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UV-SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF PALONOSETRON IN BULK AND PHARMACUTICAL DOSAGE FORM

SPANDANA R[1*], SUCHITRA D[2], SUDHA BHARGAVI CH[3], MADHURI P[4]

1: Siddhartha Institute of Pharmacy, Narapally, Ghatkesar, Hyderabad, Telangana, India

2: Vision College of Pharmaceutical Sciences and Research, Boduppal, Hyderabad, Telangana, India

3: Omega College of Pharmacy, Edulabad, Ghatkesar, Hyderabad, Telangana, India

4: Princeton College of Pharmacy, Chowdariguda, Ghatkesar, Hyderabad, Telangana, India

***Corresponding Author: Mrs. Racha Spandana: E Mail: rachaspandana_xf@siddhartha.co.in**

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ABSTRACT

The main objective of the present research work is mainly focused on development of a novel, rapid, accurate and UV- Spectrophotometric method by using an LABINDIA double beam UV-Visible Spectrophotometer. The analytical method was developed using water. The absorbance was measured Over a range 200-400nm and the λmax was found to be 256nm. The develop method obeyed beers lamberts law Showing good linearity over a range of 5-25µg/ml. The developed method was found to be Accurate and precise Showing good recovery value and having %RSD with in the acceptance criteria. Thus, the developed method Can be used routinely for quality control analysis of palonosetron drug. The obtained Limit of Detection and Limit of Quantitation values of 2.004µg/ml and 6.072µg/ml respectively proved the sensitivity of the established method. Thus, the developed method can be used routinely for quality control analysis of palonosetron drug in bulk.

Keywords: Palonosetron, validation, UV-Spectrophotometric method, %Relative Standard deviation, 5-HT$_3$ antagonist

INTRODUCTION

Palonosetron, chemically known as (3aS)-2-[(3S)-1- Azabicyclo [2.2.2] oct-3-yl]-2, 3, 3a, 4, 5, 6 hexahydro-1Hbenz [de] isoquinolin-1-one, is a specific and selective serotonin 5-HT_3 antagonist with antinauseant and antiemetic activity. It is prescribed for the prevention of nausea and vomiting associated with cancer chemotherapy and postoperative nausea and vomiting. Chemotherapeutic agents cause the release of serotonin, which then stimulates medullary vomiting center and 5-HT_3 receptors and thus initiating the vomiting reflex, causing nausea and vomiting. The antiemetic activity of palonosetron is brought about by the inhibition of 5-HT_3 receptors present both in the medullary chemoreceptor zone and gastrointestinal tract **[1-4]**.

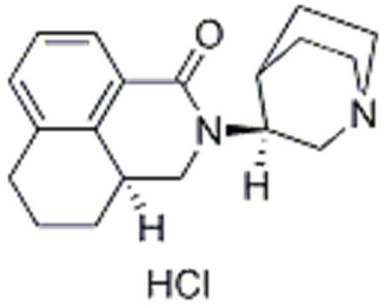

Figure 1: Chemical structure of palonosetron

To develop suitable mobile phase, optimize chromatographic condition and selection of suitable detection wavelength for the preparation of standard calibration curve of selected drugs. To develop novel, rapid, precise, and UV-Spectrophotometry method by using a Lab India double beam UV-visible spectrophotometer. The method can be developed and validated for estimation of Palonosetron drug bulk in pharmaceutical formulation **[5-7]**.

MATERIALS AND METHODS

Acetonitrile, Methanol, Potassium di-Hydrogen Phosphate, Ortho Phos phosphoric Acid, Hydrochloric acid, Sodium hydroxide, Hydrogen peroxide (50%) was procured from Merck and Finar Reagent. Palonosetron Hydrochloride standard Gifted by Zydus Cadila Health Care, Moraiya, Ahmedabad.

Preformulation studies

Preformulation study is defined as the study of the physical and chemical properties of the drug molecular prior to the compounding process. It is the most important study in the development of any new dosage form of a drug. The main objective of the preformulation studies are as follows:

- ✓ To establish the physicochemical

parameter of new drug activity.

