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Review

A review on analytical method development and validation of Ziprasidone HCL by UV spectroscopy inbulk and marketed formulation

M. Sangeetha*, A. Swarna Mahalakshmi, T. Rama Rao

Department of Pharmaceutical Chemistry, CMR College of Pharmacy, Kandlakoya (V), Medchal, Hyderabad-501401, Telangana, India.

*Author for Correspondence: M. Sangeetha
Email: sangeetha.kodiganti@gmail.com

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Abstract

This review article provides a comprehensive overview of the development and validation of a UV-Spectroscopic method for the quantification of Ziprasidone Hydrochloride (HCl) in both bulk and marketed formulations. Ziprasidone HCl, an atypical antipsychotic used in the treatment of schizophrenia and bipolar disorder, requires precise analytical methods for its quantification due to its clinical importance. The study emphasizes the methodological aspects, including the selection of solvents, determination of the maximum absorbance wavelength (λmax), and the preparation of standard solutions. The validation process covers key parameters such as linearity, accuracy, precision, specificity, and sensitivity. The method's specificity is confirmed by the lack of interference from common excipients. This UV spectroscopic method is concluded to be simple, reliable, cost-effective, and suitable for routinequality control analysis of Ziprasidone HCl in pharmaceutical preparations. The article also includes a review of the latest literature on analytical methods for Ziprasidone HCl, highlighting recent advancements and comparisons with other techniques such as HPLC.

Keywords: Ziprasidone Hydrochloride, UV-Spectroscopy, method development,pharmaceutical analysis, quality control, HPLC comparison, atypical antipsychotic, schizophrenia, bipolar disorder.

INTRODUCTION

Pharmaceutical analysis plays an important role right from testing of raw materials, in-processquality checks to the analysis of the finished product. It is considered to determine the identity,strength, quality, and purity of drug samples.

Spectroscopy

Spectroscopy is the study of the interaction of electromagnetic radiation with matter. Anotherapproach often used to study the interaction of electromagnetic radiation with matter is one whereby a continuous range of radiation (e.g., white light) is allowed to fall on a substance; then the frequencies absorbed by the substance are examined. The resulting spectrum from thesubstance contains the original range of radiation with dark spaces that correspond to missing,or absorbed frequencies. This type of spectrum is called an absorption spectrum. In spectroscopy, the emitted or absorbed radiation is usually analyzed, i.e., separated into the various frequency components and the intensity is measured through an instrument called a spectrometer. The resultant spectrum is mainly a graph of the intensity of emitted or absorbedradiation versus wavelength or frequency.

Spectrophotometry is a method to measure how much a chemical substance absorbs light by measuring the intensity of light as a beam of light passes through a sample solution. The basicprinciple is that each compound absorbs or transmits the light over a certain range of wavelengths. This measurement can also be used to measure the amount of a known chemicalsubstance. Spectrophotometry is one of the most useful methods of quantitative analysis in various fields such as chemistry, physics, biochemistry, material and chemical engineering, and clinical applications. In biochemistry, for example, it is used to determine enzyme-catalyzed reactions. In clinical applications, it is used to examine blood or tissues for clinical diagnosis. There are also severalvariations of spectrophotometry such as autonomic absorption spectrophotometry and atomic emission spectrophotometry.

Electromagnetic spectrum

The electromagnetic (EM) spectrum is the range of all types of EMR Ultraviolet (UV) and visible radiation comprise only a small part of the electromagnetic spectrum, which includes such other forms of radiation as radio, infrared (IR), cosmic, and X rays. Electromagnetic radiation can be expressed in terms of energy, wavelength, or frequency. Frequency is measured in cycles per second or Hertz. Wavelength is measured n meters. Energy is measuredin electron volts. Each of the three quantities for describing EM radiation is related to each other in a precise mathematical way.

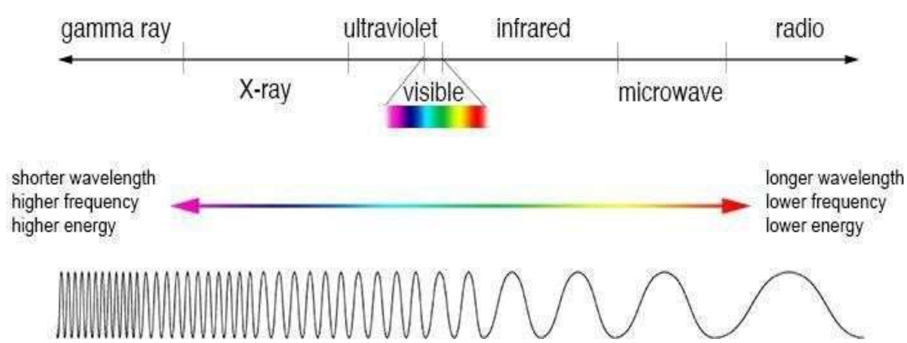


Fig 1: Electromagnetic spectrum

The energy associated with electromagnetic radiation is defined by the following equation

$E = hv$

Where E is energy (in joules)

H is Planck's constant (6.62×10^{-34}Js), V is the frequency (in seconds).

