EJPMR, 2026, 13(9), 377-383 **Research Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

NEW ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF UV -VISIBLE SPECTROSCOPY AND USING FTIR STUDY OF CHEMICAL STRUCTURE OF VORTIOXETINE HYDROBROMIDE

Nandankumar K.*, Mr. Sumanth S., Ms. Sonalika Y. S., Ms. Vinutha Y.

Department of Pharmaceutical Analysis, Bharathi College of Pharmacy, Bharathinagara, Maddur Taluk, Mandya District, Karnataka, India -571422.

***Corresponding Author: Nandankumar K.**

M PHARM (Assistant Professor), Department of Pharmaceutical Analysis, Bharathi College of Pharmacy, Bharathinagara, Maddur Taluk, Mandya District, Karnataka, India -571422.

DOI: https://doi.org/10.5281/zenodo.22269765

How to cite this Article: Nandankumar K.*, Mr. Sumanth S., Ms. Sonalika Y.S., Ms. Vinutha Y. (2026). New Analytical Method Development And Validation Of Uv -Visible Spectroscopy And Using Ftir Study Of Chemical Structure of Vortioxetine Hydrobromide. European Journal of Pharmaceutical and Medical Research, 13(9), 377–383.

Article Received on 05/08/2026 **Article Revised on 25/08/2026** **Article Published on 02/09/2026**

ABSTRACT

Creation and application of a straightforward, accurate, and precise zero order spectroscopic technique for the measurement of vortioxetine HBR in tablet and bulk dose forms. According to Beer's law, the drug shows the maximum absorption (λmax) at 227 nm in ethanol solutions, and the absorption spectrum's AUC is measured in the wavelength range of 222 to 232 nm at concentrations between 4 and 20 µg/ml. A linearity analysis revealed an R2 of 0.9996. The results showed that the LOD and LOQ were 1.809 and 5.484µg/ml, respectively. It was discovered that the %RSD was less than 2%. According to ICH criteria, the method has been verified for linearity, precision, accuracy, robustness, ruggedness, LOD, and LOQ. This approach complies with Beer's law and satisfies all necessary requirements within the constraints. The active pharmaceutical substance Vortioxetine HBr has distinct wave number peaks according to FTIR research. In addition to meeting the necessary requirements, FTIR data interpretation provides information on the sample's quality and purity.

KEYWORDS: Vortioxetine HBr, UV Spectroscopy, FTIR, ICH Guidelines.

INTRODUCTION

Major depressive disorder (MDD) is the main condition for which vortioxetine hydrobromide (Vortioxetine HBr), a multimodal antidepressant in the piperazine derivative class, is used. It works by blocking the serotonin transporter (SERT) and modifying a number of serotonin receptors, such as 5-HT_4A receptor agonism, 5-HT_1B partial agonism, and antagonism at 5-HT_3, 5-HT_1D, and 5-HTß receptors. This multimodal serotonergic pathway is responsible for its antidepressant action and may also help alleviate cognitive symptoms linked to depression. Vortioxetine HBr is not categorised as an antipsychotic medication and is not primarily prescribed for schizophrenia, vertigo, or functional gastrointestinal disorders, in contrast to dopamine receptor antagonists. It is a useful therapeutic alternative for the treatment of major depressive illness because of its effectiveness and tolerability.

The Beer-Lambert equation, which states that the absorbance (A) of a solution is exactly proportional to the concentration (c) of the analyte and the path length (b) of the light flowing through the sample, is the foundation for the quantitative measurement of vortioxetine HBr using UV-visible spectrophotometry. The formula for the relationship is A = a × b × c, where an is the analytes absorptivity or molar absorptivity. The device used in UV-visible spectrophotometry compares the initial intensity of the incident light with the intensity of light transmitted through the sample. A UV-visible spectrum, which shows the wavelengths absorbed by the analyte and the accompanying absorbance intensities, is created by performing measurements over a range of wavelengths.

1. MATERIALS AND METHODS

Instrument: UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with

UV probe software. All weights were taken in analytical balance.

Chemicals: Vortioxetine HBr was given as a gift sample by Pharmaceutical manufacturing company Medreich Pvt LTD, Bengaluru.

