EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 9
Issue: 8
316-320
Year: 2022

# DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRICMETHOD FOR THE ESTIMATION ANDCOMPARISON OF ONDANSETRON HYDROCHLORIDE IN BULK AND MARKETED TABLET DOSAGE FORMS

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**Article Received on 27/05/2022** **Article Revised on 17/06/2022** **Article Accepted on 07/07/2022**

**ABSTRACT**
A simple, accurate, precise, reproducible, highly sensitive economic spectrophotometric method has been developed for the estimation ofOndansetron hydrochloride in tablet dosage forms. UV spectrophotometric method is based on measurement absorption of maximum wavelength 306 nm in methanol. The developed method was validated with respect to linearity, accuracy (recovery), precision, LOD and LOQ. Beer's law was obeyed in the concentration range of 1- 5 µg/mL with correlation coefficient value. Results of the analysis were validated statistically and by recovery study. Also compared the assay results of different available marketed tablet formulations of Ondansetron hydrochloride. All the brands were found to be within the limit as per Indian pharmacopoeia.

**KEYWORDS:** UV visible spectrophotometry, Ondansetron hydrochloride, Tablet, Methanol, Validation.

## INTRODUCTION

Analytical method development is the process of selecting an accurate assay procedure to determine the composition of a formulation. A standard analytical procedure should include all sufficient detail to allow a competent analyst to reproduce the necessary condition and obtain results within the proposed acceptance criteria.

Validation of the analytical method is the process by which it is established by the laboratory studies, that the performance characteristics of the method meet the requirement for the intended analytical application. UV-visible spectrophotometry is one of the most frequently employed techniques in pharmaceutical analysis. It involves measuring the amount of ultraviolet or visible radiation absorbed by a substance in the solution. Analytical method development and validation are continuous and interconnected activities conducted throughout the drug development process.

Nausea and vomiting are common symptoms with many possible causes, including the adverse effects of drugs. An antiemetic is a drug that iseffective against vomiting and nausea. They are typically used to treat motion sickness and the side effects of opioid analgesics, general anaesthetics, and chemotherapy directed against cancer. Antiemetics are **serotonin antagonists**. They act by inhibiting serotonin 5-HT 3 receptors. During chemotherapy, there may be 5-HT released from injury to the GI tract, which stimulates vomiting centrally.

Antiemetics are drugs used in the prevention and treatment of vomiting. Vomiting is a protective mechanism aimed at eliminating the unwanted harmful material from the stomach. But in some situations, vomiting may not serve any useful purpose and may only be troublesome. It can cause dehydration, weakness, and electronic imbalance. In such circumstances, vomiting needs to be suppressed with drugs.

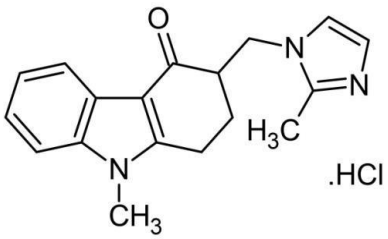



**Fig. 1: Molecular structure of Ondansetron hydrochloride.**

Ondansetron is a 5-$HT_3$ receptor antagonist that is commonly used to treatnausea and vomiting.

## MATERIALS AND METHOD

**Reagents and chemicals**

- Ondansetron hydrochloride Reference Standard (RS)
- Methanol

- Commercially available Ondansetron hydrochloride tablets

**Vomikind tab 4mg (Mankind) Ondem tab 4mg (Alkem)**

**Instruments**

- Shimadzu uv-vis Spectrophotometer.
- Wensar analytical balance.

**Methodology adapted**

- Assessment of the solubility of the drug.
- Preparation of standard solution.
- Study of spectral characteristics of Ondansetron hydrochloride.
- Calibration curve of Ondansetron hydrochloride RS in methanol.
- Stability profile
- Estimation and comparison of assay results of Ondansetron hydrochloride in different marketed tablet dosage forms.
- Validation of the proposed method.

a) Accuracy (Recovery studies)
b) Precision
c) Limit of detection (LOD) and Limit of quantitation (LOQ)
d) Linearity range

**Assessment of solubility**

Review of various material safety data sheets regarding Ondansetron hydrochloride, reported that the drug is soluble in methanol, yet different solvents tried as per the literature study, and the data obtained are given in the table below.

**Preparation of standard solution**

Weighed accurately 100mg of Ondansetron hydrochloride RS, transferred into a 100mL standard flask, dissolved and made up to the volume with methanol. The final solution had a concentration of 1000µg/mL (solution A).

Accurately pipetted out 1mL of solution A into a 100mL standard flask and the volume was made up to 100mL using methanol to get a concentration of 10µg/mL (solution B).

Accurately pipetted out 1mL, 2mL, 3mL, 4mL and 5mL of standard solution (solution B) into 5 labeled standard flasks and the volume was made up to the mark with methanol. The absorbance of each solution was measured at 306nm with methanol as blank.

