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Original Article

UV spectroscopic estimation of oseltamivir in bulk drug and formulation

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ABSTRACT

A simple, accurate and precise UV spectroscopy method has been developed for the estimation of Oseltamivir. It is a medication used for the treatment of influenzas A and influenza B. It inhibits the influenza's neuraminidase enzyme. The enzyme cleaves the sialic acid which is found on glycoproteins on the surface of human cells that helps new virions to exit the cell. Here we have developed a UV spectroscopic method for the quantitative determination of Oseltamivir in the bulk and tablet dosage forms. The parameters linearity, precision, accuracy, limit of detection and limit of quantification were studied according to international conference on harmonization guidelines (ICH). The determination was carried out at an absorption maximum of 218 nm using distilled water as solvent. In the present method, linearity over the concentration range of Oseltamivir was found to be 10-50 µg/ml, with a correlation coefficient of 0.9998. The results of analysis have been validated statistically for linearity, accuracy and precision, LOD and LOQ of the processed method. The developed method was successfully applied for the quantitative analysis of commercially available dosage form.

Keywords: Oseltamivir, UV spectroscopy, Validation, ICH Guidelines, Quantification

INTRODUCTION

Oseltamivir is chemically known as Ethyl (3R,4R,5S)-5-amino-4-acetamido- 3-(pentan-3-yloxy) -cyclohex-1-ene-1- carboxylate. It is used for the treatment of influenza A&B. It belongs to Anti-Viral classification. It is used to inhibit influenza's Neuraminidase enzyme. The enzyme cleaves the sialic acid which is found on glycoproteins on the surface of human cells that helps new virions to exit the cell. Thus, oseltamivir prevents new viral particles from being. It is taken by mouth. The most common side-effects of Oseltamivir include diarrhoea, abdominal pain, nausea, vomiting, bronchitis, dizziness, vertigo, fatigue, headache, nosebleed, eye redness, skin

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rash, itchiness, insomnia, cough and respiratory problems.

In the present study, the method UV-Spectroscopy was based on estimation of Oseltamivir. Absorption spectrometry is the measurement of the selective absorption by atoms, molecules of electromagnetic radiation having a definite and narrow wavelength range [1–2]. Absorption spectroscopy encompasses the wavelength regions: UV (200-380nm) Visible (380-780nm)· Near –IR (780nm - 2.5µm) and Far -IR (2.5 - 40µm) from the UV spectra 218nm was selected as λmax for analysis of Oseltamivir, using distilled water solvent. It was observed that Oseltamivir in distilled water was stable for 3 hrs.

MATERIALS AND METHODS

Oseltamivir was obtained as a gift sample from Zydus Cadila Healthcare Ltd, the pharmaceutical company, Vadodara, Gujarat. The brand of Oseltamivir tablets used was Tamiflu and procured from a local Pharmacy. All the solvents and chemicals used were of analytical reagent grade and procured from Quietens India pt. Ltd., and Lobe Chemist India Ltd.

Instruments: Kerro P5 Series Precision Electronic Balance, Model Bl -3003, T60 UV-Visible spectrophotometer with 1 cm matched quartz cells, Sonicator Sonica Ultrasonic cleaner model 2200 mH.

Method – Simple UV- Spectroscopy [3-6]: The solubility of Oseltamivir was determined in a variety of solvent ranging from non-polar to polar using essentially a method of Schefter and Higuchi. The drug was found to be freely soluble in distilled water, methanol, ethanol, 1 M NaOH, 0.1M HCl Sparingly soluble in DMSO, Chloroform, Glacial acetic acid, 1M HCl Considering the economic factor and the drug were stable in distilled water for 3 h. Distilled water was selected as the solvent for method.

Preparation of standard stock solution: 10 mg of Oseltamivir raw material was accurately weighed and transferred into the 100 ml volumetric flask and dissolved in minimum quantity of distilled water and made up to 100 ml with distilled water.

Selection of λ_{max} and stability studies[7-9]: The standard stock solution was further diluted with distilled water to get 10 µg/ml concentration. The solution was scanned between 200 and 400 nm range using distilled water as blank. From the UV Spectra 218nm was selected as λ_{max} for analysis of Oseltamivir. Stability of the Oseltamivir in distilled water was studied by measuring the same solution at this λ_{max} in different time intervals. It was observed that Oseltamivir in distilled water was stable for 3 hours.