Solvent: Ethanol is used as a solvent and distilled water. (Analytical grade). All the reagents and chemicals are provided by our Institution.

Selection of analytical wavelength: Appropriate dilutions were prepared for drug from the standard stock solution and the solution was scanned in the wavelength range of 200-400 nm. The trial and error method [1] gives absorption spectra in Ethanol acid and it shows maximum absorbance at 227 nm & Good solubility and Stability.

2. PREPARATIONS OF ANALYTICAL SAMPLES

a) **Preparation of Ethanol Solution:** Accurately measure the required quantity of ethanol and transfer it into a 500 mL volumetric flask**.** Make up the volume to 500 mL with distilled water and mix well to obtain the required ethanol solution.

b) **Preparation of standard stock solution:** Accurately weigh 100mg of Vortioxetine HBR [3] was transferred into 100ml volumetric flask and diluted with Ethanol up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with Ethanol up to the mark, from this solution pipette out **(4, 8, 12, 16 and 20ml)** into 10ml individual volumetric flask and add Ethanol up to the mark, this gives **4, 8, 12, 16, & 20 µg/ml** concentrations.

c) **Preparation of sample solution:** Vortioxetine HBr API was obtained from Medreich Pvt LTD, Bengaluru. From this weighed 100mg of drug and transferred into 100 ml volumetric flask then it was diluted with the Ethanol solution and made up to the mark and the solution was filtered through what man filter paper NO. 41. From the above solution 10 ml was pipette out into 100 ml volumetric flask and the volume was made up to the mark with Ethanol. The final concentration of Vortioxetine HBr was brought to 100µg/ml. From that above solution make required concentrations of 4, 8, 12, 16 and 20µg/ml concentrations.

3. METHOD AND VALIDATION

The method was validated according to the ICH guidelines[20] of Q2R2 & ICH Q14.

4. RESULTS AND DISCUSSION

Method: Zero order derivative spectroscopy.

Linearity: The linearity of an analytical method is its dimension to show the test results that are directly proportional to the concentration of the analytic in the sample within the determined range. The linearity was established in the range of **4-20µg/ml** was measured at 227nm and absorbance values are shown in (Table-02). The calibration curve was prepared by plotting graph against the concentration and absorbance and therefore the graph shown in Fig-05. Statistical variables like slope, intercept, regression equation, correlation coefficient and Sandell's sensitivity were determined[20] (Table-03).

Precision: The precision of an analytical method expresses the closeness of a series of individual analytic measurements obtained from multiple sampling of the equivalent sample. Precision was established by intra-day and inter-day studies. Intra-day precision was determined by analyzing the same concentration for five times within same day. Inter-day precision was determined by analyzing the same concentration daily for five days[20] (Table-04).

Ruggedness: The ruggedness is defined as the reliability of results when the method is performed under the variation in conditions. This includes distinct analyst, laboratories, instruments, temperature etc. Ruggedness was determined between distinct analysts, the value of %RSD was found to be less than 2[20] (Table-05).

LOD and LOQ: The limit of detection is an individual analytical method is the smallest amount of analytic in a sample which can be reliably detected by the analytical method. The limit of quantitation is a discrete analytical procedure is the smallest amount of analytic in a sample which can be quantitatively determined. LOD and LOQ were calculated by using following formula.

LOD = 3.3(SD)/S and LOQ = 3(LOD)

LOD and LOQ value of were found Vortioxetine HBR 1.976 and 5.98µg/ml.

FTIR: Fourier Transform Infrared (FTIR) spectroscopy has emerged as a powerful analytical tool in medical research, offering non-invasive and precise examination of the molecular composition of biological samples. The primary objective of this review is to underscore the benefits of FTIR spectroscopy in medicinal research, emphasizing its ability to delineate molecular fingerprints and assist in the identification of biochemical structures and key peaks in biological samples.