- ✓ To establish its compatibility with common excipients.
- ✓ Physical characterization of Palonosetron

The physical characterization of procured drug sample of Palonosetron was determined on the basis of following parameters **[8-10]**.

Melting point

The melting point of Palonosetron was determined using capillary melting point method. Small quantity of drug was filled in a thin-walled capillary tube, sealed from one end. This capillary was then put in the melting point apparatus. The temperature at which the drug started melting and temperature at which it completely melts was recorded **[11, 12]**.

Fourier transform infrared spectroscopy (FTIR)

FTIR spectrum was used as an analytical technique for identification of pure drug sample. The spectra for the sample were recorded using a Bruker Vertex 70 FTIR spectrophotometer by KBr pellet method. The samples were analyzed by mixing with potassium bromide (1:10) individually and pressed to form a thin pellet by applying pressure using KBr press. The formed pellets were placed within the sample holder. Spectral scanning was taken in the wavelength region between 4000-400 cm^{-1}. FTIR scans of Palonosetron were recorded. The analysis of the drug was carried out by UV-Visible method which was validated on analytical parameters like linearity and range as per guidelines laid down by International Conference on Harmonization (ICH) **[7, 14]**.

Determination of λmax by UV spectroscopy

Calibration curve of Palonosetron was prepared with the help of UV spectroscopy. Calibration curve of Palonosetron was prepared in water **[6, 13]**.

Preparation of stock solution

Accurately weighed 100 mg of Palonosetron was transferred in 100 ml volumetric flask. The drug was dissolved and diluted up to the mark with water to give a solution with concentration of 1000 µg/ml. An aliquot of 10 ml from the above solution was withdrawn and diluted up to 100 ml with water to obtain a stock solution having concentration of 100µg/ml.

Preparation of solutions to obtain calibration curve

Appropriate aliquots from stock solution of Palonosetron (0.5, 10, 15, 20, 25) were accurately withdrawn in 100 ml volumetric flask and diluted up to the mark with water to obtain the final concentration of solution in range of 5-25 µg/ml and scanned at λ_{max}. Absorbance of these solutions of Palonosetron were recorded at their λ_{max} using water as

blank. Calibration curve of Palonosetron in water as solvent **[14, 15]**.

UV method validation

The ultraviolet spectrophotometric method was validated for different parameters like solubility, linearity accuracy precision LOD and LOQ.

Solubility

Solubility was done by polar and non-polar solvents. So, the common solvent was found to be water for analysis of Palonosetron drug soluble in DMSO, propylene glycol, ethanol is used as a secondary solvent. 100mg of Palonosetron raw material was weighed and transferred into 100ml volumetric flask made up to the volume with water. The solution is further diluted with water, which contains 1000µgr/ml. Now, the Palonosetron stock solution was diluted with distilled water and the final solution contains 10 µgr/ml, was scanned between 200-400nm using water as blank from the spectra the 256 nm wavelength is selected because the absorbance of the drug is 0.254. Hence, the estimation of Palonosetron can be done. The drug shows calculated and corrected absorbance of same solution at different time intervals.

Linearity

Different stock solution of Palonosetron was transferred into 100ml volumetric flask separately and madeup to volume with water. The absorbance of different concentration solution was measured at 256nm. The calibration curve is plotted at their respective wavelengths. Palonosetron showed the linearity in the range of 5 to 25 µg/ml at 256 nm.

Accuracy

The recovery experiment was done by adding known concentration of Palonosetron raw material to the pre-analyzed formulation. 100 mg equivalent of Palonosetron was weighed and transferred into 100ml volumetric flask and dissolved in water. The solution was subjected to ultrasonic vibrations for 30min and the solution was made up to the required volume and the solution was filtered through a Whatman filter paper 41. Then, the solutions of concentrations 5, 10, 15, 20, 25 µg/ml of Palonosetron made up the required volume and measured the absorbance at their selected wavelengths of determination of Palonosetron. The recovery of the sample was found to be 99.13%.

