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Stability indicating UV-spectrophotometric method development and validation of iguratimod

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Abstract
In this study, a novel UV-spectrophotometric method was developed and validated for the quantitative estimation of Iguratimod in bulk and tablet formulations using zero-order and first-order derivative techniques. The method demonstrated simplicity, precision, and accuracy. A 10 µg/ml Iguratimod solution was prepared and scanned within the UV range of 200-400 nm. Quantification was performed at 258 nm for the zero-order and 270 nm for the first-order derivative method. Linearity was observed over 2-10 µg/ml ($R^2 = 0.9997$) for zero-order and 5-25 µg/mL ($r^2 > 0.9998$) for first-order methods. The percentage recovery ranged from 99.52% to 100.66%, confirming accuracy. The LOD and LOQ were 0.4553 and 1.3799 µg/mL (zero-order) and 0.9443 and 2.8615 µg/mL (first-order), respectively. The validated method proved reliable, efficient, and suitable for routine quality control and quantitative analysis of Iguratimod in pharmaceutical dosage forms.

Keywords: Iguratimod, UV-visible spectrophotometric methods, method validation, quantitative analysis, forced degradation studies

Introduction
Pharmaceutical analysis is a key discipline within practical chemistry that focuses on identifying, quantifying, purifying, and characterizing chemical substances, along with separating the individual components of mixtures and determining their structural composition. These substances may exist either as pure compounds or as mixtures, formulated in various dosage forms. Validation of analytical methods forms the foundation of process validation, as a dependable measurement system is essential to confirm that a manufacturing process consistently performs as intended. Every newly established analytical technique must therefore be validated to ensure its precision, accuracy, and reliability. Among the various analytical tools available, spectrophotometric techniques are widely favored due to their simplicity, cost-effectiveness, and operational convenience when compared with advanced methods such as chromatography and electrophoresis [1-7].

Beer's and Lambert's law (BLL) [8] describes about relationship between the properties of medium where the light passes through is also known as the Beer-Lambert-Bouguer principle. BLL is popular because it is helpful in integrate the calculation system, explain proportional correlation between the detected light intensity and absorbance of the medium and it demands minimal computational effort power as compared with other models like diffusion approximation [9, 10].

Iguratimod (IGU) is an innovative synthetic low-molecular-weight disease-modifying anti-rheumatic drug, currently approved exclusively in Japan and China. [11]. IUPAC name for Iguratimod is N- [(formylamino)-4-oxo-6-phenoxy-4Hchromen7-yl] methane sulfoanamide [12].

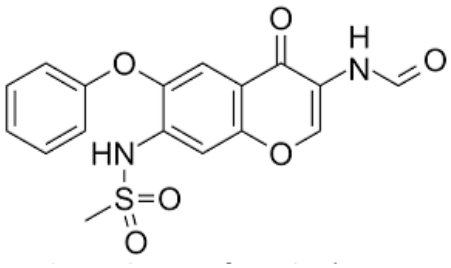

Fig 1: Chemical Structure of Iguratimod [12]

A review of the literature indicated the existence of a few analytical approaches for Iguratimod determination, including HPLC in rat plasma [13], HPLC in human plasma [14] and HPTLC [15] for both bulk drug and tablet formulations. In this study, a straightforward, cost-effective, and rapid spectrophotometric method was developed for the quantification of Iguratimod in bulk material and tablets. The proposed method was validated in terms of accuracy, precision, linearity, LOD, LOQ, and robustness. Therefore, the primary aim of this research was to develop and validate a simple UV-spectrophotometric method for the estimation of Iguratimod in bulk and tablet dosage forms in accordance with ICH guidelines.

Materials and Method

Experimental apparatus

Analysis carried out on Shimadzu double beam UV-Visible spectrophotometer (Model UV-1700) high scanning spectrophotometer (200-400nm) with spectral band width of 1 nm and Lab India 3000 double beam Ultra-Visible Spectrophotometer were used for all spectral measurements. Single pan electronic balance (Model Shimadzu AUX-220) for weighing purpose, sonication of the solutions was carried out using an Ultrasonic cleaner (2100 MH) and hot air oven InfraDIGI-250 ℃ were used for the study.

