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Original Article

# Development and Validation of a New UV-Spectroscopic Method for the Estimation of Vortioxetine Hydrobromide in Bulk and Pharmaceutical Formulation

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## ABSTRACT

**Background:** Major depressive disorders are treated with the antidepressant vortioxetine. In the current work, UV-Vis Spectroscopy was used to establish a new, simple, reliable, precise, selective, and ecologically sound approach for determining vortioxetine in bulk and pharmaceutical formulation. **Materials and Methods:** A novel UV-Spectrophotometric method was developed using Shimadzu UV-1800 Spectrophotometer, the diluent was composed of 20% methanol and 80% water and the wavelength was set 225nm based on the highest absorbance exhibited vortioxetine hydrobromide. According to ICH Q2R2 guidelines, the method's linearity, precision, robustness, ruggedness, limit of detection and limit of quantitation, accuracy, and assay were all verified. **Results and Discussion:** With a correlation coefficient ($R^2$) of 0.9997, the technique complies with Beer-Lambert's law in the concentration range of 2 to 10 µg/mL. By calculating the percentage relative standard deviation of less than 2%, the approach demonstrated exceptional precision, durability, and ruggedness. The assay result was 99.08% and the method demonstrated an outstanding recovery between 100.28% to 102.60%. The eco-friendliness of the method was assessed using AGREE software with the score of 0.9. **Conclusion:** Therefore, for the routine and systematic examination of vortioxetine hydrobromide, the developed and validated method was proved to be having a number of benefits.

**Keywords:** Analytical GREEnness (AGREE), Green Analytical Chemistry (GAC), ICH Q2(R2), Vortioxetine Hydrobromide

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## INTRODUCTION

Depression is a brain disorder characterized by symptoms like deep despair, lack of pleasure, disturbed sleep patterns, Fluctuating eating habits, Fatigue and the feeling of regret (Rang *et al*., 2016). An estimated 280 million people worldwide and about 13% of Indian adults require intervention for mental health issues, representing a significant public health burden (World Health Organization [WHO], 2023).Vortioxetine Hydrobromide (VRT HBr), chemically, 1-[2-(2,4-dimethylphenyl)-sulfanyl phenyl]-piperazine (Figure 1), pharmacologically belongs to the class of selective serotonin reuptake inhibitors. It is crucial to quantify these medications precisely and accurately in in order to guarantee the best possible therapeutic efficacy and patient safety. Vortioxetine hydrobromide has been estimated using a number of techniques, including HPLC, LCMS, UPLC, and LC-ESI. In addition to the aforementioned approaches, which were costly, time-consuming, and produced additional waste (Carnezza *et al*., 2023; Dhuri & Hamrapurkar, 2019; Diego *et al*., 2018; Dong *et al*., 2016; Douša *et al*., 2015; Kall *et al*., 2015; Karaca *et al*., 2020; Landge *et al*., 2020; Liu *et al*., 2016; Mali *et al*., 2021; Mondal & Singh, 2024; Nirmal *et al*., 2022; Patel *et al*., 2025; Petruczynik *et al*., 2020; Ravisankar *et al*., 2021; Sonawane & Ware, 2022; Sulthana *et al*., 2017; Tapkire & Bachhav, 2022; Tiris *et al*., 2020; Viranchi *et al*., 2019; Wróblewski *et al*., 2017; Wróblewski *et al*., 2022). One UV Spectroscopic approach has also been reported for the determination of VRT HBr in bulk and pharmaceutical formulation utilising diluent, Methanol:Water in a 1:1 v/v ratio (Pravallika *et al*., 2017). An attempt was made to create a UV spectroscopic method for VRT HBr estimate in order to lower the organic solvent ratio and create a green analytical technique.

The goal of Green Analytical Chemistry (GAC) is to make analytical processes safer for people and less harmful to the environment. When evaluating the greenness of an analytical process, many factors are taken into account, including the quantity and toxicity of reagents, generated waste, energy requirements, the number of procedural steps, miniaturisation, and automation. The Analytical GREEnness calculator (AGREE),

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a thorough, adaptable, and simple evaluation method that yields an understandable and instructive outcome. The evaluation criteria are converted into a single 0–1 scale using the 12 principles of green analytical chemistry (Pereira *et al.*, 2020). These 12 principles are used to compute the final score. The outcome is a pictogram that shows the user-assigned weights, the final score, and the analytical procedure's success in each criterion.

