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Assay of Lurasidone by a Stability Indicating RP-HPLC Method

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ABSTRACT

A simple isocratic RP-HPLC method was developed for the estimation of Lurasidone in bulk and pharmaceutical dosage forms by using Waters (Alliance) HPLC (2695 series) System operated with Empower software-2. The optimized chromatographic conditions were found to be buffer of 0.05% Trifluroacetic acid in 0.01 M Potassium dihydrogen orthophosphate solution, mobile phase of buffer and acetonitrile in the ratio 60: 40, Inertsil ODS, C_{18}, 150mm x 4.6mm, 5µ particle size HPLC column at temperature of 30°C, 20 µL of injection volume, 1.0ml/min flow rate and UV detector with detection wavelength 231nm. Retention time and peak area of standard or sample were found to be 5.428min or 5.431 min. and 4128545 or 4126122 respectively. System precision and method precision were found to be less than 2.0%. The method was found to be linear within the limits 2.5-15.0µg/ml with good correlation coefficient 0.9999. The percent of recovery (accuracy) was found from 99.34 to 99.97%. Ruggedness and robustness studies were carried out and the results were found to be satisfactory. Stability of Lurasidone was studied under the different stressed conditions and found to be stable (96.37-93.55%). The % of assay of different dosage of Latuda tablets was found between 99.68 -100.18%. The proposed method was found to be sensitive, precise, accurate, linear, rugged and robust, and applied for the analysis of pharmaceutical formulations and percent of assay was evaluated, hence the proposed method can adopt for the routine analysis in any quality control laboratory.

Keywords: Lurasidone, RP-HPLC, Latuda, Validation, Assay and Quality control.

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INTRODUCTION

Lurasidone (LSN) (trade name Latuda) is an atypical antipsychotic belonging to the chemical class of benzisothiazol derivatives. It is used for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults and also for the treatment of schizophrenia. LSN is chemically known as (3aR,4S,7R,7aS)-2-{(1R,2R)-2-[4-(1,2-benzisothiazol-3-yl)piperazin 1ylmethyl]cyclohexylmethyl}hexahydro-4,7-methano-2H-isoindole-1,3-dione hydrochloride and it molecular structure is represented in Figure-1. LSN available as Lurasidone Hydrochloride and its molecular formula and molecular weight are $C_{28}H_{36}N_4O_2S$•HCl and 529.14 grams/mole respectively. The physical state of Lurasidone hydrochloride is a white to off-white powder and very slightly soluble in water, ethanol and sparingly soluble in methanol. It is available as Latuda tablets; each tablet contains 20 mg, 40 mg, 60 mg, 80 mg, or 120 mg of lurasidone hydrochloride as an active pharmaceutical ingredient and mannitol, pregelatinized starch, croscarmellose sodium, hypromellose, magnesium stearate, Opadry and carnauba wax are the inactive ingredients that are present in each tablet.

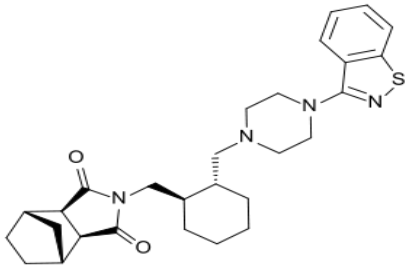

Figure.1: Molecular structure of Lurasidone

Thorough literature survey reveals that a few UV-Spectrophotometric methods [1-5] and RP-HPLC methods [6-12] were reported for the determination of Lurasidone in pure and formulations, Two RP-HPLC methods [13-14] were reported for the estimation of Lurasidone hydrochloride in blood plasma of rats and human. Two LC-MS/MS methods [15-16] were reported in the literature for the estimation of Lurasidone in rat plasma. One HPTLC method [17] was found for the analysis of formulations. The reported spectrophotometric methods were less sensitive and more over lack of degradation studies. In the reported RP-HPLC methods, one method [6] was though rapid it was less sensitive, in another method [7] though it was sensitive, it had longer run time. The method [8] though it was rapid; the main disadvantage was lack of degradation studies. LC-MS/MS methods [15-16] were comparatively costly than HPLC methods. Therefore there is a need to develop a rapid, sensitive, cost effective RP-HPLC method for the estimation of Lurasidone in pure and formulations, hence the main objective of the present work is to develop a sensitive, rapid and eco friendly RP-HPLC

method keeping the principles of green chemistry in mind. The method is aimed at cost effective, stability testing and to apply in quality control studies.

MATERIALS AND METHODS

Instrumentation

Waters (Alliance) HPLC System (2695 series), equipped with Empower software-2, consisting four pump, auto sampler with five racks, each has twenty four vials holding capacity with temperature control was used for the present investigation. Auto injector has capacity to inject 5µL to 500µL. UV-Vis Detector with PDA was adopted for the detection of the components in the present investigation. Thermostat column compartment connected to it has a capacity to maintain 5°C to 60°C column temperature.

Chemicals and Reagents

Lurasidone drug compound of purity 99.6% was obtained as a gift sample from Hetero Drugs Laboratory, Hyderabad, India. The pharmaceutical formulations like Latuda tablets of different dosage forms were purchased from the local pharmacy. Analytical grade Trifluroacetic acid, Potassium dihydrogen orthophosphate, Hydrogen peroxide, Hydrochloric acid, Sodium hydroxide and HPLC grade Acetonitrile were procured from Merck (India). HPLC grade water obtained from Millipore system was used throughout the analysis.

Mobile phase preparation

About 0.05% trifluroacetic acid in 0.01 M potassium dihydrogen orthophosphate solution was prepared and used as buffer solution. Mobile phase was prepared by mixing buffer solution and acetonitrile in the ratio 60: 40 sonicated for five minutes and filtered using vacuum filtration through 0.4 micron membrane filter.

Standard preparation (10.0µg/ml)

Accurately weighed quantity of Lurasidone working standard equivalent to 100 mg of Lurasidone was transferred into 100 mL volumetric flask, about 50mL of diluent was added and sonicated for five minutes to dissolve and diluted to volume with diluent and filtered using vacuum filtration through 0.4 micron membrane filter. Then, about 1.0 mL of standard stock solution was transferred into 100 mL volumetric flask and diluted to volume with diluent.

Sample Preparation (10.0µg/ml)

Average weight of twenty tablets was determined, made into a fine powder in mortar with piston, and weighed an amount of the powder equivalent to 100 mg of Lurasidone and transferred into 100 mL volumetric flask, dissolved in 50 mL of diluent, diluted to volume with diluent and

filtered using 0.4 micron membrane filter. Then about 1.0mL of the stock was diluted to 100mL in a standard flask.