Chemicals and reagents

The reference standard of Iguratimod API was supplied as gift sample from Chennai. Tablet sample with label claim 25 mg per tablet were purchased from Medplus.
Chemicals such as 0.1 N H_2SO_4, 0.1 N KOH, HPLC grade water, 0.3% Hydrogen peroxide, 10% Sodium bisulfate.

UV- Spectrophotometry

Solvent system determination

The solubility profile of Iguratimod was evaluated across different solvents includes distilled water, ethanol, methanol, chloroform, acetone, dimethyl formamide, acetonitrile, 0.1 M Sodium hydroxide, 0.1 M Hydrochloric acid, petroleum ether, 0.1 N Sulfuric acid, 0.1 N Potassium Hydroxide, 0.3% Hydrogen peroxide and 10% Sodium bisulfate. From the study, the selected solvent was Methanol.

Selection of wavelength

The UV Spectrum of Iguratimod was analysed for zero order and first order derivative method. The maximum absorbance for zero order method was 258 nm and for first order derivative was 270 nm. These selected wavelengths ensure precise and accurate quantification for Iguratimod.

Preparation of Reference Stock Solution:

Reference stock solution of Iguratimod (1000 µg/ml) was obtained by dissolving 25 mg of Iguratimod in 25 ml of methanol.

Method 1: Zero Order Method

Preparation of working stock solution

From the prepared stock, 2 ml was pipetted into a 10 mL flask and diluted with solvent to achieve 200 µg/ml.

Selection of wavelength

A working solution of Iguratimod (10 µg/ml) was prepared from the stock solution and scanned over the UV range of 200-400 nm. Based on the obtained spectra, 258 nm was selected as the analytical wavelength for quantification. Various standard concentrations of Iguratimod were prepared in 10 ml volumetric flasks by accurately transferring appropriate volumes of the working solution and diluting to the mark with methanol. These solutions were scanned in spectrum mode within 200-400 nm. Absorbance data from the zero-order spectra at 258 nm were recorded, and a calibration curve was constructed for Iguratimod over the concentration range of 2-10 µg/ml.

Method 2: First Order Derivative Method

Preparation of working stock solution

From the Reference stock solution, 1 ml was pipetted and transferred into 10 ml volumetric flask to getting the concentration 100 µg/ml.

Selection of wavelength

In this method, a 10 µg/ml solution of Iguratimod was prepared from the working stock solution, diluted with methanol, and scanned in spectrum mode over the 200-400 nm range. Based on the obtained spectra, 270 nm was selected as the analytical wavelength. Various standard concentrations of Iguratimod were prepared in 10 ml volumetric flasks by accurately transferring measured volumes of the working solution and diluting to the mark with methanol. These solutions were scanned in spectrum mode across 200-400 nm, and absorbance values from the first-order derivative spectra at 270 nm were recorded. A calibration curve for Iguratimod was then constructed over the concentration range of 5-25 µg/ml.

Quantification of Tablets

Twenty tablets were accurately weighed, powdered, and an amount equivalent to 25 mg of Iguratimod was transferred into a 25 ml volumetric flask. The powder was dissolved in methanol and sonicated for 15 minutes, followed by shaking and dilution to the mark with methanol. The resulting solution was filtered through Whatman filter paper. From this stock solution, 2 ml was pipetted into a 10 ml volumetric flask and diluted with methanol. Subsequently, 0.2 ml of this solution was transferred to another 10 ml volumetric flask and diluted to the mark with methanol to obtain a final concentration of 4 µg/ml, which was used for the zero-order method, with absorbance measured at 258 nm.
For the first-order derivative method, 1 ml of the original stock solution was pipetted into a 10 ml volumetric flask and diluted with methanol. From this solution, 1 ml was further transferred to another 10 ml volumetric flask and diluted with methanol to obtain a 10 µg/ml solution. The spectra were recorded and measurements were taken at 270 nm for Iguratimod

Analytical Procedure Validation [16]

The Developed Analytical Method was Validated as per the ICH guidelines, which includes the parameters such as Linearity, Precision, Accuracy, Repeatability, Limit of Detection and Limit of Quantification.

