International Journal of Pharmacy and Pharmaceutical Sciences

ISSN- 0975-1491 Vol 10, Issue 12, 2018

Original Article

METHOD DEVELOPMENT, VALIDATION AND STABILITY STUDIES FOR DETERMINATION OF LURASIDONE HYDROCHLORIDE IN TABLET DOSAGE FORM BY RP-HPLC

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Received: 11 Jul 2018 Revised and Accepted: 13 Nov 2018

ABSTRACT

Objective: To develop a simple, rapid, sensitive, precise, accurate, economical and validated reverse phase high performance liquid chromatographic (RP-HPLC) method for the estimation of lurasidone hydrochloride in tablet dosage form.

Methods: The chromatographic separation was carried out on a prontosil C18, AQ (100 mm×4.6 mm, 3 µm) column. A mixture of phosphate buffer (pH 3.0): acetonitrile (ACN) (55:45v/v) was used as a mobile phase. Flow rate of 1.0 ml/min and 10 µl injection volume was used for the assay. PDA detector was used, and the detection wavelength was 230 nm. The retention time (RT) of lurasidone hydrochloride was found to be 4.505±0.01 min. The method was validated according to the ICH guidelines.

Results: The calibration curve for lurasidone hydrochloride was linear with a correlation coefficient value 0.999 in the concentration range of 25-125%. Specificity, accuracy (% mean recovery, 99.08%), precision, detection limits, robustness (% RSD<2) and system suitability were found to be within limits. Degradation studies were performed under different stressed conditions, and the results of degradation studies reveal that the developed method was stable.

Conclusion: The developed method was simple, reliable, economical and stable and it can be applied for the routine quality control analysis of lurasidone hydrochloride in tablet dosage forms.

Keywords: RP-HPLC, Lurasidone hydrochloride, Method validation, Forced degradation studies

DOI: http://dx.doi.org/10.22159/ijpps.2018v10i12.27895

INTRODUCTION

Lurasidone hydrochloride, chemically (3aR, 4S, 7R, 7aS)-2-{(1R, 2R)-2-[4-(1, 2benzisothiazol-3-yl) piperazin1ylmethyl] cyclohexylmethyl} hexahydro-4, 7-methano-2H-isoindole-1, 3-dione is a potent antipsychotic drug belonging to the class of benzothiazole 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. Lurasidone hydrochloride is a white to off-white crystalline powder, slightly soluble in water, ethanol, sparingly soluble in methanol, practically insoluble in 0.1 N HCl, toluene, and very slightly soluble in acetone. Lurasidone hydrochloride acts as an antagonist at Dopamine type-2 (D2) and 5-hydroxytryptamine (5-HT2A) receptors. It also has moderate antagonistic activity at alpha 2C-and alpha 2A-adrenergic receptors and is a partial agonist at 5-HT1A receptors. This medication exhibits minimal or no affinity for histamine type-1 (H1) or muscarinic type-1 (M1) receptors.

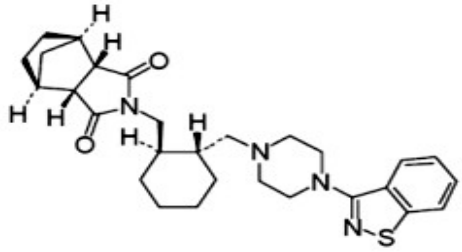

Fig. 1: Chemical structure of lurasidone

A survey of literature for the determination of lurasidone hydrochloride in pure and formulations revealed that various methods such as UV spectrophotometric [1-5], HPLC [6,7], RP-HPLC [8-11] methods and LC/MS/MS [13, 14] method for determining in rat plasma were available. However, some of these methods have certain drawbacks like longer run time, complexity in the composition of the mobile phase, a higher amount of buffer that can affect column performance and elution technique. It affects sensitivity, precision, and accuracy of the method. So, an attempt was made to develop simple, fast and validated RP-HPLC method for the estimation of lurasidone hydrochloride in pure and tablet dosage forms.

MATERIALS AND METHODS

Instrumentation

The chromatographic separation with good retention was carried on Shimadzu LC AHT 2010 HPLC system with a prontosil C18 column of dimensions 100 mm x 4.6 mm and particle size 3 µm. Water alliance 2690 HPLC PDA detector with automatic injector was used for the method development.

