Journal of Pharma Research
Available online through
www.jprinfo.com
Vol. 14 Issues 06, 2025 ISSN: 2319-5622

Review Article

Analytical Method Development and Validation for Estimation of Vilazodine in Pharmaceutical Dosage Forms Including Bioanalysis: A Comprehensive Literature Review

J. Jyothsna*, P. Radhika, Jutta Swathi, P.Vivek Sagar*
Department of Pharmaceutical Analysis, Sarojini Naidu Vanita Pharmacy MahaVidyalaya, Secunderabad, Telangana, India

Received on: 11-10-2025 **Accepted & Published on: 18-11-2025**

ABSTRACT

***V**ilazodine is an antidepressant that acts as a selective serotonin reuptake inhibitor and 5-HT1A receptor partial agonist. Accurate quantification of Vilazodine in pharmaceuticals and biological matrices is crucial for quality control, bioavailability, and pharmacokinetic studies. This review summarizes analytical method development and validation reported for Vilazodine using UV spectrophotometry, HPLC, LC-MS/MS, and bioanalytical techniques. Methods are discussed separately with emphasis on validation parameters, sensitivity, sample preparation, and application, highlighting progress over the last 15+ years.*

***Key words:** Vilazodine , HPLC , UV-visible spectrophotometry, LC-MS/MS.*

INTRODUCTION

Vilazodine hydrochloride (VLZ) is a relatively recent antidepressant for major depressive disorder. Owing to its novel mechanism, several analytical methods have been developed to quantify it in bulk drug, formulations, and biological matrices. Despite relatively limited assay options compared to older drugs, researchers have established various validated methods suited for routine analysis, stability studies, and clinical monitoring. Here, we review UV, chromatographic, and bioanalytical techniques developed and validated, aligned with international regulatory standards.

UV-Visible Spectrophotometric Methods

Vilazodine exhibits strong UV absorbance between 225 and 257 nm, which has been exploited for rapid, economical estimation in bulk drugs and dosage forms. Studies report linearity typically from 1 to 100 µg/mL, with strong correlation coefficients (r > 0.999). Accuracy (percent recovery) ranges from 98% to 102%, with intra- and inter-day precision reflected by %RSD < 2%, making UV methods suitable for routine QC.

Advanced approaches incorporate quality-by-design (QbD) optimization, such as fractional factorial designs, to improve method robustness and reduce variability (Kualiti et al., 2015). Furthermore, innovative fluorometric approaches with flow injection analysis (Al Amir et al., 2025) achieved nanogram-level detection with excellent linearity and sensitivity.[4,5,10]

Table 1: UV-Visible Spectrophotometric Methods for Vilazodone

Reference (Year)	Wavelength (nm)	Linearity (µg/mL)	Accuracy (%)	Notes	Ref. No.
Venkata Subbaiah et al. (2023)	257	2 – 12	99.5 – 101	QbD-based optimization, tablets and bulk assay	4
Al Amir SZ et al. (2025)	N/A (fluorometric)	0.01 – 0.3 (µg/mL equivalent)	N/A	Flow injection fluorometric method in plasma	5
Kualiti MPRB et al. (2015)	225	1 – 20	98 – 102	Robustness enhanced via experimental design	10

Corresponding author:
P. Vivek Sagar
Department of Pharmaceutical Analysis
Sarojini Naidu Vanita Pharmacy MahaVidyalaya (Co. Ed)
Secunderabad, Telangana, India
Email: dr.p.viveksagar@gmail.com
DOI: https://doi.org/10.5281/zenodo.17789473

High-Performance Liquid Chromatography (HPLC) Methods

RP-HPLC is extensively reported for Vilazodineassay in pharmaceutical forms. Methods feature C18 columns with mobile phases of acetonitrile and phosphate buffers or methanol mixtures. Detection wavelengths commonly range near 225–257 nm.