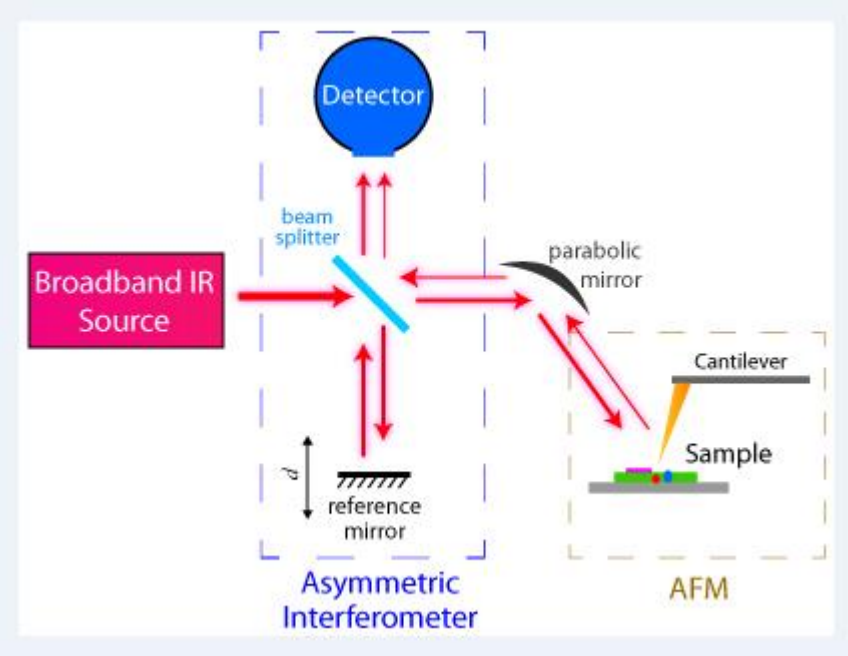

Fig. No, 01: FTIR Interferometer diagram.

FTIR STUDY & INTERPRETATION OF PURE VORTIOXETINE HBr

FTIR stands for **Fourier Transform Infrared Spectroscopy**. It is an analytical technique used to identify organic, polymeric, and, in some cases, inorganic materials by measuring how infrared light is absorbed by a sample. When a sample is exposed to infrared radiation, different chemical bonds vibrate at characteristic frequencies, absorbing specific wavelengths of the IR light. The resulting absorption spectrum acts as a molecular "fingerprint" that can be used to identify and analyze the material.

The infrared spectra of Vortioxetine HBR pure drug were recorded at a range of 400-4000 cm−1 on QATR-S IR Spirit FOURIER TRANSFORM INFRARED SPECTROSCOPY (FTIR)[21] spectra of the pure Vortioxetine HBr show spectrum peak points as below Table No. 01.