Chemicals and reagents

The lurasidone hydrochloride standard was obtained as a gift sample from Orchid health care, and dosage form latuda of Sunovion Pharmaceuticals Inc was purchased from local market. HPLC grade acetonitrile and methanol were purchased from Merck. Analytical grade HCl, NaOH and H2O2 were purchased from Finar and Merck. Milli-Q water was obtained from millipore.

HPLC conditions

The mobile phase used was a combination of previously degassed phosphate buffer (pH 3.0) and ACN in the ratio of 55:45. The elution mode was isocratic with a flow rate of 1.0 ml/min. The volume of the sample injected was 10 µl. Column temperature was maintained at 30 °C. The analyte was quantified at 230 nm.

Standard preparation

An accurately weighed amount, 20 mg of lurasidone hydrochloride was transferred into a 100 ml volumetric flask. 70 ml of diluent was added to it and sonicated. Then final volume was made with diluent to prepare the primary stock solution. From the above solution, serial dilutions were made with diluent to obtain 120 ppm of lurasidone hydrochloride.

Sample preparation for 20 mg tablets (120 ppm)

For the sample preparation, 12 tablets were grinded into fine powder, and an accurate weight equivalent to 20 mg was transferred into a 100 ml volumetric flask. 70 ml of diluent was added to it and kept the volumetric flask on a rotary shaker for 15 min at 200 RPM. It was sonicated for 30 min with intermediate shaking and diluted to the volume with diluent and mixed to get a primary sample stock solution. 10 ml of the above solution was centrifuged at 2500 RPM for 10 min. Then the solution was filtered through 0.45 µm poly tetra fluoro ethylene (PTFE) filter by discarding first 2 ml of the filtrate. Then serial dilutions were made with diluent and mixed well to get 120 ppm of the sample.

Procedure for assay

Six replicates of standard and sample were analyzed. 10 µl of the blank, standard solution prepared from active pharmaceutical ingredient (API) and test solution prepared from formulation was injected into the HPLC. The chromatogram was recorded, and the lurasidone hydrochloride peak area was used for calculating the percentage purity.

Method validation

The proposed method was validated [15-19] for specificity, linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), robustness and system suitability as per international conference on harmonization (ICH) guidelines.

Specificity

Specificity is the ability of the analytical method to assess the analyte even in the presence of components which may expect to be present in the sample. Blank, standard, sample and placebo solutions were prepared and injected into the HPLC system to check the interference and to establish specificity.

Linearity

Linearity is the ability of the method to produce test results which are directly proportional to the concentration of the analyte in the given sample. Solutions for linearity analysis were prepared from the stock solution of the working standard to obtain the solutions at 25%, 50%, 75%, 100%, and 125%. These solutions were analyzed by injecting 10 µl into the HPLC system for 3 replicates.

Accuracy

Accuracy of the method reveals the degree of similarity between the true value and the mean analytical value. Percentage recovery was determined at three concentration levels, i.e. 50%, 100% and 150% of the known concentration of the drug for 3 replicates.

Precision

Six different standard solutions were prepared from the homogeneous sample and were analyzed using the proposed method over a short period of time by the same analyst, on the same equipment, on the same day. The assay results and relative standard deviation were calculated, which indicates the intraday precision of the method.

Limit of detection and limit of quantification (LOD and LOQ)

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not quantified as an exact value. The quantification limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined. To determine LOD and LOQ, a series of solutions were injected, and the signal-to-noise ratio for each injection was calculated.

$$LOD = 3.3 \times \frac{\text{Standard deviation of intercept}}{\text{Average of slope}}$$

$$LOD = 3.3 \times \frac{59.16}{19308} = 0.0101\ \mu g/ml$$

$$LOQ = 10 \times \frac{\text{Standard deviation of intercept}}{\text{Average of slope}}$$

$$LOQ = 10 \times \frac{59.16}{19308} = 0.0306 \mu g/ml$$

Robustness

Robustness was performed to know the ability of the method to resist small changes in the analytical procedure, and it indicates the reliability of the method. To determine robustness, one set of analysis was carried out by using the same homogenous sample by making minor, but deliberate changes in the analytical procedure. The robustness of the method was determined by making slight changes in the chromatographic conditions, i.e. flow variation±0.2 ml/min (0.8 and 1.2 ml/min), temperature variation±5 °C variation (25 °C and 35 °C), variation in buffer pH±0.2 units (pH 2.8 and pH 3.2). The system suitability parameters were evaluated.

