WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.421
Volume 7, Issue 8, 614-632 Research Article ISSN 2278 – 4357

METHOD DEVELOPMENT AND VALIDATION OF LURASIDONE HCL IN BULK AND PHARMACEUTICAL DOSAGE FORMS BY U.V SPECTROPHOTOMETRY

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Article Received on
25 May 2018,

Revised on 15 June 2018,
Accepted on 05 July 2018

DOI: 10.20959/wjpps20188-12064

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ABSTRACT

The UV-spectroscopic method was developed and validated for the estimation of Lurasidone HCl in accordance with ICH guidelines. A simple fast accurate and precise UV-spectroscopy method was developed by using Methanol: Water (70:30) was used as the solvent in method 1 and Acetonitrile: Water (50:50) was used as solvent in method 2. The λ_{max} of Lurasidone was found to be 230 nm and it was proved linear in the concentration range of 2.5–15 µg/ml with a correlation coefficient value of 0.999. The accuracy studies of UV-spectroscopy was performed at three different levels, i.e., 50%, 100%, and 150% and recovery was found to be in the range of 100.1-100.6% and 99.2. The limit of detection (LOD) and limit of quantification (LOQ) were found for UV-spectroscopy. The % RSD is <2% which indicates the accuracy and precision of the method. The above method was a rapid tool for routine analysis of Lurasidone in the bulk and in the pharmaceutical dosage form.

KEYWORDS: UV-spectroscopic method, correlation coefficient, limit of quantification.

INTRODUCTION

Among the physico-chemical methods that are available for the estimation of drugs, the most important are optical (refractometry, polarimetry, emission, fluorescence methods of analysis, photometry including photocolorimetry and spectrophotometry covering UV-Visible and IR regions andnephlometry or turbidimetry) and chromatographic (column, paper, thin-layer, gas liquid) HPLC methods.

UV-Visible Spectroscopy

Spectroscopy is the branch of science that measures the interaction between the matter and Electromagnetic radiation. Ultraviolet (UV) and visible absorption technique encompass analytical methods based upon measurement of light absorption by substances in the wavelength (λ) region from approximately 200 to 750 nm where as the region from 200 to 400 nm is the UV region and from 400 to 750 nm the visible region of the spectrum.[1]

Quantitative description of light absorption

When a beam of light is passed through a transparent cell containing a solution of an absorbing substance, a portion of light is reflected at the inner and outer surfaces of the cell, a portion of light is scattered by particles in solution, a portion of light is absorbed by molecules in the solution and the remaining portion is transmitted from the cell.[2] The intensity of the total incident light is then given by.

$I = I_{reflected} + I_{scattered} + I_{absorbed} + I_{transmitted}$

The reflections at the cell surfaces can be compensated by a reference cell containing the solvent only, and scatter may be eliminated by filtration of the solution. The intensity of light absorbed is then given by.

$I_{Absorbed} = I_O - I_T$

Where I_O is the original intensity incident on the cell I_T is the reduced intensity transmitted from the cell.

Transmittance (T) is the ratio of I_T/I_O.

$$\%T = \frac{100 I_T}{I_0}$$

Instrument used for UV-visible spectroscopy measure the intensity of incident (I_O) and transmitted light (I_T).

Criteria for method development by U.V. spectroscopy

a) Compound must fall in absorbance range 200-400 nm.
b) Compound should have a chromophore, or the chromophore should be reactive to some derivatizing agents.
c) Compound should be unsaturated.
d) Compound should follow Lambert-Beers law

e) To follow Lambert-Beers law, concentration of the compound should be very low.

All molecules have absorption bands; therefore solvent taken must be transparent within the wavelength range being examined.[3]

Visible spectroscopic method development

To develop a new method for the determination of concentration of the substance by absorption spectrophotometry, the first step will be the selection of analytical wavelength at which absorption measurements are made. The analytical wavelength can be chosen either from literature or experimentally by means of a scanning spectrum in the UV/Visible region. In order to enhance the sensitivity of the method and signal to noise ratio, the wavelength of maximum absorbance is chosen as analytical wavelength.[4]

Calibration

Calibration is one of the most important steps in drug analysis. A good precision and accuracy can only be obtained when good calibration procedure is used. In spectrophotometric methods the concentration of a sample cannot be measured directly, but is determined using another physical measuring quantity, "Y" (absorbance of a solution). An unambiguous empirical or theoretical relationship can be shown between this quantity and the concentration of analyte.[5]The calibration, function Y = g (x) is directly useful and yields by inversion of the analytical calculation function.

