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## Review on Spectrophotometric Determination of Fimasartan in Pharmaceutical Dosage Form



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### ABSTRACT

A simple, precise, accurate, cost-effective stability-indicating UV-visible spectrophotometric method has been developed for estimation of fimasartan in bulk and tablet dosage form. Fimasartan shows the highest  $\lambda$ -max at 475nm. Beer's law (linearity response) was found over a concentration range 50-250 mg/ml with good correlation coefficient ( $r^2=0.998$ ). The detection limit (DL) & quantification limit (QL) were found to be 0.286 $\mu$ g/ml and 0.869  $\mu$ g/ml respectively. The result of fimasartan recovery analysis were found to be 97.54 $\pm$ 0.001 to 99.95 $\pm$ 0.001. The proposed spectrophotometric method was validated as per ICH Q1A (R2) guidelines. While estimating the fimasartan in tablet formulation, there was no interference of additives & excipients. Hence this method can be safely being employed for the routine quality control analysis of fimasartan in bulk and tablet dosage form.



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## INTRODUCTION

### SPECTROSCOPY

Spectroscopy is perhaps the most amazing asset accessible for the investigation of nuclear and sub-atomic design and is utilized in the examination of a wide scope of tests. Spectroscopy and its applications structure a critical piece of present-day science and physics. Spectroscopy is the investigation of the assimilation of electromagnetic radiation or ultrasonic waves through electron changes between electronic energy levels. Spectroscopic procedures incorporate low-goal atomic attractive reverberation spectroscopy, bright noticeable spectroscopy, infrared spectroscopy, ultrasonic spectroscopy, microwave spectroscopy, nuclear spectroscopy, and so on<sup>1</sup>.

### UV-VISIBLE SPECTROSCOPY

UV-apparent spectroscopy is worried with the investigation of ingestion of noticeable radiation whose frequency goes from 200nm-800nm. The frequency at which the most extreme ingestion of radiation happens is called  $\lambda_{max}$ . This  $\lambda_{max}$  is trademark for each shaded substance and is the subjective angle.  $\lambda_{max}$  isn't impacted by the convergence of substances.

UV spectrophotometry is one of the most often utilized methods in drug examination. It includes estimating how much bright or noticeable radiation consumed by a substance in arrangement. An instrument that estimates the proportion, or capacity of proportion, of the force of two light emissions in the UV area are called UV spectrophotometers. In subjective examination, natural mixtures can be recognized by the utilization of spectrophotometer, assuming that any recorded information is accessible, and quantitative spectrophotometric investigation is utilized to find out the amount of atomic species engrossing the radiation<sup>6</sup>. Spectrophotometric method is basic, fast, modestly unambiguous and appropriate to little amounts of mixtures. The principal regulation that administers the quantitative spectrophotometric examination is the Beer-Lambert regulation.

The frequency scope of UV radiation begins at the blue finish of the noticeable light (around 4000 A°) and closes at 2000A°. The bright locale is partitioned into two ghastly areas.

- 1) The locale between 2000-4000 A° is known as close to a bright area, and
- 2) The area under 2000 A° is known as the far or vacuum bright district.

Frequencies in the bright district are typically communicated in nanometres (1 nm  $10^{-7}$ cm) or angstroms ( $\text{A}^\circ$ ) (1 A- $10^{-8}$  cm.) Occasionally, retention is accounted for in wavenumbers ( $\nu = \text{cm}^{-1}$ ).

UV radiation has adequate energy to energize valence electrons in numerous particles of atoms thus, UV is engaged with electronic excitation. Spectroscopically, apparent light demonstrations similar as UV light; henceforth it is by and large thought about piece of the electronic excitation locale. Therefore, we observe that business UV hardware frequently works with frequencies somewhere in the range of 800 and 200 nm<sup>2</sup>.

Lager's regulation: It expresses that the force of a light emission monochromatic radiation diminishes dramatically with the number of engrossing atoms. As such, absorbance is relative to the focus.

