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RECENT ANALYTICAL TECHNIQUES FOR THE QUANTIFICATION OF OMEPRAZOLE IN PHARMACEUTICAL DOSAGE FORMS: A COMPREHENSIVE REVIEW

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ABSTRACT

The quantification of omeprazole in pharmaceutical formulations remains a critical aspect of quality control in the pharmaceutical industry. This review focuses on the review of analytical methodologies in omeprazole determination and their development in terms of the dosage forms. This phenomenon makes analytical methods involving omeprazole quite unique, to the extent that a typical benzimidazole derivative, an antiproton pump drug, is highly susceptible to light, heat, and acidic environments. The paper gives a detail overview of both traditional and contemporary techniques, both simple (UV spectrophotometry) and advanced (hyphenated techniques such as LC-MS/MS). In particular, the analysis of combination formulations of omeprazole with antibiotics or NSAIDs is discussed separately due to their specific demands in the matter. The discussion critically discusses each method with respect to the principles of each technique, parameters of the methods, aspects of validation and uses in practice. Recent technological developments are brought to attention especially use of green analytical methods and small systems. The comparison of different techniques against each other in terms of these factors, sensitivity, cost, time to conduct analysis, effects on the environment are provided. The paper ends by looking at future trends especially in pharmaceutical analysis with the involvement of artificial intelligence and automation. This detailed review is a useful tool to analyze chemists and pharmaceutical scientists who analyze and develop methods of quality control of omeprazole.

Keywords: Omeprazole, Analytical techniques, Chromatography, Spectrophotometry, LC-MS

INTRODUCTION

Since its introduction toward the end of the 1980s, omeprazole has transformed the management of acid related disorders **[1]**. In view of being one of the most commonly prescribed drugs in the world, it is essential in treatment of conditions such as gastroesophageal reflux disease, peptic ulcers and Zollinger-Ellison syndrome **[1]**. Such a high prevalence among the population of different patient groups including those of pediatrics and geriatrics makes quality control of the drug especially important **[2]**. It is interesting to a chemical perspective because omeprazole (5-methoxy-2- [[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole) poses intriguing analysis challenges **[3]**. It is composed of acidic and basic functional groups in its molecular structure, and is therefore amphoteric **[1]**. This property, together with its famous instability in some situations, requires special attention when designing methods of analysis **[4]**. The compound has an easy degradation when placed in acidic conditions, it is photodegraded and may form multiple impurities during storage which are all key parameters affecting the selection of analytical methods **[5]**. Omega-prozole is available as immediate-release or delayed release in capsules, in suspension form and also as an injectable drug in the pharmaceutical market **[1]**. The different formulation types will come with different sets of excipients and manufacturing procedures that require specialised analytical techniques **[6]**. In addition, the emergence of fixed dose combinations especially the omeprazole-clarithromycin and omeprazole-amoxicillin combinations in treatment of H. pylori further complicates the analytical scene **[7]**. The problems in the quality control labs are aimed at coming up with methods that not only are precise and accurate but also take a reasonable time and are affordable **[6]**. The optimum analytical technique must not only identify the presence of omeprazole in the presence of its degradation products, but must measure it precisely in various levels of concentration, and be able to separate it off co-formulated drugs in case there is any need **[8]**. Also, regulatory demands insist on robust, reproducible and transferable methods **[9]**.

The innovation of methods of analysis of omeprazole follows the general trend of development of pharmaceutical analysis **[8]**. Initial techniques were based mainly on titrimetric and simple spectrophotometric techniques **[10]**. But with increasing awareness about the behavior of the drug and increasingly higher standards of regulation it became inevitable to turn to more complex instrumental methods **[8]**. Putting all of this to one side, the current analytical armory provides everything,

including high-performance liquid chromatography with different detection modes, up to state-of-the-art mass spectrometric methods capable of detecting and quantifying trace level impurities **[11]**.

In this review, the author seeks to present a detailed evaluation of the methods of analysis that can be applied to quantify omeprazole **[8]**. We do not merely, though, want to catalogue published methods but instead present critical discussions pertinent to the selection of techniques, optimization of methods as well as (practical) suggestions towards potential method applications in the context of routine analysis. Since this paper closes the gap between theoretical studies and their industrial employment, it can become at the same time both the educational tool and the guide to the work on new methods in analysis **[5]**.