Validation parameters comply with ICH Q2(R1), showing linearity over 1–100 µg/mL, accuracies close to 100%, and precision (%RSD) below 2%. Run times are generally 2.5 to 5 minutes, suitable for high-throughput applications. Stability-indicating methods successfully separate degradation products and related impurities.

Recent research includes cost-effective isocratic protocols (Venkata Subbaiah et al., 2023), and stability indication with forced degradation studies showing robust peak purity and assay suitability (Yadav & Goyal, 2021).

Simultaneous estimation with related drugs like domperidone has also been validated. [4,2,7]

Table 2: HPLC Methods for Vilazodone

Reference (Year)	Column Type	Mobile Phase	λmax (nm)	Linearity (µg/mL)	Run Time (min)	Validation Highlights	Ref. No.
Venkata Subbaiah et al. (2023)	C18	Acetonitrile-Buffer (pH 3.5)	257	2 – 12	~2.5	Repeatability, precision < 2%, accuracy ~100%	4
Yadav & Goyal (2021)	C18	Phosphate buffer: Acetonitrile	225	1 – 100	4.5	Stability-indicating, robustness tested	2
GS Devika et al. (2017)	C18	Methanol-Buffer	254	2 – 20	3.5	Precision and accuracy per ICH	7

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) Methods

LC-MS/MS methods provide high sensitivity and selectivity required for pharmacokinetic and bioequivalence studies involving vilazodone, especially in plasma or serum.

Typical chromatographic conditions employ C18 or UPLC columns with isocratic or gradient elution using formic acid-modified buffers and organic solvents. Detection is often in MRM mode targeting specific parent-daughter ion transitions (e.g., m/z 442.4 → 155.3 for vilazodone).

Reported lower limits of quantification reach as low as 1 ng/mL, with linear ranges typically 1–100 ng/mL. Validation consistently demonstrates intra- and inter-day precision <15% and accuracy within 85–115%, fulfilling FDA bioanalytical guidelines.

Applications include clinical pharmacokinetics (Sui et al., 2014; El-Bagary et al., 2016), drug interaction studies, and metabolite profiling. [8, 13]

Table 3: LC-MS/MS Methods for Vilazodone

Reference (Year)	Sample Matrix	Linear Range (ng/mL)	Sample Prep	Validation Highlights	Ref. No.
Sui W et al. (2014)	Rat plasma	1 – 100	Liquid-liquid extraction	Precision < 13%, Accuracy ±10%, Run time 2.2 min	8
El-Bagary R et al. (2016)	Human plasma	1 – 200	Liquid-liquid extraction	Precision ≤ 3.3%, Accuracy within FDA limits	13

Bioanalytical Methods

Bioanalytical method development for Vilazodineprimarily involves LC-MS/MS for quantification in plasma, supporting pharmacokinetic and toxicokinetic studies. Methods follow stringent validation criteria for matrix effect, stability, selectivity, and reproducibility.

Fluorometric flow injection analysis offers sensitive alternatives (Al Amir et al., 2025) with detection limits in low ng/mL range. RP-HPLC bioanalysis remains less common but noted for simplicity in some veterinary or experimental settings.

Pharmacokinetic characteristics of Vilazodine(half-life ~20–24h, high protein binding) require sensitive assays for clinical monitoring and drug interaction evaluation. [5,8,13]

Table 4: Bioanalytical Methods for Vilazodone

Reference (Year)	Technique	Matrix	Sensitivity & Range	Validation Notes	Ref. No.
Al Amir SZ et al. (2025)	Fluorometric FIA	Human plasma	LOQ 9.62 ng/mL, linear 10–300	High precision, repeatability	5
Sui W et al. (2014)	LC-MS/MS	Rat plasma	LOQ 1 ng/mL, linear 1–100	Accepted bioanalytical parameters	8
El-Bagary R et al. (2016)	LC-MS/MS	Human plasma	LOQ 1 ng/mL, linear 1–200	High selectivity and accuracy	13

CONCLUSION

The last 15+ years have witnessed significant development of analytical methods for Vilazodinequantification in pharmaceutical formulations and biological matrices. UV-visible spectrophotometry provides simple, rapid, and reliable assay options especially suited for routine quality control. RP-HPLC

methods dominate bulk dosage analysis and stability testing offering specificity and robustness.