System suitability

System suitability is generally performed to check whether the developed method suits the intended purpose or not. It can be demonstrated by injecting five replicates of standard stock solutions into HPLC system. For the preparation of the standard stock solution, an accurately weighed amount 20 mg of lurasidone hydrochloride was transferred into a 100 ml volumetric flask. 70 ml of diluent was added to it and sonicated. Then final volume was made with diluent to prepare the primary stock solution. From the above solution, serial dilutions were made with diluent to obtain 120 ppm of lurasidone hydrochloride. 10 µl of this prepared solution was injected five replicates into the HPLC system and the results obtained were used to express the system suitability of the developed method.

Forced degradation studies

Forced degradation studies were performed to determine the stability of lurasidone hydrochloride in tablet dosage form. The drug was subjected to oxidative, acidic, basic, photolytic, relative humidity (RH) and thermal stress conditions.

Peroxide degradation studies

To perform peroxide degradation studies, an accurate amount of tablet powder which was quantitatively equivalent to 20 mg of lurasidone hydrochloride was taken in a 50 ml volumetric flask. 5 ml of 6% H2O2 solution was added and kept in a water bath at 80 °C for 15 min; then the volumetric flask was removed from the water bath and allowed to cool. 30 ml of diluent was added, sonicated for 30 min. The final volume was made with diluent. Then it was filtered through 0.45µm PTFE filter. Serial dilutions were made to obtain 120 ppm concentration of lurasidone hydrochloride solution. From the resultant solution (12 0 ppm) 10 µl was injected into the HPLC system, and the chromatogram was recorded to assess the stability of the sample.

Acid degradation studies

Acid degradation studies were performed by weighing an accurate amount of tablet powder which was quantitatively equivalent to 20 mg of lurasidone hydrochloride. This was taken in a50 ml volumetric flask. 5 ml of 2N HCl was added and kept in a water bath at 80 °C for 2 h. Then the volumetric flask was removed from the water bath, allowed to cool and 5 ml of 2N NaOH solution was added. 25 ml of diluent was added and sonicated for 30 min. Final volume was made with diluent. Then it was filtered through 0.45µm PTFE filter. Serial dilutions were made to obtain 120 ppm concentration of lurasidone hydrochloride solution. 10 µl from the resultant solution was injected into the HPLC system, and the chromatogram was recorded to assess the stability of the sample.

Alkali degradation studies

Alkali degradation studies were performed by weighing an accurate amount of tablet powder which was quantitatively equivalent to 20 mg of lurasidone hydrochloride. This was taken in a50 ml volumetric flask. 5 ml of 2N NaOH was added and kept in a water bath at 80 °C for 2 h. Then the volumetric flask was removed from the water bath, allowed to cool and 5 ml of 2N HCl solution was added. 25 ml of diluent was added and sonicated for 30 min.

Final volume was made. Then it was filtered through 0.45µm PTFE filter. Serial dilutions were made to obtain 120 ppm concentration of lurasidone hydrochloride solution. 10µl of 120 ppm solution was injected into the HPLC system, and the chromatogram was recorded to assess the stability of the sample.

Photolytic condition

To perform the Photolytic degradation study, an accurately weighed amount of the sample which was quantitatively equivalent to 20 mg of lurasidone hydrochloride was taken on to a clean and dry petri dish. Then petri dish was placed in the photo-stability chamber for intensity at 200W. hr/m^2 for 6 h. The dried sample was taken, and a solution of concentration 120 µg/ml was prepared with diluent. From the 120 ppm solution, 10 µl solution was injected into the HPLC system, and the chromatogram was recorded to assess the stability of the sample.

Humidity condition

To perform humidity degradation studies, the drug solution was exposed to 90% RH for 10 d. The solution was diluted to120 µg/ml with diluent. From the resultant solution, 10 µl solution was injected into the HPLC system, and the chromatogram was recorded to assess the stability of the sample.