OVERVIEW OF OMEPRAZOLE

Chemical Structure and Properties

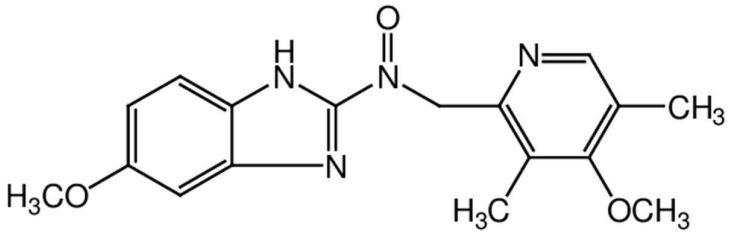

Figure 1: Chemical Structure of Omeprazole

Omeprazole belongs to the benzimidazole class of compounds, with a rather complex molecular structure that directly influences its pharmaceutical behavior **[1]**. The molecule consists of a substituted benzimidazole ring system connected via a sulfoxide bridge to a substituted pyridine moiety **[1]**.

IUPAC Name: 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole

The molecular formula: C17H19N3O3S

Molecular weight: 345.42 g/mol

Uses:

- Treatment of GERD (acid reflux, heartburn)
- Healing and prevention of peptic ulcers
- Zollinger-Ellison syndrome (high acid secretion)
- Prevention of NSAID-induced and stress ulcers
- Management of dyspepsia **[1]**

From a physicochemical perspective, omeprazole exhibits some quirky characteristics **[1]**. It's a weak base with pKa values around 4.0 and 8.8, making it practically insoluble in water but freely soluble in alkaline solutions **[12]**. This pH-dependent solubility is actually clever pharmaceutical design - the drug remains stable in alkaline conditions but rapidly degrades in acidic environments **[5]**. The

compound has the form of a white to off-white crystalline powder that in light it might change to yellow or purple discoloration **[4]**.

Another issue is temperature stability. Omeprazole will melt at approximately 156 o C, cold storage but the all-important factor is the storage conditions **[1]**. The drug is infamously photosensitive and hygroscopic, and great care must be taken in handling it during manufacturing and even during analysis **[4]**. Its degradation is more complicated because it leads to a variety of benzimidazole derivatives and sulfone products that have to be taken into consideration by the analysts **[13]**.

Dosage Forms

Table 1: Various dosage forms of Omeprazole

Dosage Form	Description	Strength available	Key features	Analytical Considerations	References
Delayed-Release Capsules	Capsules with enteric-coated pellets	10 mg, 20 mg, 40 mg	Protects drug from gastric acid; releases in small intestine	Extraction from enteric coating; assay of pellets	[1]
Delayed-Release Tablets	Compressed tablets with enteric coating	20 mg, 40 mg	Similar technology to capsules but in tablet form	Tablet dissolution and coating integrity testing	[1]
Orally Disintegrating Tablets	Tablets that dissolve on the tongue	Variable	Useful for patients with swallowing issues; taste-masked; needs stability	Taste masking evaluation; disintegration testing	[2]
Oral Suspension (Powder)	Powder for reconstitution into liquid	Pediatric & adult doses vary	Uses sodium bicarbonate for stabilization and palatability	Stability in liquid; uniformity of suspension	[2]
Granules for Oral Suspension	Granules to be mixed with water before administration	Pediatric flexible dosing	Used in some countries for easy pediatric administration	Dosing accuracy; granule dispersibility	[1]
IV Injection	Lyophilized powder for intravenous administration	40 mg	Rapid acid suppression; hospital use only; needs reconstitution	Reconstitution accuracy; short stability window post-preparation	[1]

ANALYTICAL TECHNIQUES FOR OMEPRAZOLE QUANTIFICATION

SPECTROSCOPIC METHODS

UV-Visible Spectrophotometry

In order to use UV-Visible spectrophotometry, omeprazole is affected by UV absorption of its conjugated aromaticity system, specifically, a benzimidazole heterocyclic ring junction and a pyridine heterocyclic ring **[15]**. This method has its absorption peaks at 280nm and 305nm wavelength with the best analytical criteria being alkaline solutions which should be at pH of 9-11 to stabilize the drug **[16]**. Ordinary solutions are the 0.1 M sodium hydroxide, phosphate buffer at pH 11 or methanol- water mixtures with base added in **[10]**. The technique has major benefits which comprise easiness, affordability, swift digestion time of 10 minutes, affordable costs, and environment friendly green chemistry concepts **[17]**. Nevertheless, the method is associated with inadequate specificity and reasonable sensitivity and offers a 5-25 µg/mL narrow linear range **[10]**. Primary applications

include content uniformity testing and routine quality control analysis **[12]**.