The calibration function can be obtained by fitting an adequate mathematical model through the experimental data. The most convenient calibration function is linear, goes through the origin and is applicable over a wide dynamic range. In practice, many deviations from this ideal calibration line may occur. For the majority of analytical techniques the analyst uses the calibration equation.

$Y = a + bX$

Where Y=Regression equation

b=Slope

a =Intercept

In calibration, univariate regression is applied, which means that all observations are dependent upon a single variable "X".

The Method of Least Squares

Least squares regression analysis is used to describe the relationship between signal and concentration.[6] All models describing the relationship between response (Y) and concentration (X) can be represented by the general function.

Y = f (X, a1, b1,.....bm)

Where a1, b1,.....bm are the parameters of the function

We adopt the convention that the „X" values relate to the controlled or independent variable and the „Y" values to the dependent variable. This means that „X" values have no error. On the condition that errors made in preparing the standards are significantly smaller than the measuring errors this assumption is realistic in calibration problems. The values of the unknown parameter a1, b1,.....bm must be estimated in such a way that the model fits the experimental data points as far as possible. The true relationship between X and Y is considered to be given by a straight line. The relationship between each observation pair (Xi, Yi) can be represented as $Yi= \alpha + \beta Xi+ ei$

The signal Yi is composed of a deterministic component predicted by linear model and a random component ei. The component ei represent the differences between the observed Yi values and predicted Yi value by the model. The ei are called the residuals, „a" and „b" are the intercept and slope respectively.

MATERIALS AND METHODS

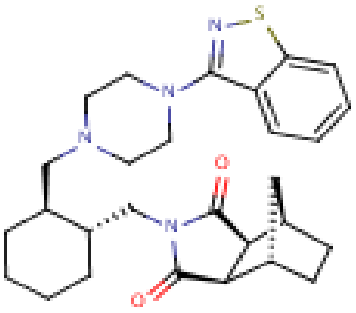
Instrumentation

S. No.	Name of Instrument	Model	Make
1	Precision balance	CA123	Contech
2	pH Meter	3 Star	Global
3	Column	Eclipse C_{18}(100mm x 4.6mm),3.5µm	Agilent
4	UV-Spectrophotometer	UV-1800	Shimadzu
5	UV-Spectrophotometer	UV®-3000	Lab India
6	Sonicator	UCB 70	Life care

Drug Profile

Drug name : Lurasidone

Chemical Structure



CAS : 367514-87-2

Molecular formula : $C_{28}H_{36}N_4O_2S$

Molecular mass : 529.137

Chemical name : (1R,2S,6R,7S)-4-{[(1R,2R)-2-{[4-(1,2-benzothiazol- 3-yl) piperazin-1-yl]methyl}cyclohexyl]methyl}-4-azatricyclo[5.2.1.0^{2,6}]decane-3,5-dione. HCl

pKa : 7.6

Category : Anti psychotic drug

Brand name : Latuda

General Properties

Colour : White

State : solid

Solubility : It is very slightly soluble in water, slightly soluble in ethanol, sparingly soluble in methanol, practically insoluble or insoluble in toluene and very slightly soluble in acetone.

Storage : Store below 25^{o}C Protect from moisture. Do not Freeze

Dose : 20mg, 40mg, 80mg, 120 mg tablets taken orally.

Bioavaliability : 9 to 19% (oral)

Protein binding : 99%

Dose and dosage form : Immediate Release Tablets (20,40,80,120 mg)

UV Spectrophotometric Method

Double beam UV-Visible Spectrophotometer (Shimadzu-1800) connected to a computer loaded with Shimadzu UV Probe 2.33 software was used for all the spectrophotometrimeasurements in all proposed spectrophotometric methods.

Preparation of stock solution of Lurasidone

Method 1

Standard Lurasidone of 10mg was accurately weighed and transferred into a 10ml volumethric flask. About 5ml of methanol: water (70:30) is added and is subjected to sonication and then the volume is made up with the respective solvent to give a concentration of 1000µg/ml. From this stock solution 1ml is pipetted out and transferred into a 10ml volumetric flask and the volume is made up to the mark with solvent to give a concentration of 100µg/ml. Further dilutions were made to get a concentration of 10µg/ml.