Lambert's regulation: It expresses that the power of a light emission monochromatic radiation diminishes dramatically as it goes through a mode of homogeneous thickness. A mix of these two regulations yields the Beer-Lambert regulation.

Brew Lambert regulation: When light emission is gone through a straightforward cell containing an answer of an engrossing substance, a decrease of the power of light might happen. Numerically, Beer-Lambert regulation is communicated as  $A = a b c$  Where  $A = \text{absorbance or optical thickness}$

$a = \text{absorptivity or annihilation coefficient}$

$b = \text{path length of radiation through example (cm)}$

$c = \text{concentration of solute in arrangement}$

Both  $b$  and  $a$  are consistent so  $a$  is straightforwardly corresponding to the focus  $c$  When  $c$  is in gm/100 ml, then, at that point, the steady is known as  $A$  (1%, 1 cm).

$$A = A (1\%/1\text{cm}) b c$$

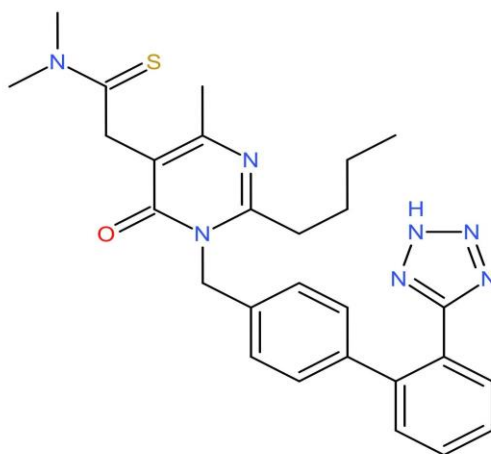
Evaluation of therapeutic substance involving spectrophotometer may did by getting ready arrangement in straightforward dissolvable and estimating its absorbance at appropriate frequency The frequency ordinarily chose is the frequency of most extreme ingestion ( $\lambda_{\text{max}}$ ), where little blunder in setting the frequency scale significantly affects estimated absorbance<sup>3</sup>.

**Table 1: Regions of the electromagnetic spectrum**

Region	Wavelength
Far ultraviolet	10-200 nm
Near ultraviolet	200-400nm
Visible	400-750 nm
Near infrared	0.75 -2.2 $\mu\text{m}$
Mid infrared	2.5-50 $\mu\text{m}$
Far infrared	50-1000 $\mu\text{m}$

## INTRODUCTION TO FIMASARTAN

Fimasartan is a non-peptide angiotensin II receptor antagonist utilized for the treatment of hypertension and cardiovascular breakdown. Through oral organization, fimasartan blocks angiotensin II receptor type 1 (AT1 receptors), decreasing prohypertensive activities of angiotensin II, like foundational vasoconstriction and water maintenance by the kidneys. The simultaneous organization of fimasartan with diuretic hydrochlorothiazide has been demonstrated to be protected in clinical preliminaries. Fimasartan is being advertised in India under the brand name of Fimanta and Fimagen through Ajanta Pharma Ltd<sup>4</sup>.



2-[2-butyl-4-methyl-6-oxo-1-[[4-[2-(2H-tetrazol-5-yl) phenyl] phenyl] methyl] pyrimidin-5-yl]-N, N- dimethylethanethioamide.

## **MECHANISM OF ACTION**

Fimasartan follows up on the kidney's renin-angiotensin overflow, which starts when renin discharge from the kidney causes the breakdown of angiotensinogen into angiotensin I. Angiotensin-changing over a catalyst (ACE) then catalyzes the response that structures angiotensin II, which follows up on AT1 receptors on the veins, heart, and kidneys. On veins, the AT1 receptor is coupled to an intracellular pathway that causes vasoconstriction of veins. In obstructing the AT1 receptor, fimasartan restrains vasoconstriction, inclining toward vasodilation. ARBs like fimasartan have additionally been demonstrated to be defensive against stroke, myocardial localized necrosis, and cardiovascular breakdown.