Nuclear Magnetic Resonance (NMR)

Nuclear Magnetic Resonance spectroscopy provides structural identification and quantitative analysis capabilities for omeprazole **[18]**. 1H-NMR spectroscopy reveals characteristic signals including methoxy groups at 3.8 ppm, aromatic protons at 7-8 ppm, and the distinctive benzimidazole NH proton ,13C- NMR spectroscopy offers complementary information with the sulfoxide carbon resonating around 60 ppm for structural confirmation **[1]**. Quantitative NMR enables absolute purity determination without requiring identical reference standards, making it valuable for reference standard certification **[18]**. The technique finds applications in identity confirmation, impurity structure elucidation, and establishing reference material purity **[1]**.

Vibrational Spectroscopy

Infrared spectroscopy provides rapid identity confirmation through characteristic absorption bands including S=O stretching at 1030 cm^{-1}, aromatic C=C stretches at 1580-1600 cm^{-1}, and C-O-C vibrations from methoxy groups **[19]**. Attenuated Total Reflectance Fourier Transform Infrared (ATR-FTIR) spectroscopy enables direct solid analysis without sample preparation requirements **[1]**. Raman spectroscopy offers complementary advantages being water-insensitive and suitable for through-package analysis, making it excellent for polymorph identification and crystal form differentiation **[4]**. Near-infrared spectroscopy enables non-destructive analysis of intact dosage forms and supports Process Analytical Technology monitoring applications **[1]**.

CHROMATOGRAPHIC METHODS

High Performance Liquid Chromatography (HPLC)

High Performance Liquid Chromatography represents the gold standard for omeprazole analysis through reversed-phase separation mechanisms **[20]**. The technique typically employs C18 columns as the preferred choice, though C8 phases also provide adequate performance **[21]**. Mobile phases consist of phosphate or ammonium acetate buffers maintained at pH 7-8 combined with acetonitrile or methanol as organic modifiers **[14]**. Detection systems include UV detection at 280- 305 nm, fluorescence detection, and photodiode array detection for enhanced selectivity **[22]**. Temperature control at 30-35°C ensures optimal reproducibility and peak shape **[23]**. The method excels in assay determination with relative standard deviations below 1% impurity profiling using gradient elution stability-indicating analysis and combination product evaluation **[5]**. HPLC offers high specificity, quantitative precision, and regulatory acceptance though

it involves higher costs, longer analysis times, and increased solvent consumption compared to simpler methods **[8]**.

High Performance Thin Layer Chromatography (HPTLC)

High Performance Thin Layer Chromatography provides visual separation with minimal solvent consumption for omeprazole analysis **[8]**. The technique utilizes silica gel 60 F254 or RP-18 plates as stationary phases, with mobile phases consisting of chloroform-methanol-ammonia in ratios of 8:2:0.1 for normal phase separations **[8]**. Detection methods include UV densitometry at 280-305 nm and fluorescence detection with 366 nm excitation. Primary applications encompass identity testing with visual comparison, stability monitoring where multiple samples can be analyzed on a single plate, and cleaning validation procedures **[6]**. The method offers advantages of simultaneous multiple sample analysis, visual confirmation capabilities, and low solvent usage, though it exhibits lower precision than HPLC and requires manual sample application **[8]**.

Gas Chromatography (GC)

Compound omeprazole is of minimal volatility, so Gas Chromatography needs derivatization in the analysis **[4]**. The best derivatization method is done by an N,O-bis(trimethylsilyl)trifluoroacetamide (BSTFA), trimethylchlorosilane at 60 o C, 30 minutes **[24]**. Examples of its use are examination of residual solvents by headspace GC-FID, profile of volatile impurities, and tracking of synthetic intermediates **[8]**. The technique is able to make very good volatile compounds separation and complements the information of liquid chromatography methods though it comes with derivatization procedures that complicate the analysis process **[4]**.

HYPHENATED/MASS SPECTROMETRY METHODS

LC-MS/MS

Liquid Chromatography coupled with tandem Mass Spectrometry provides ultimate specificity through the combination of chromatographic separation and mass-selective detection **[25]**. The technique employs electrospray ionization in positive mode, generating a precursor ion at m/z 346 corresponding to $[M+H]^+$ **[26]**. Tandem mass spectrometry monitors product ions at m/z 198 as the quantifier and m/z 136 as the qualifier ion **[11]**. Mobile phases utilize volatile buffers such as ammonium acetate or formate with 0.1% formic acid to optimize ionization efficiency **[27]**.