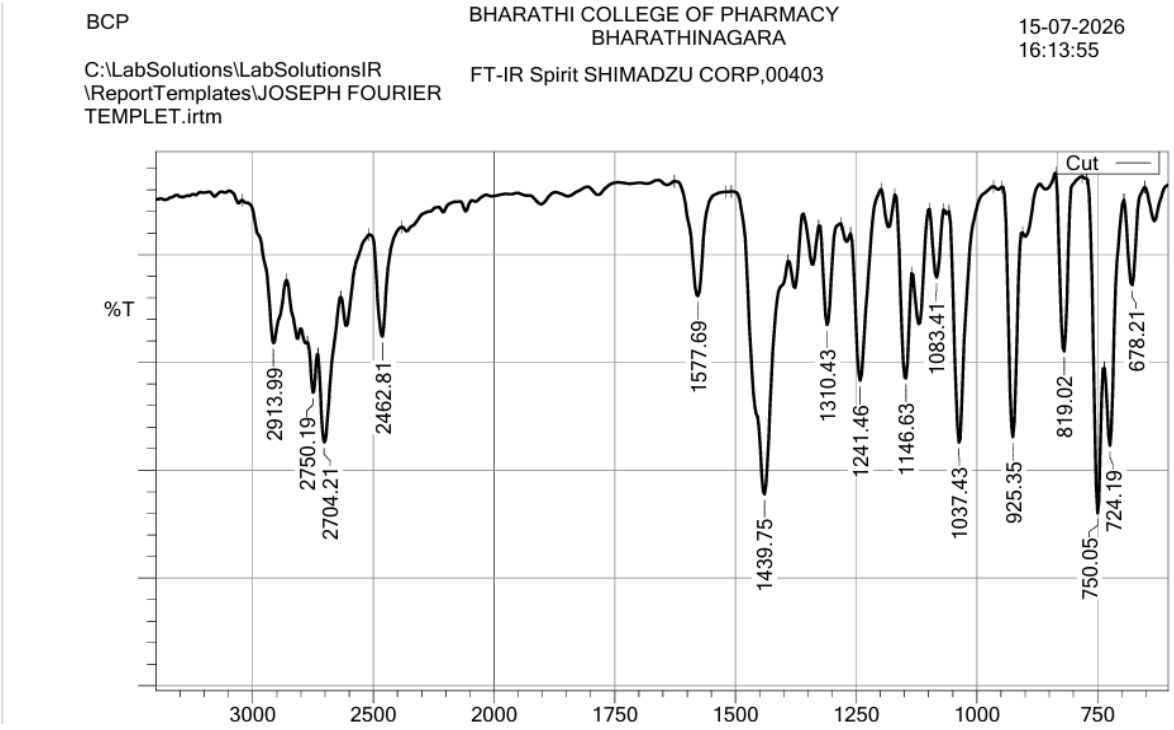

Fig. 02: IR Spectra of Vortioxetine HBr drug.

Table 01: Interpretation of FTIR data of Vortioxetine HBr.[22]

Group frequency range (cm^{-1})	Peak obtained range (cm^{-1})	Confirmation of functional groups
2850–3000 cm^{-1}	**2913.99 cm^{-1}**	C–H stretching of aliphatic groups OF Alkanes (CH_2/CH_3)
1450–1470 cm^{-1}	**1439.75 cm^{-1}**	C–H bending / deformation of aliphatic groups
1500–1600 cm^{-1}	**1577.69 cm^{-1}**	Aromatic C=C stretching vibration
1250–1350 cm^{-1}	**1310.43 cm^{-1}**	C–N stretching vibration of piperazine/amine moiety
1200–1270 cm^{-1}	**1241.46 cm^{-1}**	C–N / aromatic C–C stretching vibration
1100–1180 cm^{-1}	**1146.63 cm^{-1}**	C–N / C–C stretching vibration
1000–1100 cm^{-1}	**1083.41 cm^{-1} & 1037.43 cm^{-1}**	C–N/C–C stretching vibrations in the fingerprint region

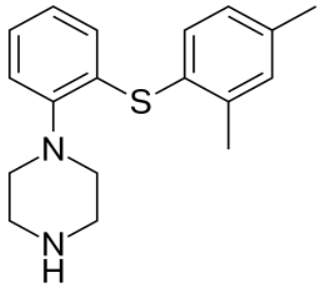

Fig. No. 03: Structure of Vortioxetine HBr.

Table 02: Results of calibration curve at 227nm by zero order spectroscopy.

SL NO	Concentration in µg/ml	Absorbance ± Standard deviation*
01	4	0.5833 ± 0.0103
02	8	0.6733 ± 0.0103
03	12	0.7667 ± 0.0075
04	16	0.8617 ± 0.0117
05	20	0.9617 ± 0.0117

**Average of six determinations.*

Table 03: Regression parameter Vortioxetine HBr for by zero order spectroscopy.

Regression parameter	Results
Range(µg/ml)	4-20
λ_{max}(nm)	227nm
RegressionEquation	0.01565mcg / cm^2
Slope(b)	0.023
Intercept(a)	0.4858
Correlationcoefficient(r^2)	0.9996
Sandells sensitivity(µg/cm^2)	0.01565mcg / cm^2
Limit of detection(µg/ml)	1.976.
Limit of quantitation(µg/ml)	5.98

** All the values are there with in the Specified standards.*

Table 04: Determination of precision results for Vortioxetine HBr at 227 nm by zero order spectroscopy.