## MATERIALS AND METHODS

Vortioxetine Hydrobromide was obtained as a gift sample from Morpen Laboratories Ltd. Analytical grade Methanol, Type-III milipore water, Shimadzu UV-1800 and Shimadzu UV-1900 was used for the analysis. Voxigain-10 tablets were purchased from the local store.

### Method Development

#### *Selection of solvent and preparation of Standard Stock Solution (SSS)*

The choice of solvent is crucial for ensuring the analyte is fully dissolved and remains stable while providing transparent background in the UV region.

### Solvent screening

VRT HBr possessing the solubility of 3.62µg/ml in water (DrugBank, n.d.). A range of solvent combinations mentioned in Table 1, were tested obtain the desired solubility and absorption maxima. Among the following the combination containing 20% methanol and 80% water was selected based on the absorbance obtained. Beyond the above-mentioned ratio, in an attempt to increase the ratio of water, VRT HBr was found to be insoluble in-spite of sonication, and resulting in a milky white solution.

### Preparation of Standard Stock Solutions (SS-I)

An SSS of VRT HBr was prepared by weighing 10 mg of drug substance and transferring it to 10 mL volumetric flask. It was then dissolved in 2 mL of methanol and the volume was made upto the mark using water to obtain a solution containing 1000µg/ml VRT HBr.

### Determination of Maximum Wavelength ($\lambda_{max}$)

The $\lambda_{max}$ is the wavelength which exhibits the highest molar absorptivity of the analyte, minimizing the interference of impurities and maximizing the sensitivity of the analyte. To obtain the same a working stock solution containing 10 µg/mL VRT HBr in methanol:water (20:80% v/v) was prepared and scanned over the range of 200 to 400 nm in the Shimadzu UV-1800 spectrophotometer using methanol:water (20:80% v/v) as blank. Resulting UV Spectrum was recorded and showed in Figure 2.

### Preparation of Calibration Curve and Linearity studies

The linearity study establishes the ability of VRT HBr to produce a response directly proportional to its concentrations. Linear regression was used to examine the results for linearity, and the precision was represented as a percentage of RSD.

### Preparation of working solutions

From SS-I a series of working standard solutions were prepared via serial dilutions using Methanol:Water (20:80% v/v) solvent, solutions ranging from 2 µg/mL to 10 µg/mL, yielding 5 data points. The absorbance of each solution was measured in triplicate at 225nm against using Methanol:Water (20:80% v/v) as blank.

### Construction of Calibration Curve

Calibration curve was constructed by plotting mean absorbance on Y-axis and concentration on X-axis, the responses were subjected to linear regression analysis to determine the correlation coefficient ($R^2$), slope, and Y-intercept.

### Preparation of sample solution

The average weight of 20 tablets of Voxigain 10 was calculated and the sample equivalent 10mg of Vortioxetine Hydrobromide was transferred to 10ml Volumetric flask and the volume was made upto the mark with the selected solvent, followed by dilution to prepare the solution containing an equivalent to 10µg/ml with the aid of filtration by Wathman filter paper.