Applications encompass bioanalytical methods with ng/mL sensitivity, genotoxic impurity analysis at ppm levels, structural elucidation of unknown compounds and metabolite identification studies **[28]**. The method delivers unmatched specificity and sensitivity along with structural information

capabilities, though it requires high capital investment, complex instrumentation, and extensive method development time **[27]**.

ELECTROPHORETIC METHODS

Capillary Electrophoresis (CE)

Capillary Electrophoresis achieves separation based on charge differences rather than traditional partitioning mechanisms **[29]**. The technique employs phosphate or borate buffers maintained at pH 8- 9 under conditions of 15-25 kV applied voltage and 15-25°C temperature control with UV detection at 280-305 nm. Micellar electrokinetic chromatography represents a valuable variation of the basic technique **[4]**. Applications include chiral separation when cyclodextrins are added to the running buffer combination product analysis and metal ion interaction studies **[29]**. The method offers different selectivity compared to chromatographic techniques, requires minimal sample volumes, and eliminates the need for stationary phases, though it suffers from limited sensitivity and reproducibility challenges **[4]**.

ELECTROCHEMICAL METHODS

Voltametric Techniques

Voltametric methods exploit the electrochemical oxidation of omeprazole at glassy carbon electrodes with an oxidation potential of +0.8 V versus Ag/AgCl reference electrode. Differential pulse voltammetry provides enhanced sensitivity, achieving detection limits at sub-µg/mL levels **[30]**. The technique finds applications in simple, low-cost analysis for process monitoring applications **[31]**. Advantages include simplicity, low cost, and elimination of chromatographic equipment requirements, though the method suffers from matrix effects and limited selectivity **[30]**.

Ion-Selective Electrodes

Ion-selective electrodes utilize PVC membrane electrodes incorporating specific ionophores for omeprazole detection **[1]**. These electrodes enable rapid analysis suitable for process monitoring applications and offer real-time monitoring capabilities **[1]**. However, the technique exhibits limited selectivity and suffers from interference from other ionic species present in the sample matrix **[30]**.

COMPARATIVE ANALYSIS OF ANALYTICAL METHODS

Table 2: Comparative analysis of Analytical Methods

Analytical Method	Analysis Time	Sample Preparation	Limit of Detection (LOD)	Limit of Quantification (LOQ)	Linearity	Precision	Accuracy	Advantages	Applications	Reference
HPLC	4–16 minutes	Mobile phase optimization required	OMZ: 0.4–131.27 ng/mL	5 ng/mL	5–1000 ng/mL (serum), R^2 not stated	±15% RSD	±15% deviation	High specificity, precision	Pharmaceutical formulations, QC	[7,40]
LC-MS/MS	3 minutes	Complex preparation	Not specified	1.2 ng/mL	1.2–1200 ng/mL	1.43–5.25%	96.14–109.45%	High sensitivity	Bio-analytical validation	[40]
HPTLC	Fast separation	Simple handling	OMZ: 0.005–40.83 ng/spot	9.8 ng/spot	100–500 ng/band, $R^2 > 0.998$	Within limits	Within criteria	Simultaneous analysis	Drug formulations	[41]
UV-Spectrophotometric	10 minutes	Simple preparation	OMZ: 0.105 µg/mL	0.47 µg/mL	2–12 µg/mL, $R^2 = 0.99545$	Within criteria	Statistical validation	Cost-effective	Pharmaceutical analysis	[42]
IR	Rapid	KBr pellet	Not specified	Not specified	Not specified	0.3% to 13.7%	93.5% to 107.2%	Non-destructive, no pretreatment	Raw material testing	[1,41]
NMR	128 scans	DMSO-d6, internal standard	~0.01 mg/mL	Not specified	r = 0.9999	%RSD <1.08	—	No labelling required	Concurrent assay	[1,41]
GC	20–45 minutes	Volatile/derivatized	Parts per trillion	Varies by solvent	$r^2 > 0.997$ (for residual solvents)	0.05%	4.24%	High sensitivity	Residual solvents	[41]
CE	<8 minutes	Nano liter volumes	OMZ: 0.31 mg/L	Not specified	Not specified	RSD <2.5%	84–104% recovery	High separation efficiency	Chiral separation	[4,41]

RECENT ADVANCEMENTS IN ANALYTICAL TECHNIQUES

The analytical landscape for omeprazole continues evolving, driven by technological innovation and changing regulatory expectations **[8]**. Recent years have witnessed remarkable developments that promise to reshape how we approach pharmaceutical analysis.