Optimization of chromatographic method

To optimize the HPLC method, one of the chromatographic conditions such as HPLC column, composition of mobile phase, injection volume, flow rates, column temperature and detection wavelength was varied keeping other constant, chromatograms were recorded for each variation, and chromatographic parameters such as retention time, number of theoretical plates, tailing factor, area of the peak and peak height were obtained. About 20 µL of standard or sample solution was injected into Inertsil ODS, C_{18}, 150mm x 4.6mm, 5µ particle size HPLC column maintained at a constant temperature of 30°C. Mobile phase of 0.05% trifluroacetic acid in 0.01 M pottassium dihydrogen orthophosphate buffer and acetonitrile at 60 : 40 ratio (isocratic mode) was allowed to flow at a rate of 1.0ml/min for the elution of the components and were detected at 231 nm using a UV-detector.

Method validation

Method validation is generally a one-time process performed after the method has been developed to demonstrate that the method is scientifically sound and that it serves the intended analytical purpose. The validation of the assay procedure was carried out using the following parameters.

Specificity

Specificity is the ability to asses unequivocally the analyte in the presence of components which include impurities, degradants and matrix. To find out specificity, about 20µL of blank (mobile phase), working standard and sample solutions of concentration 10.0µg/mL were injected separately into the HPLC system and chromatograms were recorded under the optimized chromatographic conditions.

Precision

Precision refers to the reproducibility of replicate measurements and expressed as standard deviation or percent of standard deviation (%R.S.D.) of a definite number of replicate measurements and the acceptance criteria is %R.S.D. must be less than or equal to 2.0%. The precision of the developed method was expressed in two different ways namely system precision and method precision. To find the system precision, about 20 µL of working standard solution of concentration10µg/mL was injected into the HPLC system six times; chromatographic parameters such as retention time, peak area, peak height, tailing factor and number of theoretical plates were obtained. To obtain method precision, six standards of concentration 10µg/ml were

prepared and chromatogram under the normal conditions and chromatographic parameters were obtained.

Linearity

The objective of linearity studies is to know whether the response (peak area) of the instrument (HPLC System) is proportional to concentration of the analyte or not. In the present investigation, linearity was established by preparing a series of six standard solutions over the range of concentration 2.5 to 15.0 µg/mL and chromatograms were obtained under the optimized conditions by injecting each of the solution twice into the system and thus chromatographic parameters were evaluated.

Sensitivity

Sensitivity of an analytical technique is defined as the response of the instrument to the lowest concentration of the analyte. The sensitivity is expressed in terms of limit of detection (L.O.D.) and limit of quantitation (L.O.Q.). The L.O.D. of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. The L.O.Q. is a parameter of quantitative assay for low levels of compounds in sample matrices, and is used particularly for the determination of impurities and/or degradation products. To determine sensitivity, a series of six concentration solutions were prepared and chromatograms were obtained under the optimized conditions by injecting each of the solution twice into the system and thus chromatographic parameters were evaluated.

Accuracy

Accuracy relates to the difference between results and the true value. The accuracy of the test method is demonstrated by % of recovery. For analytical methods, there are two possible ways of determining the accuracy, absolute method and comparative method. In the proposed method accuracy was evaluated by using comparative method in which three concentration levels (80% 100% and 120% with respect to precision concentration) of the sample were prepared and each solution was injected three times, chromatograms were recorded and chromatographic parameters were evaluated.

Ruggedness

The ruggedness of an analytical method is the degree of reproducibility of test results obtained by the analysis of the same samples under a variety of conditions, such as different laboratories, different analysts, different instruments, different lots of reagents, different elapsed assay times, different assay temperatures, different days, etc. In the proposed method, the study of ruggedness

was carried out by preparing working standard solutions of 10.0µg/ml and analyzed under the suitable chromatographic conditions in two different laboratories, instruments and different days.

Robustness

The robustness of an analytical procedure is a measure of its capacity to remain unchanged by small but deliberate variations in method parameters like polarity of the solvent, pH of the buffer solution, temperature and wave length. It provides an indication of its reliability during normal usage. The robustness of test method is demonstrated by carrying out intentional method variations like mobile phase flow changes and column oven temperature variations. In the present investigation, working standard solution of concentration 10µg/ml was prepared and chromatogram was obtained for deliberate variations in method parameters like flow rate and temperature.

DEGRADATION STUDIES

Acid/ Base Hydrolysis

Transferred an amount of sample quantitatively equivalent to 100 mg of Lurasidone in to 200 mL RB flask, added 100 mL of freshly prepared 0.01 N HCl (or 0.1N NaOH) and left it for 12 hours, after that filtered the solution through 0.4 micron filter, and neutralized the solution with suitable 0.1 N NaOH (or 0.1N HCl) base. About 1.0 mL of filtrate was diluted to 100 mL with mobile phase and chromatograms were obtained under the optimized conditions.

Oxidation (Peroxide)

An amount of the sample equivalent to 100 mg of Lurasidone was accurately weighed and transferred in to 200 mL RB flask, added 100 ml of freshly prepared 1.0% Hydrogen peroxide and left it for 12 hours. After that filtered the solution and diluted 1.0 mL of filtrate to 100 mL with mobile phase and chromatogram was obtained under the same conditions.

Heat / UV Exposure

To perform heat or UV exposure study, an amount of the sample quantitatively equivalent to 100 mg of Lurasidone was accurately weighed and transferred on to a clean and dry Petri dish, spread it throughout the plate, and placed the petri dish in an oven which is maintaining at 100°C or UV Chamber for 12 hours. After 12 hrs transferred contents in to 100 mL volumetric flask, added 50 mL of diluents, sonicated for 10 minutes and diluted with diluents, further filtered the solution. Then diluted 1.0 mL of filtrate to 100 mL with mobile phase and then chromatogramed

Assay

An amount of Lurasidone working standard or sample equivalent to 100 mg of Lurasidone was in 50mL of diluents, sonicated, diluted to final volume and filtered through 0.4 micron

membrane filter. Then, about 1.0 mL of standard stock or sample solution was transferred into 100 mL volumetric flask and diluted to volume with diluent. About 20µL of standard or sample was injected, chromatograms were obtained under the optimized conditions (Figure-18 &Figure-19).

RESULTS AND DISCUSSION

The experimental data and results of various studies such as specificity, precision, accuracy, sensitivity, robustness, ruggedness, degradation and assay in the present investigation were presented below.

Specificity

The chromatograms of blank, standard and sample were represented in Figure-2, Figure-3 and Figure-4 respectively. Retention time and peak area of standard (or sample) were found to be 5.428min (5.431 min.) and 4128545(or 4126122) respectively. No additional peaks were found in blank, placebo and sample except drug peak. The system suitable parameters and chromatographic parameters were presented in Table-1.

