RASĀYAN *J. Chem.*
Vol. 19 | No. 3 | 1515-1519 | July-September | 2026
ISSN: 0974-1496 | e-ISSN: 0976-0083 | CODEN: RJCABP
http://www.rasayanjournal.com
http://www.rasayanjournal.co.in

GREEN ANALYTICAL METHOD IN PRACTICE: AN ULTRASENSITIVE SPECTROFLUORIMETRIC METHOD FOR LURASIDONE HYDROCHLORIDE

C. Mathew[1,✉], R. Bejjarapu[1], S. Metri[1], D. V. Durga[1], and P. B. Mare[2]
[1]Gokaraju Rangaraju College of Pharmacy, Hyderabad-500090, Telangana, India.
[2]Arya College of Pharmacy, Hyderabad-500090, Telangana, India.
✉Corresponding author: ceema8003@grcp.ac.in

ABSTRACT
An ultra-sensitive spectrofluorimetric method was developed for Lurasidone Hydrochloride, an FDA-recognised atypical antipsychotic. The process effectively quantifies the drug in bulk materials, tablets, and biological fluids. Excitation and emission wavelengths were 328 nm and 410 nm, respectively. Environmentally friendly solvents were used, classifying the method as green. A linear relationship was observed over the 0.2–10.0 µg/mL range. The method extends to drug estimation in spiked human plasma and urine at spiking levels of 0.2-10.0 and 2.0-10.0 µg/mL, respectively. Its sensitivity makes it suitable for bioanalytical studies. Application to marketed tablets showed an assay value of 99.37%. The method was validated by the International Conference on Harmonisation Guidelines.
Keywords: Lurasidone Hydrochloride, Spectrofluorimetry, Antipsychotic, Validation, Green Analytical Method.
RASĀYAN *J. Chem.*, Vol. 19, No.3, 2026

INTRODUCTION

Drugs in the antipsychotic class are extensively employed to treat psychosis, which is marked by hallucinations, delusions, chaotic thinking or behaviour, difficulty expressing emotions, etc. First-generation antipsychotics, frequently referred to as typical antipsychotics, are seldom utilised due to their untoward effects. Because they have fewer side effects, atypical antipsychotics, commonly referred to as second-generation antipsychotics, are more frequently applied. The lock and key mechanism by which antipsychotics function can be explained as follows:

Atypical antipsychotics function by blocking specific dopamine and serotonin receptors and activating some other receptors of both categories.[1] Figure-1 depicts the chemical structure of lurasidone hydrochloride (LRD), which is (1R, 2S,6R, 7S)-4- [{(4-(1, 2-benzthiazol-3-yl) piperzin-1-yl] methyl] cyclohexyl} -4- aza-tricyclo (5210 decane) 3,5 dione hydrochloride, an atypical antipsychotic medicine recognised by the FDA.[2] It can be used with valproic acid or lithium carbonate when treating schizophrenia or manic depression in adults and adolescents.[3] LRD is sold as tablets of 20, 40, 80, and 120 mg, with a suggested dosage of 40-80 mg per day.[4] Clinical research indicates LRD's rapid and successful treatment of schizophrenia in adults.[5] It exerts depressive and anxiolytic effects by inhibiting the dopamine type 2 (D2) and serotonin type 2A (5-HT2A) receptors.[6]

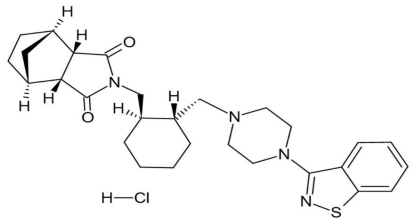


Fig.-1: The Molecular Structure of LRD

Photoluminescent-based analytical techniques offer superior selectivity and sensitivity compared to UV and colourimetric techniques.[7] Given these advantages, and after reviewing existing literature, it was noted that analytical methods for Lurasidone Hydrochloride rely on UV spectroscopy[8-13], HPLC[14-22], HPTLC[23], and LC-MS.[24] However, a simple spectrofluorimetric technique for LRD remains undeveloped.