Green Analytical Chemistry Approaches

Environmental consciousness has sparked a revolution in method development. Researchers increasingly prioritize eco-friendly approaches without compromising analytical performance. For omeprazole, this translates to innovative strategies that minimize environmental impact **[8]**.

Supercritical fluid chromatography (SFC) emerges as a compelling alternative to traditional HPLC. Using supercritical CO2 as the primary mobile phase dramatically reduces organic solvent consumption **[32]**. Recent methods achieve baseline separation of omeprazole from impurities using minimal methanol modifier (5-10%). Run times under 5 minutes and simplified waste disposal make SFC increasingly attractive. The technique particularly excels for chiral separations, resolving omeprazole enantiomers without expensive chiral mobile phase additives **[29]**.

Solid-phase microextraction (SPME) concentrates omeprazole from complex matrices using minimal solvent **[7]**. Dispersive liquid-liquid microextraction (DLLME) achieves similar results using microliters rather than milliliters of organic solvents **[33]**. These approaches not only reduce environmental impact but often improve sensitivity through analyte concentration **[8]**.

Water-based mobile phases represent another green frontier **[28]**. Using surfactants above their critical micelle concentration creates a pseudo-stationary phase for separation **[34]**. Micellar liquid chromatography methods for omeprazole use sodium dodecyl sulfate solutions with small amounts of organic modifier. While resolution may not match traditional reversed-phase methods, the environmental benefits prove compelling for routine analyses **[28]**.

Artificial Intelligence Integration

AI algorithms predict optimal chromatographic conditions based on molecular structure, dramatically reducing development time **[35]**.

For omeprazole HPLC methods, neural networks trained on historical data suggest starting conditions likely to achieve desired resolution **[8]**. The models consider factors like pKa, logP, and molecular volume to predict retention behavior **[1]**. By training on databases of known omeprazole degradation products, AI systems can suggest structures for unknown peaks based on retention time and UV spectra **[5]**. This

accelerates stability studies and helps ensure comprehensive impurity control **[13]**.

Automated method validation leverages AI to design efficient experimental protocols **[6]**. Rather than testing every combination of validation parameters, intelligent design of experiments identifies the most informative conditions **[32]**. The approach reduces validation time while ensuring thorough method characterization **[6]**.

Continuous Flow Analysis

The pharmaceutical industry's shift toward continuous manufacturing demands compatible analytical techniques. Flow injection analysis (FIA) and sequential injection analysis (SIA) provide real-time monitoring capabilities **[36]**.

Recent FIA methods for omeprazole achieve sampling rates exceeding 120 samples/hour **[8]**. By eliminating chromatographic separation, the techniques sacrifice some specificity for speed. However, chemometric data treatment can resolve overlapping signals, enabling selective quantification even in combination products **[7]**.

Continuous-flow NMR represents a breakthrough for structure-sensitive analysis **[1]**. Low-field benchtop NMR systems now offer sufficient resolution for omeprazole quantification in flowing streams. While sensitivity remains limited compared to high-field instruments, the ability to monitor structural integrity continuously proves invaluable for process understanding **[18]**.

FUTURE PERSPECTIVES

Integration of Artificial Intelligence and Machine Learning

The convergence of analytical chemistry and artificial intelligence promises revolutionary advances in omeprazole analysis, moving beyond simple automation toward intelligent analytical systems **[32]**.

Predictive Method Development

Machine learning models trained on chromatographic databases now predict optimal conditions before laboratory experimentation **[8]**. For omeprazole analysis, inputting molecular structure and separation goals yields AI-generated method suggestions with 80-85% first-attempt success rates **[8]**. Deep learning networks identify subtle correlations between mobile phase additives and peak shape, or between column temperature and degradation product formation **[4]**. One pharmaceutical company reduced omeprazole method development time from three weeks to three days using AI-guided optimization **[8]**.