Concentration (µg/ml)	Intra-day Absorbance ±SD**	%RSD	Inter-day Absorbance ±SD**	%RSD
1	0.5833 ± 0.0103	1.77	0.5832 ± 0.0073	1.25
2	0.6733 ± 0.0103	1.53	0.6742 ± 0.0090	1.33
3	0.7667 ± 0.0075	0.98	0.7668 ± 0.0070	0.91
4	0.8617 ± 0.0117	1.36	0.8617 ± 0.0088	1.02
5	0.9617 ± 0.0117	1.22	0.9632 ± 0.0100	1.04

***Average of five determinations, **percentage relative standard deviation.*

Table 05: Determination of Ruggedness results for Vortioxetine HBR at 227 nm by Zero order spectroscopy.

Analysts	Analyst 1	Analyst 2
Mean absorbance	0.7667	0.764
±Standard deviation*	0.0075	0.00869
%RSD	0.978	1.138

***Average of six determinations, **percentage relative standard deviation.*

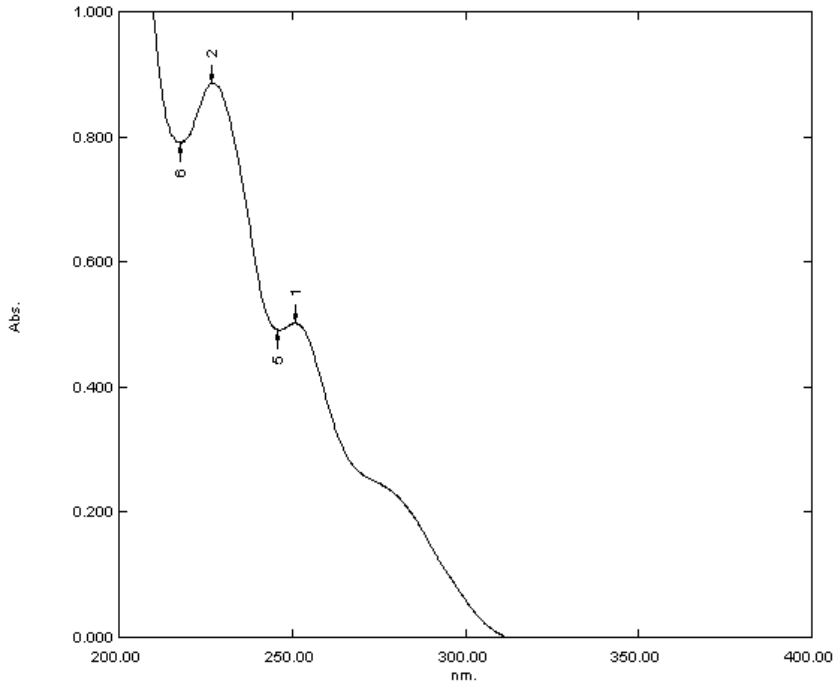

Fig.04: Zero order spectrum of Vortioxetine HBR (4µg/ml) at 227nm.