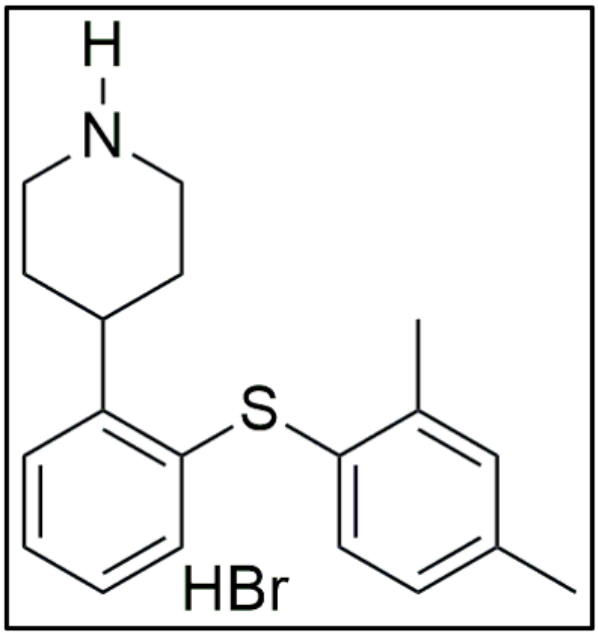



**Figure 1:** Structure of Vortioxetine Hydrobromide.

## RESULTS AND DISCUSSION

### Method Validation

Following the development of the UV spectrophotometric method, a comprehensive validation was conducted to confirm the method's suitability for its intended purpose, in accordance with ICH Q2(R2) guidelines. The following parameters were evaluated: Linearity, Accuracy, Precision, Limit of Detection (LOD), Limit of Quantitation (LOQ), and Robustness (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH], 2023).

### Linearity

The linearity was established during the method development phase, using five concentrations ranging from 2 µg/mL to 10 µg/mL and were analysed in triplicates. The regression equation was found to be y = 0.0691x + 0.0036, and Correlation Coefficient ($R^2$) was 0.9997, indicating an excellent linearity across the tested concentration range. The results of linearity are showed in Table 2, the calibration curve is showed in Figure 3a and the overlay spectra of all the five concentrations in Figure 3b.

### Precision

To assess the closeness of responses from multiple samplings, the precision was assessed at three levels, repeatability interday and intraday precision.

### Repeatability

Three independent solutions containing 2 µg/mL, 6 µg/mL and 10 µg/mL were prepared separately in six replicates, absorbance of each solution was recorded and the Mean, Standard Deviation (SD) and Percentage Relative Standard Deviation (%RSD) was calculated, which was found well withing the acceptable limit of 2%, demonstrating the repeatability. The results of repeatability are showed in Table 3.

### Interday and intraday precision

Similar to repeatability, interday precision was also assessed by analysing the three different concentrations in triplicates at a triduum and on same day at three equal intervals. The mean, SD and % RSD was calculated. The results of interday and intraday precision are showed in Tables 4 and 5 respectively. The overall % RSD of interday and intraday precision was found less than 2% confirming the precision of the developed method.

**Table 1: List of solvent combinations tested and their absorbance.**

| Sl. No. | Combinations of solvents tested | Absorbance |
|---|---|---|
| 1. | Methanol:Water (50:50% v/v) | 0.555 |
| 2. | Methanol:Water (40:60% v/v) | 0.608 |
| 3. | Methanol:Water (30:70% v/v) | 0.693 |
| 4. | Methanol:Water (20:80% v/v) | 0.701 |

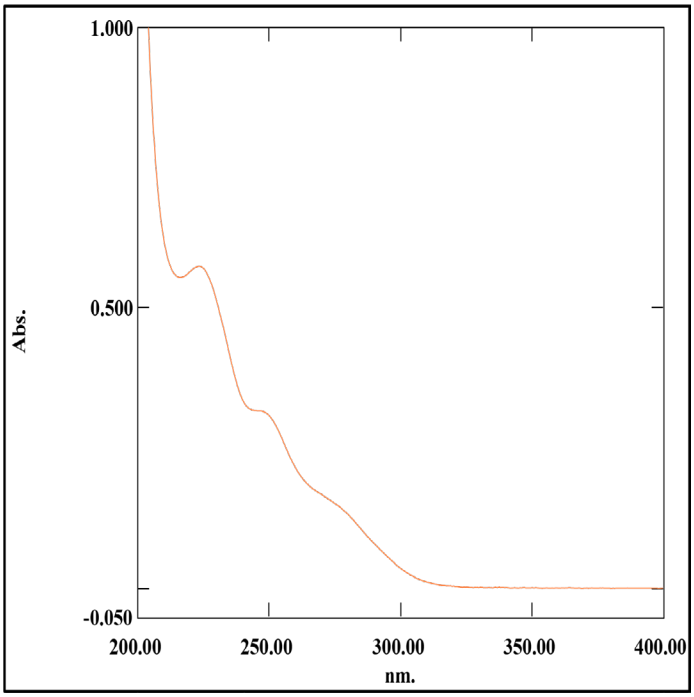



**Figure 2:** The UV Spectrum of VRT HBr in Methanol:Water (20:80% v/v).

### LOD and LOQ

The sensitivity of the method was established by defining the LOD and LOQ which was calculated based on standard deviation and the slope of calibration curve. The LOD was found to be 0.373 µg/mL and LOQ was 1.322 µg/mL.