Table-1: System suitable parameters of the developed RP-HPLC method

S.No.	Name of the Peak	Retention time	Area of the peak	Height of the peak	%of Area	USP Tailing factor	USP Plate count
Blank	No peaks	--	--	--	--	--	--
Standard	Lurasidone	5.428	4128545	294645	100	1.10	3471
Sample	Lurasidone	5.431	4126122	294752	100	1.11	3482

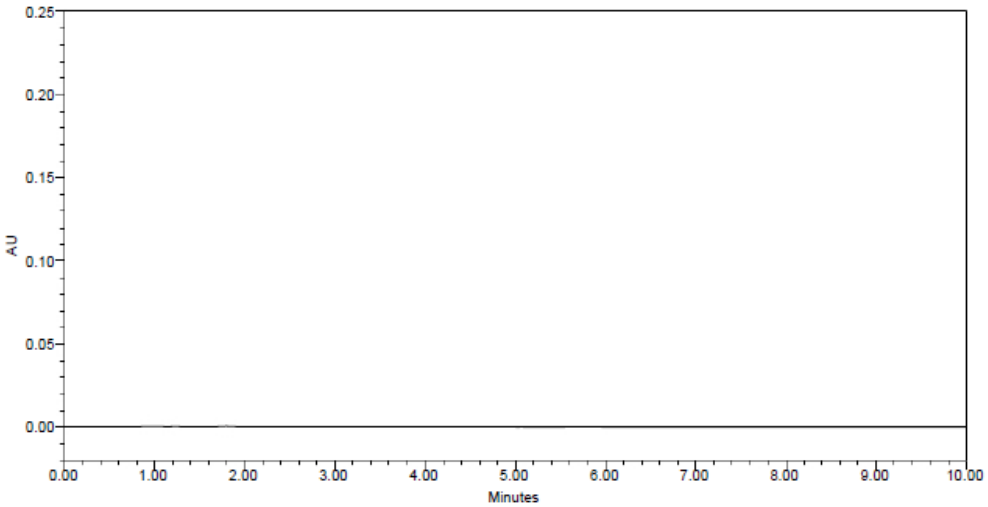

Figure-2: A typical RP-HPLC Chromatogram of Mobile phase (Blank)

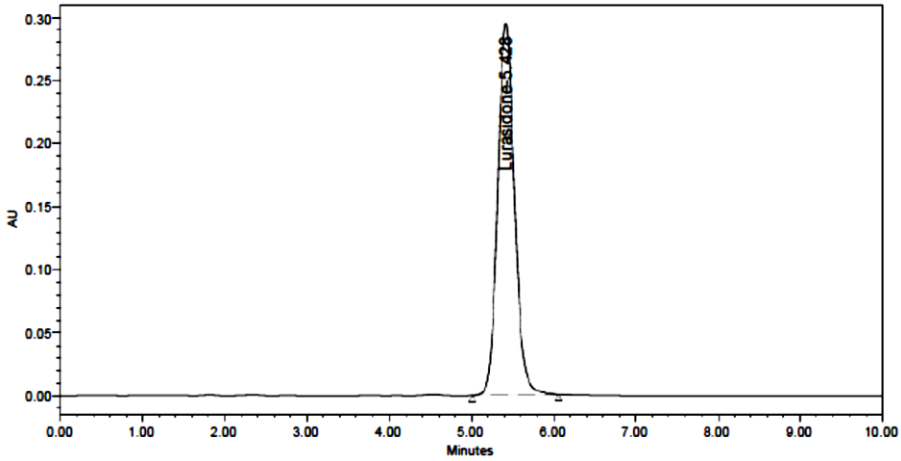

Figure-3: A typical RP-HPLC Chromatogram of Lurasidone standard

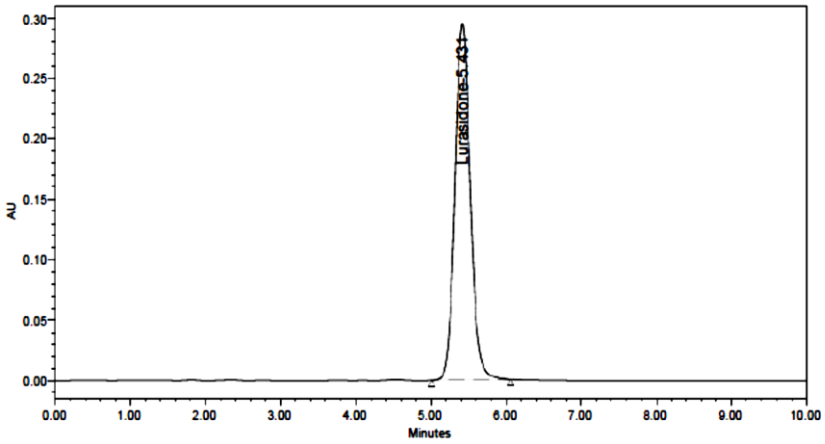

Figure-4: A typical RP-HPLC Chromatogram of Lurasidone sample

Precision

In the study of precision, area of the peaks were determined and mean, standard deviation and % R.S.D.of six replicate measurements were calculated using Microsoft Excel Sheet 2007 and the results of system precision and method precision were presented in Table-2.

Table-2: Results of system precision and method precision

S No	System Precision		Method Precision	
	RT	Area	RT	Area
1	5.425	4114655	5.441	4138670
2	5.444	4158361	5.431	4141419
3	5.441	4130670	5.425	4129592
4	5.443	4131565	5.428	4117408
5	5.448	4131581	5.431	4135514
6	5.432	4115841	5.435	4121545
Mean	5.438	4130446	5.432	4130691
S.D.	0.0086	15777	0.0056	9626
%R.S.D.	0.1583	0.3819	0.1031	0.2330

RT: Retention time

Linearity

A calibration plot was constructed by plotting mean peak area against concentration of Lurasidone in µg/ml. Slope, intercept and Pearson correlation coefficient for bivarient data were determined using Microsoft Excel Sheet 2007 and found to be 412611.474, -8625.067 and 0.9999 respectively. The experimental results of linearity studies were presented in Table-3 and the calibration plot was represented by Figure-5.

Table-3: Results of Linearity studies of the proposed method

S.No.	Concentration in µg/mL	Mean peak area*
1	2.50	1011933
2	5.00	2065535
3	7.50	3095750
4	10.00	4115453
5	12.50	5134167
6	15.00	6187514
Slope		412611.474
Intercept		-8625.0667
Correlation coefficient		0.9999

**Mean of two determinations*

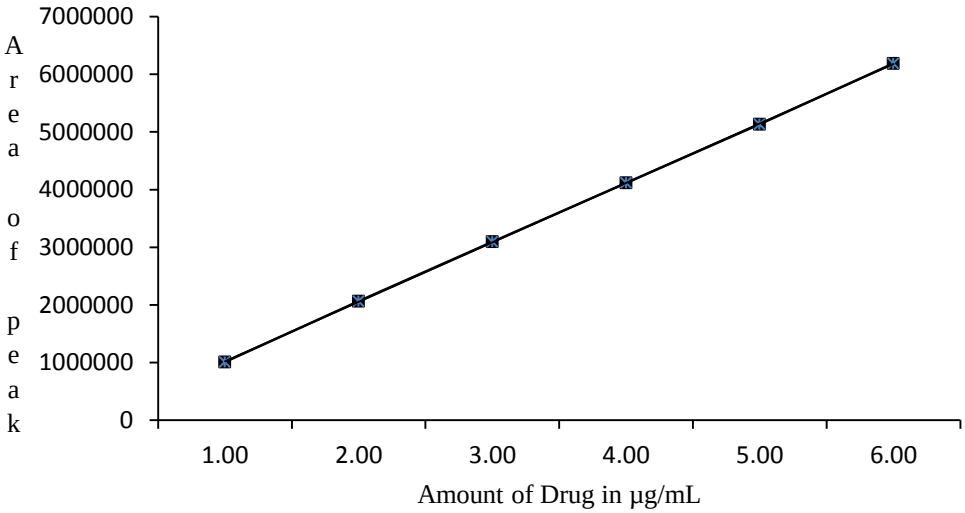

Figure-5: Calibration plot drawn mean peak area against concentration of Lurasidone