http://doi.org/10.31788/RJC.2026.1939756

Addressing this gap, we developed, optimised, and validated a highly sensitive green analytical methodology based on photoluminescence for drug estimation in tablets and spiked biological samples. The developed work implements SDG-3 (Good Health and Well-Being) by developing a sensitive spectrofluorimetric method for accurate pharmaceutical analysis. This method was selected because spectrofluorimetric approaches are particularly valuable for their sensitivity and selectivity in biological samples, enabling pharmacokinetic studies that require highly sensitive methods.

EXPERIMENITAL

Materials and Methods

A Shimadzu RF-5301 PC Spectrofluorophotometer with RFPC software was used for data collection. Lurasidone hydrochloride **(**purity = 99% w/w) was obtained from Airis Pharma Pvt. Ltd., Hyderabad, and Lurata tablets with an 80 mg LRD labelled strength, generated by Roche Products (India) Pvt. Ltd. Tween 80 and Tween 60 (each with purity = 98% v/v**)** were procured from Quality deals India, Hyderabad. SLS (purity = 99.5%) and urea AR grade (purity = 99.5% w/w) were from Sisco Research Laboratories Pvt. Ltd. Methanol (purity = 99.85%) was obtained from Qualigens, Mumbai. CMC (purity =99.89%), Na_2HPO_4, and NaH_2PO_4 (both are Extrapure grade) were obtained from Himedia Laboratories.

Solvent Optimization

In the spectrofluorimetric method**,** selecting the appropriate solvent is essential, as it can enhance emission intensity. We tested a variety of solvents (methanol, SLS, Tween 80, Tween 60, urea, CMC, phosphate buffer, etc.), and Tween 80 produced the highest fluorescence intensity. Upon testing various Tween 80 concentrations, 0.5% v/v Tween 80 in water was selected as the solvent strength. In the spectrofluorimetric method**,** selecting the appropriate solvent is essential, as it can enhance emission intensity. We tested a variety of solvents (methanol, SLS, Tween 80, Tween 60, urea, CMC, phosphate buffer, etc.), and Tween 80 produced the highest fluorescence intensity. Upon testing various Tween 80 concentrations, 0.5% v/v Tween 80 in water was selected as the solvent strength.

Validation of Analytical Technique

In accordance with ICH recommendations, we expanded the method's validation study for accuracy, precision, linearity, LOD, and LOQ.[25] For statistical analysis, each parameter was duplicated three times.

Linearity and Range

10 mg of LRD is dissolved in 10 mL of Tween 80 (0.5%v/v) and methanol at a ratio of 3:2, from which suitable aliquots were diluted using Tween 80 (0.5%v/v) to get LRD dilutions of 0.2, 0.4, 0.6, 0.8, 1.0, 2.0, 4.0, 6.0, 8.0, and 10.0 µg/mL, and the emission spectra were recorded. After scanning, the excitation (λex) and emission (λem) wavelengths were found to be 328 and 410 nm, respectively.

Accuracy

The standard spiking method was adopted for the accuracy study and expressed as the percentage recovery of LRD. 10 mg equivalent of LRD powdered tablet was spiked with the standard at 80%, 100%, and 120%, and the volume was brought to 10 mL in a standard flask with 0.5% v/v Tween 80 and methanol in a 3:2 ratio. The solution was sonicated and strained. An aliquot was diluted such that the experimental concentration of the three sets of spiked preparation would be in the linearity range. We measured the emission intensity at 410 nm to estimate the drug content (using the regression equation in linearity research).

Precision

By measuring the medication's emission responses at concentrations of 0.2, 2.0, and 10.0 µg/mL thrice on the same day and thrice on additional days, the intra- and inter-day precision of the approach could be determined. Precision was measured as the % relative standard deviation (%RSD).

