A REVIEW ON ANALYTICAL METHODS FOR ESTIMATION OF OMEPRAZOLE, AMOXICILLIN AND RIFABUTIN IN PHARMACEUTICAL FORMULATIONS ANDBIOLOGICAL MATRICES

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ABSTRACT

Omeprazole belongs to a class of drugs known as proton pump inhibitors (PPIs).It works by decreasing the amount of acid made in the stomach.Omeprazole can be used in the treatment of gastro esophageal reflux disease (GERD), peptic ulcers, erosive esophagitis, Zollinger-Ellison syndrome, and eosinophilic esophagitis. amoxicillin, a semisynthetic antibiotic, Amoxicillin is an analog of ampicillin, with a broad spectrum of bactericidal activity against many Gram-positive and Gram-negative microorganisms. Amoxicillin is used to treat many different types of infection caused by bacteria, such as tonsillitis, bronchitis, pneumonia, and infections of the ear, nose, throat, skin, or urinary tract.Amoxicillin is also sometimes used together with another antibiotic called clarithromycin (Biaxin) to treat stomach ulcers caused by Helicobacter pylori infection.Rifabutiin is a broad-spectrum antibiotic that inhibits DNA-dependent RNA polymerase activity in susceptible cells. It is bactericidal and has a very broad spectrum of activity against most gram-positive and gram-negative organisms (including Pseudomonas aeruginosa) and specifically Mycobacterium tuberculosis. The present review article represents the compilation and discussion of analytical methods published in the literature for estimation of Omeprazole, Amoxicillin And Rifabutinin pharmaceutical samples and biological matrices consisting of HPLC, Stability indicating HPLC, UV-Visible method, Colorimetric method, Bioanalytical method, and hyphenated techniques such as LC-MS; LC-MS-MS, etc.

Keywords: Amoxicillin, Omeprazole, Rifabutin, UV Spectrophotometry, HPLC and LC-MS/MS.

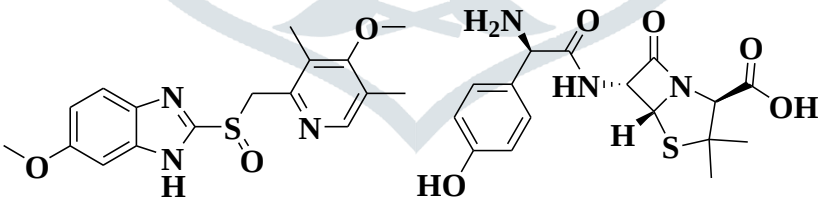
I. INTRODUCTION

Omeprazole (OMP, Fig.1A) (RS)-6-methoxy-2-((4-methoxy-3, 5-dimethylpyridin-2-yl) methyl sulfinyl)-1H-benzo (d) imidazole is a proton pump inhibitor (PPI) and an anti-secretory compound. Omeprazole is used to

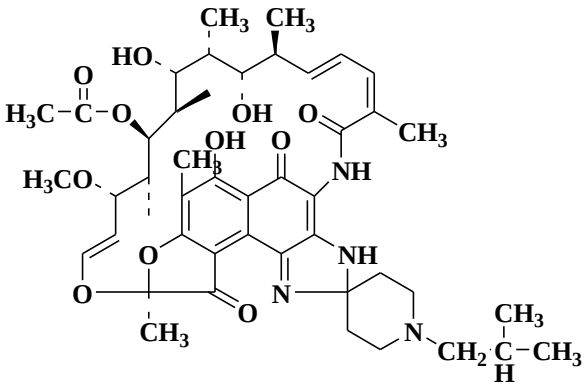
treat symptoms of gastroesophageal reflux disease (GERD) and promote healing of erosive esophagitis. It works by suppressing gastric acid secretion by inhibiting the gastric H+ /K+ATPase (hydrogen-potassium adenosine triphosphatase) at the secretory surface of the gastric parietal cell [1, 2].