Intelligent Data Analysis

Real-time spectral interpretation transforms routine analysis through AI algorithms monitoring HPLC- DAD data, flagging unusual peaks and baseline anomalies as they occur **[37]**. For omeprazole stability studies, this enables immediate detection of

unexpected degradation products rather than discovery during data review **[13]**. Pattern recognition in complex datasets reveals hidden relationships, with machine learning analyzing batch data to identify correlations between raw material properties and finished product stability **[6]**.

Quality Prediction and Control

Predictive models using multivariate analysis forecast quality issues before manifestation **[6]**. By combining analytical data with process parameters, AI predicts the batch compliance before manufacturing completion, enabling proactive adjustments **[38]**. Digital twins of analytical methods simulate performance under various conditions, reducing validation workload and improving change control decisions **[6]**.

Automation in Pharmaceutical Analysis

Laboratory automation continues transforming the analysis from labor-intensive to largely autonomous operations.

Sample Preparation Revolution

Robotic sample preparation systems handle complete workflows for tablet analysis, including weighing, grinding, extraction, filtration, and dilution preparation **[24]**. Integration with laboratory information systems eliminates manual data entry while reducing error rates **[2]**. Automated solid-phase extraction for bioanalytical samples achieves unprecedented consistency, crucial for drug metabolite studies where manual variation previously limited precision **[39]**.

Real-time Monitoring Systems

The pharmaceutical industry's shift toward continuous manufacturing demands analytical techniques capable of real-time quality assessment **[8]**.

Process Analytical Technology Implementation

Near-infrared probes embedded in production equipment monitor omeprazole content continuously, with chemometric models translating spectral data into concentration values every few seconds [8]. Raman spectroscopy offers additional chemical specificity, monitoring polymorphic form during crystallization to ensure consistent solid-state properties **[1]**.

Continuous Flow Chemistry Applications

Flow chemistry platforms with integrated analytics enable reaction optimization in hours **[34]**. For drug synthesis, reaction mixtures flow through inline HPLC or NMR, providing immediate conversion and selectivity data **[20]**. Continuous crystallization with inline microscopy controls particle properties through image analysis algorithms monitoring crystal size and shape **[1]**.

CONCLUSION

The current review tracked the development of omeprazole easy-to-use and state of the art analysis methods arising due to the changes in the quality and safety of pharmaceuticals. The analysis district proves to be very diverse. Still present but

only because of its ease and convenience is traditional UV-Vis spectrophotometry whereas newer technologies achieve higher sensitivity and specificity using LC-MS/MS. The techniques are used to address the particular analytical objectives depending on the resources available and regulations. Among the most emerging trends, there is a rise in the need of specificity and increased sensitivity, automation and digitalization of laboratories, and the implementation of AI to grow into predictive approaches of the method development and smart data analysis. Green analytical chemistry has come to shape the choice of method in the preference of techniques that conserve the use of solvents and produce minimum wastes. The latest trends will be the demand for continuous manufacturing that necessitates real-time analytical skills, personalized medicine necessitating companion diagnostics and the drive towards sustainability to increase the adoption of green methods. To analytical chemists, the choice of technique should aim at short-term uses and the future demands as well. The efficiency and capability are enhanced by investing in highly advanced technologies and training of personnel. The segment of pharmaceutical industry is at the cross road of age-old ways of analysis and newer disruptive technologies. The ideal case study of this evolution is the analysis of omeprazole, and every improvement of the analysis leads to safer, more efficient medicine used by patients all over the world. The future is full of unheard powers that can be brought with the help of technological innovation and profound pharmaceutical knowledge that guarantees this important drug to maintain its top-notch qualifications and increase analytical sciences.

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CONFLICT OF INTEREST:

The authors declare that NO conflict of interest among us.

REFERENCES

[1] Al-Badr AA. Omeprazole. In: Profiles of Drug Substances, Excipients, and Related Methodology. Volume 35. Amsterdam: Elsevier Inc.; 2010. p. 151-262.

[2] Indian Pharmacopoeia. Government of India, Ministry of Health and Family Welfare. Ghaziabad, New Delhi: The Indian pharmacopoeia commission publisher; 2010. p. 1813-1814.

[3] Espinosa Bosch M, Ruiz Sanchez AJ, Sanchez Rojas F, Bosch Ojeda

B. Analytical methodologies for the determination of omeprazole: An overview. J Pharm Biomed Anal. 2007;44(4):831-844.

[4] Berzas JJ, Castañeda G, Rodríguez V. Study of controlled degradation processes and electrophoretic behaviour of omeprazole and its main degradation products using diode-array and ESI-ITMS detection. Anal Methods. 2013;5:3299-3306.

