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METHOD DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ONDANSETRON IN API AND PHARMACEUTICAL DOSAGE FORM

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Abstract

This study's main goal is to develop a new, simple, affordable, accurate, sensitive, linear, and precise UV spectrophotometric method that complies with International Conference on Harmonization (ICH) guidelines for quantifying ondansetron in bulk and pharmaceutical formulations. Procedure: The wavelength of maximum absorbance of a solution containing spiking Ondansetron was measured with a UV-visible spectrophotometer. Conclusion: In light of the results, the suggested approach was effectively used to evaluate Ondansetron in tablet form. Findings: 297 nm was shown to be the optimal wavelength for Ondansetron's absorbance. The regression coefficient was found to be 0.9993 for the concentration range of 5–25 µg/ml. For ondansetron, the limits of detection (LOD) and quantification (LOQ) were determined to be 0.163796µg/ml and 0.496352µg/ml, respectively. The technique was successfully used to evaluate Ondansetron in formulations that are sold commercially, producing outcomes that are in line with the label's claims.

Keywords: Ondansetron, Distilled water, UV–Visible Spectrophotometric method, Development, Validation.

INTRODUCTION

Chemically, ondansetron is represented as 9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-2,3,4,9-tetrahydro-1H-carbazol-4-one.has a molecular weight of 293.4 g/mol and a formula of C18H19N3O. With oral or intramuscular administration, ondansetron is a medicine that prevents nausea and vomiting and effectively treats gastroenteritis. Serotonin receptor subtype 5-HT3 is selectively antagonistic to ondansetron. [3.4.5] When enterochromaffin cells of the small intestine produce serotonin (5-HT), it is likely that this may cause a vomiting reflex by stimulating 5-HT3 receptors on vagal afferents. Cytotoxic chemotherapy and radiation therapy contribute to this phenomenon. Ondansetron has the potential to inhibit the onset of this response. The region postrema's chemoreceptor trigger zone, which is situated on the fourth ventricle's floor, may also release serotonin centrally when vagal afferents are activated. [3.4.5] Accordingly, ondansetron's antiemetic effect is most likely caused by the specific antagonistic action of 5-HT3 receptors on neurons found in the central or peripheral nervous systems, or both[3.4.5.]

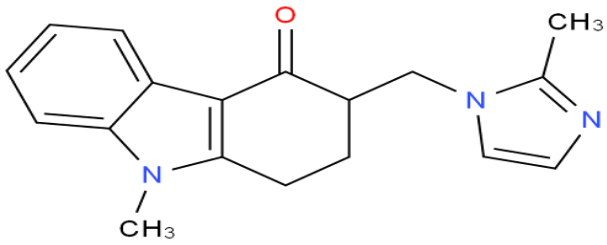

Fig.1: Chemical structure of Ondansetron

Materials And Method:

Materials: Maharshi Labs Ltd. Gujarat provided a complimentary sample of ondansetron. Vomiford-4 MD tablets were bought from a nearby market; the label said that each tablet contained 4 mg. Analytical grade chemicals and regents were all used.

Instruments: The absorbance was measured using a double-beam UV visible spectrophotometer (Systronic-2201 Spectrophotometer), while the weighing balance (Shimadzu AY220) and sonicator (Microclean-1103) were used for experiments.

Chemical and Reagent: Distilled water, filter paper were used.

Experimental Work:

Method Development:

Selection of solvent: Experiments were carried out using distilled water and other solvents to ascertain the solubility of Ondansetron. Upon recording the UV spectra of Ondansetron, it was noted that the absorbance value peaked when distilled water was used as the solvent. Distilled water was selected as the recommended solvent for more research due to its affordability.

Preparation of Standard stock solution: Ten milligrams of Ondansetron, precisely weighed, were added to a 10 milliliter (ml) volumetric flask, dissolved in distilled water, and the volume was adjusted with distilled water (concentration 1000µg/ml). Pipette 1 milliliter (ml) of the Ondansetron stock solution into a 10 milliliter (ml) volumetric flask. Dilute with distilled water to the required level (concentration: 100 µg/ml).

Preparation of Sample Stock Solution: Twenty tablets were weighed and then triturated in a mortar and pestle. After weighing the powder, which equated to 10 mg of ondansetron, it was added to a 10 ml volumetric flask along with 5 ml of distilled water. After 10 minutes of sonication, add distilled water to get the volume up to 10 millilitres. Additionally, pipette 1 ml of the Ondansetron stock solution into a 10 ml volumetric flask, diluting it with distilled water to the appropriate level. (Percentage = 100µg/ml).

Method Validation: The International Conference on Harmonization's guidelines were followed in developing the process validation of the suggested technique, namely section Q2 (R1).