Amoxicillin (AMX Fig. 1B) is a β-lactam antibiotic drug which belongs to the group of penicillin group drugs [3]. It is a moderate-spectrum β-lactam antibiotic used to treat infections caused by penicillin-sensitive Gram-positive bacteria as well as some Gram-negative bacteria [4]. AMX chemically as (2S, 5R, 6R) [[(2R)-2-amino-2 (4 hydoxyphenyl) acetyl] amino]-3, 3-dimethyl-7-oxo-4-thia1-azabicyclo [3.2.0] heptanes-2-carboxyic acid [5, 6].Rifabutin (RFB Fig. 1C) is a synthetic derivative of rifamycin S isolated from Amycolatopsisrifamycinica that acts by inhibiting the DNA dependent RNA-polymerase of bacteria; it has been shown to have significant mycobactericidal (hence anti-tuberculosis) activity. RFB is a less potent microsomal enzyme inducer than rifampin, therefore it is the preferred rifamycin class antibiotic for treatment of TB in HIV-infected patients. RFB is readily absorbed from the gastrointestinal tract with a Cmax of about 375ng/ml reached 3.3h after a single 300-mg oral dose, under fasting conditions. RFB is actively degraded to its 25-O-desacetyl derivative in vitro with an activity almost equivalent to that of its parent compound [7, 8].

Different analytical methods have been reported for quantification of omeprazole, amoxicillin and rifabutinin pharmaceutical formulations andbiological matrices.In the present work, some of the recently published analytical methods for estimation of Omeprazole, Amoxicillin and Rifabutin are reviewed.



(A) (B)



(C)

Figure 1: Chemical structure of (A) Omeprazole (B) Amoxicillin (C)Rifabutin

II. REPORTED METHODS

A.Spectrophotometric methods for estimation of Omeprazole, Amoxicillin and Rifabutin

UV specrophotometric method based on single point method and colorimetric methods have been reported. Apart from these kinetic, Indirect and extractivespectrophotometricmethodshave also been reported. Spectrophotometric methods for estimation of Omeprazole, Amoxicillin and Rifabutin are shown in Table 1.

Table No.1: Summary of Spectrophotometricmethods for the quantification of Omeprazole, Amoxicillin and Rifabutin

Drugs	Method	Wavelength/ λ max (nm)	Linearity and Correlation coefficient	Percent Recovery	Ref.
Amoxicillin Trihydrate	Colorimetric method	455	0.3 – 30.0 µg/mL 0.9999	99.19-102.51	9
Amoxicillin Trihydrate	UV Method	231	2.5-50 µg/mL 0.9996	99.84-101.36	10
Amoxicillin	Spectrophotometric method	610	5-45 µg/mL 0.9953	97.846-97.935	11
Amoxicillin	Two colorimetricmethods (Method A: diazotized p-amino benzoic acid and method B diazotized procaine used as dye	A: 435 B: 450	A:0.4 to 10 µg/mL B:0.4 to 14 µg/mL -	A: 99.329-100.942 B: 98.721-101.079	12
Amoxicillin	Indirect Spectrophotometric Determination	500	1 – 10 µg/mL -	96.66-107.5 0.9997	13
Omeprazole	Extractive spectrophotometric Method A: bromophenol blue Method B: orange G	A: 408 nm B: 508 nm	A:5 - 30 µg/ml B: 50 - 250 µg/ml	A: 100.7±0.7 B: 98.0±0.7	14
Omeprazole	KineticSpectrophotometricMethods	362 & 418	0.10–3.00 and 0.50–25.00µgmL−1	98.91–100.32%±0.94–1.84	15
Omeprazole	Spectrophotometric Method	217	2.0 to 12.0µg/mL , 0.999	97.62-101.10	16
Rifabutin	Colorimetric methods	520 and 460	25-150 g/ml,	-	17

		nm	10-60 g/ml.		
Rifabutin	UV- visible spectrometry method	237	1-20 µg/mL 0.999	99.18 to 99.93 %	18

B. Chromatographic methods for estimation of Omeprazole, Amoxicillin and Rifabutin

Many Chromatographicmethods were reported for the estimation ofOmeprazole, Amoxicillin and Rifabutin individually in different marketed formulations and biological samples like plasma. Chromatographic methods based on RP-HPLCand Stabilty indicating HPLC have been reported. Apart from these LC-MS-MS and bioanalytical methods have also been reported.Chromatographic methods for estimation of Omeprazole, Amoxicillin and Rifabutin are shown in Table 2.