Method 2

Standard Lurasidone of 10mg was accurately weighed and transferred into a 10ml volumetric flask. About 5ml of Acetonitrile: water (50:50) is added and is subjected to sonication and then the volume is made up to the mark with solvent to give a concentration of 1000µg/ml. From this stock solution 1ml is pipetted out and transferred into a 10ml volumetric flask and the volume is made up to the mark with solvent to give a concentration of 100µg/ml. Further dilutions were made to get a concentration of 10µg/ml.

Selection of analytical wavelength

The absorbance of the standard stock solution (10µg/ml) was measured against respective blank in the UV region of 200-400 nm, which shows maximum absorbance at 230 nm.

Selection of analytical concentration ranges

From the standard stock solutions of Lurasidone (100µg/ml), appropriate aliquots of 0.25ml, 0.5ml, 0.75ml, 1ml, 1.25ml, 1.5ml was pipetted out and transferred into a 10ml volumetric flasks and dilutions were made with to obtain working standard solutions with concentration ranging from 2.5 to 15µg/ml in both methods.

Calibration curve for lurasidone

Appropriate aliquots from standard lurasidone stock solutions were transferred into different volumetric flasks of 10ml capacity. The volume was adjusted to the mark to obtain concentrations of 2.5, 5, 7.5, 10, 12.5, 15µg/ml. Absorbance spectra of each solution against distilled water as blank were measured at 230nm and the graph of absorbance against concentration were plotted and the regression equation and correlation coefficient were determined for both the methods.

Preparation of sample solutions

Twenty tablets of Lurasidone formulation were weighed and powdered. The powder equivalent to 10mg was calculated and transferred into a 10ml volumetric flask and 4ml of solvent(methanol: water 70:30) in method 1 and Acetonitrile: water (50:50) in method 2 is added and sonicated for 30min. The volume was shaken and made up to the mark with the respective solvent to obtain solutions of 1000µg/ml. The solutions was filtered through Whatmann filter paper (No. 41) and used for the estimation.

Validation of UV spectroscopic method

Linearity and range: The linearity of analytical method is its ability to elicit test results that are directly proportional to the concentration of analyte in the sample within the range. The range of the analytical method is the interval between the upper and lower levels that have been demonstrated to be determined within a suitable level of precision, accuracy and linearity. The method was found to be linear in the concentration range of 2.5-15µg/ml for both methods.

Precision

The precision of an analytical method is the degree of agreement among individual test results, when the method is applied repeatedly to multiple sampling of homogeneous samples. It provides an indication of random error results and is expressed as relative standard deviation (%RSD).

Repeatability

Repeatability expresses the analytical variability under the same operating conditions over a short interval of time. The repeatability studies were carried out by selecting 5µg/ml as the standard concentration and repeating it for six times for both methods.

Intermediate precision

Intra and Inter-day precision

Variation of results within the same day (intra-day) and variation of results between days (inter-day) were analysed for both methods. Intra-day precision was determined by analyzing lurasidone for 6 times on the same day at 230nm. Inter-day precision was determined by analyzing 3 concentrations of lurasidone on the preceding day at 230nm and %RSD was calculated. For method 1-5, 10, 15µg/ml was analysed and for method 2- 2.5, 5, 7.5 µg/ml were analysed.

Accuracy

Accuracy is the closeness of the results obtained by the method to the true value. Recovery studies were carried out at 50%, 100% and 150% by adding known amount of standard drug solutions for method 1 & method 2 i.e. (2.5, 5, 7.5 µg/ml) to the sample solutions whose concentration is maintained constant, i.e. 5µg/ml. The %recovery was calculated.

Ruggedness

The solutions were prepared and analysed with change in the analytical conditions like different instrument and different analyst. Standard concentrations of 5µg/ml were carried used to carry out the ruggedness studies for both methods.