### Robustness and ruggedness

The new developed method, its capacity of being unaffected by deliberate variations was demonstrated by changing the wavelength by ±2nm. Testing the ruggedness involved variations like changing the instrument and the analyst. Both, ruggedness and robustness were also performed using three different concentrations, each analysis done in triplicate. The result of robustness and ruggedness are showed in Table 6. The results showed that the overall % RSD of all variations was less than 2% confirming the methods robust and rugged nature.

### Specificity and selectivity

The specificity of the newly developed method was established by comparing the UV Spectrum of the API procured from Morpen laboratories to that of the marketed formulation. This confirms, no major interference of the substance from the excipients co-absorb at 225nm. Also to confirm no interference from the solvent used, the comparison of UV spectrum of API and the solvent was done. The overlay spectrums of API and the formulation together and the spectrum of API and the solvent are showed in Figure 4. The two overlaid UV spectra were found to be superimposable, with identical $\lambda_{max}$ and similar absorbance. This demonstrates that the excipients present in the formulation do not significantly interfere with the absorbance signal of the

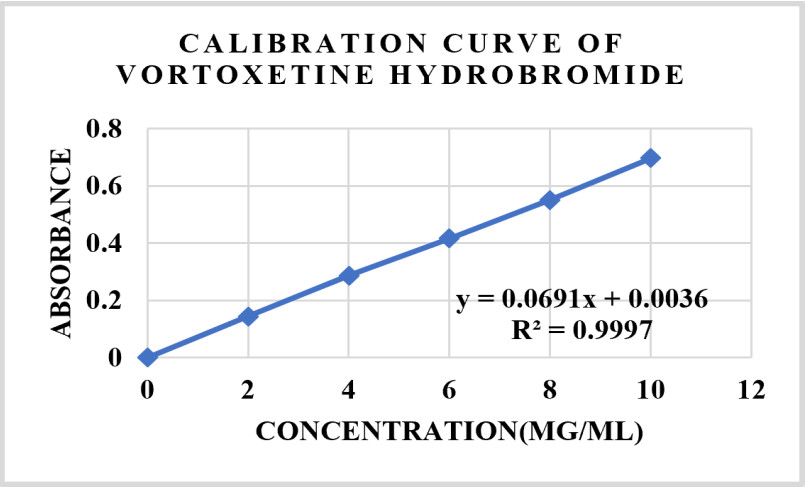
analyte at the chosen analytical wavelength, thus confirming the method's specificity for the API. The overlaid spectra of API and the solvent demonstrated no interference by the solvents used, confirming the methods selectivity for the VRT HBr.

**Table 2: Results of Linearity studies.**

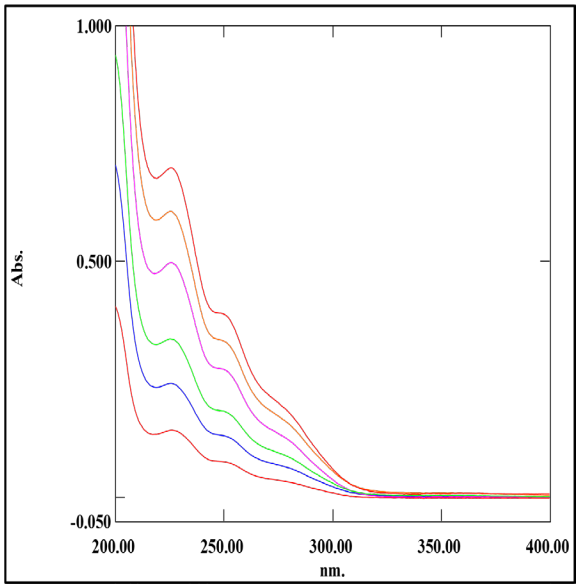
| Concentration ( µg/mL) | Absorbance |
|---|---|
| 0 | 0 |
| 2 | 0.144 |
| 4 | 0.286 |
| 6 | 0.416 |
| 8 | 0.551 |
| 10 | 0.697 |

## Assay and accuracy

To demonstrate the application of validated method to the content in the final formulation, working sample solution containing 10 µg/mL equivalent to VRT HBr was prepared in six replicates and the absorbance recorder at 225nm. The percentage drug content was calculated and was found to be 99.08%. The closeness of test results to that of true value was demonstrated by standard addition method. The accuracy was assessed by spiking the working sample solution with the standard stock solution containing 4 µg/mL at 80%, 100% and 120% concentrations levels. Three replicates of each level were prepared and the absorbance was recorded and the % Recovery was calculated. The results of Recovery studies are showed in Table 7.