## **PHARMACOLOGICAL ACTION**

Fimasartan is quickly consumed and has a negligible collection in the body 7 days after organization. Fimasartan has a half-existence of 9 to 16 hours, proper for day-to-day dosing. Fimasartan was viewed as successful in abstained or taking care of states, with an assortment of dosing regimens. Fimasartan was found generally in unmetabolized structure in the plasma and in bile discharges. Urinary disposal of the medication was low, at under 3% 24 hours after organization, involving that the fimasartan doesn't go through renal discharge.

## **METHOD VALIDATION**

Validation is concerned with assuring that a measurement process produces valid measurements. Results from method validation can be used to judge the quality, reliability, and consistency of analytical results. It is an integral part of any good analytical practice. A measurement process producing valid measurements for an intended application is fit for purpose. Analytical methods need to be validated or revalidated, before their introduction into routine use; whenever the conditions change for which the method has been validated.

## **ICH guidelines (ICH Q2R1) for analytical procedure and validation**

The insightful strategy alludes to the approach to playing out the investigation. It ought to depict exhaustively the means important to play out each scientific test. This might incorporate yet isn't restricted to: the example, the reference standard and the reagents arrangements, utilization of the contraption, age of the adjustment bend, and utilization of the equation for the computation.

- Accuracy
- Precision
- Repeatability
- Specificity
- Linearity
- Range
- Robustness
- Ruggedness

### **AIM AND OBJECTIVE**

Drug discharge number of logical techniques, basic and financial UV-spectroscopic to be created for mass medication and plan. This work manages the approval of the created strategy for the examination of Fimasartan from its dose structure (tablets). Henceforth, the technique can be utilized for routine quality control investigation and steadiness. The point and extent of the proposed work are as under:

- To create an appropriate spectrophotometric technique for the examination of Fimasartan tablet.
- Play out the approval for the strategy.

### **MATERIALS AND METHODS**

- Fimasartan standard was provided by Ajanta Pharma Pvt. Ltd. (India). Fimagen tablets containing Fimasartan 60 mg were procured from market.
- Methanol
- 2,4-Dinitrophenylhydrazine reagent
- 0.1 M Hydrochloric acid
- Distilled water

## **INSTRUMENTS**

- Systonics double beam UV-visible spectrophotometer (model number:2022)
- Electronic balance (model number:30D)

## **OPTIMISATION OF ANALYTICAL PARAMETERS**

### **SELECTION OF CONCENTRATION OF 0.1M HCl**

- Add 0.1, 0.2, 0.3,0.4,0.5ml reagent into 5 different standard volumetric flask which already contain 8ml stock solution and 0.3ml DNPH. Scanned in 400-800 nm range using UV-visible spectrophotometer.
- The selected peak is shown in 0.4ml 0.1M HCl solution containing the sample. The result shown in table -1 and figure-1.

### **SELECTION OF CONCENTRATION OF 2,4 DINITROPHENYLHYDRAZINE**

- Add 0.1,0.2,0.3,0.4,0.5ml reagent into 5 different volumetric flasks. which is already containing 8ml stock solution and 1 ml 0.1M HCl. Scan in 400-800 nm range using UV-visible spectrophotometer.
- Selected peak shows in 0.3 dye solution containing sample. Result shown in table-2 and figure- 2.

## **PREPARATION OF 2,4 DINITROPHENYLHYDRAZINE REAGENT**

Preparation of 0.5% (w/v) DNPH solution Accurately weighed 250 mg of DNPH in a 50 ml volumetric flask, added 20 ml of methanol swirled to mix then the solution made up to the mark with methanol.

## **PREPARATION OF STANDARD SOLUTION**

- A standard stock solution of fimasartan was prepared by using methanol.
- Made suitable dilutions to get a concentration range of 50,100,150,200 and 250 µg/mlg/ml.
- An amount of 0.3ml DNPH reagent and 0.4ml 0.1M HCl was added to each volumetric flask.

