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

ISSN 2349-8870
Volume: 9
Issue: 7
399-403
Year: 2022

COMPARATIVE STUDY FOR THE EVALUATION OF MARKETED FORMULATIONS OF ONDANSETRON HYDROCHLORIDE INJECTIONS BY UV VISIBLE SPECTROPHOTOMETRIC METHOD

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Article Received on 19/05/2022 **Article Revised on 09/06/2022** **Article Accepted on 29/06/2022**

ABSTRACT
To compare assay results of marketed Ondansetron hydrochloride injections. The method is truly based on measuring UV absorbance maximum at 306nm using methanol as solvent. Five different brands of Ondansetron hydrochloride injections were purchased from the market for the analysis. A standard solution of drug was initially prepared in methanol to get a concentration of 3µg/mL. The different aliquots of solution of five different brands were prepared to get a concentration of 3µg/mL. The percentage assay of each brand was calculated and their regression analysis was also performed. As per Indian pharmacopoeia, Ondansetron injection formulations should contain not less than 95.0% and not more than 105.0% of stated amount of Ondansetron hydrochloride. So from the results of our study, all selected brands were found to be within the limit.

KEYWORDS: UV visible spectrophotometry, Ondansetron hydrochloride, Methanol, Injection, assay comparison.

INTRODUCTION
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. A molecule can absorb UV radiation in discrete packets of photon when the energy of the incident radiation is sufficient to induce electronic transition and its associated vibrational and rotational transitions. Electrons are arranged in distinct energy levels in a molecule and absorption of radiation induces transition of electrons in to higher energy levels.

Analytical chemistry is the study of separation, quantification and identification of chemical components of natural and artificial materials constituted with one or more compounds or elements. Analytical chemistry is separated into two main categories; qualitative analysis that is to say the identification with regard to the chemical components exists in the sample, whereas quantitative analysis estimates the amount of elements or compounds in the substance i.e., sample.

In the field of pharmaceutical research, the analytical investigation of bulk drug materials, intermediates, drug products, drug formulation, impurities and degradation products, and biological samples containing the drugs and their metabolites are very important. From the commencement of pharmaceutical analysis analytical assay methods were included in the compendial monographs with the aim to characterize the quality of bulk drug materials by setting limits of their active ingredient content.[1-7]

An antiemetic is a drug that is effective 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. Vomiting is a protective mechanism aimed at eliminating the unwanted harmful material from the stomache. 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.[8]

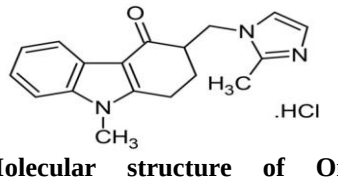


Fig. 1: Molecular structure of Ondansetron hydrochloride.

Ondansetron is a 5-HT_3 receptor antagonist that is commonly used to treat nausea and vomiting.

MATERIALS AND METHOD[9-11]

Reagents and chemicals

- Ondansetron hydrochloride Reference Standard (RS)
- Methanol
- Commercially available Ondansetron hydrochloride Injections

i. **CIPLA (2mg/ 2ml) INJECTION**
ii. **CIPLA (4mg/ 4ml) INJECTION**
iii. **MANKIND (2mg/ 2ml) INJECTION**
iv. **ALKEM (2mg/ 2ml) INJECTION**
v. **GOVERNMENT SUPPLY (2mg/ 2ml) INJECTION**

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.
- Estimation of Ondansetron hydrochloride in dosage forms (INJECTION)

Assessment of solubility

Review of various material safety data sheets regarding Ondansetron hydrochloride, reported that the drug is soluble in methanol.

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)

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 INJECTIONS

- **CIPLA (2mg/ 2ml) INJECTION**

- Sample preparation:-

2 ml of cipla injection is taken and transferred into a 100ml standard flask and made up to the volume with methanol. The final solution had a concentration of 20µg/mL (stock A).

Accurately pipetted out 1.5ml of the solution A into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3 µg/mL (stock B).

Absorbance was noted at 306 nm.