Calibration graph and linearity: In this aliquot of stock solution of Oseltamivir (1-5 ml) were transferred in to 100 ml volumetric flask and made up to the mark with distilled water. The absorbance of different concentration solutions was measured at 218 nm against blank. The samples were found to be linear from 10-50 µg /ml. The calibration curve was plotted using concentration Vs absorbance. The curve obtained was linear in the concentration range of 10-50 µg /ml.

Quantification of formulations: Contents of twenty capsules of formulation (Tamiflu) containing 75mg of Oseltamivir was accurately weighed to find out the average weight. Capsule powder equivalent to 10 mg of Oseltamivir was transferred in to 100 ml volumetric flask, added distilled water and made up to the volume. Then the solution was sonicated for 15 minutes. After sonication, the solution was filtered through Whitman filter paper No.41. From the clear solution, further dilution was made to bring a 10 µg /ml using distilled water. The prepared solution was measured at 218 nm. The amount of Oseltamivir was determined by using slope and intercept values from calibration graph.

Recovery studies [10-14]: From each of the preanalyzed formulation, known quantities were taken and the raw material solution was added in ascending amounts (1, 2, 3, 4, and 5 ml) to 50 ml standard flasks. The contents were mixed well, finally made up to the mark and filtered. The absorbance was measured at 218nm using distilled water as blank and the amount of drug recovered from each formulation was calculated by the mathematical relation followed by Sane *et al*

Statistical Validation: The obtained results were treated for statistical validation parameters like Standard Deviation (SD) and Percentage Relative Standard Deviation (% RSD).

RESULTS AND DISCUSSION

The solubility profile of Oseltamivir was determined as per procedure followed by Schefter and Higuchi. Using various polar to non-polar solvents and from the solubility studies, the drug was found to be freely soluble in distilled water, methanol Ethanol, 1 M NaOH and Sparingly soluble in DMSO, 0.1M HCl, Chloroform.

The optical parameters like Beer's law limits (10-50 µg/ml), Sandell's sensitivity (0.01750 µg/cm^2), correlation coefficient (0.9998), slope (0.0150m),

intercept (0.0110c), limit of detection (2.08µg/ml), and limit of quantification (6.93µg/ml) were calculated for Oseltamivir in distilled water and produced in Table 1. Quantification of Oseltamivir from tablets dosage form was performed and the amount present was determined by average of six replicate analysis and the amount in percentage purity is found to be 99.50%– 100.01% and shown in table 2.

To evaluate the accuracy of the method and for knowing the interference from excipients recovery study was performed. The Recovery of Oseltamivir by UV- Spectroscopic method was found to be 98.61% - 100.52% and the results are shown in Table 3. The values of co-efficient of variance were satisfactorily low and recovery was close to 100 % indicating reproducibility of the methods. The excipients in the formulation did not interfere in the accurate estimation of Oseltamivir in tablet dosage form.