Precision

The repeatability of the method was confirmed by the repetitive analysis of formulation for 5 times withthe same concentration.

Inter & Intraday precision: The inter and intra precision of Palonosetron was determined by measuring the absorbance of 100% solution on different days under identical conditions.

The %RSD was found to be 0.43144208 & 0.351%

LOD and LOQ

LOD and LOQ was calculated by using the average of slope and standard deviation of intercept **[15-20]**.

RESULTS AND DISCUSSION

Physical characteristics of Palonosetron

The physical characteristics of Palonosetron are matching with those reported in the standard literature thus supporting its identity.

Table 1: physical characteristics

Physical characteristics	Reported	Experimental
Colour	White	White
Odour	Odourless	Odourless
Taste	Tasteless	Tasteless
Appearance	Crystalline powder	Crystalline powder

Melting point

The reported melting point of Palonosetron was in the range of 87-88 °C. The observed melting point was found at 87 °C. It confirms that the given powdered drug is pure in nature and it complies that powder is a Palonosetron.

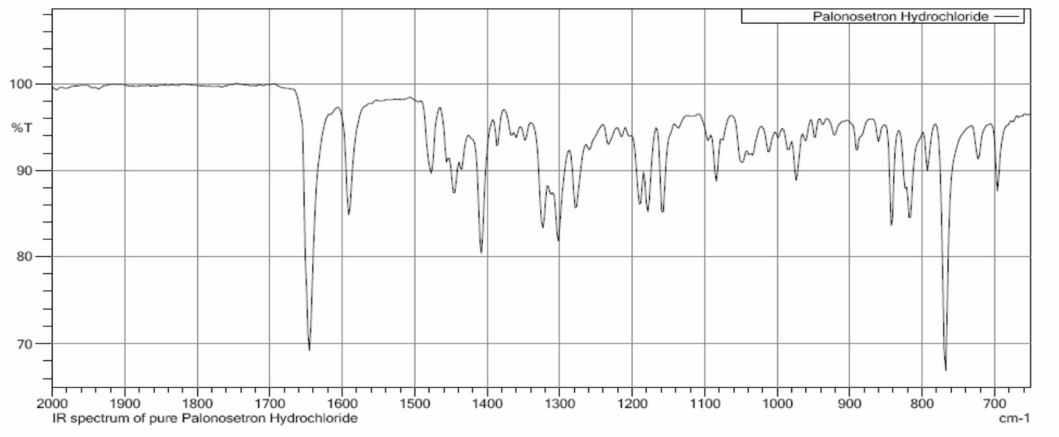

Figure 2: FT-IR of Palonosetron

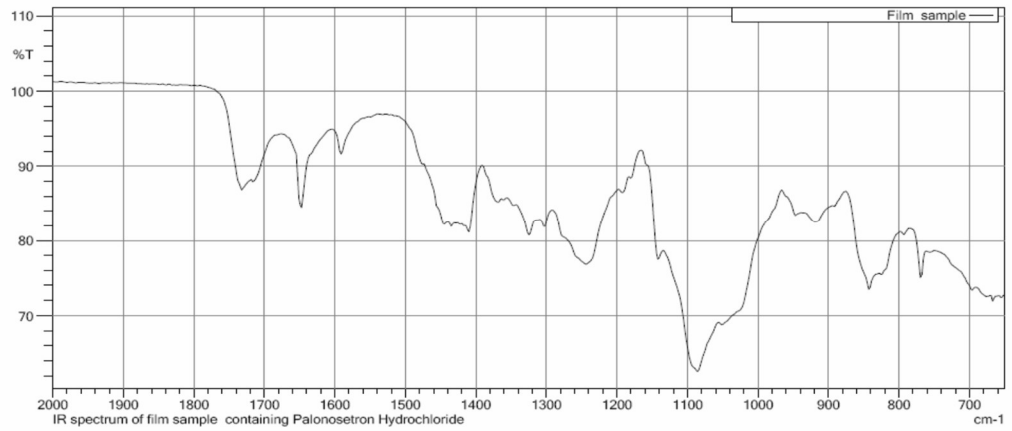

Figure 3: FTIR spectra of mixtures of palonosetron hydrochloride and excipients

In the infrared spectrum, various functional groups exhibit distinct peak positions. Alkane halides show a peak at 653 cm^{-1} due to C–H bending. Benzene rings have a peak at 857 cm^{-1} indicating CH_3 bending. Amines display a peak at 1180 cm^{-1} associated with C=C stretching. Carboxylic acids have a peak at 1321 cm^{-1} due to C–O stretching, and alkanes exhibit C–H stretching at 1442 cm.

A simple, rapid, precise and accurate UV-Spectrophotometric method was developed and validated for the estimation of Palonosetron in bulk sad pharmaceutical dosage form. After many trials and errors, the water has shown the highest absorbance at max wavelength of 256 nm. It was finalized and proceeded for method validation. The method was shown to be linear in the concentration range of 5-30 µg/ml. The %RSD Was foundto be <2% and the recovery was found to be within the acceptance criteria. LOD and LOQ was found to be 2.004 µg/ml and 6.072 µg/ml respectively which proved the sensitivity of the method.

