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UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR QUANTITATIVE ESTIMATION OF ONDANSETRON HCL

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ABSTRACT

UV Spectrophotometric Method Development and Validation for quantitative estimation of Ondansetron Hydrochloride (HCL). U.V Spectrophotometric method have been widely employed in determination of individual components in a mixture or fixed dose combination. Our aim is to develop spectroscopic method for estimation of the Ondansetron HCL in ternary mixture by using U.V spectrophotometry. The method was validated as per ICH guidelines. The recovery studies confirmed the accuracy and precision of the method. It was successfully applied for the analysis of the drug in bulk and could be effectively used for the routine analysis.

KEYWORDS

Ondansetron HCL, UV spectrophotometric method and Validation.

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INTRODUCTON

Ondansetron HCL is chemically 1, 2, 3, 4– tetrahydro-9-methyl-3-(2-methylimidazol- 1- yl methyl) carbazol-4-one hydrochloride is a selective 5HT3 receptor antagonist. A survey of literature revealed Spectrophotometric methods and HPLC methods for the estimation of drug. The aim of the study was to develop a simple, precise and accurate spectrophotometric method for the estimation of ondansetron HCL in pure and in its pharmaceutical dosage form[1-2].

MATERIAL AND METHODS

Material

Reference standard of Ondansetron HCL API was supplied as gift sample by Lupin Laboratory Park, Aurangabad, India.

Apparatus

A Shimadzu UV/Visible double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells were used in present study for spectral and absorbance measurements.

Method

Selection of solvent

After the solubility study of ondansetron HCL in different solvents, methanol was confirmed as a common solvent for developing spectral characteristic.

Preparation of standard stock solution

According to European pharmacopoeia, 10 mg of ondansetron HCL was dissolve in 100ml of methanol (100µg/mL). Out of this stock 0.3-1.5ml was pipetted and diluted up to 10ml by methanol (3-15µg/mL) and examined between 200-400 nm. The maximum absorbance was determined using UV-Vis Specrophotometer (UV-1700, Shimadzu, Japan) to confirm the λmax of the drugs.

Validation of analytical method

The analytical performance characteristics which may be tested during methods validation: % Recovery, Precision, Ruggedness and sensitivity[3-6].

RESULTS AND DISCUSSION

Method Development

The solution of ondansetron HCL in methanol was found to exhibit maximum absorption at 309 nm after scanning on the UV-Vis spectrophotometer which was reported as λmax in the literature and the procured drug sample of ondansetron HCL complies with the reference spectra (Figure No.1).

Linearity

Accurately weighted ondansetron HCL (10 mg) was dissolved in 100 ml of methanol to obtain working standard of 100 µg/ml. Aliquots were pipetted from the stock solution of drug and were transferred to 10 ml volumetric flask, the final volume was adjusted with methanol so that concentration of 3-15 µg/ml could be made.

Absorbance of the above solution were taken at 309 nm by using UV-Vis spectrophotometer (UV-1700, Shimadzu, Japan) against the blank solution prepared in the same manner without adding the drug. A graph of absorbance vs concentration was plotted (Figure No.2) and R^2 was found to be 0.9997.

VALIDATION OF ANALYTICAL METHOD

Recovery

Recovery study is performed by standard addition method by adding the known amount of ondansetron HCL (Working standard) at two different concentration levels i.e 80%, 100% of assay concentration and % recovery for all these drug were calculated. Result was reported in Table No.1.

Precision

Intra-day precision was determined by analysing, the two different concentrations 3mg/ml, 4mg/ml containing ondansetron HCL, for three times in the same day (n = 3) Table No.2. Inter-day variability was assessed using above mentioned two concentrations analysed on three different days, over a period of one week (n = 3) Table No.2.

Ruggedness

From stock solution, sample solution containing ondansetron HCL (3µg/ml) was prepared and analyzed by two different analysts using similar operational and environmental conditions (Table No.3) (n = 3).

Sensitivity

Sensitivity of the proposed method were estimated in terms of Limit of Detection (LOD) and Limit of Quantitation (LOQ) (Table No.4).

Table No.1: Recovery study

S.No	Drug	Initial amount (µg/ml)	Added Amount (µg/ml)	% Recovery	% RSD (n = 3)
	Ondansetron HCL	3	2.9	99.79	0.01
		3	3.0	100.44	0.06

Table No.2: Presion study

S.No			Intra - Day		Inter - Day	
	Drug	Con. (µg/ml)	Mean ± SD	% RSD	Mean ± SD	% RSD
1	Ondansetron HCL	3	3.0 ± 0.0028	0.07	3.0 ± 0.0016	0.01
2		4	4.0 ± 0.0041	0.03	4.0 ± 0.0049	0.03

Table No.3: Ruggedness study

S.No		% Amount Found		% RSD	
	Drug	Analyst I	Analyst II	Analyst I	Analyst II
1	Ondansetron HCL	100.77	100.29	0.01	0.01