Linearity studies

Determination of Five points calibration curve for Iguratimod were obtained from the working stock solutions 200 µg/ml (Zero order) and 100 µg/ml (First order).
For zero order method, 0.1, 0.2, 0.3, 0.4 & 0.5 ml was

pipetted from the 200 µg/ml stock, which was transferred into five 10 mL volumetric flasks and adjusted to the final volume using methanol to achieve the desired concentrations 2, 4, 6, 8 & 10 µg/ml solutions. The absorbance of these five concentrations were measured at 258 nm.

For First order derivative method, 0.5, 1, 1.5, 2 & 2.5 ml were pipetted drawn from the 100 µg/ml reference solution, which was individually transferred into five 10 mL volumetric flasks and diluted to the mark with methanol to achieve the desired concentrations 5, 10, 15, 20 & 25 µg/ml solutions. The absorbance values for these concentrations were determined at 270 nm.

Precision

Precision was evaluated in terms of both intraday and interday variability. Iguratimod solutions at concentrations of 4 µg/ml and 10 µg/ml were analyzed six times each for the zero-order and first-order derivative methods, respectively. For intraday precision, the two concentrations were assessed six times within the same day, whereas interday precision was determined by analyzing the same concentrations over six consecutive days.

Accuracy

Accuracy of the zero-order and first-order methods was assessed at three levels: 50%, 100%, and 150%. Known amounts of standard Iguratimod were spiked into pre-analyzed sample solutions at each level. The absorbance was measured and recorded at 258 nm for the zero-order method and 270 nm for the first-order method.

Limit of Detection and Limit of Quantification

Various approaches exist for the determination of LOD and LOQ, depending on whether the analytical method is instrumental or non-instrumental. In this study, the LOD and LOQ were calculated using the following equations:

$$LOD = \frac{3.3 \times \text{Standard deviation}}{\text{Slope}}$$

$$LOQ = \frac{10 \times \text{Standard deviation}}{\text{Slope}}$$

Ruggedness

The ruggedness of the proposed method was assessed using 4 µg/mL (zero-order) and 10 µg/mL (first-order) Iguratimod solutions. The analyses were performed on aliquots from a uniform batch by two different analysts under varied operational and environmental conditions.

Forced Degradation Studies [17, 24]

Stability studies are conducted to evaluate the appropriate storage conditions and shelf life of a pharmaceutical product. According to the Committee for Proprietary Medicinal Products (CPMP) guidelines, these studies assess how the quality of the drug substance or drug product changes over time under various environmental conditions. [17, 18]

Forced degradation studies, also referred to as stress testing, involve assessing the stability of drug substances and drug products under conditions more severe than those used in accelerated stability studies [19]. Such studies aid in the identification of degradation products, providing insights into the drug's degradation pathways and inherent stability. Additionally, they help in demonstrating the stability-indicating capability of analytical methods, in accordance with ICH guidelines on stability testing [20]. In this study, Iguratimod was subjected to various stress conditions, including acidic, basic, hydrolytic, oxidative, reductive, photolytic, thermal, and UV light exposure.

For stress testing, Iguratimod's working stock solution concentration (200 µg/ml) was utilized.

Acid Degradation [21]

1 ml of 0.1 N sulfuric acid was added to a 10 ml clean volumetric flask from that 0.2 ml of the working stock solution had been pipetted out. After allowing the mixture to degrade for 24 hours, 1 ml of 0.1N KOH was added to neutralize the solution. After adding methanol to get the volume up to volume, the sample's absorbance was measured at 258 nm.