Electromagnetic radiation can be considered a combination of alternating electric and magneticfields that travel through space with wave motion. Because radiation, which is related by the following equation:

$V = C/\lambda$

Where V is the frequency (in seconds), C is the speed of light (3×10^8 ms1$^-$), and, λ is the wavelength (in meters).

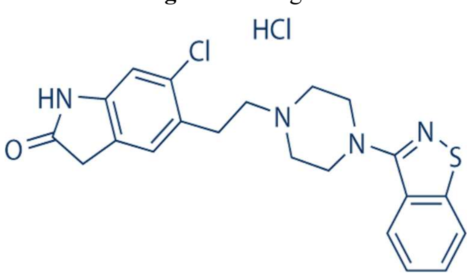
In UV- visible spectroscopy, wavelength usually is expressed in nanometers (1nm = 10 m). It follows from the above equations that radiation with shorter wavelength has higher energy. In UV- visible spectroscopy, the low-wavelength UV light has the highest energy.

Table 1: Electromagnetic spectrum

Types of radiation	Frequency range (Hz)	Wavelength range	Types of transitions
Gamma-rays	10^{20} - 10^{24}	<10^{-12} m	Nuclear
X-rays	10^{17} – 10^{20}	1 nm-1pm	Inner electron
Ultra violet	10^{15} – 10^{17}	400 nm – 1nm	Outer electron
Visible	4-7.5x 10^{14}	750 nm – 400nm	Outer electron
Near-infrared	1x10^{14} – 4x10^{14}	2.5 mm – 750nm	Outer electron MolecularVibrations
Infrared	10^{13} – 10^{14}	25 mm – 2.5mm	Molecular Vibrations
Microwaves	3x10^{11} – 10^{13}	1 mm – 25mm	Molecular RotationsElectron spin flips*

The aim of present Review article is to collect UV-Spectroscopic methods for Estimation Method development and validation of Ziprasidone HCl by UV-Spectroscopy in bulk and marketed formulation. To compile various UV-Spectroscopic methods developed for the estimation ofZiprasidone HCl in bulk and marketed formulations. To critically evaluate the validation parameters of these methods, including accuracy, precision, and sensitivity. To provide a comprehensive overview of the methodological approaches used in UV-Spectroscopy for Ziprasidone HCl analysis. To identify challenges and advancements in the development of UV-Spectroscopicmethods for the estimation of Ziprasidone HCl. To offer insights into the applicability of these methods for routine quality control andanalysis of Ziprasidone HCl in pharmaceutical formulations.

Drug Profile of Ziprasidone HCl
Generic Name: Ziprasidone Hydrochloride
Description: Ziprasidone HCl is an atypical antipsychotic drug primarily used to treat schizophrenia and bipolar disorder. It works by modulating the effects of neurotransmitters inthe brain, particularly serotonin and dopamine.
Solubility: Soluble in water, sparingly soluble in ethanol, and practically insoluble in chloroform and ether.
Melting Point: Approximately 300°C (572°F) with decomposition.
Molecular Formula: $C_{21}H_{21}ClN_4OS\cdot HCl$
Molecular Weight: 467.42 g/mol



Molecular Structure: Ziprasidone HCl
Chemical Name: 5-[2-(4-(1,2-Benzisothiazol-3-yl)piperazin-1-yl)ethyl]-6-chloro-1,3-dihydro- 2H- indol- 2-one hydrochloride

Mechanism of Action
Ziprasidone acts as an antagonist at dopamine D2 and serotonin 5-HT2A receptors. It also inhibits the reuptake of serotonin and norepinephrine, which may contribute to its antipsychoticand antidepressant effects.