**Study of spectral characteristics of Ondansetron hydrochloride RS in methanol:**

Shimadzu uv-vis Spectrophotometer was used for scanning Ondansetron hydrochloride RS in methanol (solution A and solution B) from 200-400 after enabling blank correction in the above region. An absorption band ranging from 200-400 was observed with maximum absorption at 306nm. Using solution A, the absorption intensity was beyond the limits of the instrument

**ASSAY OF ONDANSETRON HYDROCHLORIDE IN DIFFERENT MARKETLY AVAILABLE TABLET DOSAGE FORMS**

Ondem tab 4mg (Alkem)Twenty tablets of Ondansetron (Ondem 4 mg) were taken from the pack. Accurately weighed the tablet and the average weight was calculated. Thetablets were finely powdered in a glass mortar and weighed an amount equivalent to 50 mg of ondem and made up to 50 ml with methanol. The final solution had a concentration of 1 mg/ml (stock A). Solution filtered using a whats mann filter paper.

1 ml of the solution was pipetted in to a 100 ml conical flask and made upto the volume with methanol to get a concentration of 10µg/ml (stock B). Accurately pipetted out 3 ml of the solution B into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3µg/ml.

**Mankind**

Twenty tablets of Ondansetron (Mankind 4mg) were taken from the pack. Accurately weighed the tablet and the average weight was calculated. The tablets were finely powdered in a glass mortar and weighed an amount equivalent to 50 mg of Ondansetron hydrochloride and made up to 50 ml with methanol. The final solution had a concentration of 1 mg/ml (stock A). Solution filtered using a whatmann filter paper.

1 ml of the solution was pipetted in to a 100 ml conical flask and made upto the volume with methanol to get a concentration of 10µg/ml (stock B). Accurately pipetted out 3 ml of the solution B into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3 µg/ml.

**RESULTS**

**Table 1: Solubility profile of Ondansetron hydrochloride.**

| | |
|---|---|
| Water | Slightly soluble |
| Methanol | Soluble |

**Table 2: Calibration data of Ondansetron hydrochloride in methanol.**

| Concentration of ondansetronhydrochloride | Absorbance at 306 nm |
|---|---|
| 1 µg/ml | 0.102 |
| 2 µg/ml | 0.207 |
| 3 µg/ml | 0.303 |
| 4 µg/ml | 0.401 |
| 5 µg/ml | 0.502 |

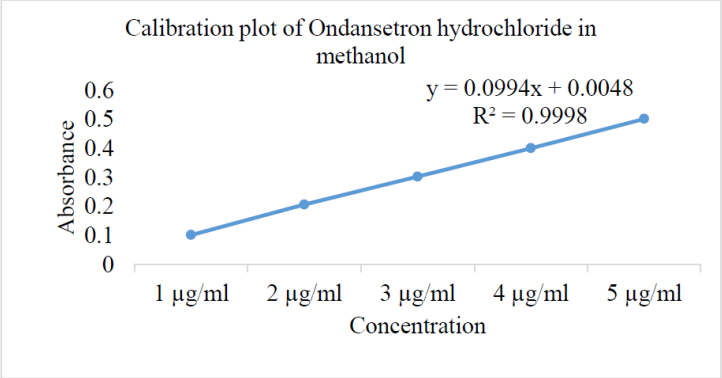
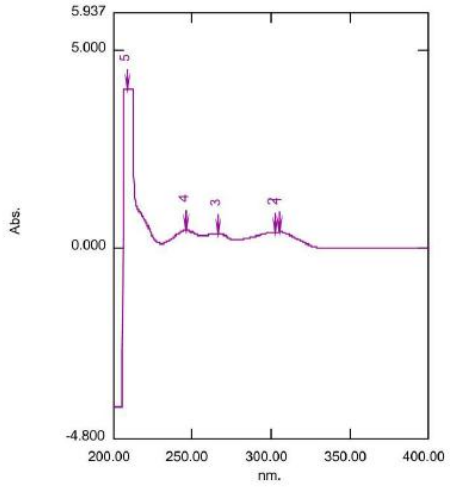



**Fig. 2: Calibration plot of Ondansetron hydrochloride in methanol.**




| No. | P/V | Wavelength nm. | Abs. | Description |
|---|---|---|---|---|
| 1 | | 306.00 | 0.424 | |
| 2 | | 303.00 | 0.405 | |
| 3 | | 266.80 | 0.369 | |

**Fig. 3: UV absorption spectra of Ondansetron hydrochloride in methanol.**

**Table 3: Stability profile of Ondansetron hydrochloride.**

| Concentrationof Ondansetron hydrochloride | Absorbance at 306 nm at 15 minutes time interval | | | | |
|---|---|---|---|---|---|
| | 0 min | 15 min | 30 min | 45 min | 60 min |
| 3µg/ml | 0.303 | 0.303 | 0.303 | 0.303 | 0.303 |