Base Degradation [21]

A 10 ml clean volumetric flask was filled with 0.2 ml of stock solution in order to measure the alkaline degradation of Iguratimod. 1 ml of 0.1N KOH was added to cause forced degradation, and the mixture was let to stand for 24 hours. 1 ml of 0.1 N sulfuric acid was then used to neutralize the solution, and methanol was added to bring it up to volume. At 258 nm, the sample's absorbance was measured.

Hydrolytic Degradation Studies [22]

In order to perform hydrolytic degradation, 0.2 ml of the stock solution was placed into a 10 ml clean volumetric flask. 3 ml of HPLC-grade water were then added to start the forced degradation process. After a 24-hour rest, the solution was diluted with methanol. After that, 1 ml of the solution was pipetted into a 10 ml volumetric flask, and methanol was added to bring it up to volume. At 258 nm, the sample's UV absorbance was measured.

Oxidative degradation Studies [23]

A 10 ml clean volumetric flask containing 0.2 ml of stock solution was filled with 1 ml of 0.3% hydrogen peroxide to induce degradation in order to assess oxidative degradation. After letting the combination rest for a full day, it was properly mixed and diluted with methanol as needed. At 258 nm, the sample's absorbance was measured.

Reduction Degradation Studies [22]

0.2 ml of the stock solution was pipetted into a 10 ml clean volumetric flask for the reduction degradation investigations. By adding 1 ml of 10% sodium bisulfate, forced degradation study were started. After being undisturbed for twenty-four hours, the mixture was diluted with methanol. The sample's absorbance was measured at 258 nm.

Photolytic Degradation Studies [24]

Iguratimod was weighed and left in the sunlight for 4 hours. After the exposure, 200 µg/ml was made, 0.2 ml of the stock solution was put into a 10 ml clean volumetric flask, and methanol was added to dilute the sample to the appropriate level. At 258 nm, the sample's UV absorbance was measured.

Thermal Degradation Studies [24]

A quantity of Iguratimod that had been weighed was dried for 24 hours at 70°C. 0.2 ml of a prepared 200 µg/ml stock solution was pipetted into a 10 ml clean volumetric flask, and the sample was diluted with methanol until it reached the desired concentration. The sample's absorbance was measured at 258 nm.

UV Degradation Studies [24]

A weighed amount of the standard was exposed to UV radiation for 24 hours. 0.2 ml of the resultant sample solution was diluted with methanol and then transferred into a 10 ml clean volumetric flask. The sample solution's absorbance was measured at 258 nm.

Results and Discussion

The method was validated in accordance with the stringent criteria for the validation of analytical techniques for the determination of linearity, precision, accuracy, LOD, LOQ, and ruggedness set forth by the International Conference on Harmonization (ICH). The spectrum of Iguratimod for zero order and first order derivative were shown in Figure 2 & 4.