- Read the absorbance at 475nm
- Plot the graph of concentration (vs) absorbance.

### **SELECTION OF WAVELENGTH**

- Scan 50 µg/ml sample solution in the wavelength range of 400-800 nm.

### **PREPARATION OF SAMPLE SOLUTION**

Precisely weighed ten tablets of 60 mg fimasartan and normal weight was determined. Amount comparable to 100 mg of tablet powder is gauged precisely and moved to 100 ml volumetric carafe. The example powder was broken down in methanol and made up to 100 ml with methanol. 10 ml of the resultant arrangement is pipetted out into another 100 ml volumetric jar and 3 ml of DNPH reagent and 4 ml of 0.1M HCl were added and blended completely. What's more, cosmetics the volume with methanol. Blend well and channel. The absorbance of the resultant arrangement is estimated at 475 nm.

### **METHOD VALIDATION**

#### **Linearity**

The linearity of a logical technique is its capacity to evoke test results that are straightforwardly correspond to the convergence of analyte in the example inside a given reach. Suitable aliquots arrangements were pipetted out from the standard stock arrangement into a progression of 10 mL volumetric carafes with adding 0.1m HCl and 2,4 dinitrophenylhydrazine. The volume was left up to the imprint with methanol to get a fixation going from 50,100,150,200 and 250 µg/ml. The absorbance of the above arrangements was estimated at 475nm. An adjustment chart of focus versus absorbance was laid out. Linearity conclusions were conveyed and the information got was broke down measurably. An adjustment chart of fixation versus absorbance was laid out. Linearity concentrates on displayed in Table and figure.

#### **Precision**

An intraday study, the grouping of imitates of medication was determined around the same time multiple times. In between day concentrate on the grouping of medication was determined on three progressive days which communicates the research centre variety in



various days. In both intra and bury day accuracy study for the techniques %RSD was determined. Accuracy concentrates on displayed in table and Table.

### **Accuracy**

Recovery studies were performed by applying the standard addition method. To a known amount of the pre-analysed drug sample, an 80 %, 100 %, and 120 % of standard drug substance was added and suitably diluted. The absorbances of the resultant solutions were measured at 475 nm. The amount recovered was determined by fitting the absorbance values in the calibration graph. The results of the accuracy studies are shown in Table.

### **Ruggedness**

Ruggedness is still up in the air between two sections or two examiners or two instruments. Strategy: Both the norm as well as the example of a similar fixation (50 µg/ml of Fimasartan) was ready and dissected by two examiners and between two instruments. Roughness concentrates on displayed in Table.

### **Limit of detection and quantification**

Limit of detection and quantification was resolved given the standard deviation of y captures of the relapse line. The standard deviation of y catches got from the five estimations (n=5) was fill in for  $\sigma$  in the identification of condition  $3.3 \sigma/S$ , and Quantification of condition  $10 \sigma/S$ , and S is the mean incline of the three-adjustment bends. The outcomes are given in table.