Table No.4: Sensitivity study

S.No	Drug	LOD	LOQ
1	Ondansetron HCL	0.38 ± 0.008	0.99 ± 0.018

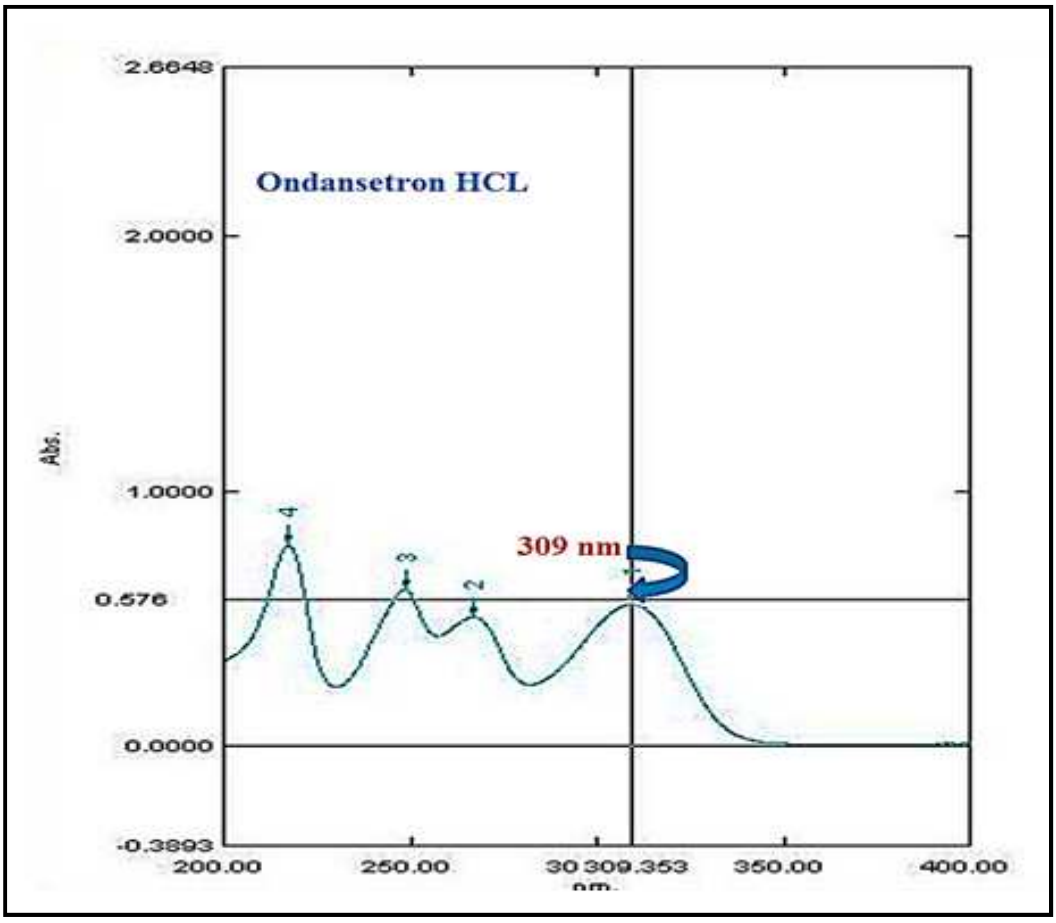

Figure No.1: UV spectra of Ondansetron HCL

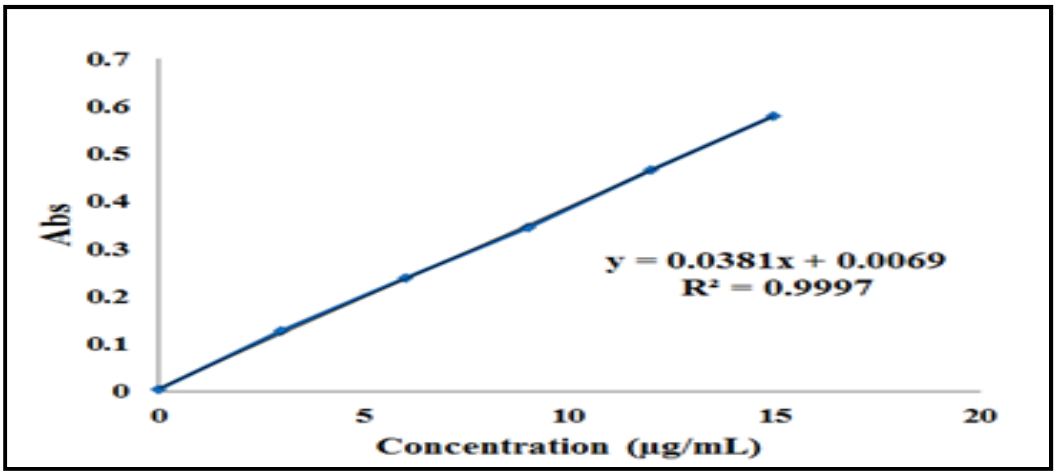

Figure No.2: Calibration curve of Ondansetron HCL

CONCLUSION

The proposed UV spectrophotometric method was found very simple, rapid and economical. The method is validated in compliance with ICH guidelines is suitable for estimation of ondansetron HCL with excellent recovery, precision and linearity.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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