery ±R.S.D.(n=3)
ESP	50	20	10	30	29.46	98.22±1.3846
	100	20	20	40	39.46	98.67± 0.7642
	150	20	30	50	50.67	101.34±0.5187
Flu	50	1	0.5	1.5	1.48	98.88 ±1.529
	100	1	1	2	1.98	99.00±0.9206
	150	1	1.5	2.5	2.54	101.80±0.7515

Table 4.13: Analysis of Marketed Formulation

Name of Drug	Label claim(mg)	Amount found (mg)	% Assay ± S.D (n=3)
ESP	10	9.85	98.5 ± 0.017
Flu	0.5	0.49	98.00 ± 0.0089

Table 4.14: Summary of Validation Parameters

Sr. No.	Parameters	Escitalopram Oxalate	Flupentixol Di-HCl
1	Wavelength (nm)	238 nm	230 nm
2	Beer's Law Limit (µg/ml)	10-50	1-5
3	Regression equation (y = mx +c)	y = 0.0013x - 0.0003	y = -0.0038x - 0.0005
4	Correlation Coefficient (R^2)	0.999	0.998
5	Intraday Precision (%RSD, n=3)	1.6733-1.5533	1.50-1.4375
6	Interday Precision (% RSD, n=3)	1.7857-1.625	1.5217-1.4425
7	Repeatability (% RSD, n=6)	1.5384	1.8796
8	LOD (µg/ml)	0.8148	0.0891
9	LOQ (µg/ml)	2.4692	0.2702
10	Accuracy (%)	98.22-101.34	98.88-101.80

Chromatography

Chromatographic condition

The optimal composition of the mobile phase was determined to be acetonitrile: phosphate buffer pH 5.8 (60:40 v/v). The mobile phase was filtered through 0.45µm membrane filter. Stock solution was prepared by dissolving ESP and Flu (10 mg each) that were weighed accurately and separately transferred into 100 ml volumetric flasks. After the immediate dissolution, the volume was made up to the mark with mobile phase. These standard stock solutions were observed to contain 100 µg /ml of ESP and Flu. Appropriate volume from this solution was further diluted to get appropriate concentration levels according to the requirement. From the above stock solutions, dilutions were made in the concentration range of10-50 µg/ml and 1-5 µg/ml for ESP and Flu respectively.

Preparation of buffer (50 mM KH_2PO_4):
Accurately weighed quantity of 1.36 g Potassium Di-Hydrogen orthophosphate (KH_2PO_4) was transferred in 1000 ml beaker, dissolved in HPLC grade water and sonicated for about 10 min and diluted with HPLC grade water. It was filtered through 0.45µm membrane filter. Buffer pH was adjusted to 3.65 using 1% Ortho Phosphoric acid

Preparation of mobile phase
60 volume of acetonitrile and 40 volume of Potassium phosphate buffer and pH of the final mobile phase were adjusted to 3.5 by using 1% orthophosphoric acid. Prepared mobile phase was used after sonication and filtered using 0.5 µm sizes.

Preparation of standard stock solution:

- **Preparation of standard stock solution of Escitalopram Oxalate (100 µg/ml):**

Accurately weighed Escitalopram Oxalate (10 mg) was transferred to a 100 ml volumetric flask, and diluted to the mark with mobile phase to obtain a standard stock solution (100µg/ml).

- **Preparation of standard stock solution of Flupentixol Di-HCl (100 µg/ml):**

Accurately weighed Flupentixol Di-HCl (10 mg) was transferred to a 100 ml volumetric flask, and diluted to the mark with mobile phase to obtain a standard stock solution (100 µg/ml).

Selection of Detection Wavelength:
The sensitivity of HPLC method that uses UV detection depends upon proper selection of detection wavelength. At 235 nm both the drug give maximum absorbance. So, 235 nm was selected for detection of Escitalopram Oxalate and Flupentixol Dihydrochloride.

The mobile phase Acetonitrile: Buffer, pH=3.5 (60:40) was selected because it was found to ideally resolve the peaks with retention time 3.6 min and 5.8 min for Escitalopram oxalate and Flupentixol Di-HCl respectively. Kromasil C8 (240 mm × 4.6 mm, 5 µm) column was used for separation of Escitalopram oxalate and Flupentixol Di-HCl with flow rate of 1.0 ml/min.