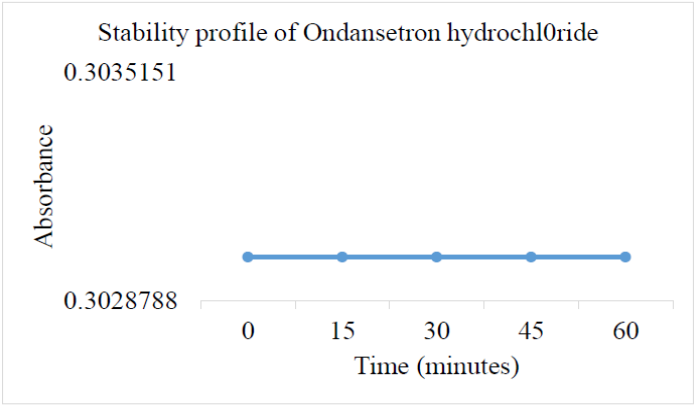



**Fig. 4: Stability profile of Ondansetron hydrochloride.**

**Table 4: Assay results of Ondansetron hydrochloride formulations.**

| Conc. (3µg/mL) | Abs. of sample | Abs. of standard | Amount insample solution | Labelclaim | % Labelclaim |
|---|---|---|---|---|---|
| Ondem (tab 4 mg) | 0.300 | 0.303 | 3.96mg | 4 mg | 99%w/w |
| Mankind (tab 4 mg) | 0.305 | 0.303 | 4.03mg | 4 mg | 100.75%w/w |

**Table 5: Results of recovery study.**

| Concentration ofOndansetron hydrochloride (µg/mL) | Standard absorbance at 306 nm | Sample absorbance at 306 nm | % recovery |
|---|---|---|---|
| 1.8 | 0.178 | 0.176 | 98.87 |
| 2 | 0.202 | 0.200 | 99 |
| 2.2 | 0.225 | 0.223 | 99.10 |

**Table 6: Results of intraday precision study.**

| Concentration | Time in hours | | | | Mean |
|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | |
| 3 (µg/mL) | 0.292 | 0.292 | 0.292 | 0.292 | 0.292 |

**Table 7: Statistical results of intraday precision study.**

| Concentration (µg/mL) | Standard deviation | Relative standard deviation (%) |
|---|---|---|
| 3 (µg/mL) | 0 | 0 |

**Table 8: Results of inter-day precision study.**

| Concentration | Absorbance | | | Mean absorbance |
|---|---|---|---|---|
| | Day 1 | Day 2 | Day 3 | |
| 3(µg/mL) | 0.292 | 0.292 | 0.284 | 0.289 |

**Table 9: Statistical results of inter-day precision study.**

| Concentration (µg/mL) | Standard deviation | Relative standard deviation (%) |
|---|---|---|
| 3 (µg/mL) | 0.00378 | 1.307 |

**Table 10: Results of LOD and LOQ.**

| | |
|---|---|
| Limit of detection (LOD) | 0.013 |
| Limit of quantification (LOQ) | 0.040 |

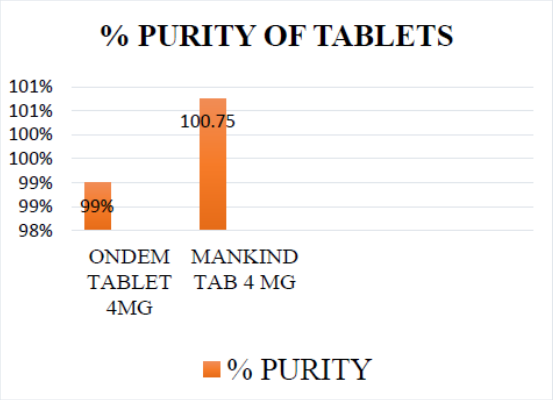



**Figure 14: Comparison of assay results of Ondansetron hydrochloridetablet.**

## CONCLUSION

The novel UV spectrophotometric method was developed and assay results of available tablets of Ondansetron hydrochloride was compared using reference standards. Indian pharmacopoeia prescribes Ondanstron tablet should contains not less than 95.0 % and not more than 105.0% of the stated amount of Ondansetron. According to our results ONDEM TAB 4MG (ALKEM) and VOMIKIND TAB 4MG (MANKIND) are within the IP range. The standard deviation and % RSD calculated are low, indicating high degree of precision. Recovery study results shows high degree of accuracy for the proposed methods. Hence it can be concluded that the proposed methods are novel, simple, precise, sensitive, cost-effective, safe and can be successfully applied for the routine analysis of Ondansetron hydrochloride in pharmaceutical dosage form.

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