(a)




(b)

**Figure 3:** a) Calibration of VRT HBr and b) Overlay spectra of five concentrations of VRT HBr.

**Table 3:** Results of Repeatability studies.

| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
|---|---|---|---|
| 2 | 0.147 | 0.001 | 0.860 |
| 6 | 0.414 | 0.003 | 0.670 |
| 10 | 0.693 | 0.004 | 0.528 |

**Table 4:** Results of Interday.

| 1st Hour | | | |
|---|---|---|---|
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
| 2 | 0.146 | 0.002 | 1.049 |
| 6 | 0.413 | 0.003 | 0.726 |
| 10 | 0.693 | 0.004 | 0.629 |
| 4th Hour | | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
| 2 | 0.144 | 0.001 | 0.694 |
| 6 | 0.418 | 0.003 | 0.73 |
| 10 | 0.687 | 0.004 | 0.589 |
| 8th Hour | | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
| 2 | 0.142 | 0.001 | 0.704 |
| 6 | 0.421 | 0.005 | 1.123 |
| 10 | 0.692 | 0.004 | 0.601 |

**Table 5:** Results of Intraday Precision.

| Day 1 | | | |
|---|---|---|---|
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
| 2 | 0.147 | 0.002 | 1.037 |
| 6 | 0.414 | 0.004 | 0.869 |
| 10 | 0.693 | 0.005 | 0.742 |
| Day 2 | | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
| 2 | 0.145 | 0.002 | 1.056 |
| 6 | 0.417 | 0.002 | 0.480 |
| 10 | 0.694 | 0.002 | 0.300 |
| Day 3 | | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD |
| 2 | 0.146 | 0.001 | 0.685 |
| 6 | 0.415 | 0.002 | 0.368 |
| 10 | 0.694 | 0.004 | 0.600 |

