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A Review on Analytical Method Development and Validation of Omeprazole by UV Spectroscopy Method

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Abstract: *The analysis of omeprazole in the capsule has been developed using two straightforward spectrophotometric techniques. The discovery, development, and production of pharmaceuticals depend on the development and validation of analytical methods. Ethanol was used as a solvent in the method's development. The solvent in this procedure is sodium hydroxide, 0.1 N. The under curve area method was used at wavelengths between 281.60 nm and 333.60 nm, whereas the absorbance method was used at 304.80 nm. At a concentration range of 10 g/mL to 18 g/mL, both methods were found to be linear. The UV method is based on a multi-component analysis methodology and absorption correction. The technique was approved in accordance with ICH recommendations.*

Keywords*:* Omeprazole, UV spectroscopy, Multi Component, Ethanol

I. INTRODUCTION

A subfield of chemistry known as analytical chemistry is concerned with the quantitative and qualitative analysis of the introduction of components into substances, samples, or mixtures. **Quantitative analysis** and **qualitative analysis** are two distinct types of analysis.

It is based on the Beer-Lambert rule, according to which the concentration of the absorbing species in a solution and the path length are directly inversely related to the absorbance of that solution. An optical spectroscopy technique that utilises light in the visible, ultraviolet, and near-infrared wavelengths is known as ultraviolet (UV) spectroscopy.

As a result, it can be used to determine the absorber concentration in a solution for a particular path length.For the past 37 years, UV-VIS spectroscopy has been used extensively and has developed into the most important analytical tool in the contemporary laboratory. Understanding how quickly the absorbance changes with concentration is essential. Although there are many applications where other techniques could be used, none are as user-friendly as UV-VIS spectroscopy.

The object will show absorption in the visible or ultraviolet spectrum when radiation causes an electronic change in the structure of a molecule or ion. Because of this, when a sample absorbs light in the visible or ultraviolet range, the molecules inside the sample go through an electronic state transition. The energy of the light will promote electrons from their ground state orbitals to higher energy orbitals, such as excited state orbitals or anti-bonding orbitals. There could be three different kinds of ground state orbitals involved.

a) σ (Bonding) molecular
b) π (Bonding) molecular orbital
c) n (non-Bonding) atomic orbital

Validation:

The process of confirming through laboratory tests that a method's performance characteristics meet the requirements of the intended analytical application is known as validation of an analytical technique.

Parameters of method validation :

- Accuracy
- Precision
- Linearity
- Limit of detection

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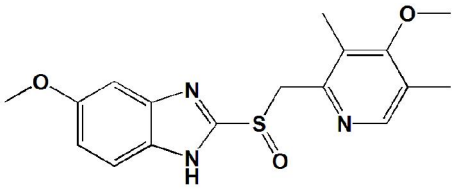
- Limit of quantitation
- Specificity
- Range
- Robustness
- Repeatability

Drug Profile:



omeprazole

Proton pump inhibitors like omeprazole are used to treat conditions like Zollinger-Ellison syndrome, peptic ulcer disease, gastroesophageal reflux disease, and dyspepsia. The liver, namely the cytochrome P-450 system (CYP), completely breaks down omeprazole. The sulfone, the sulphide, and hydroxyomeprazole have been identified as plasma metabolites.

IUPAC Name	6-methoxy-2-((4-methoxy-3,5-dimethylpyridine-2-yl)-1H-benzo(d)imidazole
Category	Proton pump inhibitor
Solubility	Methanol
Moleclar formula	C17H19N3O3S
Molecular weight	345.42
Melting point	200
Odour	Unpleasant breath odour
Nature	White granules
Purity	99.5%
pKa value	8.8

II. MATERIAL & METHODS

Instrument:

Shimadzu UV1800 Double Beam UV-Visible Spectrophotometer was used for spectral studies.

Chemicals and reagents:

Omeprazole (API) standard medication samples were purchased from Yarrow Chem Products in Mumbai, India. Omeprazole was purchased in its commercial form from a nearby pharmacy.

Solubility

As per solubility studies it was found that both the drug sample are freely soluble in ethanol.

Preparation of standard stock solution

Omeprazole standard stock solution:

In a 10 mL volumetric flask, 10 mg of OMZ was precisely weighed, and 8 mg of methanol was added. For about 10 minutes, the mixture was ultrasonically dissolved. Omeprazole standard stock solution (1 mg/mL) was then created by adding ethanol to the volume until it reached the desired level.

Linearity study of OMZ at 301 nm.