Sensitivity

In the present investigation, the sensitivity (L.O.D. and L.O.Q.) was determined from the slope (s) and standard deviation of intercept (σ) of a calibration plot of a series of six standard solutions (2.5 to 15.0 µg/mL) by using the formulae L.O.D.=3σ/s and L.O.Q.=10σ/s. The experimental results were found to be 0.0899 and 0.2999 respectively.

Accuracy

Accuracy (percent of recovery) of the proposed method was determined from the mean peak area of triplicate measurements of standard and sample at three concentrations. Reference chromatograms at three different concentrations in accuracy studies were presented from Figure-6 to Figure-8. The results were presented in Table-4.

Table-4: Results of accuracy studies of the proposed method

	Standard		**80% Level**		**100% Level**		**120% Level**	
	RT	Peak area	RT	Peak area	RT	Peak area	RT	Peak area
1	5.385	4115612	5.392	3288541	5.384	4120412	5.382	4904122
2	5.385	4114425	5.394	3265528	5.385	4111235	5.385	4911125
3	5.382	4117425	5.398	3298625	5.381	4112442	5.383	4904167
Mean		4115821		3284231		4114696		4906471
Amount added		--		80.00		100.00		120.00
Amount Recovered		--		79.79		99.97		119.21
% Recovery		--		99.74		99.97		99.34

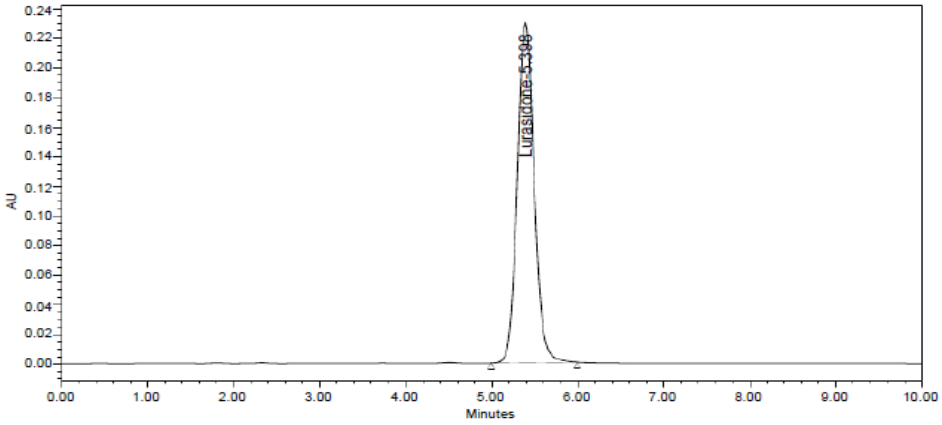

Figure.6: A reference RP-HPLC Chromatogram of sample at 80% concentration level

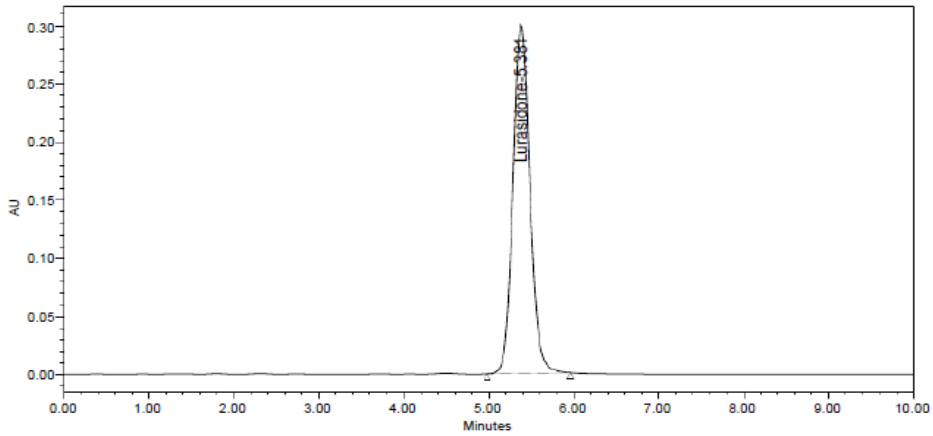

Figure.7: A reference RP-HPLC Chromatogram of sample at 100% concentration level

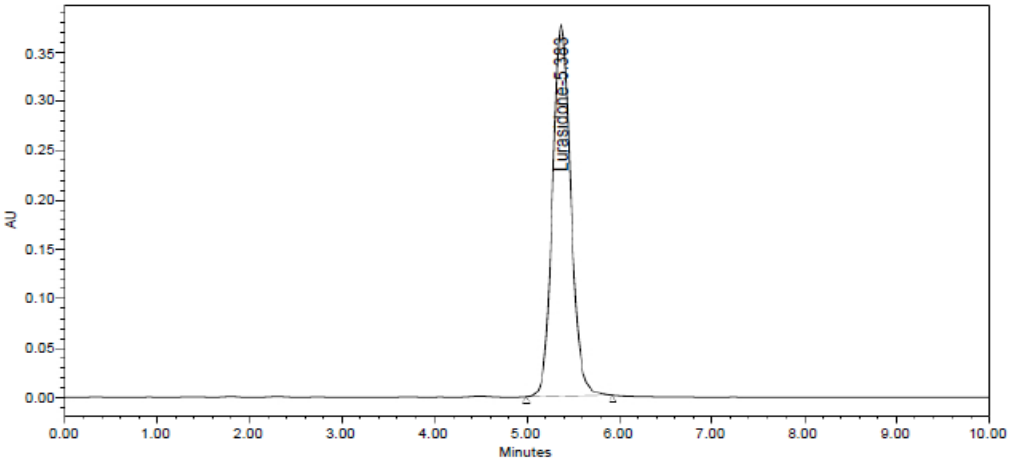

Figure.8: A reference RP-HPLC Chromatogram of sample at 120% concentration level

Ruggedness

In the present development, ruggedness was demonstrated by carrying out precision studies (%R.S.D.) between two different days, different labs and different HPLC systems and the results were presented in Table-5.