### **Robustness**

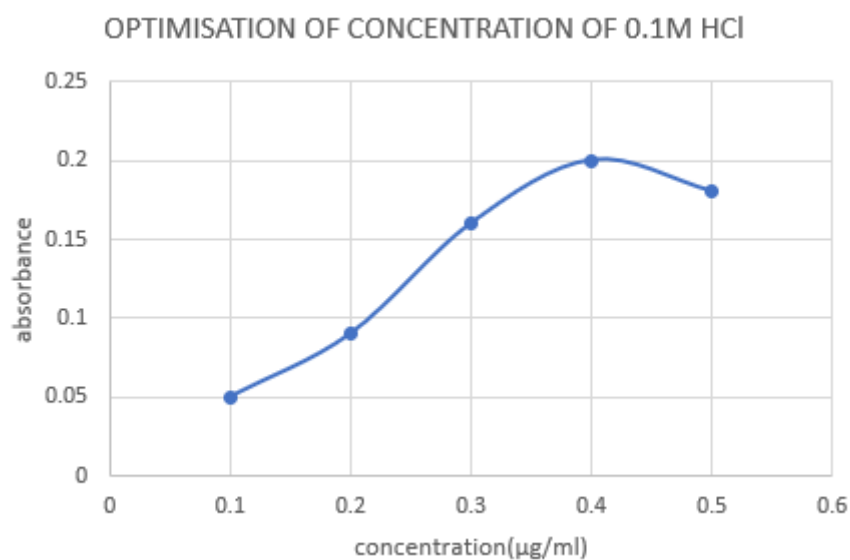
The conspicuous piece of strength is to foster techniques that consider unsurprising varieties in the detachment boundaries. For the assessment of strategy strength, boundaries, for example, variety in locator frequency shift inside an exact reach and the quantitative impact of the still up in the air. The investigation showed % RSD under two which demonstrates that the strategy laid out is vigorous, concentrated on displayed in table.