[5] Karljikovic-Rajic K, Novovic D, Marinkovic V, Agbaba D. First-order UV-derivative spectrophotometry in the analysis of omeprazole and pantoprazole sodium salt and corresponding impurities. J Pharm Biomed Anal. 2003;32(4-5):1019-1027.

[6] Prabhavathi K, Chandra Rekha K. Analytical Method Development for Assay of Omeprazole in Bulk and Pharmaceutical preparations. Int J Pharm Sci. 2024;2(8):2593-2598.

[7] Lotfy HM, Hagazy MA. Comparative study of novel spectrophotometric methods manipulating ratio spectra: an application on pharmaceutical ternary mixture of omeprazole, tinidazole and clarithromycin. Spectrochim Acta A Mol Biomol Spectrosc. 2012;96:259-270.

[8] El-Kimary EI, Ragab MAA. Recent Analytical Methodologies for the Determination of Omeprazole and/or Its Active Isomer Esomeprazole in Different Matrices: A Critical Review. Crit Rev Anal Chem. 2020. DOI: 10.1080/10408347.2020.1791042.

[9] United States of Pharmacopoeia. Convention inc., Rockville; 2009. p. 2796-2797.

[10] Wahbi AAM, Abdel-Razak O, Gazy AA, Mahgoub H, Moneeb MS. Spectrophotometric determination of omeprazole, lansoprazole and pantoprazole in pharmaceutical formulations. J Pharm Biomed Anal. 2002;30(4):1133-1142.

[11] Woolf EJ, Matuszewski BK. Simultaneous determination of omeprazole and 5-hydroxyomeprazole in human plasma by liquid chromatography-tandem mass spectrometry. J Chromatogr A. 1998;828:229-238.

[12] Rivai H, Hasanah R, Azizah Z. Development and Validation of Omeprazole Analysis Methods in Capsules with Absorbance Methods and Areas under Curves Methods with UV-Vis Spectrophotometry. Int J Pharm Sci Med. 2018;3(3):21-32.

[13] El-Kousy NM, Bebawy LI. Stability-indicating methods for determining omeprazole and octylonium bromide in the presence of their degradation products. J AOAC Int. 1999;82(3):599-606.

[14] Bharathi DV, Hotha KK, Jagadeesh B, Chatki PK, Thriveni K, Mullangi R, Naidu A. Simultaneous estimation of four proton pump inhibitors--lansoprazole, omeprazole, pantoprazole and rabeprazole: development of a novel generic HPLC-UV method and its application to clinical pharmacokinetic study. Biomed Chromatogr. 2009;23(7):732-739.

[15] Dousa M, Hosmanova R. Rapid determination of amoxicillin in premixes by HPLC. J Pharm Biomed Anal. 2005;7(2):373-377.

[16] Bhandage A, Bhosale A, Kasture A, Godse VP. Extractive spectrophotometric determination of omeprazole in pharmaceutical preparations. Trop J Pharm Res. 2009;8(5):449-454.

[17] Gallardo V, López-Viota M, Sierra J, Ruiz MA. Spectrophotometric and chromatographic determination of omeprazole in pharmaceutical formulations. Pharm Dev Technol. 2009;14(5):516-523.

[18] Tolonen A, Leinonen A, Juvonen R, Raunio H, Pelkonen O. Simple and efficient method for the determination of labile protons in drug metabolites using postcolumn infusion of deuterium oxide in LC/MS experiments. J Mass Spectrom. 2004;39(10):1173-1181.

[19] Abualhasan MN, Qaddumi A, Zaid AN. A validated FTIR method for the rapid and ecofriendly assay of omeprazole in pharmaceutical formulations. Res J Pharm Technol. 2022;15(8):3577–3582.

[20] Sluggett GW, Stong JD, Adams JH, Zhao Z. Omeprazole determination using HPLC with coulometric detection. J Pharm Biomed Anal. 2001;25(3-4):357-361.

[21] Zarghi A, Foroutan SM, Shafaati A, Khoddam A. HPLC determination of omeprazole in human plasma using a monolithic column. Arzneimittelforschung. 2005;55(8):472-476.

[22] Mahmoud AM, Ahmed SA. A Validated High-Throughput Fluorometric Method for Determination of Omeprazole in Quality Control Laboratory via

Charge Transfer Sensitized Fluorescence. J Fluoresc. 2016;26(2):521-529.