Table-5: Results of study of ruggedness

Statistical parameters	Day-I	Day-II	Lab-I	Lab-II	System-I	System-II
Mean	4130446	4121851	4125647	4201647	4142568	4119754
S.D.	15776.56	1146.577	14873.24	15124.68	16438.57	11486.11
R.S.D.	0.381958	0.027817	0.04876	0.2876	0.0975	0.0476

Robustness

In the study of robustness, retention time, area of the peak, height of the peak, tailing and plate count were determined form the chromatograms for different flow rate (Figure-9&Figure-10) and temperature (Figure-11&Figure-12) and found to be not significantly different. The results were presented in Table-6.

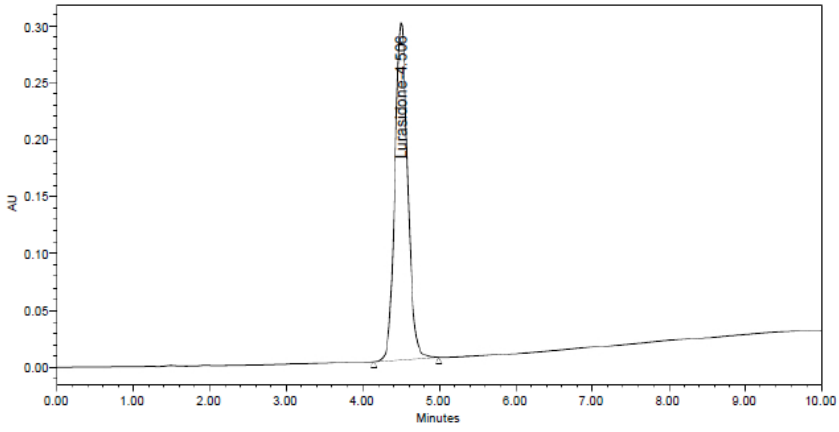

Figure-9: A typical RP-HPLC Chromatogram at less flow rate

Table-6: System suitable parameters in study of robustness

Parameter	Change in Parameter	Retention time	Area of the peak	Height of the peak	%of Area	USP Tailing factor	USP Plate count
Optimized Conditions	--	5.428	4128545	294645	100	1.10	3471
Flow Rate	Less flow rate	4.506	3427114	296218	100	1.07	3524
	High flow rate	5.955	4542637	310574	100	1.11	3877
Temperature	Low temperature	5.399	4013729	302831	100	1.11	3877
	High temperature	5.405	4074330	309305	100	1.11	3971