Method 1: Zero order method

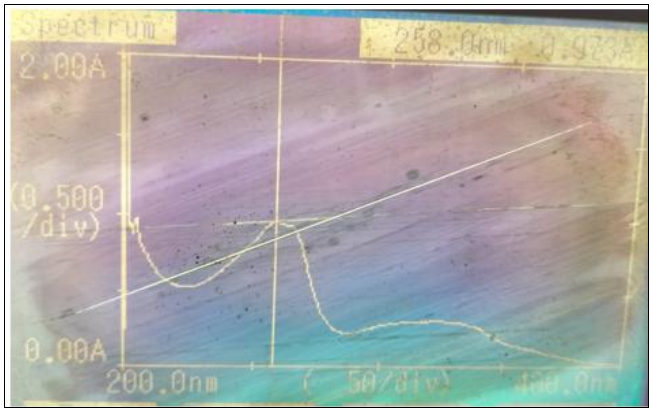

Fig 2: Zero order spectrum of Iguratimod at 258 nm

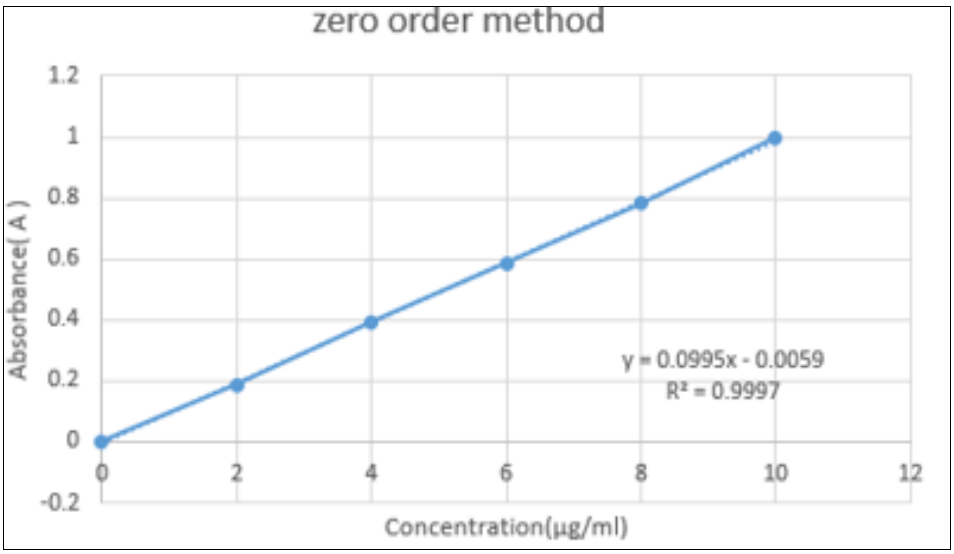

Fig 3: Calibration curve of Iguratimod (2-10 µg/ml)