**RESULT AND DISCUSSIONS**

**SELECTION OF CONCENTRATION OF 0.1M HCl**

**Table:2-selection of concentration of HCl**

concentration	absorbance
0.1	0.05
0.2	0.09
0.3	0.16
0.4	0.2
0.5	0.18

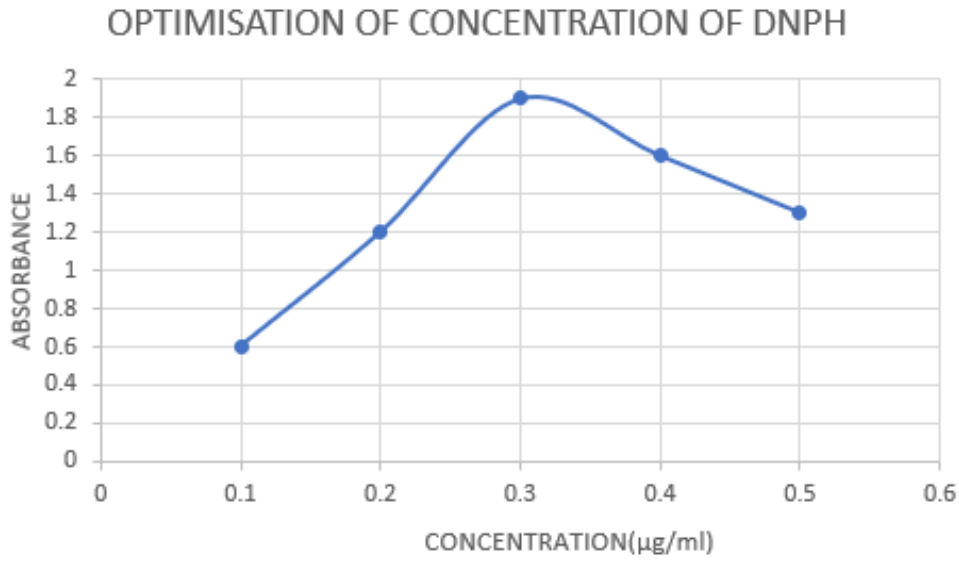


**Figure :1-slection of concentration of HCl**

**SELECTION OF CONCENTRATION OF 2,4-DNPH**

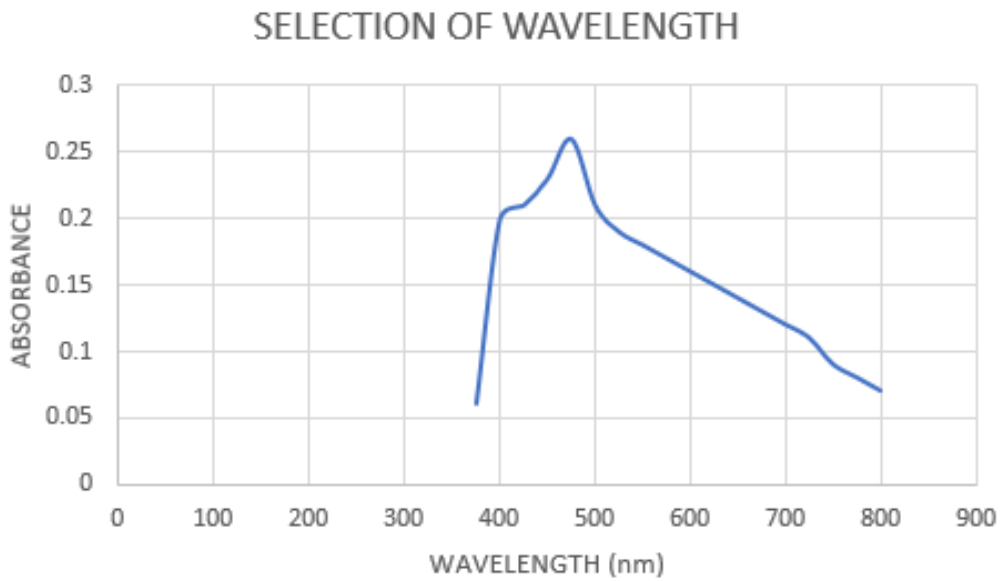
**Table:3-selection of concentration of 2,4-DNPH**

concentration (µg/ml) g/m) l	absorbance
0.1	0.6
0.2	1.2
0.3	1.9
0.4	1.6
0.5	1.3



**Figure: 2-selection of concentration of DNPH**

### SELECTION OF WAVELENGTH



**Figure:3-selection of wavelength**

METHOD VALIDATION

Linearity

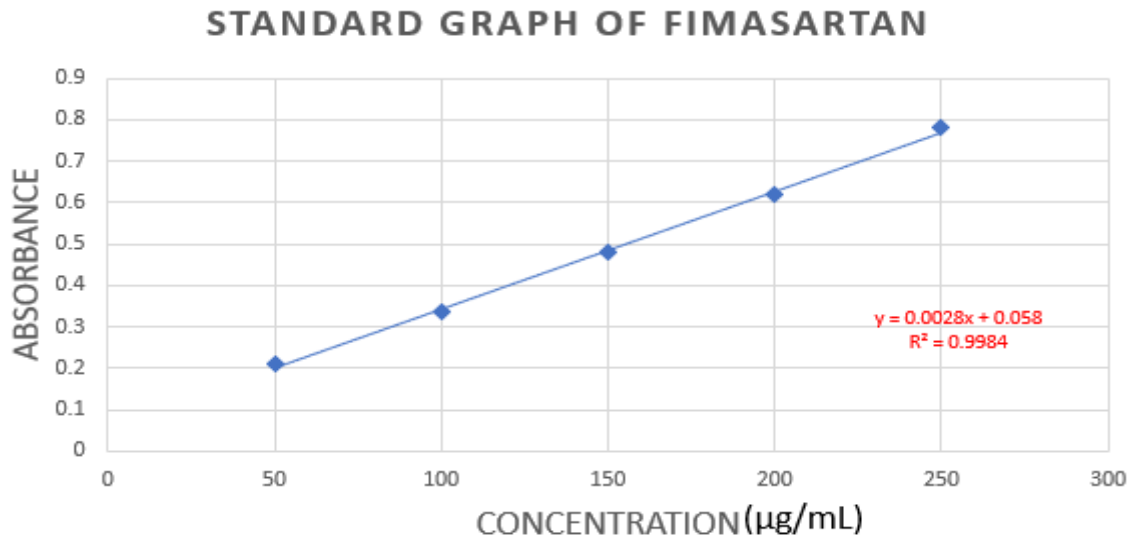


Figure:4- standard graph of fimasartan

Table 4- result of linearity

Concentration (µg/ml)	Absorbance
50	0.210
100	0.336
150	0.480
200	0.620
250	0.780

