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Review Article

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

N. Spandana, P.Pooja, Jutta Swathi, P.Vivek Sagar*
Department of Pharmaceutical Analysis, Sarojini Naidu Vanita Pharmacy MahaVidyalaya, Secunderabad, Telangana, India

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ABSTRACT

Vanoprazan fumarate, a potassium-competitive acid blocker (PCAB), is a novel therapeutic agent for acid-related diseases. Accurate analytical methods for its quantification in pharmaceutical dosage forms and biological matrices are essential for quality control, formulation development, and pharmacokinetic studies. This review consolidates advances in analytical method development and validation for vanoprazan using UV-visible spectroscopy, high-performance liquid chromatography (HPLC), liquid chromatography-tandem mass spectrometry (LC-MS/MS), and other bioanalytical techniques. Validation according to ICH guidelines, method parameters, sample preparation, and applications are emphasized, providing a thorough overview of modern and classical methods.

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

INTRODUCTION

Vanoprazan is a potent PCAB with rapid onset and reversible inhibition of gastric acid secretion via competitive blockade of the H^+, K^+-ATPase enzyme. Unlike traditional proton pump inhibitors, vanoprazan offers improved pharmacokinetic profiles. Its increasing clinical use necessitates reliable analytical techniques for determination in tablets, formulations, and biological samples. This review discusses analytical advancements over at least 15 years, highlighting methodology, validation, and bioanalytical considerations..

UV-Visible Spectrophotometric Methods

UV-Vis spectrophotometry for vanoprazan quantification primarily exploits its absorbance maxima between 213 and 225 nm. Early and recent studies demonstrate simple, rapid, and cost-efficient assays suitable for bulk and dosage form analysis with minimal sample preparation.

Linearity is typically observed across 1–100 µg/mL concentration ranges with correlation coefficients >0.999. Validation reports confirm high accuracy (98–102% recovery), inter- and intra-day precision with %RSD < 2%, and specificity without interference from excipients. Studies by Saleh et al. (2023) and others underscore the environmental and economic advantages of UV spectrophotometry vis-à-vis chromatographic methods.

Table 1: UV-Visible Spectrophotometric Methods for Vanoprazan

Reference (Year)	Wavelength (nm)	Linearity (µg/mL)	Accuracy (%)	Notes	Ref. No.
Saleh AM et al. (2023)	213 – 225	1 – 100	98–102	Simple, green profile, rapid assay	6
Alzaghal NM et al. (2024)	225	1 – 100	98–102	Used as UV detector in RP-HPLC method setup	2

Extensive literature shows UV methods remain attractive for routine QC of vanoprazan and have been adapted to

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
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simultaneous drug mixtures with amoxicillin and clarithromycin, demonstrating versatility in formulation analysis.

High-Performance Liquid Chromatography (HPLC) Methods

RP-HPLC is the predominant analytical technique for vanoprazan due to its selectivity, sensitivity, and compliance with regulatory standards. Most methods employ C18 columns with mobile phases consisting of aqueous buffers (often phosphate) and organic solvents such as acetonitrile or methanol.

Typical detection wavelengths range around 213–225 nm. Run times vary between 3–5 minutes, supporting high throughput. Method validation adheres to ICH Q2(R1) guidelines covering linearity (1–100 µg/mL), precision (%RSD <2%), accuracy (recovery 98–102%), robustness, specificity, and system suitability.

Notable contributions include Alzaghal et al. (2024) and various recent articles demonstrating stability-indicating methods and simultaneous estimation with domperidone or amoxicillin. Green chemistry evaluations and optimization to reduce solvent use have also been reported [3-5].