- **ALKEM (2mg/ 2ml) INJECTION**

2 ml of alkem injection is taken and transferred into a 100ml standard flask and made up to the volume with methanol. The final solution had a concentration of 20µg/mL (stock A).

Accurately pipetted out 1.5ml of the solution A into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3 µg/mL (stock B).

Absorbance was noted at 306 nm.

- **MANKIND (2mg/ 2mL) INJECTION**

2 ml of mankind injection is taken and transferred into a 100ml standard flask and made up to the volume with methanol. The final solution had a concentration of 20µg/mL (stock A).

Accurately pipetted out 1.5ml of the solution A into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3 µg/mL (stock B).

Absorbance was noted at 306 nm.

- **GOVERNMENT SUPPLY (2mg/ 2mL) INJECTION**

2 ml of government supply injection is taken and transferred into a 100ml standard flask and made up to the volume with methanol. The final solution had a concentration of 20µg/mL (stock A).

Accurately pipetted out 1.5ml of the solution A into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3 µg/mL (stock B).

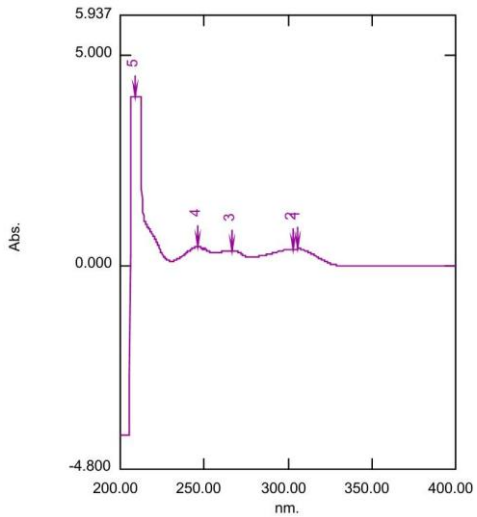
Absorbance was noted at 306 nm.

- **CIPLA (4mg/ 4mL) INJECTION**

2 ml of cipla 4mg/ 4mL injection is taken and transferred into a 100ml standard flask and made up to the volume with methanol. The final solution had a concentration of 20µg/mL (stock A).

Accurately pipetted out 1.5ml of the solution A into a 10ml standard flask and the volume was made up with methanol to get a concentration of 3 µg/mL(stock B). Absorbance was noted at 306 nm.

RESULTS



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

Fig. 2: UV absorption spectra of Ondansetron hydrochloride in methanol.

Table 1: Calibration data of Ondansetron hydrochloride in methanol.

Concentration of ondansetron hydrochloride	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

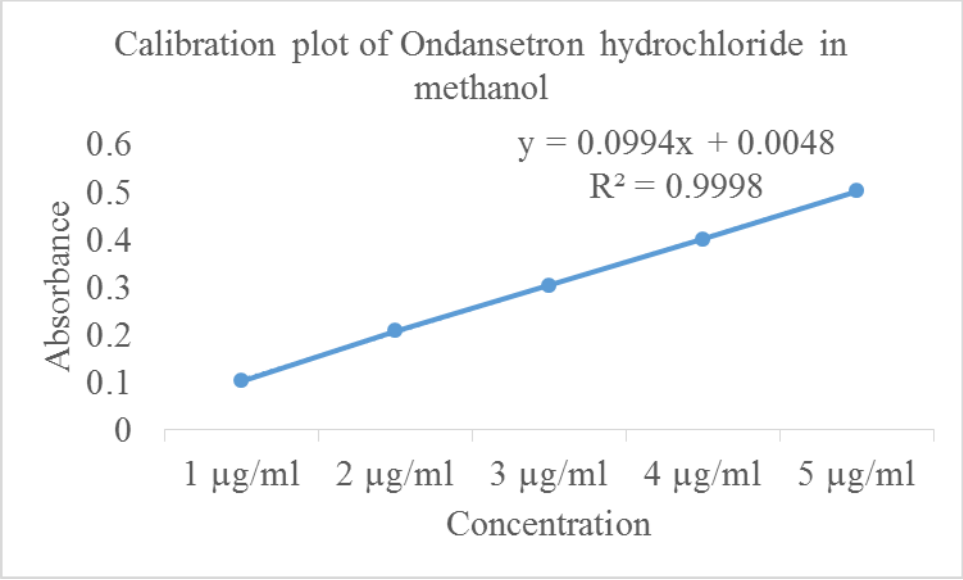


Fig. 3: Calibration plot of Ondansetron hydrochloride in methanol.

