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Method Development and Validation of Ondansetron in Bulk and Pharmaceutical Dosage Form by UV Spectrophotometer

P. Leena sruthi*, C. Ravindra Reddy, V. Sagarika, K. Girish, V. G. P. Sivakumar

Department of Pharmaceutical Analysis, Balaji College of Pharmacy, Anantapur–515001, AP, India

A B S T R A C T

A simple, rapid, precise, accurate and sensitive analytical method was developed for the UV spectrophotometric assay of ondansetron. The drug obeyed the Beer's law and showed good correlation. It showed absorption maxima at 282 nm in distilled water. The linearity was observed between 5-40 µg/mL. The results of analysis were validated by recovery studies. The recovery was more than 99%. The proposed method can be used for the routine quality control testing of the marketed formulations.

Keywords: UV Spectrophotometry, Ondansetron hydrochloride, distilled water, Tablets

A R T I C L E I N F O

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***Corresponding Author**
P. Leena sruthi
Dept. of Pharmaceutical Analysis,
Balaji College of Pharmacy,
Anantapur –515001, AP, India
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1. Introduction

Ondansetron hydrochloride is chemically 1, 2, 3, 4–tetra hydro- 9- methyl- 3- (2-methyl imidazol- 1- yl methyl) carbazol-4-one hydrochloride (Figure 1) is a selective 5HT3 receptor antagonist [1]. A survey of literature revealed Spectrophotometric methods[2-5] and HPLC methods for the estimation of drug[6-10]. The aim of the study was to develop

a simple, precise and accurate UV spectrophotometric method for the estimation of ondansetron hydrochloride in pure and in its pharmaceutical dosage form. The developed method was validated as per ICH guidelines [11, 12] and applied for analysis of Ondansetron hydrochloride tablets.

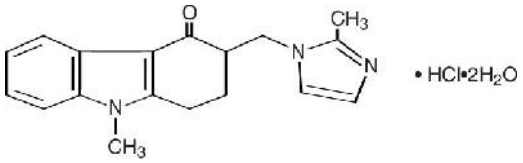

Figure 1: Chemical structure of ondansetron

2. Materials and Methods

Instrumentation:

The spectrophotometric measurements were carried out using a PG instruments T60 UV/Visible double beam spectrophotometer with 1 cm matched quartz cells. Digital Balance: BL-220H, Shimadzu was used.

Chemicals:

Pure Ondansetron hydrochloride was obtained as a gift sample from Aurobindo Pharma, (Hyderabad, India). Commercial tablets were purchased from the local market. All other chemicals and solvents used were of analytical grade. Distilled water was prepared in house using Milli-Q water purifying system.

Procedure:

100 mg of the drug was weighed accurately and transferred in to a 100 mL volumetric flask, to that 25 mL of water was added and shaken well, after complete dissolution the volume was made up to 100 mL using water. This dilution was treated as stock solution which is having 1000 µg/mL of ondansetron hydrochloride. From the above solution the suitable quantity of aliquots were taken into a series of 10 mL standard flasks to get 5,10,15,20 and 25 µg/ml of ondansetron and volume was made up to 10 mL using distilled water. The prepared solutions were scanned between 200-400 nm. The absorbance maximum was found at 282 nm (figure 2). The calibration curve was plotted by taking concentration (µg/ml) of the drug in x axis and absorbance in y axis.

Tablets analysis:

Twenty tablets of drug were weighed and powdered. The average weight was calculated. The powder equivalent to 10 mg of ondansetron hydrochloride was weighed accurately and treated with water (100 ml) to produce 100 µg/ml of the drug solution. The mixture was sonicated for 15 min and filtered through whatmann filter paper No. 40. The filtrate was further diluted with distilled water to get 10 µg/ml and absorbance was measured at 282 nm. This calibration curve was used to calculate the drug from tablets.

Validation of the method:

The analytical method was validated according to ICH guidelines[11]. Validation parameters evaluated were specificity, accuracy, precision, linearity, LOD and LOQ.

3. Results and Discussion

The UV scan of standard solution between 200 to 400 nm showed the absorption maxima at 282 nm. The λ max curve of ondansetron standard and sample was shown in figure 2a and 2b.

