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Spectrophotometric Method for Ondansetron Hydrochloride

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Patra, et al.: Spectrophotometric Method for Ondansetron

A new simple, sensitive spectrophotometric method in UV region has been developed for the estimation of ondansetron in bulk and solid dosage form. It shows maximum absorbance at 310 nm with water. Beer's law obeys in the concentration range of 5-15 μ g/ml. Results of the analysis were validated statistically and by recovery studies.

Key words: Spectrophotometric method, ondansetron HCL, optical characteristics, recovery study

Ondansetron, which is a specific antiemetic drug, is used in cancer chemotherapy and induced nausea and vomiting¹. Chemically, it is (\pm) 1,2,3,9-tetrahydro-9methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4Hcarbazol-4-one, monohydrochloride dihydrate² is a selective 5HT₃ antagonist. It acts both, peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema³.

The drug is white to off white crystalline powder, odourless, soluble in water, methanol and normal saline³. Literature survey revealed very few analytical methods which include only HPLC method for the estimation of ondansetron². The authors have developed a simple sensitive and reproducible UV spectrophotometric method for the determination of ondansetron in pure form as well as in dosage forms, which are described in present communication.

All chemicals used were of analytical grade. The commercially available tablets were procured from local market. Spectral and absorbance measurements

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were made on Shimadzu double beam UV/Vis spectrometer UV 2101.

About 10 mg of pure ondansetron was accurately weighed and dissolved in 10 ml of water. The above stock solution was further diluted with the same to get a working standard solution of 5 to 15 μ g/ml. Aliquots of test solution of ondansetron were transferred into a series of 10 ml volumetric flask and the final volume was brought to 10 ml with water. The absorbance was measured at 310 nm against water and the amount of ondansetron present in the sample solution was computed from calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, Molar extinction coefficient

TABLE 1: OPTICAL CHARACTERISTICS, PRECISION AND ACCURACY OF THE PROPOSED METHOD

| Parameters | Method |
|--|------------|
| Beer's law limit (µg/ml) | 5-15 |
| Molar extinction coefficient (mol ⁻¹ cm ⁻¹) | 15.29×1000 |
| Sandell's sensitivity (µg/cm ² /0.001 absorbance unit) | 0.002386 |
| Correlation coefficient (r) ¹ | 1.00 |
| Regression ² | |
| Slope (a) | 0.042 |
| Intercept (b) | -0.006 |

 $^1\!Y$ = a + bC, where C is concentration of analyte (mg/ml) and Y is absorbance unit. $^2\!Calculated$ from three determinations

| Labelled amount (mg) | Amount of drug added (mg) | Amount of drug obtained ¹ (mg) | | Percentage recovery ² Proposed method | Standard deviation | % Coefficient of variation |
|-------------------------|------------------------------|--|-----------------|---|-----------------------|-------------------------------|
| | | Official method | Proposed method | | | |
| 8 | 10 | 7.8 | 7.7 | 98.71 | 0.7390 | 0.7454 |
| 8 | 20 | 7.8 | 7.8 | 100.00 | | |
| 8 | 30 | 7.9 | 7.8 | 98.73 | | |

TABLE 2: RESULTS OF RECOVERY STUDY OF ONDANSETRON HCL

¹Average of three determinations. ²Recovery of amount added to the pharmaceutical formulation (average of three determinations)

(calculated from the eight measurements containing $3/4^{th}$ of the amount of upper Beer's law limits of ondansetron) and correlation were calculated for the methods and the results are summarized in Table 1.

The methods were applied for the analysis of the drugs in the tablet formulation. To evaluate the validity and reproducibility of the methods, known amount of pure drug was added to the previously analysed by proposed methods and mean percent recovery was found to be 99.14 respectively. Interference studies revealed that the common excipients and other additives usually present in the dosage form did not interfere in the proposed methods. In conclusion, the proposed methods appear to be economical, simple, sensitive, reproducible and accurate enough for the routine determination of ondansetron in bulk as well as in tablet.

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