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

The sensitivity of the proposed method for the measurement of lurasidone was estimated in terms of Limit of detection (LOD) and Limit of quantification (LOQ). The LOD and LOQ were calculated by using the slope and SD of response (intercept). The mean slope value and the SD of response were obtained from the calibration curve. The LOD and LOQ calculations were done and reported.

$$LOD = \frac{3.3\,\sigma}{S} \qquad LOQ = \frac{10\,\sigma}{S}$$

RESULTS AND DISCUSSION

The objective of the proposed work was to develop new analytical methods for the determination of Lurasidone and to validate the methods according to the ICH guidelines and applying the same for its estimation in marketed formulations.

The developed UV spectrophotometric was found to be rapid, simple, precise, accurate and economic for routine estimation of lurasidone in commercial dosage forms.

UV spectrophotometry

Method 1: Methanol:water(70:30)

Method 2: Acetonitrile:water (50:50)

Selection of wavelength

Method 1: Methanol: Water (70:30)

The standard stock solution of lurasidone of 10µg/ml concentration was scanned from 200-400nm and the absorption spectras were recorded at 230nm wavelength in UV spectrophotometer using Methanol:Water (70:30) as solvent.

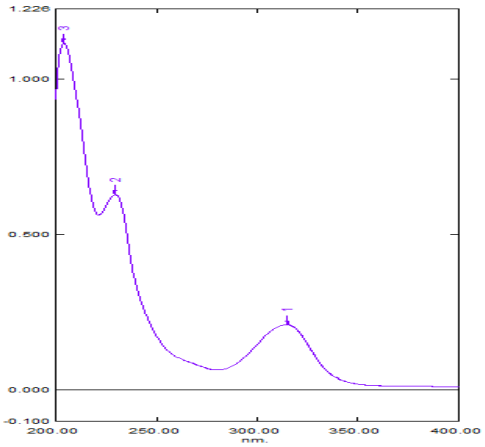


Fig. 1: Absorption srectrum of Lurasidone.

Method 2: Acetonitrile:Water (50:50)

The standard stock solution of lurasidone of 10µg/ml concentration was scanned from 200-400nm and the absorption spectras were recorded at 230nm wavelength in UV spectrophotometer using Acetonitrile:Water (50:50) as solvent.

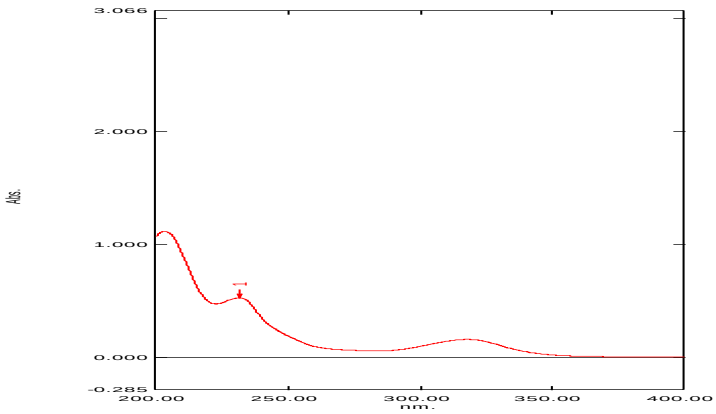


Fig. 2: Absorption srectrum of Lurasidone.

Linearity

Method 1

The linearity was found in the concentration range of 2.5- 15 µg/ml for the developed UV spectrscopy method. The X-axis is concentration and the Y-axis is absorbance. The

correlation coefficient was found to be 0.999 and the regression equation was found to be Y=0.061x + 0.007. The results are shown in **Table1** and the resulting overlay spectra is shown in **Fig. 3.**

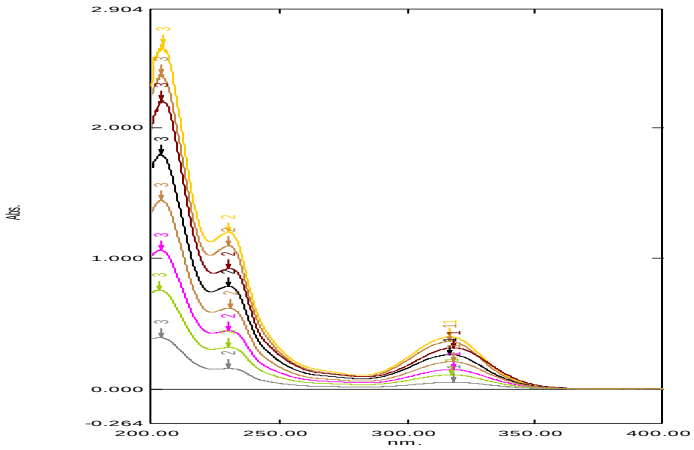


Fig. 3: Overlayspectra of Lurasidone at 230nm using methanol:water(70:30).