Table No.2: Summary of Chromatographic methods for the quantification of Omeprazole, Amoxicillin and Rifabutin

Drugs	Method	Column	Mobile Phase and Ratio	Detector wavelength (nm)	Flow rate (ml/min.)	Retention time (minutes)	Ref.
Amoxicillin	RP-HPLC	Capcell Pak C-18 (15 mm x 250 mm)	Methanol: Water 35:65	273	1	4.66	19
Amoxicillin residues	RP-HPLC	Betabasic-C18 (4.6mm x 250mm)	0.05M sodium dihydrogen phosphate: methanol (95:5v/v) adjusted to pH 4.4 with orthophosphoric acid	230	1.5	6.292	20

Amoxicillin	Stability indicating RP-HPLC	Hypersil ODS, C18 column (250mm×4.6)	Acetonitrile: 0.2M Potassium dihydrogen phosphate buffer (pH 5) (1:99v/v)	254	1	6.992	21
Amoxicillin	HPLC–UV method In-vivo study	Inertsil (ODS-3V 5µ 4.6 × 250mm2)	5.0% ACN–14.25% CH3OH–80.75% buffer solution	230	1	8.1	22
Amoxicillin	RP-HPLC	hypersil C18 column (250x4.6mm I.D., particle size 5 µm	potassium dihydrogen phosphate and methanol in the ratio 95:05 v/v.	283	1	6.30	23
Amoxicillin	RP-HPLC	Chromatopak-C18 (250mm×4.6×5micron)	Acetonitrile: 0.2M Potassium dihydrogen phosphate buffer (pH 3) (22:78v/v)	283	1	6.4	24
Amoxicillin Trihydrate	Stability indicating LC method	Capacell Pak C-18 (250mm×4.6×5micron)	Methanol: 0.02 M phosphate buffer 50:50	229	1	3.99	25
Omeprazole	RP-HPLC	Novapak C18, (250 x 4.6 mm, 5µ)	phosphate buffer (pH 7.4) and acetonitrile in the ratio	302	1	7.71	26

			of 60:40				
Omeprazole	LC-MS/MS METHOD	Purospher Star C18 column (5µ, 100X4.6mm	ACN: mobile phase buffer (5mm ammonium bicarbonate buffer) in the ratio of 70:30%v/v	346.18	1	1.25	27
Omeprazole	In-vitro HPLC	Shimadzu CLC ODS-(C-18) – 150 x 6.0 mm	acetonitrile: phosphate buffer (65:35	300	1	5.8	28
Omeprazole	HPLC	Inertsil C8 5µ, (4.6×250mm)	acetonitrile and Disodium hydrogen orthophosphate 27:73.	305	1	21.16	29
Omeprazole	HPLC-UV in vivo	Kromasil C_{18} 150mm x 4.6 mm i.d (5µm)	CH_3OH:H_2O (55:45 v/v)	302	1	8.00	30
omeprazole enantiomers	Stability indicating RP-HPLC	Chiralcel OD-H column (250 × 4.6 mm, 5 µm	85% of n-hexane, 8% of methanol and 7% a mixture of isopropylalcohol and ethanol (85:15, v/v)	301	0.75	14.088 (S)-(-)-omeprazol 15.289 (R)-(+)-omeprazole	31
Omeprazole	Bioanalytical LC-MS/MS	Cosmosil, RP-C8 (50 X 4.6mm, 5µm particle size) column	methanol: water (containing 0.5% formic acid) 80:20	-	0.6	2.02	32