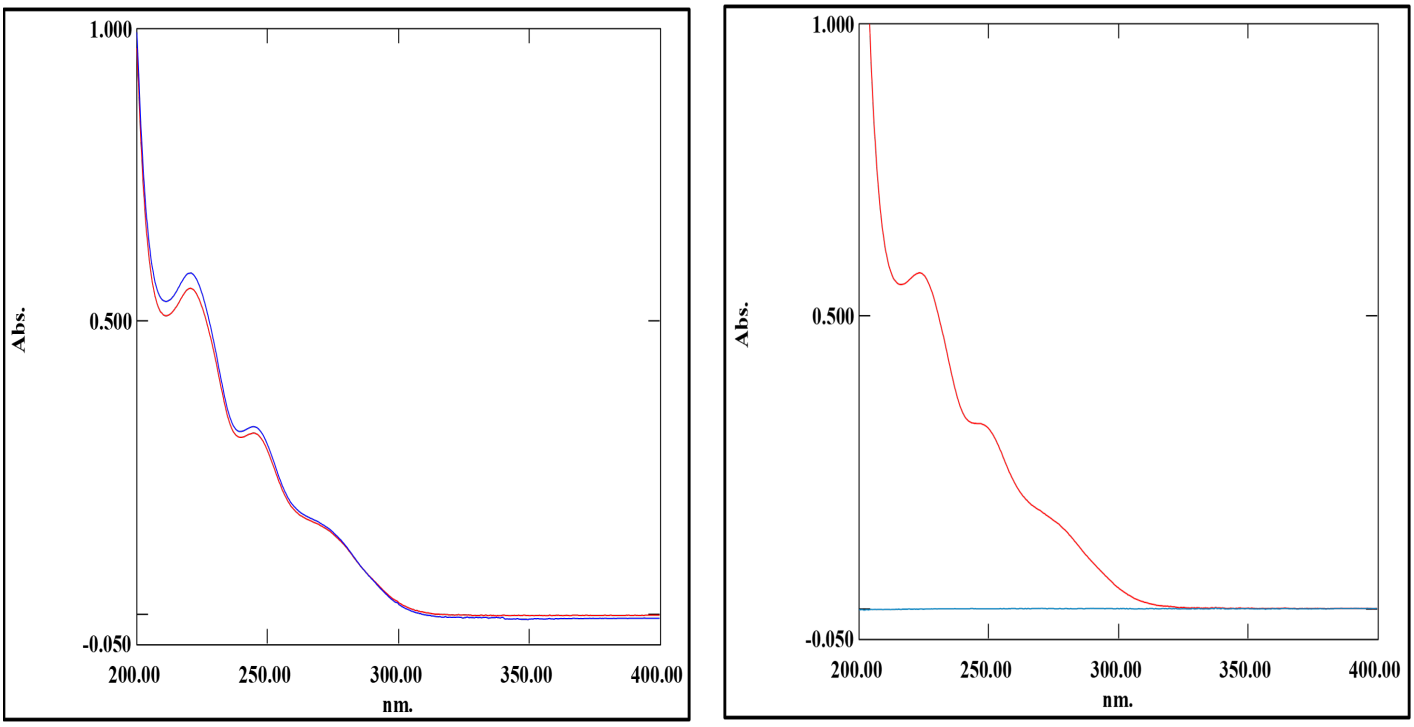



**Figure 4:** a) Overlay spectra of API and marketed formulation. b) Overlay spectra of solvent and the API.

**Table 6: Results of Robustness and Ruggedness.**

| Robustness | | | | | | |
|---|---|---|---|---|---|---|
| Wavelength | Analysis at 223 nm (-2 nm) | | | Analysis at 227 nm (+2 nm) | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD | Mean Absorbance | SD | % RSD |
| 2 | 0.133 | 0.001 | 0.752 | 0.138 | 0.001 | 0.839 |
| 6 | 0.402 | 0.003 | 0.800 | 0.404 | 0.002 | 0.495 |
| 10 | 0.683 | 0.003 | 0.387 | 0.685 | 0.004 | 0.584 |
| **Ruggedness** | | | | | | |
| Instrument | Shimadzu UV-1800 | | | Shimadzu UV-1900 | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD | Mean Absorbance | SD | % RSD |
| 2 | 0.143 | 0.001 | 0.699 | 0.147 | 0.002 | 1.037 |
| 6 | 0.418 | 0.002 | 0.366 | 0.413 | 0.004 | 1.055 |
| 10 | 0.693 | 0.003 | 0.382 | 0.694 | 0.005 | 0.725 |
| Analyst | Analyst-I | | | Analyst-II | | |
| Concentration (µg/mL) | Mean Absorbance | SD | % RSD | Mean Absorbance | SD | % RSD |
| 2 | 0.147 | 0.002 | 1.037 | 0.149 | 0.001 | 0.388 |
| 6 | 0.415 | 0.003 | 0.736 | 0.415 | 0.004 | 0.973 |
| 10 | 0.696 | 0.003 | 0.431 | 0.695 | 0.002 | 0.220 |

**Table 7: Results of recovery studies.**

| Spiking Level | Amount Added (µg/mL) | Amount Found (µg/mL) | % Recovery | Mean % Recovery |
|---|---|---|---|---|
| 80% (Replicate 1) | 3.2 | 3.23 | 100.78 | 102.60 |
| 80% (Replicate 2) | 3.2 | 3.31 | 103.53 | |
| 80% (Replicate 3) | 3.2 | 3.31 | 103.50 | |
| 100% (Replicate 1) | 4 | 3.87 | 96.75 | 100.42 |
| 100% (Replicate 2) | 4 | 3.97 | 99.25 | |
| 100% (Replicate 3) | 4 | 4.21 | 105.25 | |
| 120% (Replicate 1) | 4.8 | 4.76 | 99.17 | 100.28 |
| 120% (Replicate 2) | 4.8 | 4.87 | 101.46 | |
| 120% (Replicate 3) | 4.8 | 4.81 | 100.21 | |