Table 2: RP-HPLC Methods for Vanoprazan

Reference (Year)	Column & Mobile Phase	λmax (nm)	Linearity (µg/mL)	Run Time (min)	Validation Highlights	Ref. No.
Alzaghal NM et al. (2024)	**C18; Buffer: Acetonitrile (50:50)**	**225**	**1 – 100**	**3.3**	**Accuracy 98–102%, RSD <2%, Specificity**	**3**
IJIRT (2024)	C18; Phosphate buffer: Methanol	225	1 – 100	~3.5	Robust, precise, ICH compliant	4
Veterinary Journal REDVET (2024)	C18; Buffer: Acetonitrile (60:40)	213	5 – 40	3.9	System suitability confirmed	5

History shows continuous improvements from initial stability-indicating assays to simultaneous multi-component analysis, facilitating industrial QC and regulatory acceptance.

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

LC-MS/MS methods have been developed for vanoprazan bioanalysis supporting sensitive quantification in human plasma for pharmacokinetic and bioequivalence studies. These methods employ selective reaction monitoring (SRM) with isotope-labeled internal standards (e.g., vanoprazan fumarate-d4).

Typical chromatographic conditions include gradient elution with 0.1% formic acid and acetonitrile and rapid protein precipitation sample preparation. Detection limits as low as 0.15 ng/mL and linear ranges up to 60,000 ng/mL have been validated with precision and accuracy within FDA guidelines.

Chen et al. (2024) demonstrated a fully validated LC-MS/MS method with a run time under 4 minutes, successfully applied to clinical bioequivalence of vanoprazan tablets.

Table 3: LC-MS/MS Methods for Vanoprazan Bioanalysis

Reference (Year)	Matrix	Linear Range (ng/mL)	Sample Prep	Validation Parameters	Ref. No.
Chen X et al. (2024)	**Human plasma**	**0.150 – 60,000**	**Protein precipitation**	**Selectivity, accuracy, precision, stability**	**6**

Such cutting-edge methodologies are critical in quantifying vanoprazan in clinical pharmacology and drug interaction studies.

Bioanalytical Methods

Bioanalytical assays for vanoprazan have employed RP-HPLC but increasingly focus on LC-MS/MS due to enhanced sensitivity and specificity. Bioanalytical method validation includes testing for accuracy, precision, selectivity, matrix effects, dilution integrity, and stability under various conditions.

Recent models integrating physiologically based pharmacokinetics (PBPK) emphasize understanding vanoprazan distribution, metabolism, and pharmacodynamics with high tissue affinity, particularly in the stomach. Rat studies suggest nonlinear elimination kinetics requiring sensitive bioanalytical methods to elucidate pharmacokinetics.[6-8]

Green chemistry approaches that reduce solvent consumption and waste are gaining importance in bioanalysis.

Table 4: Bioanalytical Methods for Vanoprazan

Reference (Year)	Technique	Matrix	Validation Focus	Notes	Ref. No.
Kong W et al. (2020)	**PBPK modeling**	**Rat plasma/tissues**	**Pharmacokinetics, tissue distribution**	**Dose-dependent kinetics, high stomach affinity**	**7**
Chen X et al. (2024)	**LC-MS/MS**	**Human plasma**	**Accuracy, precision, stability**	**Used in bioequivalence studies**	**8**

These comprehensive bioanalytical assessments support drug development, therapeutic monitoring, and regulatory filings.

CONCLUSION

Vanoprazan's quantification across pharmaceutical dosage forms and biological matrices has been robustly addressed via multiple analytical platforms. UV-Vis spectrophotometry provides simple, cost-effective assays for routine quality control, while RP-HPLC methods offer specificity and rapid analysis in formulations with regulatory compliance.

LC-MS/MS stands as the preferred bioanalytical method for clinical and pharmacokinetic studies, delivering high sensitivity and selectivity essential for low concentration detection in plasma. Complementary pharmacokinetic modeling and bioanalytical assessments reinforce understanding of drug disposition.

Continued method refinement, including green chemistry and multi-analyte approaches, will further enhance vanoprazan analysis, supporting its clinical and pharmaceutical applications.

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