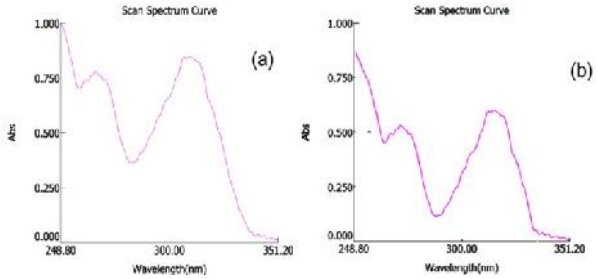

Figure 2: (a) λ max of Standard ondansetron (b) λ max of ondansetron tablet sample

Linearity:

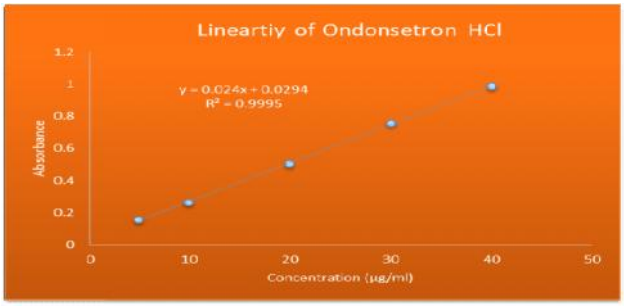

Figure 3: Linearity of Ondansetron HCl

Fresh aliquots were prepared from standard stock solution ranging from 5-40 µg/ml and the absorbance values of each concentration was recorded at 282 nm for this method using distilled water as blank. The drug shows linearity between 4-24 µg/ml for this method with R^2 = 0.9995. The linearity curve was shown in figure 3.

Precision:

In intraday study, concentration of replicates of drug was calculated on the same day for three times. In inter-day study the concentration of drug were calculated on three successive days which expresses the laboratory variation in different days. In both intra and inter day precision study for the methods %RSD was calculated. The % RSD was found to be less than 2%. The results were shown in table 1.

Table 1: Results of Precision

S. No	Absorbance
1	0.501
2	0.512
3	0.517
4	0.508
5	0.504
6	0.509
Average	0.5085
SD	0.006
% RSD	1.12

Accuracy:

Accuracy of the developed method was confirmed by performing recovery studies at three different concentration ranges 50%, 100%, 150% each one in triplicate. From the recovery studies it was clear that the method is very accurate for quantitative estimation of tablet as the statistical results were within the acceptance range. The mean % recovery ranges from 99.35- 99.90. The results of accuracy was shown in table 2.

Table 2: Results of Accuracy

Conc Level	Weight of sample	Abs	Amount added	Amount found	% Recovery	Mean % Recovery
50%	135	0.258	10.07	10.22	101.47	99.90
		0.256	10.07	10.14	100.68	
		0.248	10.07	9.82	97.54	
100%	270	0.507	20.14	20.08	99.70	99.44
		0.501	20.14	19.84	98.52	
		0.509	20.14	20.16	100.09	
150%	405	0.728	30.21	28.83	95.44	94.35
		0.712	30.21	28.20	93.34	
		0.719	30.21	28.48	94.26	

Limit of Detection and Limit of Quantification

The limit of detection and limit of quantification of Ondansetron by proposed methods were determined using calibration graphs. LOQ and LOD were calculated as

LOD = 3.3 X S.D/S

LOQ = 10 X S.D/S

Where S is the slope of the calibration curve and SD is the standard deviation of response of least concentration of calibration curve in three replicates. The LOD and LOQ was found to be 0.75 µg/ml and 2.50 µg/ml respectively.

Robustness:

Robustness of the method was determined by carrying out the analysis at three different wavelengths (± 2 nm) and three different sample temperatures (± 5°C). The respective absorbance was noted and the result was indicated by % Assay. The results of robustness were shown in table 3.

Table 3: Results of Robustness

S. No	Robust condition	Parameter	Absorbance	% Assay
1	± 2 nm	281 nm	0.501	99.58
2		282 nm	0.505	100.37
3		284 nm	0.502	99.77
4	± 5 ^{0}C	30^{0}c	0.472	93.81
5		35^{0}c	0.505	100.37
6		40^{0}c	0.483	96.00

Assay of marketed formulation:

The proposed method was applied to analyze commercially available ondansetron tablets having content equivalent to 4 mg. Ten tablets were weighed and powder equivalent to 100 mg transferred in 100 ml volumetric flask and

dissolved in distilled finally volume was made up to mark with the same. The solution was then filtered through whattman filter paper #41. This filtrate was diluted suitably with solvent to get the solution of 20 µg/ml. The absorbance was measured against distilled water as blank. The readings were taken in triplicate by performing the same experimentation in three times. The % Purity and content of the drug in tablet dosage form was calculated. The mean assays of six replicate samples were found to be 100%. The results of Assay (% purity) was shown in table 4.

Table 4: Assay Results of ondansetron

S. No	Absorbance	% Assay
1	0.501	99.58
2	0.512	101.76
3	0.517	102.76
4	0.508	100.97
5	0.504	100.17
6	0.509	100.17
Average		100.07
SD		1.13
% RSD		1.12

4. Conclusion

The proposed method was successfully applied for the determination of ondansetron hydrochloride in pharmaceutical formulations. The results demonstrated that the procedure is accurate, precise and reproducible. This method can be applied for the estimation of Ondansetron hydrochloride in its bulk and its dosage forms.

5. Acknowledgement

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