Table 1: Results of calibration curve at 230nm for Lurasidone.

Sl. No.	Conccentration(µg/ml)	Absorbance
1	2.5	0.158
2	5	0.320
3	7.5	0.446
4	10	0.620
5	12.5	0.787
6	15	0.922

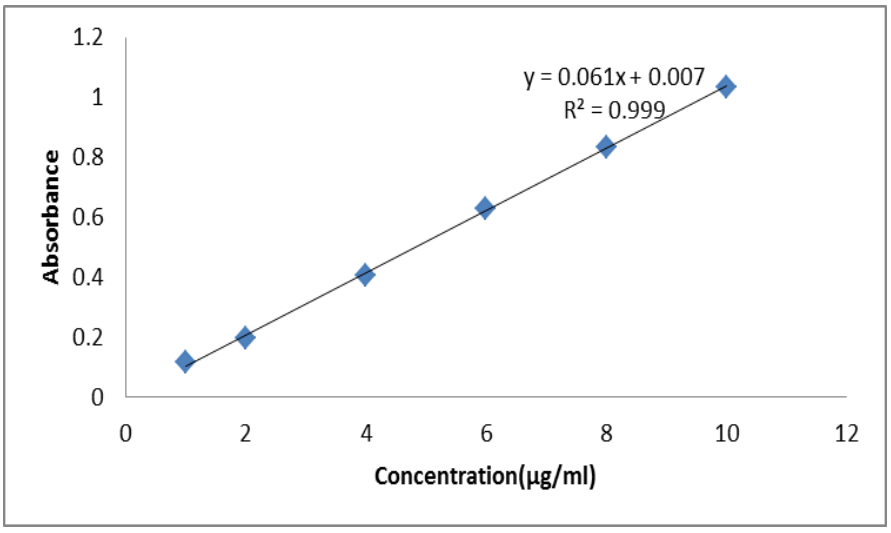


Fig. 4: Linearity graph for Lurasidone at 230nm.

Method 2

The linearity was found in the concentration range of 2.5- 15 µg/ml for the developed UV spectrscopy method. The X-axis is concentration and the Y-axis is absorbance. The correlation coefficient was found to be 0.999 and the regression equation was found to be Y=0.086x + 0.022. The results are shown in **Table 2** and the resulting overlay spectra is shown in **Fig 5.**

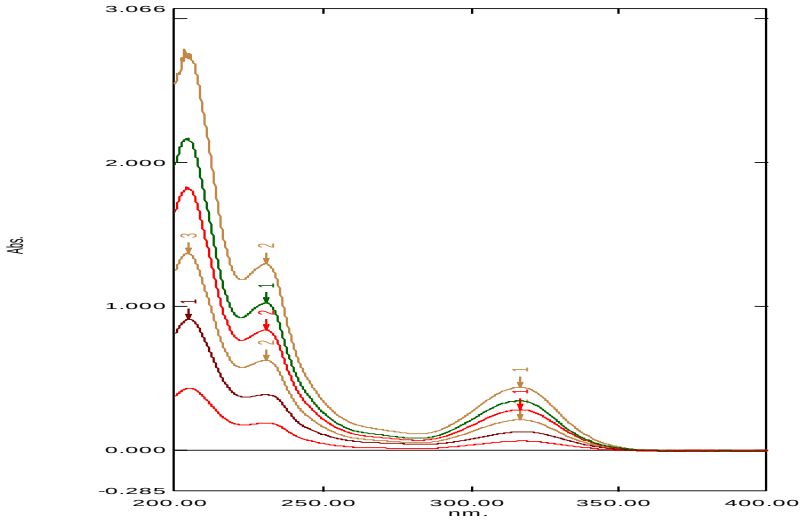


Fig. 5: Overlayspectra of Lurasidone at 230nm using acetonitrile:water(50:50).

Table 2: Results of calibration curve at 230nm for Lurasidone.