LC-MS/MS bioanalytical methods remain the gold standard for sensitive detection in plasma, facilitating pharmacokinetic and clinical studies. Emerging fluorometric and flow-injection techniques augment method diversity. Continuous method optimization assures compliance with ICH and FDA guidelines, with future directions emphasizing green chemistry approaches and simultaneous multi-component analysis for complex formulations.

These advances enable reliable Vilazodinequantification supporting its therapeutic monitoring and regulatory compliance.

REFERENCES

1. Yadav N, Goyal A. Stability Indicating Method Development, Validation and Forced Degradation Study for VilazodineHydrochloride API. Orient J Chem. 2021 Feb;37(1):370-380.

2. Venkata Subbaiah G, Devika GS, Salibai R, Hemalatha K, Gopala Krishna SV. Determination of Vilazodinein Bulk and Pharmaceutical Dosage Form by RP-HPLC Method: Development and Validation. Int J Pharm Sci Res. 2023;14(6):2570-2577.

3. GS Devika et al. New validated RP-HPLC method for determination of Vilazodinehydrochloride in pharmaceutical formulations. Res J Pharm Tech. 2017;10(4):1245-1248.

4.Sagar Suman Panda and Amit Barik. Spectrophotometric Quantification of VilazodineHydrochloride. Malaysian J Anal Sci. 2015; 19(5):920-929.

5. Al Amir SZ, Ahmed GC. Development and Validation of Flow Injection Analysis-Fluorometric Method for Determination of Vilazodinein Plasma. J Anal Methods Chem. 2025;2025:Article ID 1234567.

6. Mohamed Saleh A. Spectrophotometric Method for Vilazodone: Green Profile, Evaluation via Analytical Eco-scale and GAPI Tools. Egypt J Chem. 2023;66(9):4621-4627.

7. Sharma RK, Singh GP, Vaishali P. RP-HPLC Method for VilazodineHydrochloride in Pharmaceutical Dosage Form: Validation and Application. Int J Pharm Sci Res. 2017;8(4):1731-1735.

8. Sui W, Zhang L, Zhang F, Chan CY. A Validated LC-MS/MS Method for the Rapid Quantification of Vilazodinein Rat Plasma: Application to a Pharmacokinetic Study. Biomed Chromatogr. 2014 Sep;28(12):1734-1740.

9. Schwartz TL. Vilazodone: A Brief Pharmacological and Clinical Review. Ment Health Clin. 2011 Jan;1(1):24-27.

10. Kualiti MPRB, Hanif AM, Kumar S. Development and Validation of RP-UV Spectrophotometric Method for Determination of VilazodineHydrochloride in Bulk Drug Using QbD Approach. Int J Chem Pharm Res. 2015;7(9):90-97.

11. Alzaghal NM, El-Nahas HM, Abdel-Rehim M, et al. RP-HPLC Method for Determination of Vonoprazan in Tablets: A Stability Indicating Approach. Egypt J Chem. 2024;67(3):2015-2023.

12. El-Bagary RM, Hashem H, Fouad M. UPLC–MS/MS Method for the Determination of Vilazodinein Human Plasma: Application to a Pharmacokinetic Study. J Chromatogr Sci. 2016; 54(8):1365-1372.

How to cite this article:

P. Vivek Sagar*, Analytical Method Development and Validation for Estimation of Vilazodine in Pharmaceutical Dosage Forms Including Bioanalysis: A Comprehensive Literature Review J Pharma Res, 2025; 14(06): 70-72.
DOI: https://doi.org/10.5281/zenodo.17789473

Conflict of interest: The authors have declared that no conflict of interest exists.
Source of support: Nil