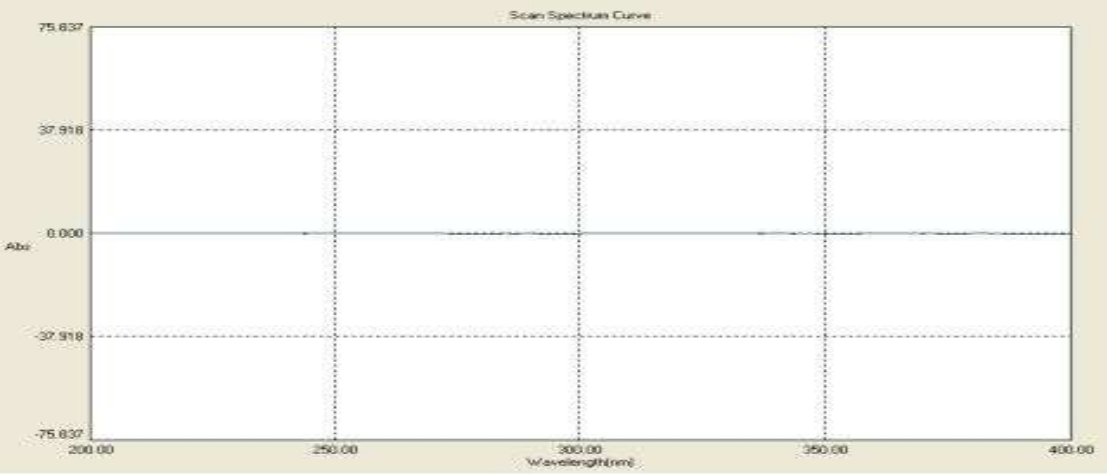

Figure 4: Blank spectrum of Palonosetron

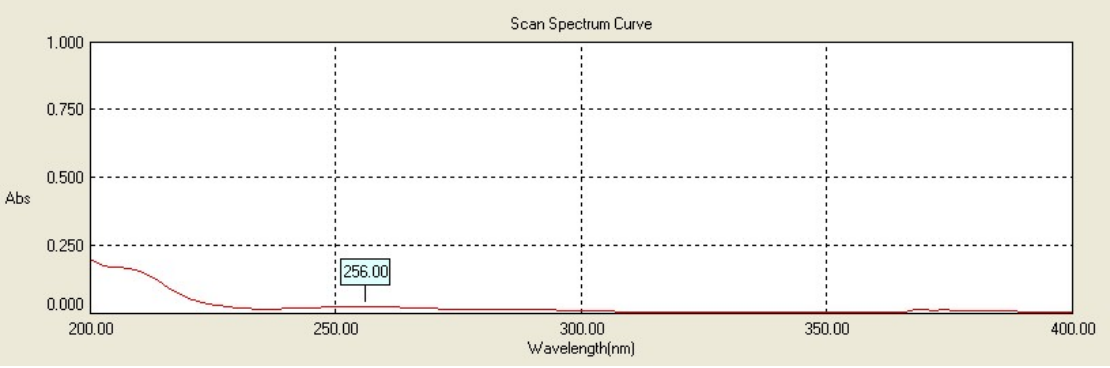

Figure 5: Standard spectrum of Palonosetron

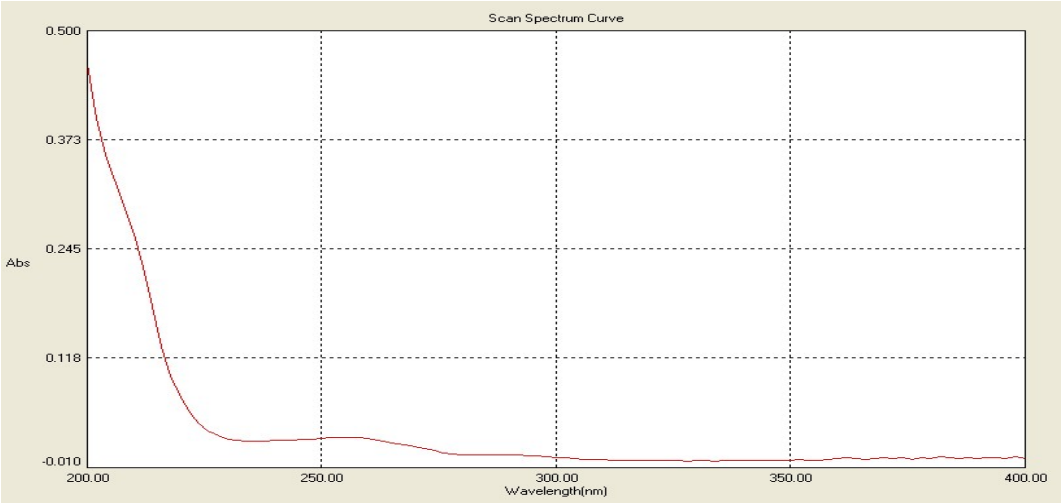

Figure 6: Absorbance maxima of Palonosetron

Method validation

Table 2: Optical characteristics of Palonosetron by absorbance correction method

Parameters	At 256 nm
Beer's law limit (µg/ml)	5-25
Correlation coefficient (r^2)	0.9992
Regression equation (y = mx + c)	y= 0.0247x + 0.0039
Slope (m)	0.0247
Intercept (c)	0.0039
LOD	2.004µg/ml
LOQ	6.072µg/ml
Standard deviation	0.0068

Table 3: Accuracy Data

Spiking level	Amount of absorbance (µg/ml)	Amount added (µg/ml)	Amount found (µg/ml)	% Recovery	Mean
50%	0.128	5	5.03	99.01%	99.7%
	0.127	5	4.99	100.05%	
	0.127	5	4.98	100.04%	
100%	0.248	10	9.98	99.1%	99.43%
	0.251	10	10	100%	
	0.249	10	9.99	99.2%	
150%	0.368	15	1.008	100.88%	100.84%
	0.368	15	1.008	100.88%	
	0.367	15	1.007	100.77%	

Table 4: Intraday analysis of Palonosetron by absorbance correction method

Concentration	
S. No.	Absorbance
1.	0.254
2.	0.254
3.	0.253
4.	0.252
5.	0.254
Mean	0.2534
Standard Deviation	0.000894427
% RSD	0.351%

Table 5: Interday analysis of Palonosetron by absorbance correction method

Concentration	
S. No.	Absorbance
1.	0.254
2.	0.254
3	0.253
4.	0.255
5.	0.254
Mean	0.2538
Standard deviation	0.001095
% RSD	0.43144208%

Linearity

From the linearity graphs, it was confirmed that the method is exhibiting linearity over the range of 5-25µg/ml. The correlation coefficient is 0.9992 which is meeting. The validation criteria. The plotted graph and linearity data are provided in the **Table 6** and spectrum of curve.