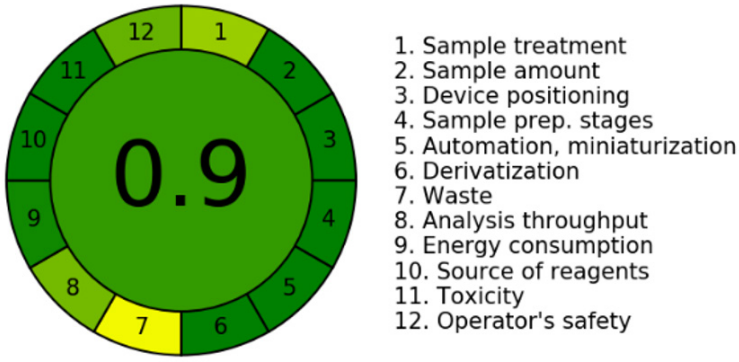



**Figure 5:** Green attributes are indicated by the AGREE.

## Evaluation of Greenness of the developed UV Spectroscopic method

According to GAC principles, AGREE software uses twelve graphical segments to determine how green an analytical process is. Each section's exact colour range is from dark green to dark red. The final score was shown as a range from zero to one, with values nearer zero indicating insufficient greenery and numbers closer to one indicating more greenness (Channabasavaiah *et al.*, 2025). The new UV Spectroscopic method's green attributes are indicated by the AGREE score of 0.9, as showed in Figure 5. The weakest section in the pictogram is 7, which refers to the generated waste. UV spectroscopy typically uses small cuvettes, which can hold upto 3.5 mL of the solvent. As the spectrophotometer is a double beam spectrophotometer, 3.5 mL solvent remains in the instrument as blank and 3.5 mL sample. Therefor a maximum of 3.5 mL solvent is discarded per sample, the cumulative quantity if calculated for whole method development and validation process, it generates more than 100 mL of the waste.

## CONCLUSION

The developed and validated UV Spectroscopic method for estimation of vortioxetine in bulk and pharmaceutical formulation was found to be green, simple, economical, sensitive, precise, robust, and accurate. Compared to previously published methods, the new developed and validated of UV spectrophotometric approach for estimation of Vortioxetine Hydrobromide, offers notable improvements. Most significantly, the optimised solvent system reduced organic waste significantly by using just 20% Methanol and 80% Water. Additionally, by carefully assessing the method's greenness using recognised metrics AGREE, the validated method confirms that this new process is not only reliable and accurate but also clearly more economical and ecologically friendly for routine analysis of vortioxetine in bulk and pharmaceutical formulations.

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## ABBREVIATIONS

**UV-vis:** Ultraviolet-visible; **ICH:** International Council for Harmonisation; **AGREE:** Analytical GREEnness; **GAC:** Green Analytical Chemistry; **WHO:** World Helath Organization;

**VRT HBr:** Vortioxetine Hydrobromide; **SSS:** Standard Stock Solution; **API:** Active Pharmaceutical Ingredient; **$\lambda_{max}$:** Maximum Wavelength; **$R^2$:** Correlation coefficient; **SD:** Standard Deviation; **% RSD:** Percentage Relative Standard Deviation; **LOD:** Limit of Detection; **LOQ:** Limit of Quantitation; **HPLC:** High-Performance Liquid Chromatography; **LCMS:** Liquid Chromatography-Mass Spectrometry; **UPLC:** Ultra-Performance Liquid Chromatography; **LC-ESI:** Liquid Chromatography-Electrospray Ionization.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## FINANCIAL SUPPORT AND SPONSORSHIP

The authors declare that no financial support, sponsorship, or external funding was obtained for this study.

## AUTHORS CONTRIBUTION

**Author 1: (Nikhil Sunil Gawas):** Conceptualization, Methodology, Data Curation, Writing—Original Draft Preparation, and Visualization.

**Author 2: (Meenaxi Maste):** Investigation, Resources, Writing—Review & Editing, Supervision, and Project Administration.

## SUMMARY

A simple, eco-friendly UV method for VRT HBr in bulk and dosage form was developed on Shimadzu UV-1800 using green diluent of 80% water and 20% methanol at 225 nm. Validated as per ICH Q2(R2), for Linearity the range of 2-10 µg/mL with corelation coefficient of 0.9997, precision with %RSD less than 2% and recovery within 100.28 to 102.60%. Sustainability was confirmed by AGREE score of 0.9. The method was fast, rugged, and is a green alternative for routine pharmaceutical quality control of VRT HBr.

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