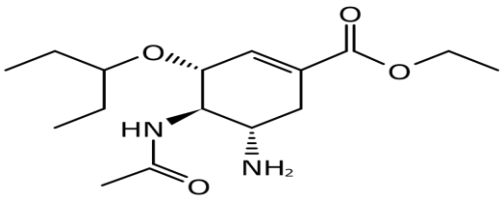

Fig 1.Structure of Oseltamivir

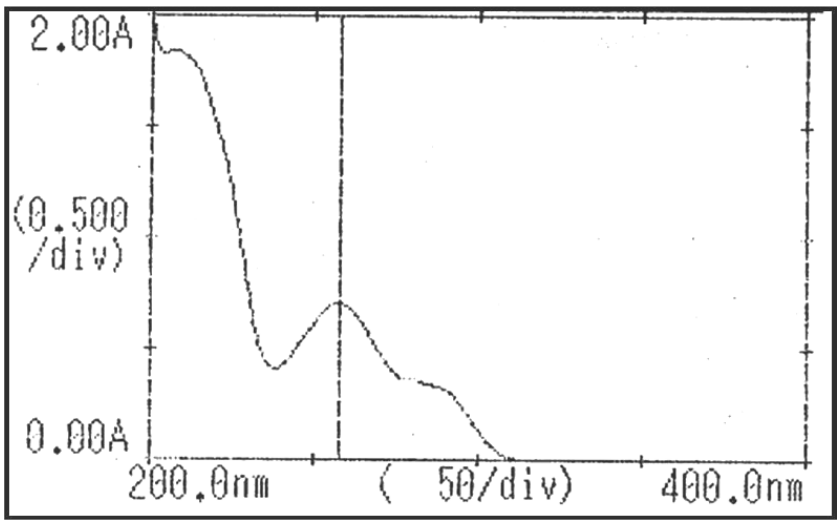

Fig 2. Uv spectroscopic spectrum

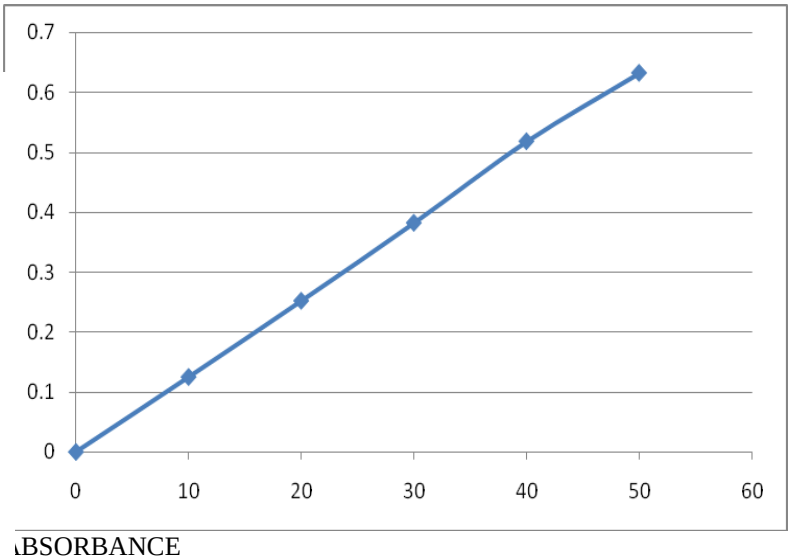

Fig 3. Linearity graph

Table: 1: OPTICAL CHARACTERISTICS OF OSELTAMIVIR IN UV METHOD

Parameters	Method Values
λ_{max}(nm)	218nm
Beer's law limit(µg/ml)	10 - 50
Sandell's sensitivity (µg/cm^2/0.001 AU)	0.01750
Molar absorbtivity(L mol^{-1} cm^{-1})	0.928×10^3
Correlation Co-efficient (r)	0.9998
Regression equation (Y= mx+c)	Y = 0.0150 X + 0.0110
Slope(m)	0.0150
Intercept(c)	0.0110
LOD(µg/ml)	2.08 µg/ml
LOQ(µg/ml)	6.93µg/ml
Standard error of mean of regression line	0.2750

Table: 2
QUANTIFICATION OF FORMULATION- TAMIFLU BY UV METHOD

S.No	Labelled Amount (mg/Tab)	Amount found (mg/Tab)	% obtained	Average %	S.D	%RSD	S.E
1	75	75.06	100.08	99.82	0.0801	1.04257	1.06874
2	75	74.71	99.61				
3	75	74.63	99.50				
4	75	74.93	99.90				
5	75	75.01	100.01				
6	75	75.02	100.03				

SD is standard deviation, % RSD percentage relative standard deviation
*Average of six determinations

Table: 3
RECOVERY STUDIES FOR FORMULATION- TAMIFLU BY UV METHOD

Name of drug	Recovery levels	Concentration (µg/ml)	Amount recovered	% Recovery with SD
Oseltamivir	80 %	30	30.002	100.02±0.80
	100 %	40	40.001	100.01±0.26
	120%	50	50.004	100.02±0.5

Summary and Conclusion: The proposed analytical methods are simple, reliable, rapid, sensitive, reproducible and accurate for the estimation of Oseltamivir. The method adopted for our studies are Simple UV-Spectroscopic method
The drug samples were analyzed by UV spectroscopy using distilled water as solvent and the average content of drug present in the formulation was found to be 99.56 mg (99.56%). The above method does not suffer from any interference due to common excipients.
Therefore it was shown that the proposed method could be successfully applied to estimate commercial Pharmaceutical products containing Oseltamivir. Thus the above studies and findings will enable the quantification of the drug for future investigation in the field of analytical chemistry.

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