Sl. No.	Conccentration(µg/ml)	Absorbance
1	2.5	0.189
2	5	0.386
3	7.5	0.626
4	10	0.836
5	12.5	1.038
6	15	1.295

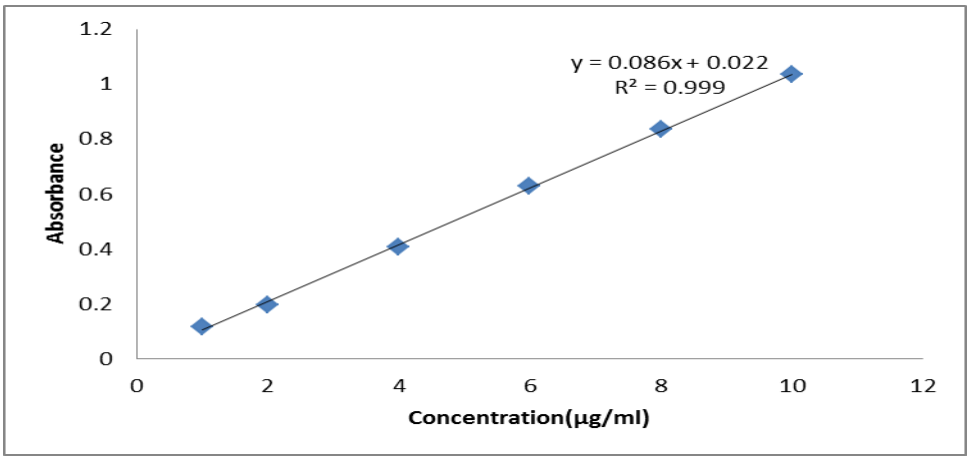


Fig. 6: Linearity graph for Lurasidone at 230nm.

Precision

Repeatability studies were carried out by taking test concentration and repeating it six times. Inter-day and intraday precision were done by taking three concentrations and repeating it three times and the values for repeatability, intraday precision and inter day precision in terms of %RSD were found.

Acceptance criteria

A method is said to be precise if the %RSD value is <2.0%. The results show that the %RSD value for repeatability, intraday and inter-day precision is <2.0% which indicate that they meet the acceptance criteria and hence the method is said to be precise.

Method 1

The values for repeatability, intraday precision and inter-day precision in terms of %RSD were found to be 1.5, 0.41-1.69 and 0.40-1.13 respectively.

Table 3: Repeatability studies of Lurasidone.

Concentration [µg/ml]	Absorbance at 230 nm	Absorbance Mean ±S.D(n=6)	%RSD
5	0.311	0.312±0.007	1.5
5	0.315		
5	0.31		
5	0.312		
5	0.312		
5	0.315		

Table 4: Intermediate precision.

Table 4.1: Intraday precision of Lurasidone.

Concentration (µg/ml)	Absorbance	Absorbance Mean ±S.D(n=3)	%RSD
5	0.320	0.314±0.002	1.69
	0.31		
	0.312		
10	0.62	0.626±0.006	0.85
	0.628		
	0.630		
15	0.922	0.926±0.004	0.410
	0.928		
	0.929		

Table 4.2: Interday precision of lurasidone.

Concentration (µg/ml)	Absorbance	Absorbance Mean ±S.D(n=3)	%RSD
5	0.308	0.312±0.001	1.13
	0.315		
	0.312		
10	0.621	0.618±0.007	0.49
	0.618		
	0.615		
15	0.918	0.922±0.014	0.396
	0.923		
	0.925		

Method 2

The values for repeatability, intraday precision and inter-day precision in terms of %RSD were found to be 0.55, 0.54-1.34 and 0.55-1.62 respectively.

Table 5: Repeatability studies of Lurasidone.

Concentration [µg/ml]	Absorbance at 230 nm	Absorbance Mean ±S.D(n=6)	%RSD
5	0.382	0.385±0.002	0.55
5	0.384		
5	0.385		
5	0.385		
5	0.387		
5	0.388		

Table 6 Intermediate precision.

Table 6.1 Intraday precision of Lurasidone.

Concentration (µg/ml)	Absorbance At 230nm	Absorbance Mean ±S.D(n=3)	%RSD
2.5	0.184	0.186±0.002	1.34
	0.187		
	0.189		
5	0.382	0.382±0.002	0.54
	0.386		
	0.385		
7.5	0.623	0.626±0.003	0.56
	0.626		
	0.630		

Table 6.2: Interday precision of lurasidone.