Thermolytic condition

To perform thermal degradation study, an accurately weighed amount of the sample which was quantitatively equivalent to 20 mg of lurasidone hydrochloride was taken on to a clean and dry petri dish, spread it throughout the plate and placed in an oven at 80 °C for 6 h. The dried sample was taken, and a solution of concentration 120 µg/ml was prepared with diluent. For HPLC study, from the resultant solution, 10 µl was injected into the system, and the chromatogram was recorded to assess the stability of the sample.

RESULTS AND DISCUSSION

The method has been developed after performing several trials. In each trial different column, mobile phase and various flow rates were selected. The suitable wavelength for quantization was determined and fixed. The runtime for every individual analysis was 10 min. Optimized chromatographic conditions were given in table 1 and chromatogram of the optimized method was shown in fig. 2.

Table 1: Optimized chromatographic conditions

S. No.	Parameters	Optimized condition
1.	Mobile phase ratio	pH 3.0 phosphate buffer: ACN(55:45)
2.	Column Prontosil	C18, AQ (100×4.6 mm,3µ)
3.	Flow rate(ml/min)	1.0
4.	Detector wavelength(nm)	230
5.	Run time(min)	10
6.	Elution mode	Isocratic
7.	Column temperature °C	30
8.	Volume of injection(µl)	10

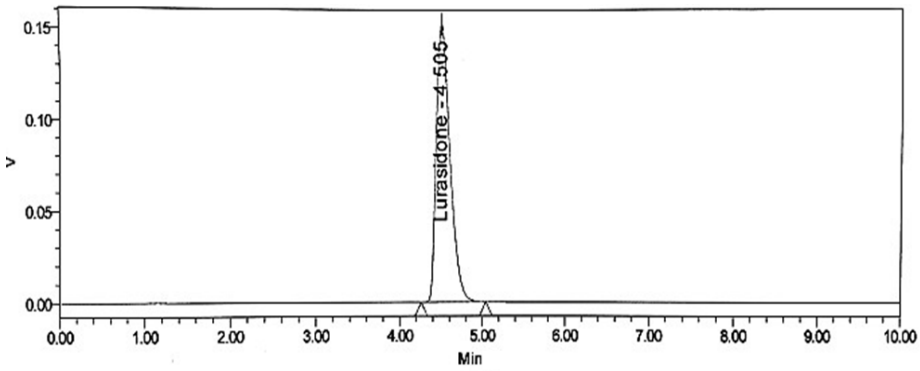

Fig. 2: Optimized chromatogram of standard lurasidone hydrochloride

Specificity

Specificity was carried out by injecting blank, placebo, standard and sample solutions individually into the HPLC system. Respective chromatographs were shown in fig. 3/fig. 3: Chromatograms for the specificity of lurasidone hydrochloride

Linearity

The linearity study of the lurasidone hydrochloride was carried out, and the calibration curves were found to be linear in the concentration range of 25-125 µg/ml with a regression coefficient of 0.999. The equation of the regression line was y = 19308x+5477. The linearity data and calibration plot for the lurasidone hydrochloride were given in the table 2 and fig. 4 respectively.

Accuracy

The percentage recovery and % RSD were calculated. The mean percentage recovery of lurasidone hydrochloride (99.08%) and % RSD were found to be within limits (table 3).

Precision

The results of method precision were within limits. Method precision was performed within 24 h time lag and the % RSD obtained for lurasidone hydrochloride was found to be 0.50% (table 4).