Rifabutin	HPLC	C-18 column (M/s Thermo Scientific, Massachusetts, USA) with dimensions of 250 × 4.6 mm and silica particle size of 5 µm.	acetonitrile + Methanol (1:1): Water (75:25)	242	1	5.30	33
Rifabutin	Stability indicating LC method	Ace5-C18 (250 x 4.6 mm, 5 µm	50 mM ammonium acetate (pH-4 by acetic acid) and acetonitrile (50:50v/v)	275	1	7.05	34
Rifabutin	HPLC in plasma	analytical column was a C18, 250 x 4.6mm ID, 5□ particle size (Lichrospher 100 RP18e, Merck, Germany)	50mM phosphate buffer, pH 4.2 (adjusted with 1N HCl) and acetonitrile (53:47 v/v).	265	1.2	8.6	35
Rifabutin	RP-HPLC	phenomenex C-8 Luna (250 × 4.6 mm, 5 µm)	Methanol and Water (75:25 v/v)	240	1	5.5	36
Omeprazole.AmoxicillinAnd Secnidazole,	isocratic RP-HPLC method	ACE 5 C18 (25 cm x 4.6 mm)	acetonitrile: potassium dihydrogen phosphate buffer (pH 7.5) (60: 40, v/v).	230	1.5	3217 1.533 2.267	37

III. CONCLUSION

The present review described the summary of all analytical methods which are reported in the literature for the estimation of Omeprazole, Amoxicillin and Rifabutin not only in bulk, pharmaceutical formulations but also in biological matrices. Analytical methods like LC-MS/MS, Stability indicating HPLC,RPHPLC, UV/Visible Spectrophotometric, and bioanalytical methods were employed for quality control determination of Omeprazole, Amoxicillin and Rifabutin in pharmaceutical dosage forms and biological matrix. The primary objective of the compilation of review is to collect maximum information available on analytical methods of Omeprazole, Amoxicillin and Rifabutin and study it in detail. The reported data for analysis of Omeprazole, Amoxicillin and Rifabutin revealed that HPLC and colorimetry is the most frequent technique was employed for the determination of Omeprazole, Amoxicillin and Rifabutin in pharmaceutical matrix and plasma. For analysis of Omeprazole, Amoxicillin and Rifabutin in pharmaceuticals HPLC with UV detection is an appropriate due to this strategy gives precise outcomes and minimal effort contrasted.The analytical methods implemented in the studies on Omeprazole, Amoxicillin and Rifabutinare shown in Table 1 and 2. It's likely to overview the dissimilarities between reported methods. Up till today there were 30 analytical methods found in which validated methods and its application in the determination of Omeprazole, Amoxicillin and Rifabutin in pharmaceutical dosage forms and biological matrix. Of those, three methods were developed by using UV-Visible method, a single Spectroflurometric method, thirteen (HPLC) methods, a single Gas chromatography (GC) method, six Hyphenated methods (LC-MS, GC-MS) and three miscellaneous methods. (Polarography, Voltammetry and CE)

IV. REFERENCES

1. Indian Pharmacopoeia. (2010) Government of India, Ministry of Health and Family Welfare, Ghaziabad, New Delhi, The Indian pharmacopoeia commission publisher, 1813-1814.
2. United States of Pharmacopoeia. (2009). Convention inc., Rockville, 2796-2797.
3. Dousa M, Hosmanova R. Rapid determination of amoxicillin in premixes by HPLC. J Pharm Biomed Anal. 2005;7(2):373–7.
4. Vu DH, Do TG. Comparative study of RP-HPLC and UV spec - trophotometric techniques for the simultaneous determination of amoxicillin and cloxacillin in capsules. J Young Pharmacist. 2010;2(2):190–5.