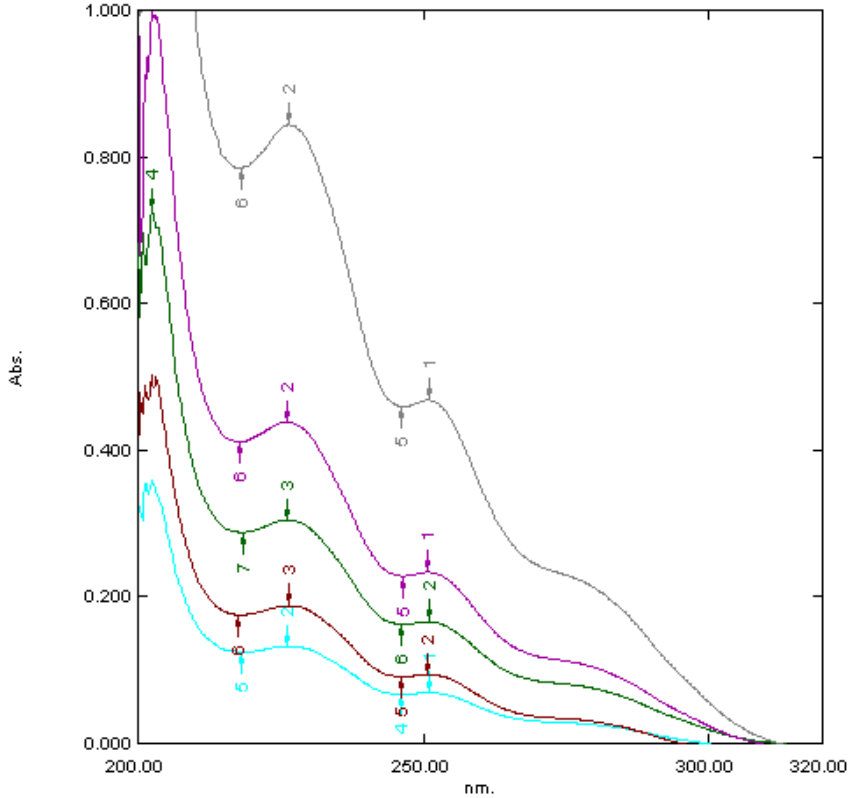

Fig.05: Zero order overlain spectra of Vortioxetine HBr showing absorbance at 227nm.

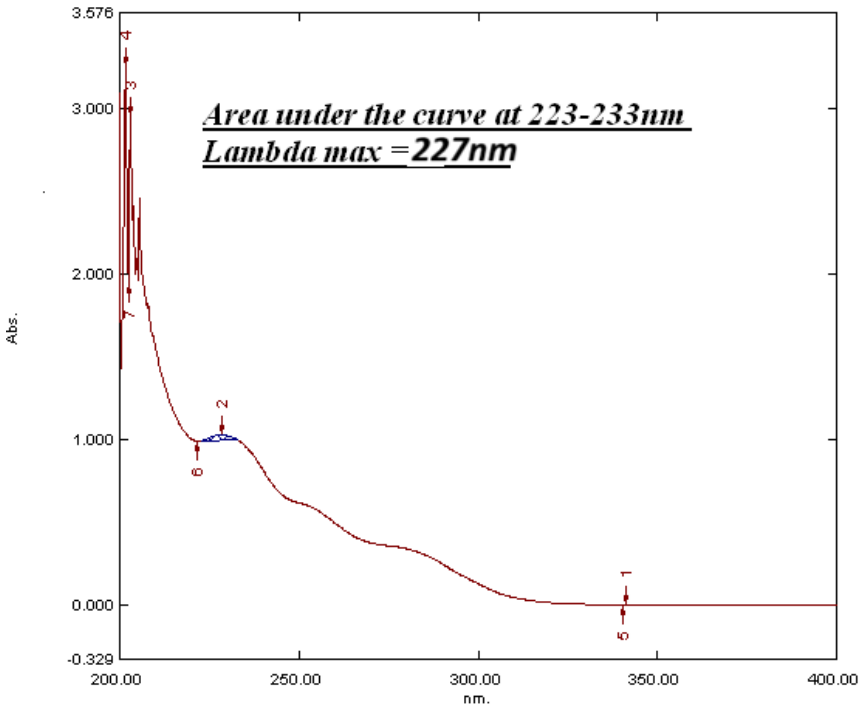

Fig.06: Area under the curve spectra of Vortioxetine HBR showing peak area at 207-217nm.