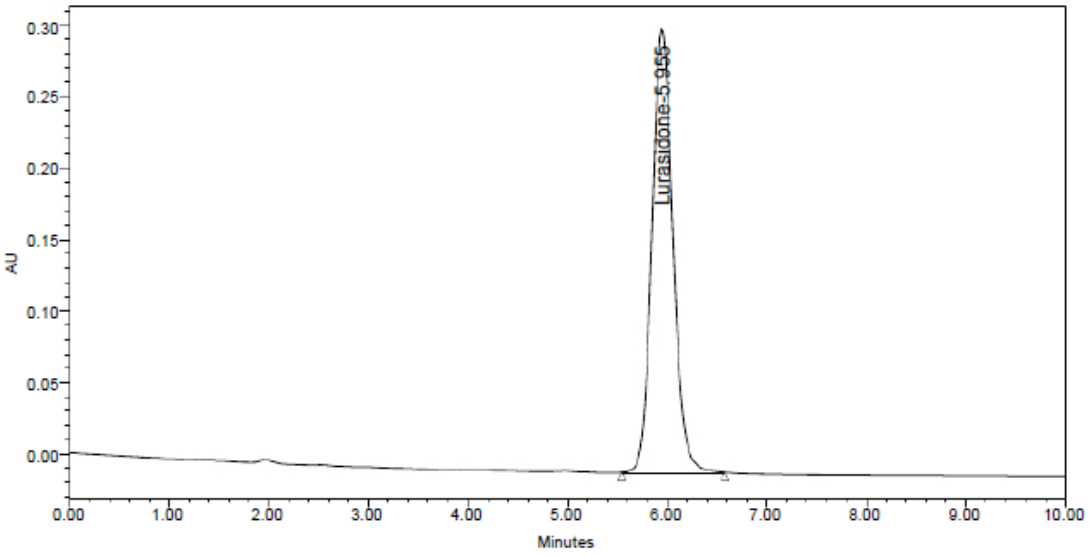

Figure-10: A typical RP-HPLC Chromatogram at high flow rate

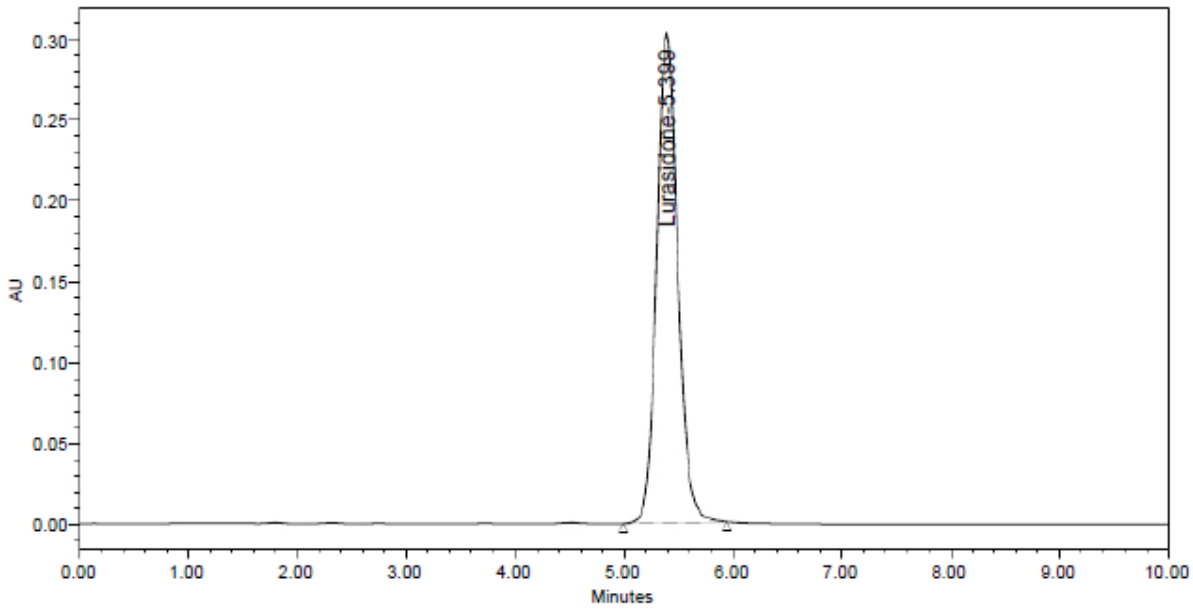

Figure-11: A typical RP-HPLC Chromatogram at less temperature

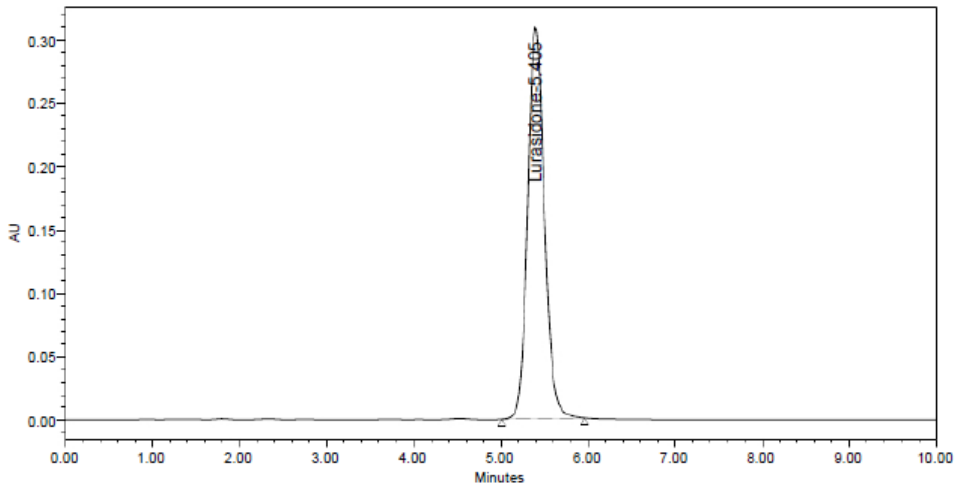

Figure-12: A typical RP-HPLC Chromatogram at high temperature

Degradation Studies

Acid/ Base Hydrolysis

Chromatographic parameters such as retention time, area of the peak, height of the peak, tailing and plate count were determined for standard and degraded sample in each degradation study. The percent of degradation and hence the stability of the drug under variety of stressed conditions was determined from the area of the fresh standard and degraded sample. The results of the stability study were presented in Table-7 and Table-8. Model chromatograms in the study of forced degradation were presented Figure-13(acid degradation), Figure-14(base degradation), Figure-15(Oxidation), Figure-16 (heat) and Figure-17(UV degradation). In acid degradation (or base degradation) two unknown peaks at 2.05 (or 2.34) and 4.54 (or 4.548) minutes having percent of area 0.652 (0.103) and 0.182 (0.166) respectively, where as in oxidation degradation, three additional peaks (peak-1: 2.338min, peak-2: 4.553min and peak-3: 5.817min) were identified in addition to main peak. In case of heat and UV degradation, two additional peaks were observed at 2.333 min (2.086), 4.544min. (4.539) but in UV studies, one more peak was also observed at 2.086 along the other peaks. The model chromatograms for the degradation studies were represented in Figure-13-Figure-17.

Table-7: Results showing number peaks and chromatographic parameters in acid/base degradation studies

S.No.	Peak	RT	Area	Height	%Area	USP Resolution	USP Tailing	USP Plate Count
Acid degradation								
1	--	2.050	26168	2346	0.652		1.12	3722
2	--	4.540	7444	653	0.185	8.00	0.99	3402
3	Lurasidone	5.416	3981148	305204	99.163	2.63	1.11	3985

Base degradation								
1	--	2.340	4049	496	0.103		1.14	3687
2	--	4.548	6540	613	0.166	8.49	1.01	3905
3	Lurasidone	5.416	3932413	299999	99.731	2.70	1.11	4041

Table-8: Results showing number peaks and chromatographic parameters in oxidation degradation studies

S.No.	Peak	RT	Area	Height	%Area	USP Resolution	USP Tailing	USP Plate Count
Oxidation degradation								
1	--	2.338	3629	465	0.093		1.27	1901
2	--	4.553	6716	614	0.173	8.53	1.02	3713
3	Lurasidone	5.425	3870212	294515	99.577	2.70	1.05	4124
4	--	5.817	6106	1098	0.157	1.50	1.39	15924

Table-9: Results showing number peaks and chromatographic parameters in heat/UV degradation studies

S.No.	Peak	RT	Area	Height	%Area	USP Resolution	USP Tailing	USP Plate Count
Heat degradation								
1	--	2.333	3810	471	0.093		1.10	3562
2	--	4.544	7528	663	0.183	8.25	0.98	3492
3	Lurasidone	5.415	3905452	312008	99.724	2.63	1.11	3977
UV degradation								
1	--	2.086	16703	2425	0.415		1.04	3873
2	--	2.326	2795	384	0.069	1.23	1.39	3872
3	--	4.539	6691	625	0.166	8.90	0.91	3832
4	Lurasidone	5.411	4003177	310618	99.35	2.69	1.11	3954

Table-10: Results showing the stability of drug under different degradation conditions

							Found Assay	% of Assay	% Degradation
Acid degradation									
3981148	100.2	1	100	100	99.6	100			
4138592	100	100	100.2	1	100		95.81	99.68	3.87
Base degradation									
3932413	100.2	1	100	100	99.6	100			
4138592	100	100	100.2	1	100		94.64	99.68	5.04
Oxidation degradation									
3870212	100.2	1	100	100	99.6	100			
4138592	100	100	100.1	1	100		93.23	99.68	6.45
Heat degradation									
3905452	100.2	1	100	100	99.6	100			
4138592	100	100	100.2	1	100		93.99	99.68	5.69
UV-Exposure degradation									
4003177	100.2	1	100	100	99.6	100			
4138592	100	100	100.5	1	100		96.05	99.68	3.63