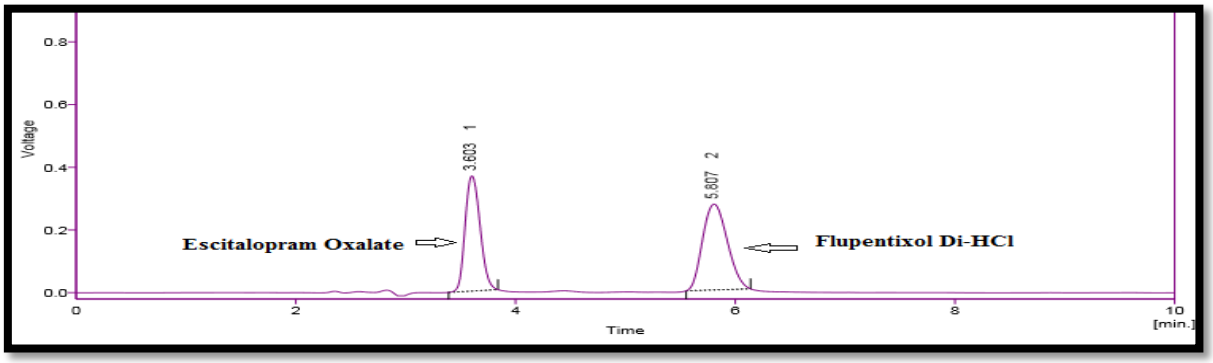


Figure 5.1: Chromatogram of ESC (30 µg/ml) and Flu (3 µg/ml) in ACN: Buffer (pH 3.5) (60:40 %v/v)

Table 5.2: System Suitability Parameter

Parameters	Retention Time	Tailing Factor	Num. of Theoretical plate	Resolution
ESP	3.603	1.324	3059	-
Flu	5.807	1.298	2835	6.341

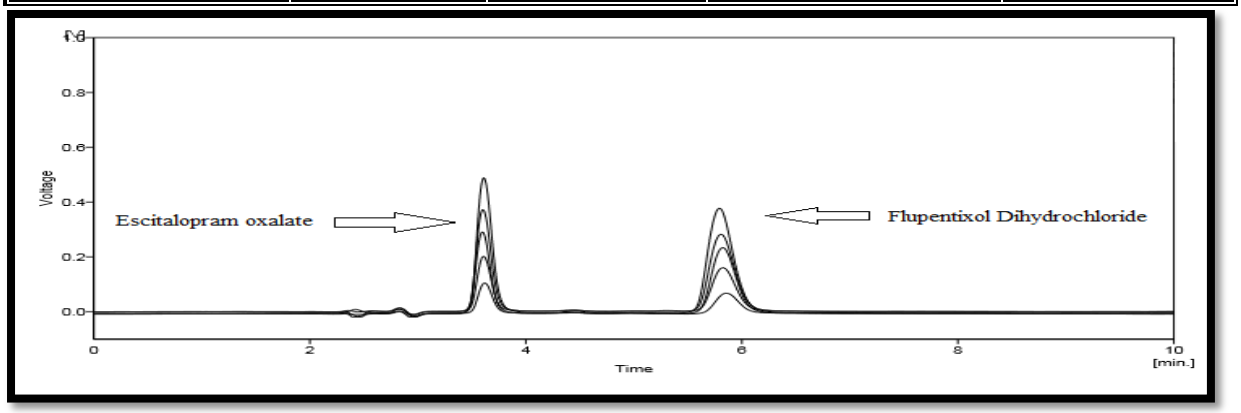


Figure 5.5: Overlay Chromatogram of ESP (10-50 µg/ml) and Flu (1-5 µg/ml)

Table 5.3: Linearity data for ESP (10-50 µg/ml) and Flu (1-5 µg/ml)