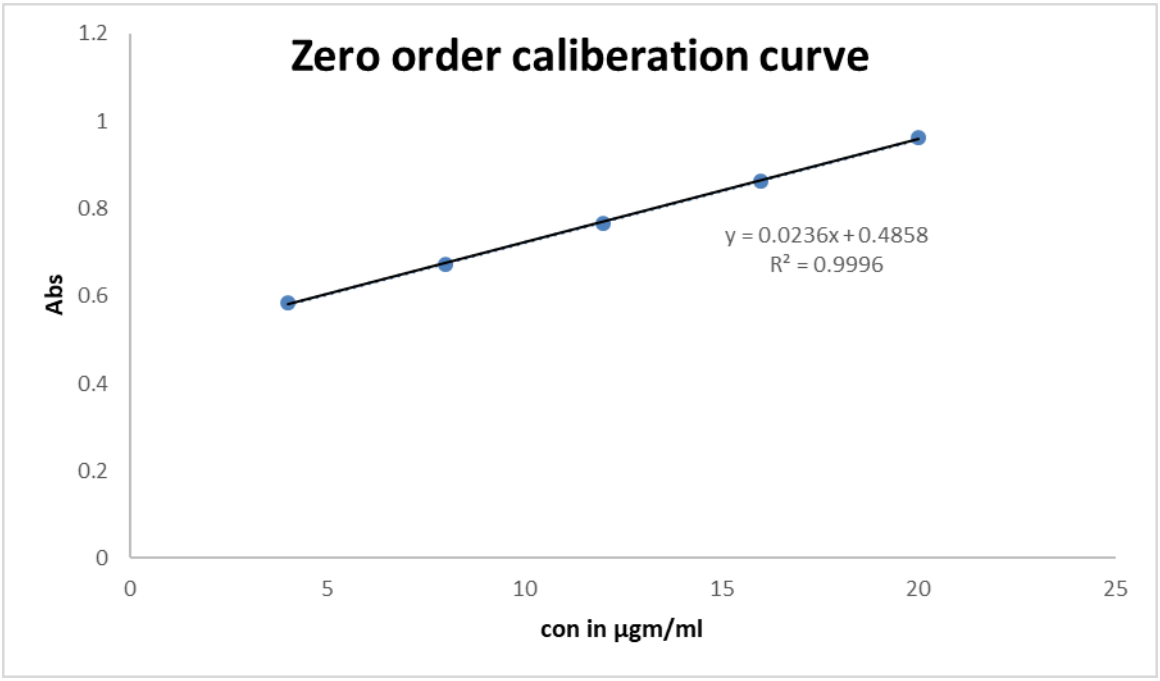

Fig. 07: Calibration curve of Vortioxetine HBr by zero order spectroscopy.

CONCLUSION

According to the ICH guidelines[20], this method was validated as a simple, accurate, precise, and reproducible approach for estimating and validating Vortioxetine HBr using a UV-Vis Spectrophotometer. It complies with the required specifications of a standard reference Infrared Spectrum (IR) and offers crucial insights into the drug's structure, functional groups, and interpretation. This method is novel and more cost-effective compared to other reported methods in the literature.

ACKNOWLEDGEMENT

We, the authors, wish to thank our management, the Head of the Department, and the Principal of the Pharmacy College for providing all the facilities in the college.

REFERENCE

1. Karajgi S, Angadi S, Potadar S, Patil CC. Vortioxetine Estimation in its Drug Formulations by fist order derivative UV Spectrophotometric