5. Nikam DS, Bonde CG, Surana SJ, Venkateshwarlu G, Dekate PG. Development and validation of RP-HPLC method for simultaneous estimation of amoxicillin trihydrate and fucloxa - cillin sodium in capsule dosage form. Int J Pharm Tech Res. 2009;1(3):935–9.
6. Shanmugasundaram P, Raj RK, Mohanrangan J, Devdass G, Arunadevi M, Maheswari R, Aanandhi MV. Simultaneous esti - mation of amoxicillin and fucloxacillin in its combined capsule dosage form by HPLC. Rasayan J Chem. 2009; 2:57–60.
7. D. Ungheri, C. Delia Brunna, A. Sanfilippo, Studies on the mechanism of action of spiropiperidyl-rifamycin on LM427 rifampicin-resistant M. tuberculosis, Drugs Exp. Clin. Res. 10 (1984) 681–689.
8. Wesley A. Graya, Byron Waldorf, ManasaGeetaRaoa, Brenda L. Stiles, J. McLeod Griffiss, Robert A. Salatac, Jeffrey L. Blumer. Development and validation of an LC-MS/MS method for the simultaneous determination of bedaquiline and rifabutin in human plasma. Journal of Pharmaceutical and Biomedical Analysis 176 (2019) 112775.
9. Qader A., Fakhre N. Spectrophotometric determination of amoxicillin trihydrate in pure and pharmaceutical dosage forms Ibn Al-Haitham Jour. for Pure & Appl. Sci. Vol. 28 (3) 2015; 142-153
10. Prakash K., Narayana P. R., Shanta K. K., Narasu M. L., Spectrophotometric estimation of amoxicillin trihydrate in bulk and pharmaceutical dosage form, E-Journal Of Chemistry, 2008, 5(S2), 1114-1116
11. Al-kadumi A. S., Fadhel S. R., Ahmed M. A., Musa L. A., Colorimetric determination of amoxicillin in pure and some pharmaceutical formulations via reaction with potassium permanganate as oxidant reagent, International Journal of Pharmaceutical Quality Assurance 2019; 10(2); 222-228
12. Al-Uzri W. A. Spectrophotometric determination of amoxicillin in pharmaceutical preparations through diazotization and coupling reaction Iraqi Journal of Science. Vol 53.No 4.2012.Pp713-723
13. Hamed A. H., Ibrahim S. K., Dhahir S. A., Mhemeed A. H. Indirect Spectrophotometric Determination of Amoxicillin by oxidative with Cerium ammonium nitrate using Arsenazo III as a reagent Journal of Pharmaceutical Sciences. & Research Vol. 11(4), 2019, 1617-1620

14. Bhandage1A., Bhosale A., Kasture A., Godse V.P.,Extractive Spectrophotometric Determination of Omeprazole in Pharmaceutical Preparations,Tropical Journal of Pharmaceutical Research, October 2009; 8 (5): 449-454

15. Mahmoud A.M., New Sensitive Kinetic Spectrophotometric Methods for Determination of Omeprazole in Dosage Forms, International Journal of Analytical Chemistry, Volume 2009, 1-11.

16. Alamin I. A., Elbashir A. A., A new study on omeprazole spectrophotometric determination using 9-Fluorenylmethylchloroformate as derivatizating agent, Journal of Analytical & Pharmaceutical Research, 2019;8(2):38–43.

17. Kishore M., JayaprakashM. Development of new spectrophotometric methods for the quantitative determination of rifabutin in pharmaceutical formulation International Journal of Pharmaceutical Sciences Review and Research 5(1) · November 2010Vol-2/Issue-10/Dec/007: 49-55

18. Bhusari S., Ansari I. A. Wakte P., Development and validation of UV-visible spectrophotometric method for estimation of rifabutin in bulk and formulation, International Journal of Pharmacy and Biological Sciences-IJPBSTM (2019) 9 (1): 1157-1162

19. Chandra R., kumar D., kumar D., Quantitative determination of amoxicillin from formulated dosage form by reversed phase high performance liquid chromatography separation technique and a new method validation Asian Journal Pharmaceutical Clinical Research, vol 9, issue 4, 2016, 308-311

20. Hassouna MEM., Mohamed MA., Development and validation of RP-HPLC method for determination of amoxicillin residues and application to NICOMAC coating machine, Journal of Analytical & Pharmaceutical Research 2018;7(5):586–594.

21. Sahoo NK, Sahu M, Algarsamy V, Srividya B and Sahoo CK. Validation of Assay Indicating Method Development of Amoxicillin in Bulk and One of Its Marketed Dosage Form by RP-HPLC. Ann Chromatogr Sep Tech. 2016; 2(1): 1014.