Table 2: Linearity data for lurasidone hydrochloride

S. No.	Sample name	Name	RT	Area	USP tailing	USP plate count
1	Linearity-25%	Lurasidone	4.527	581454	1.43	3874
2	Linearity-50%	Lurasidone	4.515	1161124	1.48	3654
3	Linearity-75%	Lurasidone	4.505	1767554	1.53	3420
4	Linearity-100%	Lurasidone	4.497	2316224	1.56	3229
5	Linearity-125%	Lurasidone	4.481	3474416	1.61	2846
Mean*				1860154		
Std. Dev				1111995.142		
% RSD				59.8		

*Number of experiments-5, % RSD: Relative standard deviation

Table 3: Recovery data for lurasidone hydrochloride

Concentration % of the spiked level	Amount added (mg)	Amount found (mg)	Sample area	% Recovery	Statistical analysis of % recovery	
50% Injection 1	360	359.97	1154224	98.90	MEAN*	98.86
50% Injection 2	360	359.95	1154690	98.90	%RSD	0.05
50% Injection 3	360	359.89	1153588	98.80		
100% Injection 1	720	720.06	2323511	100.00	MEAN*	99.87
100% Injection 2	720	720.08	2324085	100.02	%RSD	0.05
100% Injection 3	720	719.96	2325635	99.60		
150% Injection 1	1080	1079.89	3427815	97.90	MEAN*	98.53
150% Injection 2	1080	1079.94	3458067	98.80	%RSD	0.56
150% Injection 3	1080	1079.98	3463586	98.90		

*Number of experiments-3, % RSD: Relative standard deviation

Table 4: Method precision results for lurasidone hydrochloride

S. No.	Sample name	Name	RT	Area	USP tailing	USP plate count
1	Precision-1	Lurasidone	4.500	2293300	1.55	3178
2	Precision-2	Lurasidone	4.500	2292215	1.55	3188
3	Precision-3	Lurasidone	4.498	2288756	1.55	3183
4	Precision-4	Lurasidone	4.498	2270937	1.54	3194
5	Precision-5	Lurasidone	4.499	2270113	1.54	3181
6	Precision-6	Lurasidone	4.497	2270633	1.54	3186
Mean*				2280993		
Std. Dev.				11528.014		
% RSD				0.50		

*Number of experiments-6, % RSD: Relative standard deviation

Table 5: LOD and LOQ data for lurasidone hydrochloride

S. No.	The concentration of lurasidone hydrochloride (µg/ml)	Average peak area (response)
1	0	0
2	30	581454
3	60	1161124
4	90	1767554
5	120	2316224
6	180	3474416

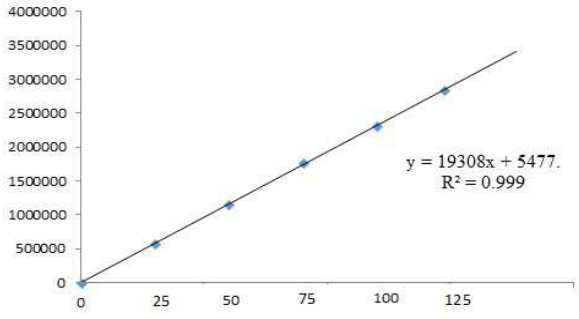

Fig. 4: Linearity plot of lurasidone hydrochloride

LOD and LOQ

LOD and LOQ were found to be 0.0101 µg/ml and 0.0306 µg/ml respectively. LOD and LOQ data were tabulated in table 5.

Robustness

Robustness was evaluated by making deliberate changes to the chromatographic parameters of the method. The obtained results (tables 6-9) indicated the minor changes in each condition did not affect the method and the system suitability parameters were found to be within limits.

System suitability

The system suitability parameters were evaluated from standard chromatograms obtained by calculating the % RSD, retention time, tailing factor, theoretical plates and peak areas from five replicated injections. The tailing factor and theoretical plate count of lurasidone hydrochloride peak from first injection and % RSD on replicating injections were recorded (table 10) and were found to be within the accepted criteria.

Forced degradation studies

In each condition of forced degradation studies, it was observed that the purity threshold value was found to be greater than the purity

angle value and no purity flag was observed, which indicates that there was no interference of degradants with the analyte peak. Degradation studies revealed that the developed method was stable. The results were incorporated in table 11.

Table 6: Data for robustness showing a change in temperature minus injections

Injection No.	Sample name	Name	RT	Area	USP tailing	USP plate count
1	Std-Column oven temp(-5 °C)	Lurasidone	4.518	2308290	1.56	3275
2	Std-Column oven temp(-5 °C)	Lurasidone	4.514	2310297	1.56	3263
3	Std-Column oven temp(-5 °C)	Lurasidone	4.520	2311462	1.56	3282
4	Std-Column oven temp(-5 °C)	Lurasidone	4.511	2313195	1.56	3237
5	Std-Column oven temp(-5 °C)	Lurasidone	4.509	2312261	1.56	3234
Mean				2311101		
Std. Dev.				1897.830		
% RSD*				0.1		

*The % RSD was calculated from a mean of 5 replicate measurements, n-5.