Method 2: First order derivative method

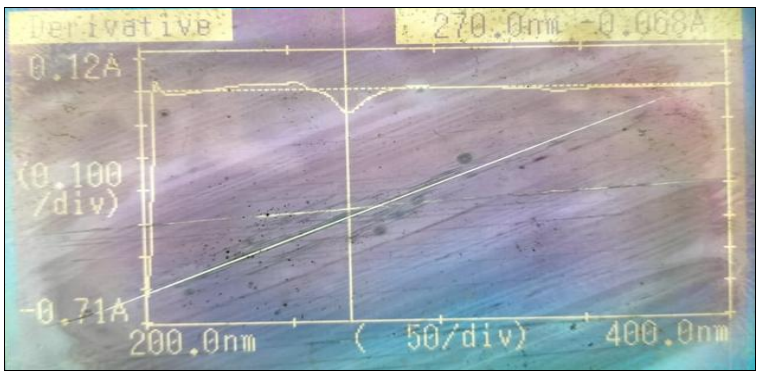

Fig 4: First order derivative spectrum of Iguratimod at 270 nm

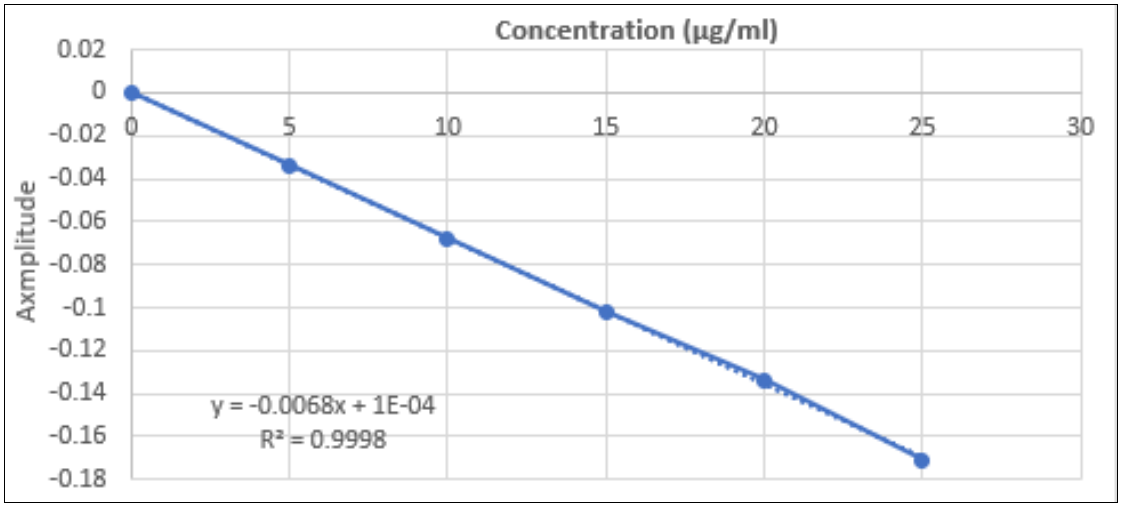

Fig 5: Calibration curve of Iguratimod (5-25 µg/ml)

Table 1: Optical Characterisation of Iguratimod

Parameters	Zero order method - Iguratimod (258nm)	First order derivative method- Iguratimod (270 nm)
Regression equation(Y=mx+c)	Y= 0.0995x-0.0059	Y= -0.0068x+0.0001
Slope (m)	0.0995	-0.0068
Intercept (c)	-0.0059	0.0001
Correlation coefficient (R^2)	0.9997	0.9998

Linearity

The calibration curve was linear across the concentration ranges of 2-10 µg/ml for the Zero order method and 5-25 µg/ml for the First order method, according to the regression data which was shown in Figure 3 & 5.

Table 2: Linearity table

Method	Concentration	Wavelength	R^2
Zero order method	2-10 µg/ml	258 nm	0.9997
First order Derivative method	5-25 µg/ml	270 nm	0.9998

Precision

The results obtained from method-1 and method-2 for repeatability in terms of% RSD should be < 2 precise characteristics of the developed analytical method. The results shown in Table 3.

Table 3: Quantification of Iguratimod Formulation

Methods	Sample number	Label claim (mg/tab)	Amount present (mg/tab)	% purity	Mean purity* (%w/v)	SD	%RSD
Zero order method	1	25	25.05	100.20	100.70	0.4313	0.4283
	2	25	25.29	101.16			
	3	25	25.30	101.20			
	4	25	25.19	100.76			
	5	25	25.06	100.24			
	6	25	25.16	100.64			
First order derivative method	1	25	25.04	100.16	100.44	0.8152	0.8116
	2	25	25.20	100.80			
	3	25	24.82	99.28			
	4	25	24.99	99.96			
	5	25	25.22	100.88			
	6	25	25.40	101.60			

For Intraday and Interday precision studies carried for the replicates of the concentrations 4 µg/ml (zero order) and 10 µg/ml (first order). The results of intraday and interday precision was shown in Table 4.

Table 4: Intraday and Interday of Iguratimod Formulation

Methods	Sample number	Label claim (mg/tab)	% purity (%w/v)		SD		% RSD	
			Intraday	Interday	Intraday	Interday	Intraday	Interday
Zero Order Method	1	25	100.04	99.56	0.3782	0.8098	0.3767	0.8054
	2	25	100.02	100.20				
	3	25	100.76	100.96				
	4	25	100.92	101.32				
	5	25	100.20	101.44				

	6	25	100.44	99.76				
First Order Derivative Method	1 2 3 4 5 6	25 25 25 25 25 25	101.60 100.76 100.88 101.48 100.20 99.28	99.40 99.28 100.88 100.08 99.96 99.28	0.8626	0.6277	0.8566	0.6288

Accuracy (Recovery study)

Accuracy was determined for three different phases i.e. 50%, 100% 150%. The percentage recovery (%) was three levels shown in Table 5.