Limits of Detection and Limit of Quantitation

The limits of detection and quantitation were calculated using samples with low analyte content. The quotient of the standard deviation of the result and the standard graph’s slope, multiplied by 3.3 and 10, respectively, yields LOD and LOQ.[25]

Tablet Analysis

An optimised, validated method was applied to the marketed LURATA tablets, which have an indicated dosage of 80 mg. Tablet powder corresponding to 10 mg of the drug was dissolved in a 10 mL solution using a 3:2 combination of Tween 80 (0.5% v/v) and methanol. The drug estimate was performed by reading the strained solution at 410 nm after dilution with Tween 80 (0.5% v/v) and applying the linear equation from the calibration graph.

Application to Biological Fluids

Lurasidone Spiked Human Plasma

We transferred about 0.5 mL of drug-free human plasma to separate centrifuge tubes, followed by aliquots of drug stock and 2 mL of acetonitrile as a protein precipitant. Each tube was filled to 5 mL with 0.5% Tween 80, centrifuged at 3000 rpm for 30 minutes, and the supernatants were scanned for fluorescence. The aliquots were selected such that the final concentration yields solutions ranging from 0.2 to 10.0 µg/mL.

Lurasidone Spiked Human urine

A similar process to plasma spiking was used for urine spiking, except that the medium was human urine. The aliquots were selected such that the final concentration yields solutions ranging from 2.0 to 10.0 µg/mL. After centrifuging at 3000 rpm for 30 minutes, the collected supernatants were scanned for fluorescence intensity.

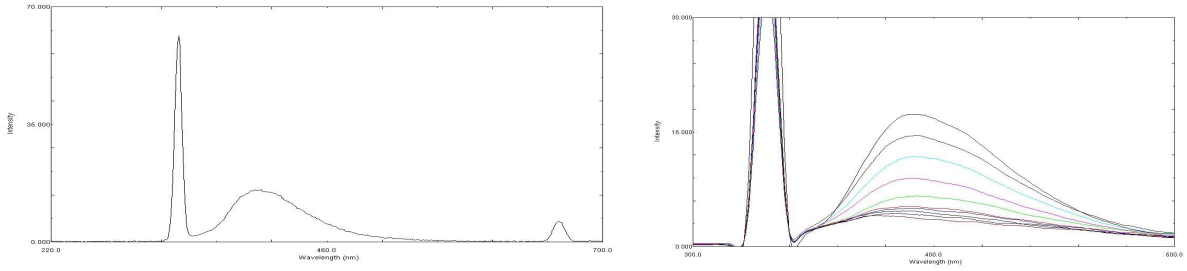
RESULTS AND DISCUSSION

Solvent Optimisation and Wavelength Selection

Tween 80 is the solvent, as it is the most effective at fluorescing lurasidone among the other solvents investigated. All subsequent dilutions were made with Tween 80 (0.5% v/v), after the stock solution was prepared with a 2:3 methanol: Tween 80 (0.5% v/v) mixture. The drug's excitation and emission wavelengths were found to be 328 and 410 nm, respectively (Fig.-2A).

Results of Linearity

LRD exhibited a proportionate correlation between concentration (µg/mL) and the observed fluorescence intensity in a range of 0.2-10.0 µg/mL. Based on the overlay emission spectra of LRD shown in Fig.-2B, a rise in concentration led to an increase in the amount of fluorescence measured at the emission wavelength of 410 nm. F(x)= 1.2458x + 3.2682 (where F(x)= fluorescence intensity and x = concentration) is the regression equation for LRD, and R2 = 0.9994 is the correlation coefficient.



(2A) (2B)

Fig.-2A: Excitation and Emission Spectra of LRD, and 2B. Overlay Emission Spectra of LRD (0.2-10.0 µg/mL)

Accuracy Results

With the standard solution spiked at 80%, 100%, and 120%, solutions made from LRD tablets were examined by spectrofluorimetry. Drug recovery was calculated by plugging the emission intensities of the spiked samples into the regression equation from the linearity results. According to Table-1, the LRD recovery ranged from 96.2% to 104.5%, ruling out potential interference from the tablet's excipients.