[23] Nataraj KS, Duza MB, Pragallapati K, Kumar DK. Development and validation of RP-HPLC method for the estimation of omeprazole in bulk and capsule dosage forms. Int Curr Pharm J. 2012;1(11):366-369.

[24] Orata F. Derivatization reactions and reagents for gas chromatography analysis. Advanced gas chromatography-Progress in agricultural, biomedical and industrial applications. 2012 Mar 21;91.

[25] Hofmann U, Schwab M, Treiber G, Klotz U. Sensitive quantification of omeprazole and its metabolites in human plasma by liquid chromatography–mass spectrometry. J Chromatogr B. 2006;831(1-2):85-90.

[26] Kanazawa H, Okada A, Matsushima Y, Yokota H, Mashige F, Nakahara K. Determination of omeprazole and its metabolites in human plasma by liquid chromatography–mass spectrometry. J Chromatogr A. 2002;949:1-9.

[27] Vittal S, Rao DV, Kumar KN, Shyale SS, Ahmed T, Murugan C. An LC-MS/MS Method For The Determination of Omeprazole in Human Plasma: Application To A Pharmacokinetic Study. Int J Pharm Sci Rev Res. 2016;27(2):81-89.

[28] Rambla M, Esteve J, Carda S. Analysis of omeprazole and its main metabolites by liquid chromatography using hybrid micellar mobile phases. Anal Chim Acta. 2009;633(2):250-256.

[29] Nevado JJB, Castañeda GG, Robledo VR. Capillary zone electrophoresis method for the separation and determination of omeprazole enantiomers in pharmaceutical preparations. Anal Chim Acta. 2005;533(2):127-133.

[30] Qaisi AM, Tutunji MF, Tutunji LF. Acid decomposition of omeprazole in the absence of thiol: a differential pulse polarographic study at the static mercury drop electrode. Pharm Sci. 2006;95(2):384-391.

[31] Murakami FS, Cruz AP, Pereira RN. Development and Validation of a RP-HPLC Method to Quantify Omeprazole in Delayed Release Tablets. J Liq Chromatogr Relat Technol. 2007;30(1):113-123.

[32] Taylor LT. Supercritical fluid chromatography. Analytical

chemistry. 2010 Jun 15;82(12):4925-4935.

[33] Frerichs VA, Zaranek C, Haas CE. Analysis of omeprazole, midazolam and hydroxy-metabolites in plasma using liquid chromatography coupled to tandem mass spectrometry. J Chromatogr B. 2005;824(1-2):71-80.

[34] Palmer CP. Micelle polymers, polymer surfactants and dendrimers as pseudo-stationary phases in micellar electrokinetic chromatography. J Chromatogr A. 1997 Sep 12;780(1-2):75-92.

[35] Singh YR, Shah DB, Kulkarni M, Patel SR, Maheshwari DG, Shah JS, Shah S. Current trends in chromatographic prediction using artificial intelligence and machine learning. Anal Methods. 2023;15(23):2785-2797.

[36] Mervartová K, Polášek M, Calatayud JM. Recent applications of flow-injection and sequential-injection analysis techniques to chemiluminescence determination of pharmaceuticals. J Pharm Biomed Anal. 2007 Nov 5;45(3):367-381.

[37] Bachhav HA, Shirsath GB, Badhe SR, Kurne DV, Sonawane SS. AI-driven data analysis for identification of impurities in HPLC chromatograms & artificial intelligent system for HPLC column selection and method development.

[38] S. Leveraging IoT data streams for AI-based quality control in smart manufacturing systems in process industry. J AI-Assist Sci Discov. 2023 Aug 8;3(3):37.

[39] Rezk MR, Basalious EB, Karim IA. Development and validation of sensitive and rapid HPLC method for simultaneous determination of omeprazole and its metabolites in human plasma. Talanta. 2007;72(2):603-611.

[40] Vijayaraghavan R, Kalaiselvi M, Nagarajan G, *et al*. International Journal of Pharmaceutical Sciences and Research. 2011;2(11):2801-2809.

[41] Siddiqui MR, AlOthman ZA, Rahman N. Analytical techniques in pharmaceutical analysis: A review. Arab J Chem. 2017;10:S1409-S1421.

[42] El-Olemy A, Abdelazim AH, Ramzy S, *et al*. Application of different spectrofluorimetric approaches for quantitative determination of acetylsalicylic acid and omeprazole.