1. Linearity: At a wavelength of 298 nm, five distinct concentrations of Ondansetron solutions were made and examined. It was discovered that the regression coefficient was 0.9993.

2. Range: The linearity of ondansetron is shown between 5 and 25 µg/ml.

3. Accuracy: The percentage recovery of Ondansetron was used to calculate the accuracy. The procedure involved adding predetermined volumes of analyte to achieve concentration levels of 80, 100, and 120%; the outcomes were reported as a percentage of recovery.

4. Precision: The relative standard deviation (RSD) percentage was used to represent precision. The computed RSD% is less than 2, demonstrating the extreme precision of the procedures employed.

5. Limit of Detection (LOD): LOD is the smallest concentration of analyte in a sample that is readily quantifiable but not always. LOD was determined using the formula below.

LOD = 3.3 *σ / S

Where, S =Slope of regression coefficient σ = Standard deviation

6.Limit of quantification (LOQ): The lowest quantity of analyte in the sample that can be quantified is known as the limit of quantification. LOQ is determined using

LOQ = 10*σ/S

Where, S= Slope of regression coefficient σ = Standard deviation

7.Assay: Calculations were also made for the tablet assay (sample solution).

8. Robustness: The examination of the Ondansetron in distilled water at different wavelengths (± 2nm) demonstrates the robustness of the developed approach, with the absorption level having no major influence.

Results and Discussion: choice of solvent Distilled water was used as a solvent to test the solubility of Ondansetron, and the drug's UV spectra were recorded. The drug's absorbance value increased at λmax when distilled water was used as the solvent. Because it is more affordable, distilled water was chosen as the solvent for more research.

Determination of Wavelength: 100 microgrammes per millilitre The λmax of Ondansetron was measured by scanning it over a 200–400 nm range with distilled water serving as a blank. Thus, it was discovered that the highest absorption occurred at 297 nm.

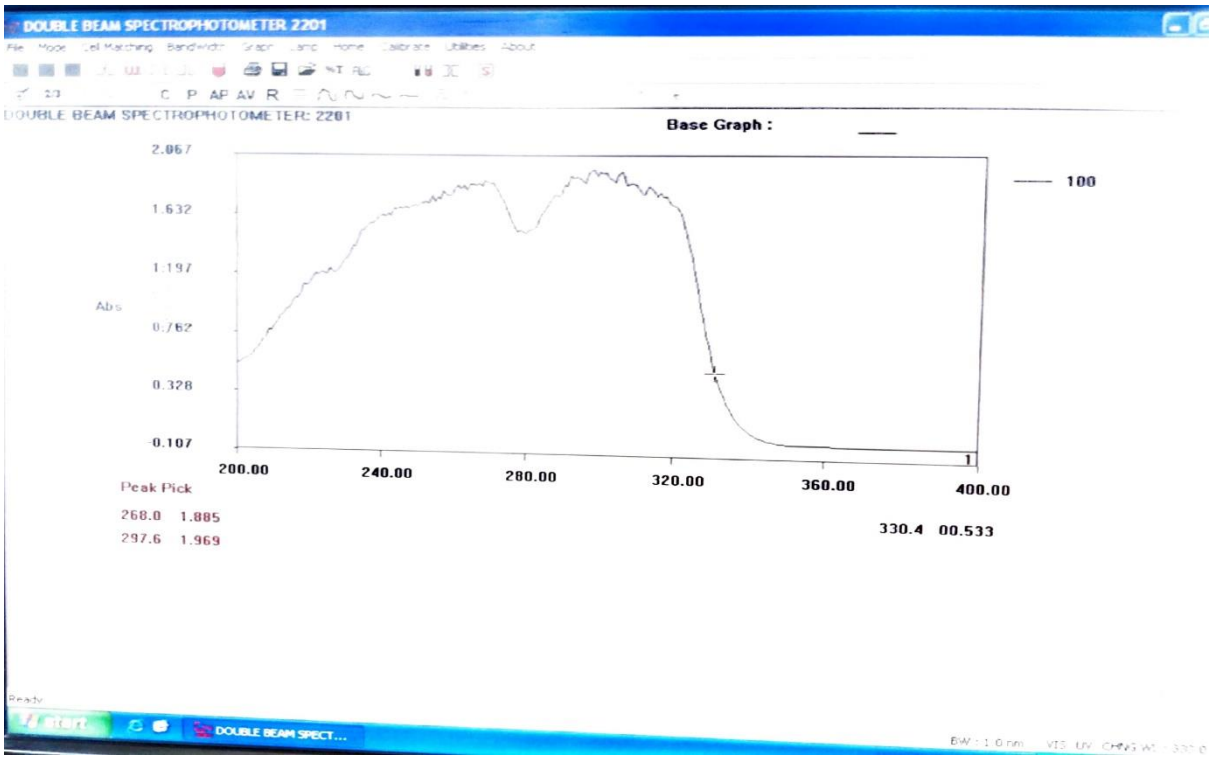

Fig.2: Chemical structure Ondansetron

Validation of method as per ICH guidelines:

1. Linearity: Five different concentrations of Ondansetron were prepared and analysed at wavelength 297 nm. The regression coefficient was found to be 0.9993.