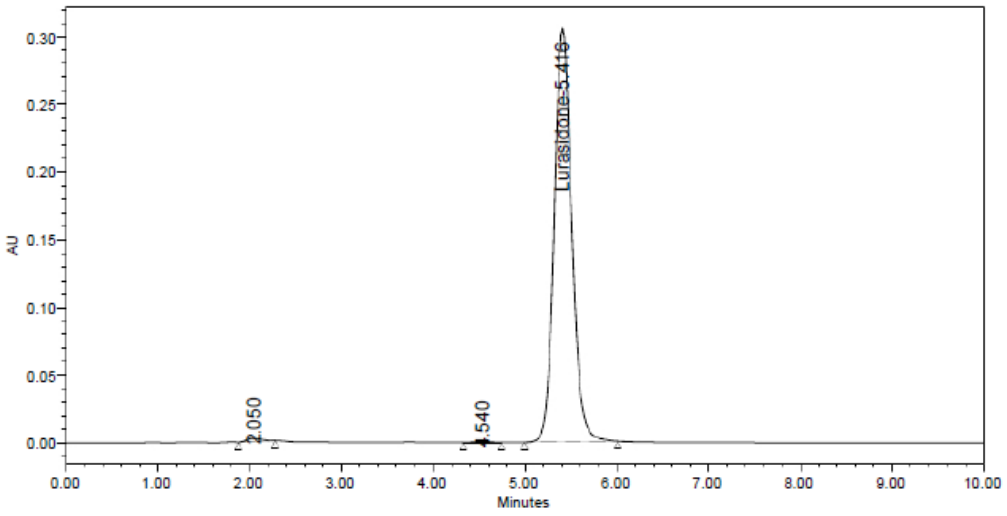

Figure-13: A typical RP-HPLC Chromatogram in acid degradation studies

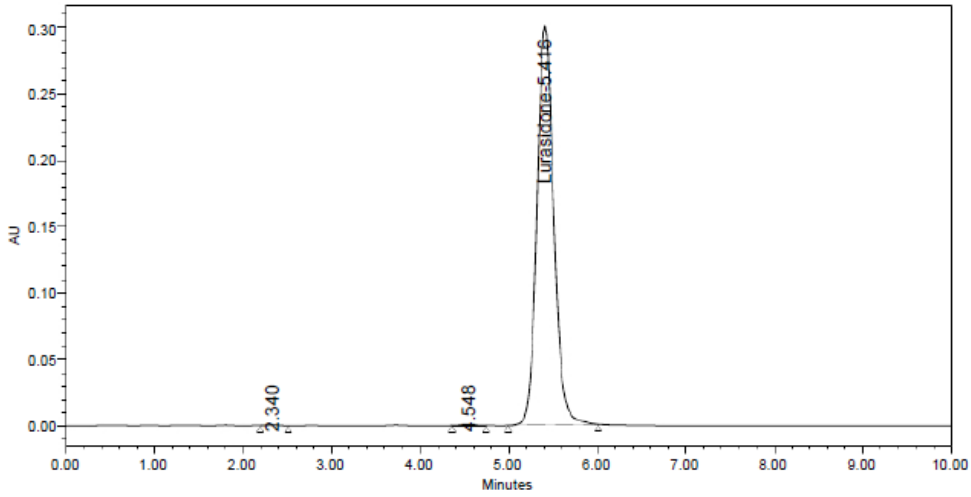

Figure-14: A typical RP-HPLC Chromatogram in base degradation studies

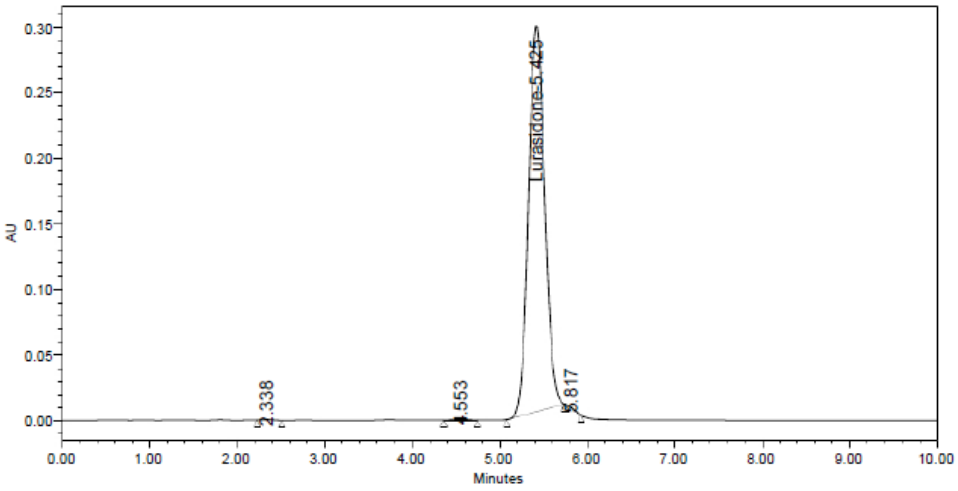

Figure-15: A typical RP-HPLC Chromatogram in peroxide degradation studies

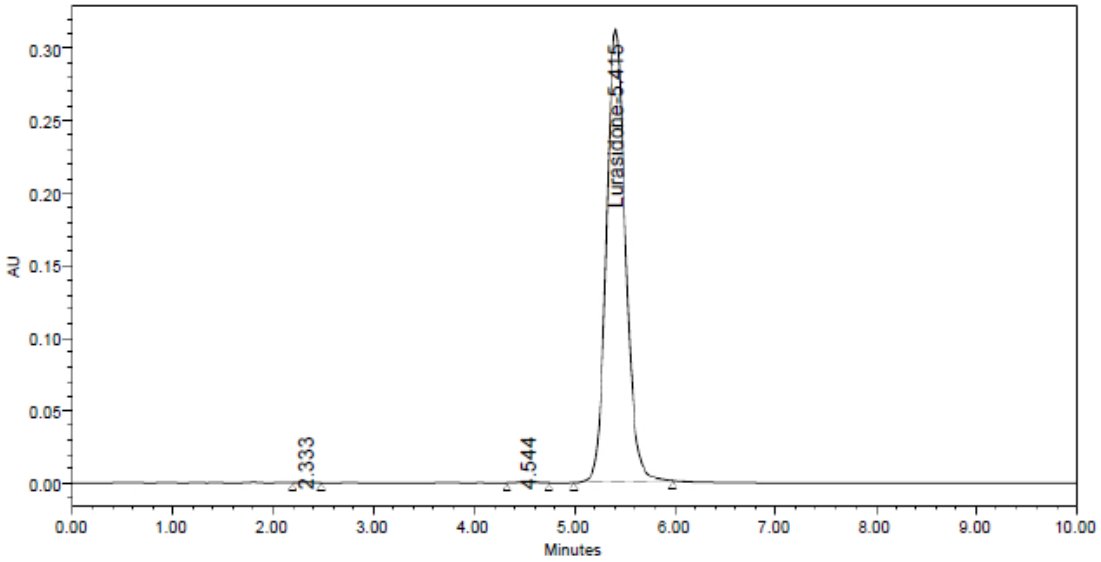

Figure-16: A typical RP-HPLC Chromatogram in heat degradation studies

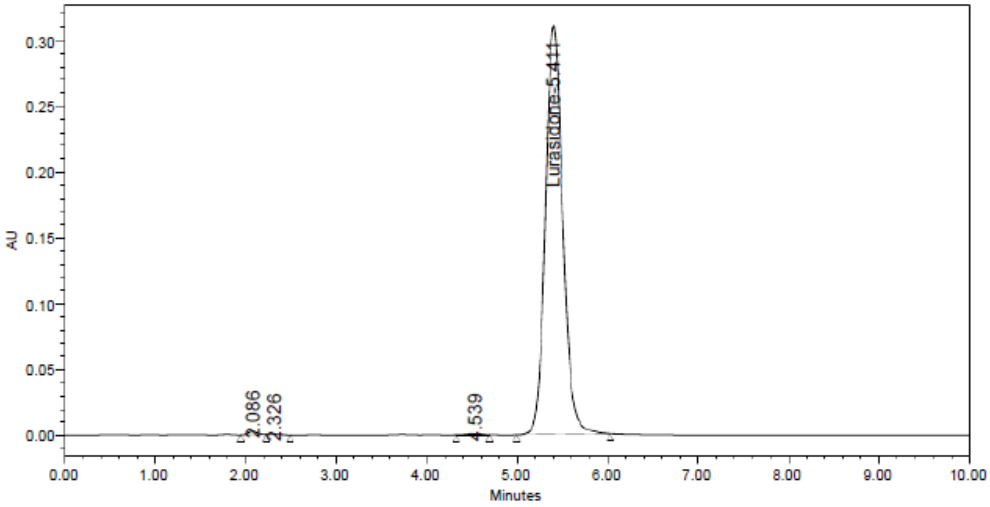

Figure-17: A typical RP-HPLC Chromatogram in ulta-violet light degradation studies

Assay

Chromatographic parameters and peak area of standard and sample were obtained under the optimized conditions and the percent of assay was determined on peak areas of standard (Figure-18) and test (Figure-19) and results were given in Table-11.