Table 6: Linearity

Concentration (µg/ml)	Absorbance
5	0.130
10	0.254
15	0.366
20	0.495
25	0.627

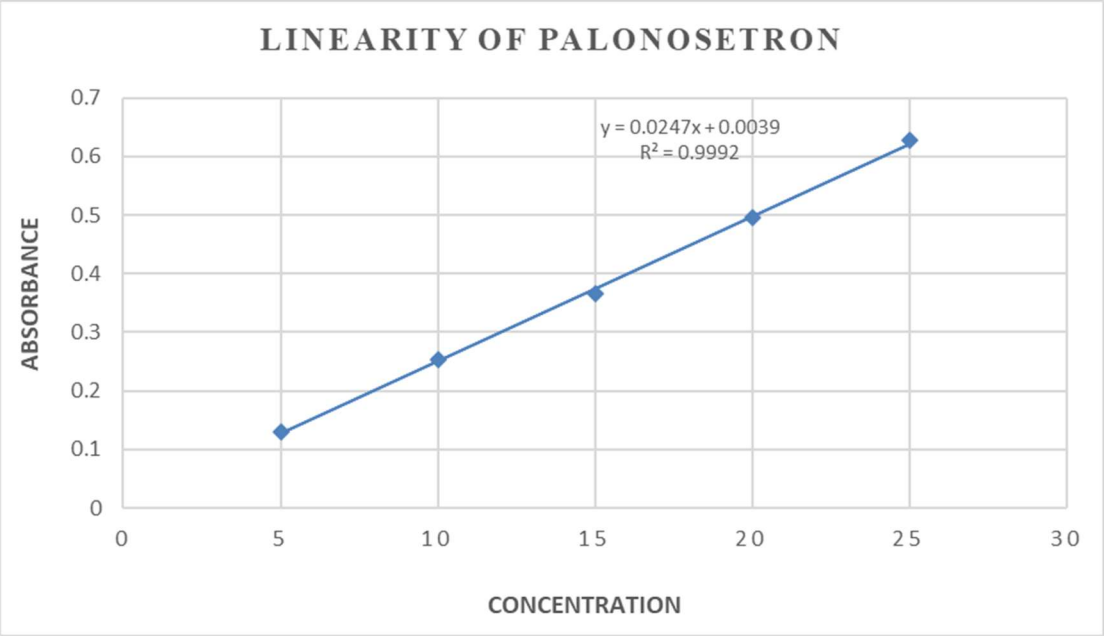

Figure 7: Calibration curve of Palonosetron

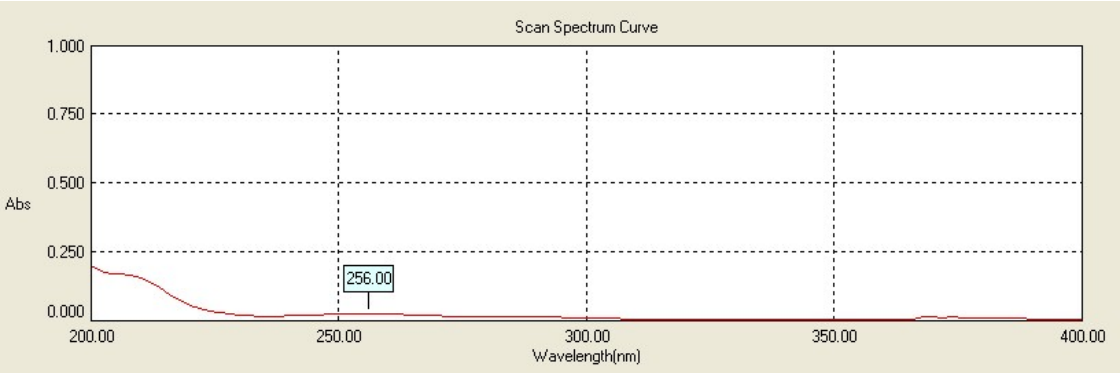

Figure 8: Spectrum showing linearity level -1(5µg/ml)