Method. Research Journal of Pharmacy and Technology, Jul. 1, 2023; 16(7): 3363-3366.
2. Karajgi S, Angadi S, Potadar S. Quantification of Vortioxetine in Pharmaceutical preparations by validated area under curve UV Spectrophotometric Analytical method. Research Journal of Pharmacy and Technology, Dec. 1, 2023; 16(12): 5986-5989.
3. Naik H, Chan S, Vakilynejad M, Chen G, Loft H, Mahableshwarkar AR, Areberg J. A population pharmacokinetic–pharmacodynamic meta-analysis of vortioxetine in patients with major depressive disorder. Basic & Clinical Pharmacology & Toxicology, May 2016; 118(5): 344-55.
4. Tiris G, Alver C, Erk N. A novel stability-indicating method for determination of a new antidepressant effect of vortioxetine in a pharmaceutical formulation by using RP-HPLC. Future Journal of Pharmaceutical Sciences, Dec. 11, 2020; 6(1): 118.
5. Meloun M, Pilařová L, Čápová A, Pekárek T. The overlapping thermodynamic dissociation constants of the antidepressant Vortioxetine using UV–VIS multiwavelength pH-titration data. Journal of Solution Chemistry, May 2018; 47(5): 806-26.
6. Pravallika KE, Ravi P, Abboodi AH, Razzaq AH, Sasivardhan O. Development and validation of UV spectrophotometric methods for the estimation of vortioxetine hydrobromide in bulk and pharmaceutical dosage forms. Research journal of pharmacy and Technology, Nov. 1, 2017; 10(11): 3928-32.
7. Çicekliyurt MM, İnan P, Günay M, Akkuş G, Çiçekliyurt A. Investigating the cytotoxicity and genotoxicity of Vortioxetine with in vivo and in silico methods. Scientific Reports, Sep. 29, 2025; 15(1): 33647.
8. Mathew A, Kumar S, Sutariya V, Vashi D. Absorbance Ratio Method of Vortioxetine and Aripiprazole in Synthetic Mixture by UV Spectrophotometry. Asian Journal of Pharmaceutical Research, Jun. 1, 2019; 9(2).
9. Gouda AA, Elsaify NE, Soliman NS, El Sayed A, Eldien AS, Abdelhamed AS, Afify MA. Simple and Sensitive Spectrophotometric Methods for Estimation of Vortioxetine HBr in Pharmaceutical Formulations. Bulletin of Faculty of Science, Zagazig University, Jul. 1, 2025; 2025(3): 52-63.
10. De Diego M, Correa D, Mennickent S, Godoy R, Vergara C. Determination of vortioxetine and its degradation product in bulk and tablets, by LC-DAD and MS/MS methods. Biomedical Chromatography, Nov. 2018; 32(11): e4340.
11. Lasan VM, Patel DM. Development and validation of analytical method for the estimation of Vortioxetine Hydrobromide. Pharma Science Monitor, 2017; 8(2): 298-305.
12. Ragi NC, Velma GR, Pallerla PK, Siddiqua S, Alugonda V, Rachamalla HK, Pabbaraja S, Sripadi P. Identification and characterization of forced degradation products of vortioxetine by LC/MS/MS and NMR. Journal of Pharmaceutical and Biomedical Analysis, Sep. 5, 2020; 188: 113442.
13. Sulthana R, Rubeena KR, Vasanthi R, Raja MA, Rao K. validated rp-hplc method for the estimation of vortioxetine in bulk and in tablets. Pharma Science Monitor, Apr. 1, 2017; 8(2).
14. Mandal S, Mukhopadhyay K, Guin A, Sorkhel R, Mitra P, Ojha B, Verma K, Mukherjee S. Efficacy and safety profile of vortioxetine as an add-on molecule in obsessive-compulsive disorder: a randomized double-blinded placebo-controlled superiority trial–a study protocol. BMC psychiatry, Nov. 24, 2025; 25(1): 1116.
15. Meloun M, Pilařová L, Čápová A, Pekárek T. The overlapping thermodynamic dissociation constants of the antidepressant Vortioxetine using UV–VIS multiwavelength pH-titration data. Journal of Solution Chemistry, May 2018; 47(5): 806-26.
16. Papalexi E, Galanopoulos A, Kontis D, Markopoulou M, Balta G, Karavelas E, Panagiotidis P, Vlachos T, Ettrup A. Real-world effectiveness of vortioxetine in outpatients with major depressive disorder: functioning and dose effects. BMC psychiatry, Aug. 12, 2022; 22(1): 548.
17. Meeker AS, Herink MC, Haxby DG, Hartung DM. The safety and efficacy of vortioxetine for acute treatment of major depressive disorder: a systematic review and meta-analysis. Systematic reviews, Mar. 1, 2015; 4(1): 21.
18. Leiser SC, Pehrson AL, Robichaud PJ, Sanchez C. Multimodal antidepressant vortioxetine increases frontal cortical oscillations unlike escitalopram and duloxetine–a quantitative EEG study in rats. British journal of pharmacology, Sep. 2014; 171(18): 4255-72.
19. Sankar K, Viswanathan S, Nazar RK, Ramasamy S, Ganesan RM. A systematic review of randomized controlled trials assessing the effect of Vortioxetine on metabolic syndrome risk indicators in patients with depression. Health Sciences Review, Dec. 1, 2023; 9: 100129.
20. Guideline IH. Validation of analytical procedures Q2 (R2). ICH: Geneva, Switzerland, 2022; 1.
21. https://en.wikipedia.org/wiki/Vortioxetine.
22. https://www.scribd.com/document/462118068/FT-IR-Spectrum-Table