Table-11: Results in the study of assay of pharmaceutical formulations

Formulation (mg)	Mean Area of the Standard	Mean area of the Sample	%of Assay
Latuda 20	4036413	4035609	99.68
Latuda 40	4036413	4047949	99.98
Latuda 60	4036413	4055752	100.18
Latuda 80	4036413	4051249	100.06
Latuda 120	4036413	4035597	99.68

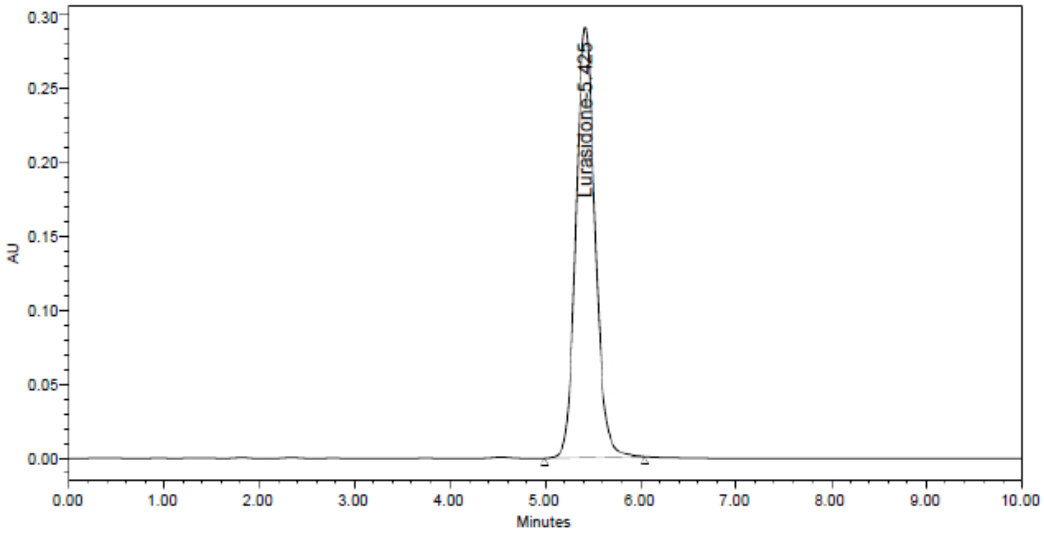

Figure-18: RP-HPLC Chromatogram of standard in assay analysis

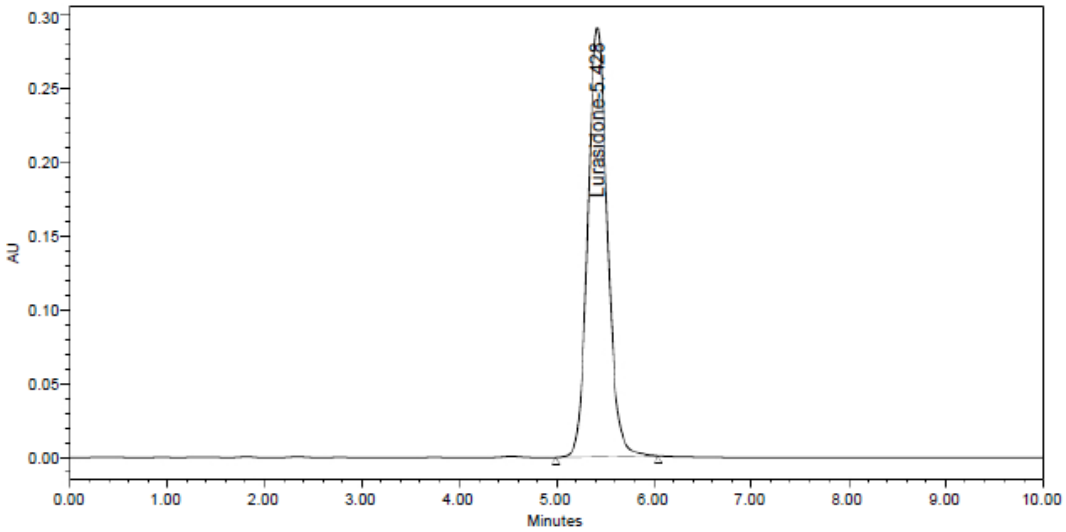

Figure-19: RP-HPLC Chromatogram of sample in assay analysis

Discussion

An isocratic RP-HPLC method was developed for the determination of Lurasidone in bulk and pharmaceutical dosage forms. A Waters (Alliance) HPLC System (2695 series) with an Inertsil ODS, C_{18}, 150mm x 4.6mm, 5µ particle size HPLC column at temperature of 30°C was used for the present investigation. The data was acquired with Empower software-2. The developed method was optimized by changing one of the chromatographic conditions such as HPLC column, mobile phase composition, injection volume, flow rates, column temperature and detection wavelength keeping other parameters constant. Finally, buffer of 0.05% Trifluroacetic acid in 0.01 M Potassium dihydrogen orthophosphate solution, mobile phase of buffer and acetonitrile in the ratio

60: 40, 20 µL of injection volume, 1.0ml/min flow rate and UV detector with detection wavelength 231nm were found to be suitable chromatographic conditions. Chromatograms for standard and sample of concentration 10µg/ml were recorded and chromatographic parameters such as retention time, number of theoretical plates, tailing factor, area of the peak and peak height were obtained and found to be within the acceptable limits. System precision and method precision were determined on retention time and area of the peak for six replicates and found to be 0.153 & 0.3819 and 0.1031&0.233 respectively. The method found to be linear in the range of concentration 2.5-15.0µg/ml, and slope, intercept and correlation coefficient were found to be 412611.474, -8625.067 and 0.9999 respectively. The percent of recovery was found to be 99.34-99.97%. Ruggedness and robustness studies were carried and the chromatographic parameters were found to be acceptable Stability studies interpret that the drug was stable under the different stressed conditions. Pharmaceutical formulations were successfully analyzed by the proposed method and the percent of assay was present in between 99.68-100.08%.

CONCLUSION

A simple isocratic RP-HPLC method was developed for the determination of Lurasidone in pure and pharmaceutical formulations. The proposed method was found to be simple, precise, accurate, robust and rugged. Therefore the method can be used for routine analysis in quality control.

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Conflict of Interest

The authors had no conflict of interest to publish the paper in our journal.

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