Table 1: Results For Linearity

Sr. No	Conc(µg/ml)	Absorbance
1	5	0.170
2	10	0.329
3	15	0.482
4	20	0.660
5	25	0.828

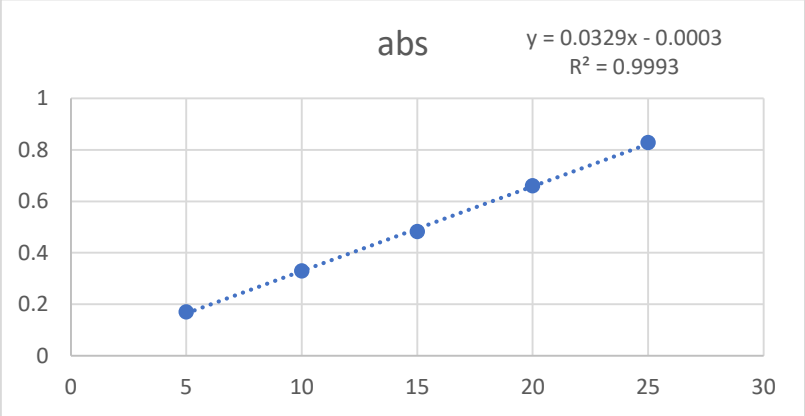

Fig.3: Calibration Curve For Ondansetron

Table 2: Optimization Parameter Of Ondansetron

Parameter	Method values
Wavelength detection	297nm
Beers law	5-25(µg/ml)
Correlation Coefficient	0.9993
Regression Coefficient	Y=0.0329x-0.0003
Slope	0.0329
Intercept	0.0003

2.Accuracy: The percentage recovery of the procedure at the three-level of percentage addition was used to measure the correctness of the suggested method. Table 3 displays the percentage recovery ondansetron, which ranged from 98.93% to 101.45%.

Table 3:Results Of Accuracy

Name of Drug	Recovery Level in %	Concentration (µg/ml)	Amount Recovered(µg/ml)	%Recovery with SD
Ondansetron	80%	18	17.82	99%
	100%	20	19.70	98.52%
	120%	22	22.31	101.45%

3.Range: Range is the range of concentration limits for the analyte (5–25µg/ml) between the highest and lowest values.

4. Precision: Intra-day accuracy tests were conducted at a concentration of 15µg/ml. Less than 2% RSD or within tolerance was discovered in the obtained results.

Table 4: Results Of Intra-Day Precision

Sr.no	Concentration(µg/ml)	Absorbance
1	15	0.478
2		0.480
3		0.482
4		0.483
5		0.481
6		0.482
	SD	0.001789
	%RSD	0.371903

Table 5: Results Of Inter-Day Precision

Sr.no	Concentration(µg/ml)	Absorbance
1	15	0.490
2		0.492
3		0.488
4		0.491
5		0.490
6		0.489
	SD	0.001414
	%RSD	0.288615

5. Limit of Detection (LOD): It was discovered that the limit of detection was 0.163796µg/ml.

6. Limit of Quantification (LOQ): It was discovered that the quantification limit was 0.496352µg/ml.

7. Assay: A sample solution containing 15µg/ml was examined at 298 nm in order to determine its purity percentage.

Table 6: Result Of Assay

Formulation	Concentration(µg/ml)	Amount obtained(µg/ml)	%Purity
Ondansetron Tablet IP 40 mg	15µg/ml	14.68	97.93%

8.Robustness: The robustness of a method is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters. Here, deliberate variation was done by changing the wavelength by ±2 nm i.e., 295nm & 299 nm.

Table 8: Result of Robustness

Robustness Wavelength (nm)	Absorbance	Average	SD	%RSD
295	0.442	0.44033	0.001528	0.3469
	0.439			
	0.440			
299	0.508	0.5056	0.002082	0.411668
	0.505			
	0.504			

CONCLUSSION

The method of using a UV spectrophotometer that was recently developed has been acknowledged for its selectivity, dependability, and ease of use. It provides more accurate quantification, heightened sensitivity, precision with reduced detection limits, and satisfactory accuracy. All cases had favourable recovery rates, and the constant adherence to the recommended protocol suggests that the suggested technique for measuring ondansetron is effective.

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