22. Unutkan T., Bakırdere S., and Keyf S., Development of an analytical method for the determination of amoxicillin in commercial drugs and wastewater Samples, and assessing its stability in simulated gastric digestion, Journal of Chromatographic Science, 2018, Vol. 56, No. 1, 36–40

23. Ahmed M., Babu G. S. Shetty A S. K., Development and validation of amoxicillin by RP-HPLC Method in bulk drug and pharmaceutical dosage forms, International Journal of ChemTech Research Vol. 3, No.3, pp 1037-1041, July-Sept 2011

24. Sivagami, B., Sharmil L.M. K., Bhaskar M., Aktar K., Nagendra B. G, Krishna E. C, Niranjan M. B., A validated RP-HPLC method development for amoxicillin in pharmaceutical dosage forms, International Journal of Advances in Pharmaceutical Analysis 2018; 08(01): 09-17.

25. Beg S., Hasnani M.S., Swain S., Kohli K., Validated stability indicating LC method for estimation of Amoxicillin trihydrate in pharmaceutical dosage forms and time dependent release formulations, International Journal of Pharmaceutical Sciences and Nanotechnology (2011) , Vol 4, Issue 2, 1423-1427

26. Kalakonda S. N., Duza M. B., Pragallapati K., Dussa K.K., Development and validation of RP-HPLC method for the estimation of omeprazole in bulk and capsule dosage forms International Current Pharmaceutical Journal 2012, 1(11): 366-369

27. SudhaT., Reddy V. K.K.,Hemalatha P.V., RavikumarV.R.,An LC- MS/MS Method For The Determination Of Omeprazole On Proton Pump Inhibitor in Human Plasma,Indonesian J. Pharm. Vol. 27 No. 2 (2016) : 80 – 91

28. Gopalakrishnan S., Jothy K., Dhanalakshmi K., Analytical method development and validation of HPLC method for the determination of omeprazole in capsule dosage form Elixir Appl. Chem. 52 (2012) 11283-11286

29. Gopalakrishnan S., Jothy K., Dhanalakshmi K., Analytical method development and validation of HPLC method for the determination of omeprazole in capsule dosage form, Elixir International Journal, 52 (2012) 11283-11286

30. Iuga C., Moldovan M., Popa A. , Leucuţa S.E. Validation of HPLC- UV method for analysis of omeprazole in presence of its metabolites in human plasma, Farmacia, 2008, Vol. vi, 3, 254-260

31. Vyas Samir, Ajay Patel, Kartik D. Ladva1 , H. S. Joshi2 , Atul H. Bapodra Development and validation of a stability indicating method for the enantioselective estimation of omeprazole enantiomers in the enteric-coated formulations by highperformance liquid chromatography Journal of Pharmacy and Bioallied Sciences April-June 2011 Vol 3 Issue 2, 310-314

32. Vijayaraghavan R., Jayababu G., Prasad R., Thirugnanam P.E., Shivkumar G., Sriraam V.T., Ramesh G. K. Bio-analytical method development and validation for omeprazole using lc-ms/ms IJPSR, 2011; Vol. 2(9): 2475-2481.

33. Singh G., Srivastava A. K., High performance liquid chromatography method validation and development strategy for rifabutinInternational Journal of Pharmaceutical Sciences and Research 2018; Vol. 9(9): 3903-3907.

34. Sangshetti J. N., Hingankar S., WaghuleA.,Shinde D. B., Stability-indicating (liquid chromatographic) LC method for the determination of rifabutin in bulk drug and in pharmaceutical dosage formAfrican Journal of Pharmacy and Pharmacology Vol. 5(3), pp. 298-305, March 2011

35. Hemanth AK K., Sudha V., Ramachandran G., Simple and rapid liquid chromatography method for determination of rifabutin in plasma, SAARC Journal of Tuberculosis, 2012;IX(2), 26-29

36. Patil Y. D., Banerjee S. K., RP-HPLC method for the estimation of Rifabutin in bulk dosage form International Journal of Drug Development & Research April-June 2012, 4 (2): 294-297

37. Baraka M. M., Elsadek M. E., Ibrahim A. M., HPLC method for the simultaneouus determination of secnidazole, Omeprazole and amoxicillin mixture in pure forms and pharmaceutical formulations, Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry. 2(4), 2014, 197 – 207