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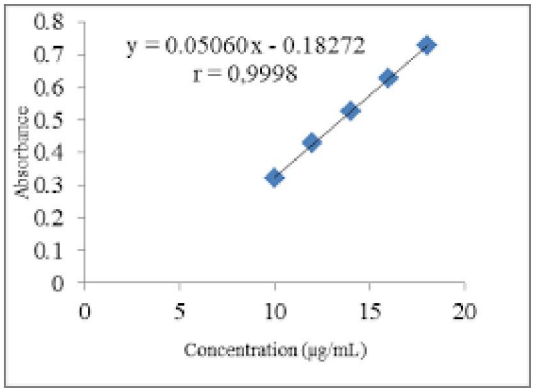
Method Development:

Preparation of the calibration curve of omeprazole:

For the creation of calibration curves, five series of omeprazole solutions at concentrations of 10 g/mL, 12 g/mL, 14 g/mL, 16 g/mL, and 18 g/mL were prepared.



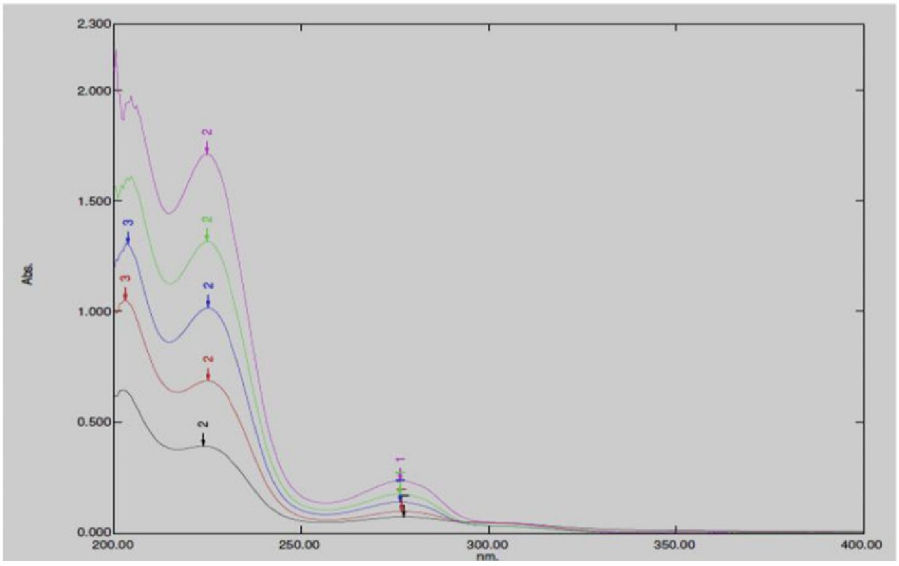
wavelength	30ppm(1)	2	3	4	5	6
299.0	0.139	0.139	0.139	0.139	0.139	0.139
299.5	0.139	0.139	0.139	0.139	0.139	0.139
300.0	0.139	0.139	0.139	0.139	0.139	0.140
300.5	0.139	0.139	0.139	0.139	0.139	0.139
301.0	0.139	0.139	0.139	0.139	0.139	0.139

Validation of proposed method :

The Proposed method was validated as per the ICH guidelines.

Accuracy:

On the basis of a recovery research conducted using the conventional addition approach, the proposed method's accuracy was determined.



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Precision:

According to ICH guidelines acceptance criteria for precision the %RSD should NMT 2%

Ruggedness:

LOD

Omeprazole were found to have limits of detection of 0.2528 g/mL and 0.2307 g/mL, respectively.

LOQ

Omeprazole were found to have limits of quantitation of 1.766 g/mL and 1.954 g/mL, respectively.

Determination of wavelength of maximum absorbance (λ max):

To achieve a concentration of 10 g/mL, the standard solutions of both OMP and DOM were further diluted. These solutions were scanned in the 200–400 nm range, and the maximum was found for Omeprazole and Domperidone at 301 nm and 287.2 nm, respectively. Figures 3 and 4 illustrate the wavelength spectra of OMP and DOM in methanol, respectively.

III. CONCLUSION

The best solvent for omeprazole analysis using the absorbance method and the UV-Vis spectrophotometry area under the curve is 0.1 N NaOH. Both methods are reliable for omeprazole analysis, according to the absorbance method and the area under the curve. The delayed omeprazole capsule level is described in Pharmacopoeia Indonesia version V 2014 as being between 90% and 110%. Both the generic and brand-name omeprazole levels discovered using these techniques meet the criteria for those stated in Pharmacopoeia Indonesia Edition V 2014. As a result, it is possible to determine the amount of omeprazole in the formulation capsule using the absorbance method and the area under the UV-Vis spectrophotometric curve.