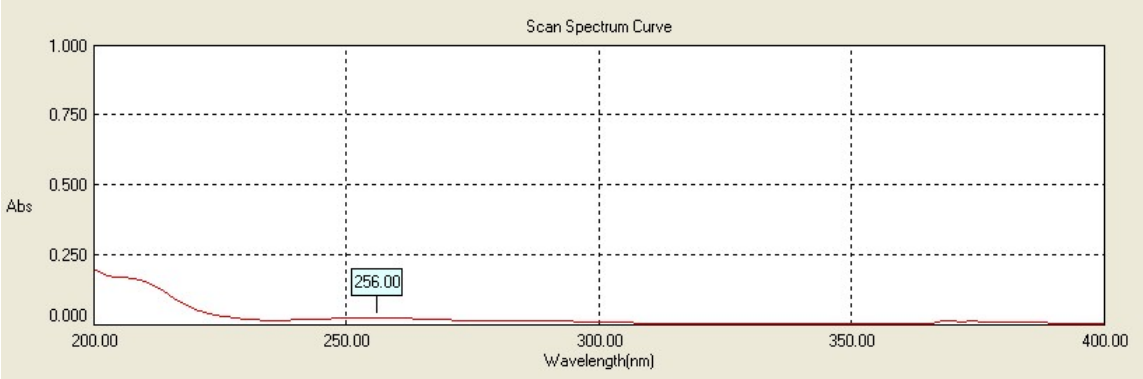

Figure 9: Spectrum showing linearity level -2(10µg/ml)

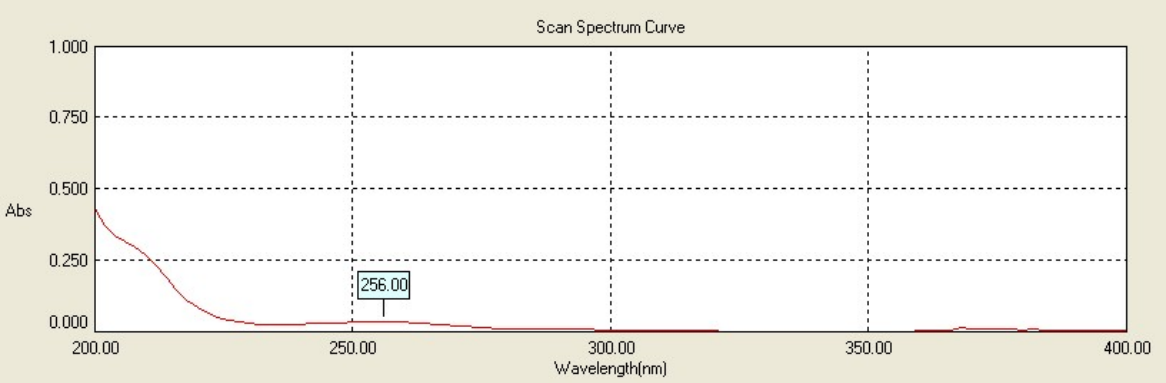

Figure 10: Spectrum showing linearity level -3(15µg/ml)