Table 5: Accuracy (Recovery Study)

Methods	% Conc	Sample Amount (µg/ml)	Amount spiked (µg/ml)	Estimated Amount* (µg/ml)	Recovered Amount* (µg/ml)	Average% recovery*	SD*	%RSD*
Zero Order Method	50	4.00	2	6.01	2.01	100.50	1.0000	0.9950
	100	4.00	4	7.98	3.98	99.50	0.3813	0.3834
	150	4.00	6	10.04	6.04	100.66	0.3350	0.3328
First Order Method	50	10.00	5	14.976	4.976	99.52	1.1547	1.1601
	100	10.00	10	20.06	10.06	100.60	0.8660	0.8608
	150	10.00	15	24.96	14.96	99.73	1.1547	1.1579

*Mean of 3 observations

LOD & LOQ

The average of the absorbance standard deviation and "S, " or the slope of the corresponding calibration curve, are used to determine the LOD and LOQ.

Table 6: Limit of Detection & Limit of Quantification

Drug	Methods	LOD (µg/ml)	LOQ (µg/ml)
Iguratimod	Method 1	0.4553	1.3799
	Method 2	0.9443	2.8615

Ruggedness

The results of ruggedness were expressed in terms of% RSD that must be less than 2. Ruggedness results were shown in Table 7.

Table 7: Ruggedness Study of Iguratimod Formulation

Methods	Conditions	Average% Obtained*	SD*	%RSD*
Zero Order Method	Analyst -1	101.11	0.5068	0.5012
	Analyst -2	100.84	0.7735	0.7670
	Instrument -1	100.70	0.8184	0.8127
	Instrument -2	100.65	0.6467	0.6425
First Order Derivative Method	Analyst-1	100.46	0.7902	0.7865
	Analyst-2	100.07	0.9693	0.9686
	Instrument-1	100.30	1.0234	1.0203
	Instrument-2	100.50	0.7725	0.7686

*Mean of 6 observations

Table 8: Forced degradation study data

Stress conditions	Study period	% Degradation
0.1 N Sulphuric Acid	24 hours	Not Degraded
0.1 N Potassium Hydroxide	24 hours	Not Degraded
HPLC grade water	24 hours	Not Degraded
0.3% Hydrogen Peroxide	24 hours	Not Degraded
10% Sodium bisulfate	24 hours	Not Degraded
Sunlight	04 hours	Not Degraded
Hot air oven (70 ℃)	24 hours	Not Degraded
UV- Light	24 hours	Not Degraded

Table- 9: Advantages of developed methods

Remember the points to be	Advantages
Novelty	UV Spectrophotometric method was developed first time for Iguratimod drug in Pharmaceutical analysis
Analytical technique parameter	Zero order method = 258 nm, First order method = 270 nm
Solvent used	Methanol
Simplicity	Easy to develop Standard UV- Spectrophotometric method
Stability-indicating capability	There was no degradants found during different stress conditions

Conclusion

Iguratimod was analyzed using the developed and validated UV-Spectrophotometric method, which was cost-effective, simple, reliable, robust, and dependable. It was used for both bulk and tablet dosage forms. The routine quality control of formulations containing iguratimod is carried out using this UV-Spectrophotometric Method.

The method was validated as per ICH guidelines with acceptable results for linearity, precision, accuracy, limit of detection, limit of quantification and ruggedness parameters. Forced Degradation studies carried under acid, base, hydrolytic, oxidative, reduction, photolytic, thermal and UV light degradation studies which helps in confirming the drug Iguratimod was stable over all stress conditions.

There was no significant interferences found in tablet formulation that confirms the methods was specific and applicable for the routine quality control of Iguratimod.

Hence, The Developed UV-Spectrophotometric method was more Suitable for periodic evaluation of quality control and stability- indicating study for Iguratimod. This method is more advantageous and simple analytical method for Pharmaceutical analysis of Iguratimod.

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Authors Contributions

All the authors contributed equally.

Conflict of Interests

Declared none.

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