Concentration (µg/ml)	Absorbance At 230nm	Absorbance Mean ±S.D(n=3)	%RSD
2.5	0.185	0.188±0.003	1.62
	0.189		
	0.191		
5	0.389	0.389±0.004	1.03
	0.386		
	0.394		
7.5	0.632	0.635±0.003	0.55
	0.635		
	0.639		

Accuracy: (method 1 and method 2)

Recovery studies were carried out at 50%, 100% and 150% by adding known amount of standard drug solution, i.e. (2.5, 5, 7.5 µg/ml) to the sample solution whose concentration is maintained constant, i.e. 5µg/ml and the accuracy of the method was confirmed by recovery studies and the % recovery for the marketed formulation was determined and were found to be in the range of 100.1-100.6 in method 1 and 100.3-100.5 in method 2.

Acceptance criteria

A method is said to be accurate if the % recovery studies is in the range of 98-102. The results for accuracy indicate that the % recovery values are within the range of 98-102 which indicate that the method is accurate as it meets the necessary criteria.

Method 1: Table 7 Determination of accuracy results for Lurasidone at 230nm.

Spiked level (%)	Formulation Conc. (µg/ml)	Pure Drug Conc. (µg/ml)	Amount recovered (µg/ml)	% Recovery	%Mean recovery ±SD	%RSD
50	5	2.5	7.48	99.8	100.6±0.59	0.591
	5	2.5	7.55	100.7		
	5	2.5	7.57	100.9		
100	5	5	10.02	100.2	100.4±0.42	0.424
	5	5	10.10	101		
	5	5	10.08	100.8		
150	5	7.5	12.53	100.3	100.1±0.33	0.336
	5	7.5	12.47	99.7		
	5	7.5	12.55	100.4		

Method 2

Table 8: Determination of accuracy results for Lurasidone at 230nm.

Spiked level (%)	Formulation Conc (µg/ml)	Pure Drug Conc (µg/ml)	Amount recovered (µg/ml)	% Recovery	%Mean recovery ±SD	%RSD
50	5	2.5	7.49	99.9	100.5±0.67	0.66
	5	2.5	7.53	100.4		
	5	2.5	7.59	101.2		
100	5	5	9.8	99.6	100.3±0.7	0.69
	5	5	10.1	101.0		
	5	5	10.03	100.3		
150	5	7.5	12.56	100.5	100.4±0.41	0.409
	5	7.5	12.49	99.9		
	5	7.5	12.59	100.7		

Ruggedness

Ruggedness of the method was performed by assaying the standard drug by two different analysts and in two different instruments. The different instruments used were lab india and shimadzu. The results for varied analysts and varied instruments in terms of %RSD were found

Acceptance criteria

A method is said to be robust if the %RSD values is <2%. The results indicate that the %RSD values for different analysts and different instruments were found to be below 2 which indicate that they meet the acceptance criteria.

Method 1

The results for varied analysts and varied instruments in terms of %RSD were found to be in the range of 1.12-1.38 and 0.811-1.12 respectively for method 1.

Table 9.1: Ruggedness results for different analysts.

Concentration (µg/ml)	Absorbance of Analyst I	mean absorbance ± SD(n=3)	%RSD	Absorbance of Analyst II	mean absorbance ± SD(n=3)	%RSD
5	0.311	0.314±0.004	1.12	0.326	0.331±0.004	1.38
5	0.315			0.335		
5	0.318			0.332		

Table 9.2: Ruggedness results for different instruments.

Concentration (µg/ml)	Absorbance of instrument I(Shimadzu)	mean absorbance ± SD(n=3)	%RSD	Absorbance of instrument II(Lab India)	mean absorbance ± SD(n=3)	%RSD
5	0.311	0.314±0.004	1.12	0.324	0.326±0.002	0.811
5	0.315			0.329		
5	0.318			0.325		

Method 2

The results for varied analysts and varied instruments in terms of %RSD were found to be in the range of 0.649-1.06 and 1.06-1.23 in method 2.

Table 10.1: Ruggedness results for different analysts.