REFERENCES

[1]. RamoleRina, MohiniBaile, Ashish Jain; A Reviewon Analytical Method Development and Validation; Sys Rev Pharm 2021;12(8): 450-454.

[2]. Shivani Sharma, SwapnilGoyal, KalindiChauhan; A Review On Analytical Method Development and Validation; International Journal of Applied Pharmaceutics ISSN- 0975-7058 Vol 10, Issue 6, 2018 08-15.

[3]. GovindaVerma and Dr Manish Mishra A Review article on Development And Optimization Of UV-Vis Spectroscopy World Journal of Pharmaceutical Research Volume 7, Issue 11, 1170-1180.

[4]. Gokul S. Sanap, Nilesh S. Zarekar, Sarita S. Pawar Review On Method Development And Validation International Journal Of Pharmaceutics & Drug Analysis; Vol.5; Issue 5, 2017; 177 – 184

[5]. Rami Reddy YV, Krishnaiah V (2012) Development and validation of HPLC method for simultaneous determination of Omeprazole and Domperidone. Scholars Research Library Der PharmaChemica 4(1):455-459.

[6]. Patta S, Afreen S, Tappa S, Nagarajan G, GnanaPrakash K. Simultaneous estimation of aspirin and omeprazole (Yosprala) in bulk by UV-spectroscopy. J Drug DelivTher. 2017;7:87-91

[7]. Indian Pharmacopoeia (2014) The Indian Pharmacopoeia Commission, Ghaziabad, India. Voilume-II: 2372(OMP) & 1612(DOM).

[8]. U.S. Pharmacopoeia National Formulary (2014) The Unites States Pharmacopoeial Convention, Rockville, MD, USA Volume III: 4063 (OMP).

[9]. Gupta KK, Sase D, Faulds (2012) Drug review on Domperidone. Asian Journal of pharmaceutical sciences 1(11): 366-369.

[10]. Patta S, Afreen S, Tappa S, Nagarajan G, GnanaPrakash K. Simultaneous estimation of aspirin and omeprazole (Yosprala) in bulk by UV-spectroscopy. J Drug DelivTher. 2017;7:87-91.

[11]. SureshKumar S, Jamadar LD, Bhat K, Musmade PB, Vasantharaju SG, Udupa N. Analytical method development and validation for Aspirin. Int J Chem Tech Res. 2010; 2:389-399.

[12]. SudhakarRao GV, Sujana K, Pedababu T (2014) Development and validation of UV spectrophotometric method for the estimation of Omeprazole in bulk and pharmaceutical formulations. International Journal of Pharmacy 2(1): 247-251.

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[13]. Asra, R., Rivai, H., & Riani, V. L. (2016). Pengembangan dan Validasi Metode Analisis Tablet Furosemid dengan Metode Absorbansi dan Luas Daerah di Bawah Kurva secara Spektrofotometri Ultraviolet. Jurnal Farmasi Higea,8(2), 110-121.

[14]. Bhandage, A., Bhosale, A., Kasture, A., & Godse, V. P. (2009). Extractive spectrophotometric determination of omeprazole in pharmaceutical preparations. Tropical Journal of Pharmaceutical Research, 8(5), 449-454.

[15]. Bhuva, S. D., & Patel, M. M. (2012). Spectrophotometric simultaneous estimation of omeprazole and cinitapride in bulk and formulation. Asian Journal of Pharmaceutical and Clinical Research, 5(4), 40-42.

[16]. Chandra, B., Rivai, H., & Apriansyah, E. (2017). Pengembangan dan Validasi Metode Analisis PropranololHidroklorida Tablet dengan Metode Absorbansi dan Luas Daerah di Bawah Kurva secara Spektrofotometri Ultraviolet.Jurnal Farmasi Higea, 9(1), 20-29.

[17]. Chandra, B., Rivai, H., & Marianis, M. (2016). Pengembangan dan Validasi Metode Analisis Ranitidin Hidroklorida Tablet dengan Metode Absorbansi dan Luas Daerah di Bawah Kurva secara Spektrofotometri Ultraviolet. Jurnal Farmasi Higea, 8(2), 96-109.

[18]. Radde, I. C. & Macleod, S. M. (1999). Farmakologi dan terapi pediatri. Penerjemah: dr. Joko Soyono. Jakarta: Hippocrates