Table 7: Data for robustness showing a change in temperature plus injections

Injection No.	Sample name	Name	RT	Area	USP tailing	USP plate count
1	Std-Column oven temp(+5 °C)	Lurasidone	4.674	2347295	1.53	3261
2	Std-Column oven temp(+5 °C)	Lurasidone	4.671	2346354	1.53	3256
3	Std-Column oven temp(+5 °C)	Lurasidone	4.671	2348570	1.54	3256
4	Std-Column oven temp(+5 °C)	Lurasidone	4.672	2348165	1.54	33259
5	Std-Column oven temp(+5 °C)	Lurasidone	4.673	2347596	1.54	3257
Mean				2347596		
Std. Dev				852.325		
% RSD*				0.0		

*The % RSD was calculated from a mean of 5 replicate measurements, n-5.

Table 8: Data for robustness showing a change in mobile phase pH minus (2.8)

S. No.	Sample name	Peak name	RT	Area	USP tailing	USP plate count
1	Standard (Low pH)	Lurasidone	4.691	2323511	1.57	2995
2	Standard (Low pH)	Lurasidone	4.691	2324085	1.58	3023
3	Standard (Low pH)	Lurasidone	4.685	2325635	1.58	3030
Mean				2324410		
Std. Dev				1098.74		
%RSD*				0.05		

*The % RSD was calculated from a mean of 3 replicate measurements, n-3.

Table 9: Data for robustness showing a change in mobile phase pH plus (3.2)

S. No.	Sample name	Peak name	RT	Area	USP tailing	USP plate count
1	Standard (High pH)	Lurasidone	4.687	2327237	1.59	3042
2	Standard (High pH)	Lurasidone	4.685	2328971	1.59	3037
3	Standard (High pH)	Lurasidone	4.687	2527337	1.59	3054
Mean				2394515		
Std. Dev				973.54		
%RSD*				0.04		

*The % RSD was calculated from a mean of 3 replicate measurements, n-3

Table 10: Data for system suitability

S. No.	Name	RT	Area	USP tailing	USP plate count
1	Lurasidone	4.506	2321880	1.53	3126
2	Lurasidone	4.493	2318789	1.54	3113
3	Lurasidone	4.491	2315816	1.55	3128
4	Lurasidone	4.488	2316057	1.56	3139
5	Lurasidone	4.484	2317289	1.56	3196
Mean*			2317966		
Std. Dev.			2486.142		
%RSD			0.1		

*The % RSD was calculated from a mean of 5 replicate measurements, n-5, the results obtained in the method development and validation were found to be better and consistent when compared to other available methods.

Table 11: Forced degradation studies data for lurasidone hydrochloride

Mode of degradation	Lurasidone hydrochloride				
	Area	% Recovered	% Degraded	Purity angle	Purity threshold
Un degradation	2451883	-	-	0.328	1.022
Peroxide	2487761	98.87	1.13	0.359	1.022
Acid	2451883	97.49	2.51	0.331	1.023
Base	2486395	98.76	1.24	0.348	1.037
Photolytic	2453780	97.57	2.43	0348	1.019
Humidity	2470186	98.19	1.81	0.334	1.019
Thermal	2459264	97.70	2.30	0.327	1.019

CONCLUSION

The proposed reverse phase HPLC method was found to be simple, economical, precise, accurate and sensitive for the estimation of lurasidone hydrochloride in bulk and pharmaceutical dosage form. Degradation studies revealed that the developed method was stable. Hence, this method can easily and conveniently be adopted for routine quality control analysis of lurasidone hydrochloride pure and its pharmaceutical dosage forms.

ACKNOWLEDGMENTS

The authors are grateful to acknowledge ORCHID HEALTH CARE, a division of Orchid Pharma Ltd, Irugattukottai for providing facilities.

AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICTS OF INTERESTS

All authors have none to declare

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