Concentration (µg/ml)	Absorbance of Analyst I	mean absorbance ± SD(n=3)	%RSD	Absorbance of Analyst II	mean absorbance ± SD(n=3)	%RSD
5	0.376	0.379±0.004	1.06	0.390	0.387 ±0.002	0.649
5	0.379			0.385		
5	0.384			0.387		

Table 10.2: Ruggedness results for different instruments.

Concentration (µg/ml)	Absorbance of instrument I(Shimadzu)	mean absorbance ± SD(n=3)	%RSD	Absorbance of instrument II(Lab India)	mean absorbance ± SD(n=3)	%RSD
5	0.376	0.379±0.004	1.06	0.381	0.382±0.004	1.23
5	0.379			0.388		
5	0.384			0.379		

Assay

Assay studies were carried out by weighing twenty tablets of Lurasidone formulation and powdered. The powder equivalent to 10mg was taken and the solution equivalent to 1000µg/ml was prepared and was used for further dilutions using method 1 and method 2. The results of %purity was found to be 100.06 and 100.26.

Acceptance criteria

A method is said to pass the %purity if it is in the range of 98-102%. The results show that the %purity was found to be in the range of 98-102 and hence meets the necessary criteria.

Method 1 and Method 2

Table 11: Assay studies of Lurasidone.

Labeled Amount (mg)	Formulation	Amount found (mg)		% Purity		Mean % purity ± SD(n=3)		%RSD	
		I	II	I	II	I	II	I	II
20	LATUDA (Tablets 20mg)	20.07	19.92	20.01	20.05	100.06 ± 0.78	100.26± 0.45	0.787	0.449
20		20.10	20.06						
20		20.88	20.5						

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

The LOD and LOQ were calculated by using the slope and SD of response (intercept). The mean slope value and the SD of response were obtained from the calibration curve. The LOD and LOQ results were found to be 0.70 and 2.11µg/ml respectively for method 1 and 0.613 and 1.85µg/ml respectively for method 2.

Table 12: Determination of LOD and LOQ results for Lurasidone at 230nm.

Parameter	Concentration (µg/ml) for method 1	Concentration (µg/ml) for method 2
Limit of detection	0.697259	0.613085
Limit of quantification	2.112905	1.86833

Optimum conditions, optical characteristics and Statistical data of the Regression equation in UV method

The optical characteristics such as Beer's law limits molar absorptivity, LOD and LOQ in each method were calculated**.** Also the regression equation like slope (b), intercept(a) and correlation coefficient(R^2) using the method of least squares were calculated**.** The results show that the methods are reasonably precise.

Table 13: Summary of UV-spectrophotometry validation parameters.

PARAMETERS	METHOD I	METHOD II
λmax (nm)	230	230
Beers law limit µg/ml	2.5-15µg/ml	2.5-15µg/ml
Correlation coefficient (r^2)	0.9995	0.9993
Molar absorbivity (l $mol^{-1}cm^{-2}$)	0.103 x 10^4	0.105 x 10^4
Sandell's sensitivity	0.0001	0.0002
Regression equation (y=mx+c)	Y=0.061x+0.007	Y=0.086x+0.022
Slope (m)	0.061	0.086
Intercept(c)	0.007	0.022
Accuracy	100.1-100.6	100.3-100.5
Precision (%RSD)	0.39-1.69	0.54-1.62
LOD (µg/ml)	0.697	0.613
LOQ (µg/ml)	2.11	1.85

CONCLUSION

Lurasidone is a recently approved drug and very few analytical methods appeared in the literature for the determination of Lurasidone. In view of the above fact, a simple analytical method like UV-spectroscopy was developed which were sensitive, accurate, precise and economical. In the present investigation, UV spectroscopy method for the qualitative and quantitative estimation of Lurasidone in bulk drug and pharmaceutical dosage forms has been developed.

The results of the validation parameters for UV-spectroscopy are as follows.

- Linearity - 2.5-15µg/ml
- Correlation coefficient - 0.999
- Precision

Repeatability - <2%

Interday precision - <2%

- Intraday precision - <2%
- Accuracy - 50%, 100%, 150%
- Ruggedness

Different instrument - <2%

Different analyst - <2%

Assay - 99%

LOD & LOQ - 0.303, 0.912

The above results indicate that the values of the validation parameters were found to be within the acceptance criteria and hence the developed methods were proved to be precise, accurate and robust.

Scope for furthur studies

The developed UV-spectroscopy can be used to perform furthur stability studies.

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