Sr. No	Concentration (µg/ml)		Mean Peak area (µv*sec) ±S. D. (n=5)		% RSD	
	ESC	FLU	ESC	FLU	ESC	FLU
1	10	1	876954.5±4074.79	781562.5±4569.55	0.464	0.584
2	20	2	1798185±4242.44	1850450±8676.95	0.235	0.468
3	30	3	2606999±4081.91	2730330±12859.75	0.156	0.470
4	40	4	3474210±7749.21	3672619±16250.45	0.223	0.442
5	50	5	4395704±1546.06	4714783±1839.32	0.035	0.039

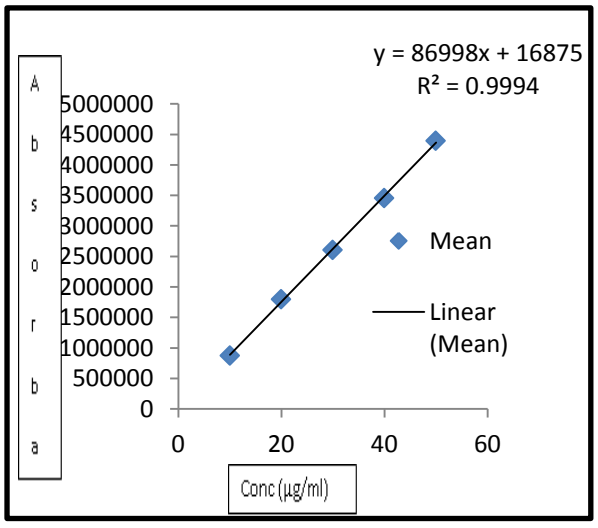


Figure 5.6: Calibration curve of ESP (10-50 µg/ml)

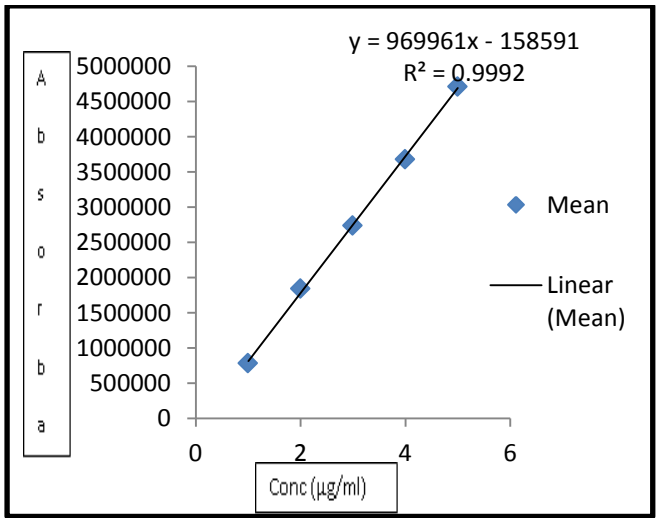


Figure 5.7: Calibration curve of Flu (1-5 µg/ml)

Table 5.4: Intraday Precision study for ESP and Flu

Drug	Concentration (µg/ml)	Mean peak area (µv*sec) ± S.D (n=3)	% RSD
ESP	20	1794988±8546.22	0.476
	30	2608859±6092.77	0.233
	40	3471429±10336.88	0.297
Flu	2	1840440±5174.68	0.281
	3	2732791±5658.33	0.207
	4	3677023±4219.85	0.114

Table 5.5: Interday Precision study for ESP and Flu

Drug	Concentration (µg/ml)	Mean peak area (µv*sec) ± S.D (n=3)	% RSD
ESP	20	1693889±7193.57	0.424
	30	2311998±11551.63	0.499
	40	3481063±6348.25	0.182
Flu	2	2048136±5770.33	0.281736
	3	2740052±4590.21	0.167523
	4	3676123±4276.12	0.11632

Table 5.6: Repeatability study for ESP and Flu

Drug	Concentration (µg/ml)	Mean peak area (µv*sec) ± S.D (n=6)	% RSD
ESP	30	2606869±3752.61	0.143
Flu	3	2746215±24421.64	0.5751

Table 5.7: Accuracy study data

Name of Drug	% Level of recovery	Amount of drug Taken (µg/ml)	Amount of drug added (µg/ml)	Total amount Taken (µg/ml)	Total amount found (µg/ml)	% Recovery (n=3)
ESP	50	20	10	30	29.99	99.97
	100	20	20	40	39.81	99.54
	150	20	30	50	49.91	99.83
Flu	50	1	0.5	1.5	1.49	99.99
	100	1	1	2	1.98	99
	150	1	1.5	2.5	2.51	100.4