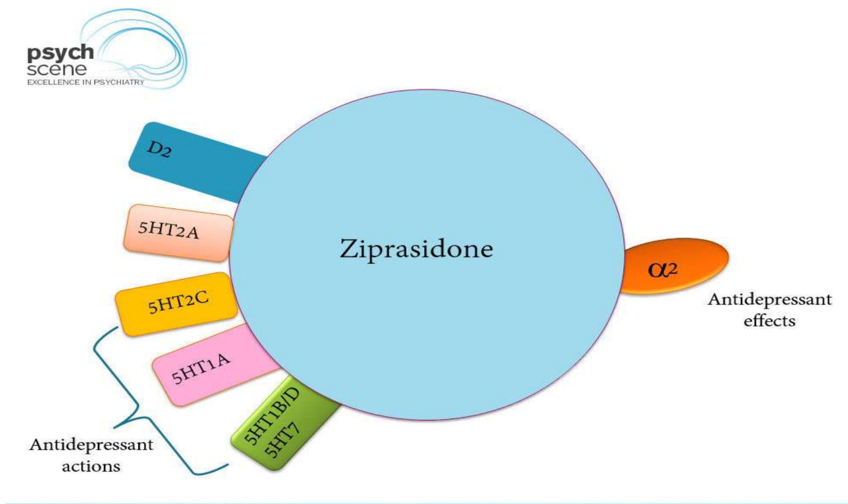


Table 2: Data on literature

S.No	Name of Author	Name of Journal	Title of Article	Analytical Conditions
1	Y. Anand kumar, M.Anitha, A.Hemanth, S. Srinivas (2010):	Digest Journal of Nanomaterials and Biostructures	Development of rapid UVspectrophotometric method for the estimationof ziprasidone hydrochloride in bulk andformulations	**Detection Wavelength:** 318nm **Solvent:** Saline buffer pH 7.4**Reagent:** Methanol (for preparing stock solution) **Linearity:** 2-10 µg/ml **Correlation Coefficient:** 0.9988
2	Kajal S Jadhav and Kiran B Erande(2016)	International Journal of Research in Pharmacy and Chemistry	Solubility Enhancement and formulation of fast Dissolving tablet of Ziprasidone Hydrochloride	**Detection Wavelength:** **:** 317 nm **Solvent: MethanolReagent:** **1M Methanolic HydrochloricAcid** **Linearity:** **Concentration Range:** 5-30ppm **CorrelationCoefficient:** **:** 0.999
3	Mahale M.V1, Todkari V.B1, Kangane M.R2, Mohite S.K1, MagdumC.S1, Hembade M.J2(2013)	International Journal of Pharmaceutical Archive	U.V-Spectrophotometric Method Development for Quantitative Estimation of Ziprasidone Hydrochloride	**Solvent:** Methanol (for preparing solutions), 1M Methanolic Hydrochloride (fordilutions) **Reagent:** Hydrochloric acid (1M methanolic hydrochlorideused for stability) **Linearity:** 10-70 µg/mL **Correlation Coefficient:**0.9989 **Wavelength:** 315 nm **LOD Value:** 0.941 µg/ml **LOQ Value:** 2.843 µg/mL
4	Todkari V. B, (2013)	International journal of research and analytical reviews	Method for Estimation of Ziprasidone Hydrochloride in Bulk andMarketed Formulation	**Detection wavelength:**315nm **Solvent:**1MMethanollic Hydrochloride Linearity:10- 70µg/ml Correlation Coefficient :0.9989
5	G.Srinubabu, B.SudhaRani (2006)	E-Journal of Chemistry	Spectrophotometric Determination of Ziprasidone in Pharmaceutical Formulations	**Detection wavelength:**490nm **Solvent:**0.1N HCl **Reagent:** dye TPooo, **Linearity:**2-10µg/ml **Sandel sensitivity** (µg/cm2/0.001absorbance unit): 0.010 **Correlation Coefficient:** 0.9994

6	M. Anitha, A. Hemanth, S. Srinivas(2010)	Digital journal ofNano materials and Biostructures	Development of Rapid UVSpectro photometric method for the estimation of Ziprasidone hydrochloride in bulk and formulations	**Detection wavelength:** 318nm**Solvent: Saline buffer P^H:**7.4 and Methanol **Linearity:**1-20µg/ml Correlation Coefficient:0.9998
7	R.Vijaya Lakshmi, N.Jahnavi, (2009),	Oriental Journalof Chemistry	Spectro photometric determination of Ziprasidone hydrochloridein pharmaceutical formulations	**Method A: Detection wavelength**:509nm **Solvent:** Ferric chloride and1,10-phenanthroline **Linearity:**0.25-2µg/ml **CorrelationCoefficient:** 0.998 Method B: **Detection wavelength:** 521nm

CONCLUSION

The various studies on UV-Spectrophotometric methods for estimating Ziprasidone Hydrochloride demonstrate the versatility and reliability of this analytical technique. Detection wavelengths between 315 nm and 521 nm, with methanol and other solventslike saline buffer and 0.1N HCl, offer robust frameworks for the quantification of Ziprasidone. High correlation coefficients, typically above 0.998, reflect excellent linearity across different concentration ranges, supporting the precision and accuracy of these methods. The use of reagents such as hydrochloric acid and dyes further enhances detection sensitivity, with LOD and LOQ values confirming their suitability for trace analysis. Overall, these validated methods provide a reliable and efficient approach to estimatingZiprasidone Hydrochloride in both bulk and formulated products. They demonstrate consistency across different experimental conditions, ensuring adaptability in routine pharmaceutical quality control. The use of UV-Spectrophotometry, with its simplicity and high accuracy, makes it a valuable tool for regulatory compliance and formulationanalysis in the pharmaceutical industry.

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