**Precision**

**Table:5-Results of method precision for intra-day precision**

Concentration( $\mu\text{g/ml}$ )	Absorbance	Mean absorbance $\pm$ S. D	% RSD (n=3)
50	0.210	0.209 $\pm$ 0.001	0.478
	0.209		
	0.208		
100	0.336	0.337 $\pm$ 0.001528	0.453
	0.339		
	0.337		
150	0.486	0.487 $\pm$ 0.002	0.4106
	0.484		
	0.488		

**Table:6-Results of method precision for inter-day precision**

Concentration( $\mu\text{g/ml}$ )	Absorbance	Mean absorbance $\pm$ S. D	% RSD (n=3)
50	0.209	0.209 $\pm$ 0.00152	0.0073
	0.211		
	0.208		
100	0.336	0.336 $\pm$ 0.0015	0.4532
	0.338		
	0.339		
150	0.487	0.486 $\pm$ 0.001	0.2057
	0.485		
	0.486		

**Table:7-Result of Accuracy data**

<b>%Recovery level</b>	<b>% Recovery</b>	<b>Mean % recovery</b>	<b>SD</b>	<b>%RSD</b>
80%	97.43 97.55 97.64	97.54	0.1053	0.108
100%	98.76 98.74 98.77	98.75	0.0152	0.015
120%	101.4 99.23 99.22	99.95	1.255	1.256

**Table:8-Result of Ruggedness data**

<b>Parameter</b>	<b>Analyst-1</b>	<b>Analyst-2</b>	<b>Instrument 1</b>	<b>Instrument 2</b>
Mean	0.209	0.210	0.209	0.210
SD	0.001	0.001	0.0015	0.001
%RSD	0.478	0.476	0.725	0.478

**Table:9-ResultLimit of detection and quantification data**

<b>Standard</b>	<b>LOD (µg/mL)</b>	<b>LOQ (µg/mL)</b>
Fimasartan	0.286	0.869

**Table:10-Result of Robustness data**

Parameter	$\lambda$ max 1	$\lambda$ max 2
Mean	0.210	0.209
SD	0.001	0.001
%RSD (N=5)	0.476	0.725

**Table:11-Result of Optical Characteristics**

Parameters	Results
Detection wavelength ( $\lambda$ max)	475nm
Regression equation ( $Y = mx + c$ ): Slope (b)	$Y=0.0028x+0.058$
The standard deviation of slope	0.0243
Intercept (a)	0.0028
Standard error (SE)	0.010886
Correlation coefficient ( $r^2$ )	0.998
Beer's law limits( $\mu$ g/mL)	50-250 $\mu$ g/mL

In this proposed method, the spectral absorbances of Fimasartan were measured against Methanol as a solvent blank at 475nm. Fimasartan obeyed Beer-Lambert's law in the concentration range of 50-250  $\mu$ g/ml with a correlation coefficient ( $r^2$ ) of 0.998. The accuracy of the method was confirmed by the recovery studies, by adding a known amount of the pure drug to the formulation and the percentage recovery was found to be between 97.54

to 99.95 % w/w, indicating that the developed method is accurate which indicates a good accuracy of the method and it shows that the method was free from the interference of excipients used in the formulation. The precision of the method was reported in terms of the relative standard deviation and it should be evaluated by using a minimum of 5 determinations over 100 % concentration which shows % RSD less than 2 indicates that the method was precise. All the results were found to be within the limits and therefore the proposed method was found to be free from interferences due to excipients in the tablet dosage form.

## CONCLUSION

- The writing audit uncovers that there were no UV-apparent spectroscopic techniques revealed for fimasartan.
- A basic, touchy, quick and financial UV-apparent spectroscopy technique was created and approved for the measure of Fimasartan in unadulterated and drug dose structures. This strategy created high recuperation with great linearity and accuracy. In this manner, the created strategy for Fimasartan was viewed as straightforward, exact, precise and practical and in undeniable reality plausible for routine example examination of Fimasartan in drug measurement structures.

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