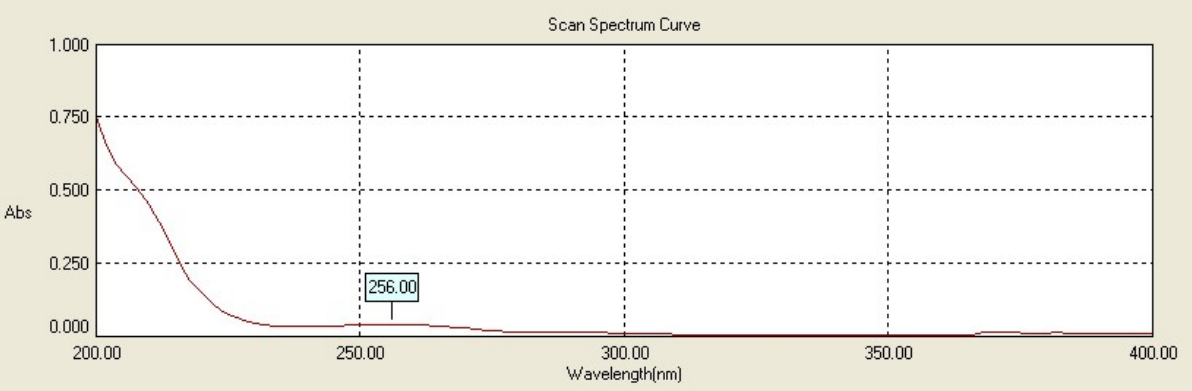

Figure 11: Spectrum showing linearity level -4(20µg/ml)

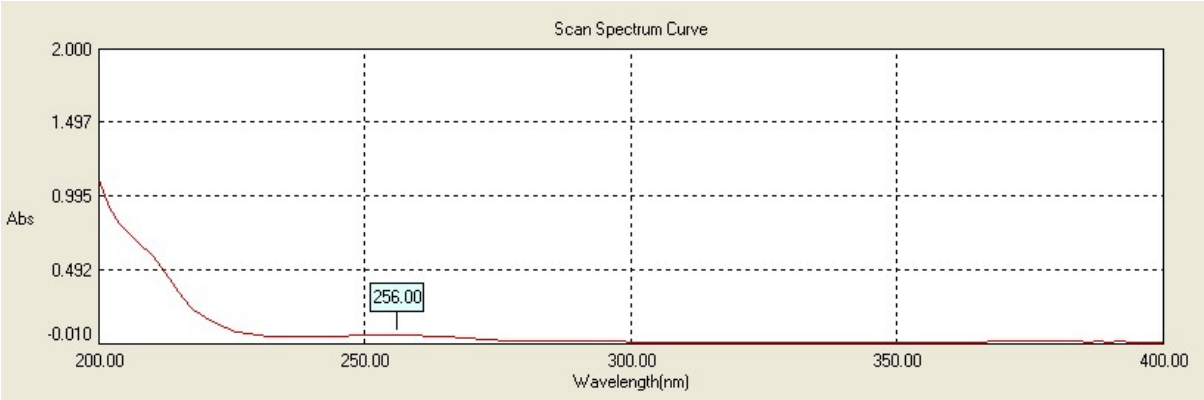

Figure 12: Spectrum showing linearity level -5(25µg/ml)

Standard deviation of intercept = Standard deviation error of intercept × √n

= 0.0068 × √5

= 0.0068×2.236

= 0.01520

Limits of detection

LOD = 3.3 × SD of Intercept/Slope

The LOD value was analysed by using the formula

= 3.3×0.015/0.0247

= 0.0495/ 0.0247

= 2.004µg/ml

Limits of Quantification

LOQ = 10 × SD of intercept/Slope

The LOQ value was analysed by using the formula

= 10×0.015/0.0247

= 0.15/0.0247

=6.072µg/ml

Linearity: The linearity for Palonosetron was determined by taking the concentration from 1-5 µg/ml for each solvent. The regression equation for water as solvent was found to be

$y = 0.0247x + 0.0039$, $R^2 = 0.9992$.

The main objective of the present research work is mainly focused on development of a novel, rapid, accurate, precise and UV- Spectrophotometric method by using an LABINDIA double beam UV-Visible Spectrophotometer. The analytical method was developed using water. The absorbance was measured Over a range 200-400nm and the λmax was found to be 256nm. The develop method obeyed beers lamberts law showing good linearity over a range of 5-25µg/ml. The developed method was found to be Accurate and precise showing good recovery value and having %RSD with in the acceptance criteria. Thus, the developed method can be used routinely for quality control analysis of palonosetron drug.

CONCLUSION

A simple, rapid, precise and accurate UV-Spectrophotometric method was developed &

validated for the estimation of palonosetron in bulk and pharmaceutical dosage forms. All the validation parameters were found to be within the acceptance criteria. Thus, the present developed method can be applied for routine quality control analysis.

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