Precision Results

We computed the degree of precision as % RSD after intra- and inter-day analyses at 0.2, 2.0, and 10.0 µg/mL of the drug's standard solution. %RSD for intra and inter-day analysis of LRD was less than 2, as reported in Table-2.

Table-1: Accuracy Data (recovery studies)

Spiking level	Sample conc. (µg/mL)	Conc. of std.	Total con. (µg/mL)	Recovered amount (µg/mL) AM±SD (n=3)	Recovery (%)	%RSD
80%	3.0	2.4	5.4	5.2 ± 0.03	96.2%	0.57
100%	3.0	3.0	6.0	5.9 ± 0.05	98.3%	0.84
120%	3.0	3.6	6.6	6.9 ± 0.08	104.5%	1.15

Table-2: Precision Data

Conc. (µg/mL)	Intra-day		Inter-day	
	Experimental value (µg/mL) ±SD (n=3)	% RSD	Experimental value (µg/mL) ±SD (n=3)	% RSD
0.2	0.19± 0.001	0.58	0.19 ± 0.001	0.52
2.0	1.85± 0.015	0.8	1.9± 0.02	1.05
10.0	9.8± 0.1	1.02	9.9 ± 0.15	1.51

Detection and Quantification Limit

We found the quantification and detection limits of the drug to be 0.12 µg/mL and 0.042 µg/mL, respectively.

Assay Result

We determined the utility of the suggested process based on the assay results for LURATA tablets with a label claim of 80 mg; the drug content was 79.5 ± 0.5 mg (arithmetic mean of triplicate samples), yielding an assay value of 99.37%.

Results from Spiked Biological Fluids

We used a highly sensitive method to estimate LRD in spiked human plasma and urine. The concentration range used for spiking in human plasma is 0.2-10.0 µg/mL, and % recovery values range from 95.50% to 99.30%. Urine samples were spiked with 2.0-10.0 µg/mL, and the % recovery values are in the range of 95.30 – 98.80%.

CONCLUSION

We developed a sensitive and straightforward photo-luminescent method to quantify LRD in pharmaceutical dosage forms, spiked plasma, and urine samples. 0.5% v/v Tween 80 is used as the solvent to estimate LRD, with the excitation and emission wavelengths at 328 nm and 410 nm, respectively. We have incorporated the practice of SDG-3: Good health and well-being, as it is intended to ensure the quality control of an important antipsychotic medication. The method falls in the category of green analytical methods and can be used for bulk drugs, tablets, IPQC samples, plasma, and urine samples. Spectrofluorimetric techniques are less expensive, less tedious, highly sensitive and specific for the analyte, can be performed without trained personnel, require less time, and are preferable to chromatographic methods.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the Principal and the management for the chemicals and lab facilities.

CONFLICT OF INTERESTS

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

The present work is related to *SDG-3: Good Health and Well-Being*. All the authors contributed significantly to this manuscript, participated in reviewing/editing and approved the final draft for publication. The research profile of the authors can be verified from their ORCID ids, given below:

Ceema Mathew https://orcid.org/0000-0001-5655-8263
Rajesh B. http://orchid.org/0009-0008-6735-3843
Shashikala Metri http://orcid.org/ 0000-0002-2072-6947
Dumpala Vijaya Durga http://orcid.org/0000-000 3-3966-2880
Prathibha Bharathi Mare http://orcid.org/0009-0004-3120-4249

Cite this article as: C. Mathew *et al.*, *Rasayan J. Chem.*, 19(3), 1515-1519(2026), https://doi.org/10.31788/RJC.2026.1939756