Table 5.8: LOD and LOQ data

Drug Name	Escitalopram oxalate	Flupentixol Di-HCl
Standard deviation	4698.189	30032.85
Slope	87133	968916
LOD (µg/ml)	0.177935	0.102288
LOQ (µg/ml)	0.539197	0.309963

Table 5.9: Application of HPLC method to combined dosage form

Drug Name	Amount in combined dosage form(mg)	Amount found (mg) (n=3)	% Recovery ±S.D. (n=3)
ESP	10	9.97	99.7±0.210
Flu	0.5	0.49	98±0.135

Table 5.10: Robustness data of Escitalopram oxalate and Flupentixol Di-HCl

Condition	Variation	Escitalopram oxalate	Flupentixol Di-HCl
		%Assay ± SD (n=3)	%Assay ± SD (n=3)
Flow rate (1 ml ± 0.1 ml/ min)	0.9 ml/min	99.98±0.04	99.9±0.030
	1 ml/min	99.25±0.037	99.83±0.015
	1.1 ml/min	99.01±0.025	99.64±0.040
Detection wavelength (235 nm ± 2 nm)	234 nm	99.98±0.025	99.99±0.036
	235 nm	99.25±0.023	99.75±0.043
	236 nm	99.01±0.04	99.21±0.020
Change in Mobile phase composition	55: 40	99.42±0.047	99.97±0.015
	60: 40	99.62±0.051	99.82±0.026
	62: 40	99.98±0.049	99.32±0.020

Table 5.11: Summary of Validation Parameters

Sr. No.	Parameters	Escitalopram oxalate	Flupentixol Di-HCl
1	Beer's Law Limit (µg/ml)	10-50	1-5
2	Regression equation (y = mx +c)	y = 86998x + 16875	y = 969961x – 158591
3	Correlation Coefficient (r^2)	0.9994	0.9992
4	Repeatability (% RSD, n=6)	0.143	0.575
5	Intraday Precision (%RSD, n=3)	0.23-0.47	0.11-0.28
6	Interday Precision(% RSD, n=3)	0.18-0.49	0.13-0.28
7	LOD (µg/ml)	0.177	0.102
8	LOQ (µg/ml)	0.539	0.309

Result and discussion

RP-HPLC and UV-method validation

- UV spectrophotometric method was developed and validated for estimation of Escitalopram oxalate and Flupentixol Dihydrochloride. Linearity of ESP and Flu were found to be 10-50 µg/ml and 1-5 µg/ml respectively. Correction Coefficients of ESP and Flu were found to be 0.9965 and 0.9998 respectively.
- RP-HPLC method has been developed and validated for the estimation of ESP and Flu. RP-HPLC method shows linearity in the range of 10-50 µg/ml and 1-5 µg/ml for ESP and Flu respectively. The correction coefficient was 0.999 and 0.998 for ESP and Flu respectively. The average percentage recoveries of ESP and Flu were found to be 99.25-99.98 and 99.25-99.99 respectively. The % assay result of ESP and Flu was found to be 99.97 % and 99.65 % respectively. This is comparable to labelled claim. System suitability test reveal that all system suitability parameters complies with standard values.
- The developed UV Spectrophotometric and RP-HPLC method were found to be simple, rapid, precise, and accurate. So, it can be concluded that they can be successfully apply for the simultaneous estimation of Escitalopram oxalate and Flupentixol dihydrochloride in combined dosage form.

Conclusion

Simple, rapid, accurate and precise RP-HPLC and UV spectrophotometric methods have been developed and validated for the routine analysis of Escitalopram oxalate and Flupentixol dihydrochloride in API and tablet dosage forms. Both methods are suitable for the simultaneous determination of ESP and Flu in multi-component formulations without interference of each other. The amount found from the proposed methods were found in good agreement with the label claim of the formulation. Also the value of standard deviation and coefficient of variation calculated were satisfactorily low, indicating the suitability of the proposed methods for the routine estimation of combined dosage forms.

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