Table 2: Assay results of marketly available Ondansetron hydrochloride injections.

Sr. no.	Conc. (3µg/mL)	Abs. of sample	Abs. of standard	Amount in sample solution	Label claim	% Label claim
1	Cipla (inj 2mg/2ml)	0.310	0.303	1.95 mg	2 mg	97.74 % w/v
2	Mankind (inj 2mg/2ml)	0.290	0.303	2.09 mg	2 mg	104.5%w/v
3	Alkem(inj 2mg/2ml)	0.299	0.303	2.02 mg	2 mg	101%w/v
4	Government supply (inj 2mg/2ml)	0.308	0.303	1.97 mg	2 mg	98.37%w/v
5	Cipla(inj 4mg/4ml)	0.301	0.303	3.99mg	4mg	99.75%w/v

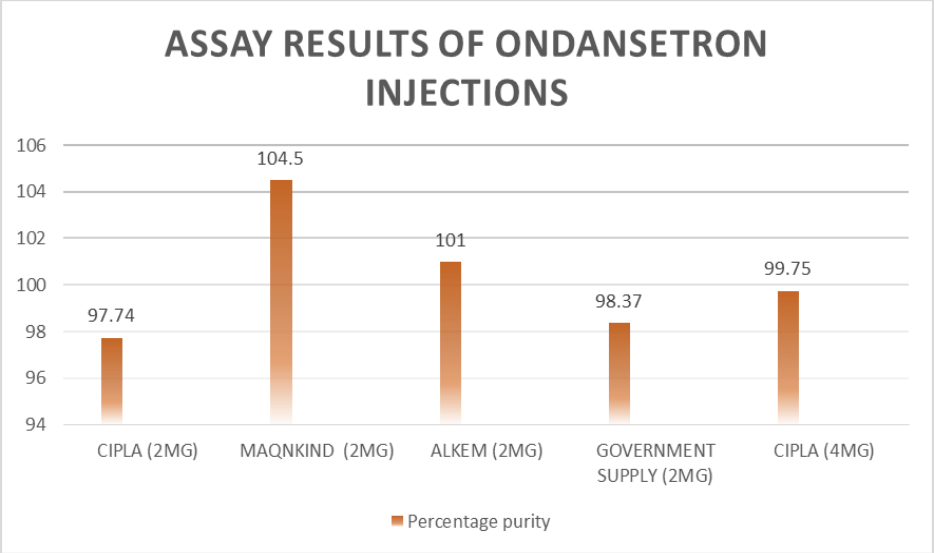


Fig. 4: assay results of Ondansetron hydrochloride injections.

DISCUSSION

The drug was soluble in methanol and also gave excellent UV detection in methanol. So methanol was chosen as a desirable solvent for this estimation technique. UV response of the drug was checked by scanning from 200-400 nm. Ondansetron hydrochloride shown maximum absorbance at 306 nm. Calibration curve for Ondansetron hydrochloride was plotted using different concentrations and shown a linear relationship between concentration and absorbance in the range of 1-5 µg/mL with a good correlation coefficient of 0.9996. Different marketed injections of Ondansetron hydrochloride was then analyzed by the developed method and the percentage purity was estimated. As per Indian pharmacopoeia, Ondansetron injection formulations should contain not less than 95.0% and not more than 105.0% of stated amount of Ondansetron hydrochloride. So from the results of our study, all selected brands were found to be within the limit.

CONCLUSIONS

The new UV spectrophotometric method was developed for the estimation of Ondansetron hydrochloride in its different marketed dosage form. Assay results of available injections of Ondansetron hydrochloride was compared. In order to ensure that the data generated with the above method is accurate and precise, experiments have been performed on calibrated equipments using suitable reference standards. The proposed method is 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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