REFERENCES

1. https://my.clevelandclinic.org/health/treatments/24692-antipsychotic-medications [accessed on 10 September 2025]
2. Lurasidone Hydrochloride, https://pubchem.ncbi.nlm.nih.gov/compound/Lurasidone-hydrochloride: [accessed on 10 June 2025]
3. Lurasidone Hydrochloride, Lurasidone HCl information: https://go.drugbank.com/salts/DBSALT000113. [accessed on 10 June 2025]
4. Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=200603 (accessed on 10 June 2025).
5. N. Yasui-Furukori, *Drug Design, Development and Therapy*, **6**,107(2012),https://doi.org/10.2147/DDDT.S11180
6. M. Fornaro, D. De Berardis, G. Perna, M. Solmi, N. Veronese, L. Orsolini, E.F. Buonaguro, F. Iasevoli, C.A. Köhler and A.F. Carvalho, *BioMed Research International*, **2017**, 3084859(2017), https:// doi.org/10.1155/2017/3084859
7. C. Mathew, S. Elipe, S. Metri and D.A. Panikumar, *International Journal of Pharmaceutical Quality Assurance*, **13(2)**, 1(2021).
8. S.S. Muvvala, *Research Journal of Pharmaceutical, Biological and Chemical Sciences*, **4(1)**, 609(2013).
9. N. Mali, J. Patel and M. Patel, *International Journal of Research in Pharmacy and Science*, **2(2)**, 44(2012).
10. N.K. Joshi, N. Shah, M. Dumasiya and A. Patel, *Pharma Science Monitor*, **3(4)**, Suppl-1 (2012).
11. P. Ravisankar, G. Rajyalakshmi, C. Devadasu, G. Devala Rao, *Der Pharmacia Sinica*, **5(5)**, 1(2014).
12. Z.G. Khan, S.V. Bhavsar, N.S. Gujarathi, B.S. Gujarathi and P.B. Patil, *Journal of PharmaSciTech*, **7(1)**, 2(2017).
13. K.V.S. Sri, S. Sravani and M. Vijayakumar, *Asian Journal of Pharmaceutical Research*, **5(2)**, 102(2015), https:// doi.org/10.5958/2231-5691.2015.00015.5
14. M.R. Vaja, R.R. Patel, B. Patel and A. Chaudhary, *Research Journal of Pharmacy and Technology*, **15(11)**, 4999(2022).
15. B. Thota, G.S. Adepu and R. Galla, *International Journal of Pharmacy and Pharmaceutical Sciences*, **10(12)**, 58(2018), https:// doi.org/10.22159/ijpps.2018v10i12.27895
16. R.K. Sangeetha, *European Journal of Pharmaceutical and Medical Research*, **2(5)**, 529(2015).
17. P. Ravisankar, G. Rajyalakshmi, C.D. Deva Dasu, P.S. Babu and P.V. Reddy, *World Journal of Pharmaceutical Research*, **3(7)**, 453(2014).
18. Suneetha, K. Manasa and S.S. Lakshmi, *Journal of Pharmaceutical Research*, **14(1)**, 15(2015).
19. S. Rapilane, T.K. Ravi and S. Thankachen, *European Journal of Pharmaceutical and Medical Research*, **2(5)**, 429(2020).
20. N. Joshi and N. Shah, *Pharma Science Monitor*, **3(4)**, 2886(2012).
21. Polawar and M. Damle, *International Journal of Research in Pharmaceutical Chemistry*, **4(1)**, 327(2014).
22. P.J. Chhabda, *International Journal of Pharmaceutical Research and Development*, **5(1)**, 103(2013).
23. A.R. Polawar and M.C. Damle, *Pharma Science Monitor*, **5(3)**, 131(2014).
24. Y.J. Chae, T.S. Koo and K.R. Lee, *Chromatographia*, **75(19–20)**, 1117(2012), https://doi.org/10.1007/s10337-012-2294-5
25. ICH Q2 (R1), *Validation of Analytical Procedures: Text and Methodology*, International Conference on Harmonisation, Geneva, 2005. [RJC-9756/2026]