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Research Article

Development and Validation of a Rapid UV Spectrometric Method for Cleaning Validation of Iguratimod on Diverse Pharmaceutical Equipment Surfaces

Dhwani Shah* and Rajshree Mashru

Faculty of Pharmacy, The Maharaja Sayajirao University of Baroda, India

***Corresponding Author:** Dhwani Shah, Faculty of Pharmacy, The Maharaja Sayajirao University of Baroda, India.

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Abstract

Cleaning validation is a critical requirement in pharmaceutical manufacturing to prevent cross-contamination when multiple drug products are produced using shared equipment. The present study describes the development and validation of a rapid, simple, and cost-effective UV spectrometric method for the cleaning validation of Iguratimod, an anti-rheumatic agent, on various pharmaceutical equipment material surfaces. The method was developed using methanol as the diluent and validated in accordance with the International Council for Harmonisation (ICH) guideline Q2(R2).

Iguratimod exhibited maximum absorbance at 257 nm, and the method demonstrated linearity over a concentration range of 2–12 µg/mL with an excellent correlation coefficient (R^2 = 0.9992). The method showed high specificity with no interference from blank or excipients. Precision studies, including repeatability and intermediate precision, demonstrated relative standard deviation values below 2%. The limit of detection and limit of quantification were found to be 0.39 µg/mL and 1.20 µg/mL, respectively [5]. Accuracy was assessed through recovery studies performed at 80%, 100%, and 120% of the limit of quantification level on stainless steel (SS-316), borosilicate glass, and high-density polyethylene surfaces, yielding recoveries within the acceptable range of 96.22% to 99.15%.

The developed method was successfully applied to the assay of Iguratimod in marketed tablet formulations, with assay values ranging from 98.47% to 99.94%. Solution stability studies confirmed the stability of both standard and sample solutions under room temperature and refrigerated conditions. The validated UV spectrometric method is specific, sensitive, reproducible, and suitable for routine cleaning validation of Iguratimod in pharmaceutical manufacturing environments.

Keywords: Iguratimod; Cleaning Validation; UV Spectrophotometry; Method Validation; Swab Recovery; Pharmaceutical Equipment

Abbreviations

UV: Ultraviolet; UV–Visible/UV-Vis: Ultraviolet–Visible; ICH: International Council for Harmonisation; Q2(R1)/Q2(R2): ICH Guideline for Validation of Analytical Procedures; API: Active Pharmaceutical Ingredient; FDA: Food and Drug Administration; csDMARD: Conventional Synthetic Disease-Modifying Anti-Rheumatic Drug; IL-1: Interleukin-1; IL-6: Interleukin-6; IL-8: Interleukin-8; TNF: Tumor Necrosis Factor; HPLC: High Performance Liquid Chromatography; HPTLC: High Performance Thin Layer Chromatography; HDPE: High-Density Polyethylene; SS/SS-316: Stainless Steel/Stainless Steel 316; MeOH: Methanol; CAN: Acetonitrile; RT: Room Temperature; RSD: Relative Standard Deviation; SD: Standard Deviation; LOD: Limit of Detection; LOQ:

Limit of Quantitation; SOP: Standard Operating Procedure; NF-κB: Nuclear Factor Kappa-Light-Chain-Enhancer of Activated B Cells; PDE: Permitted Daily Exposure; MAC/MACO: Maximum Allowable Carryover; HPLC-UV: High Performance Liquid Chromatography with UV detection.

Introduction

Pharmaceutical manufacturing facilities frequently produce multiple drug products using shared equipment, which increases the risk of cross-contamination. Residual traces of active pharmaceutical ingredients, excipients, cleaning agents, or microbial contaminants may remain on equipment surfaces after manufacturing and can compromise the quality, safety, and efficacy of subsequently manufactured products [1]. Therefore, effective cleaning procedures are essential to ensure patient safety and regulatory compliance.

Cleaning validation is a documented procedure that provides assurance that cleaning processes consistently remove residues of drug substances, excipients, detergents, and microbial contaminants from pharmaceutical equipment to acceptable and predefined limits. Regulatory authorities, including the United States Food and Drug Administration, emphasize cleaning validation as a critical component of good manufacturing practices to prevent cross-contamination between products during manufacturing changeovers [2].

Iguratimod is a novel small-molecule anti-rheumatic agent with anti-inflammatory, immunomodulatory, anti-pulmonary fibrotic, and osteoprotective properties. It exerts its pharmacological activity by inhibiting pro-inflammatory cytokines such as interleukin-1, interleukin-6, interleukin-8, and tumor necrosis factor, while also promoting osteoblastic differentiation and suppressing osteoclastogenesis [3]. Due to its potent biological activity and therapeutic use, effective cleaning validation of Iguratimod is essential in pharmaceutical manufacturing environments.

Several analytical methods have been reported in the literature for the quantification of Iguratimod using sophisticated techniques such as high-performance liquid chromatography and high-performance thin-layer chromatography [4]. In addition, cleaning validation of Iguratimod using chromatographic techniques has been reported [5]. However, these methods often require complex instrumentation, longer analysis time, and higher operational costs. To date, no UV spectrometric method has been reported for the cleaning validation of Iguratimod.

The present study aims to develop and validate a rapid, simple, and cost-effective UV spectrometric method for the cleaning validation of Iguratimod on different pharmaceutical equipment material surfaces, including stainless steel, borosilicate glass, and high-density polyethylene. The developed method was optimized and validated in accordance with the International Council for Harmonisation guideline Q2(R2) to ensure specificity, linearity, precision, accuracy, and sensitivity, making it suitable for routine application in pharmaceutical cleaning validation studies [6].

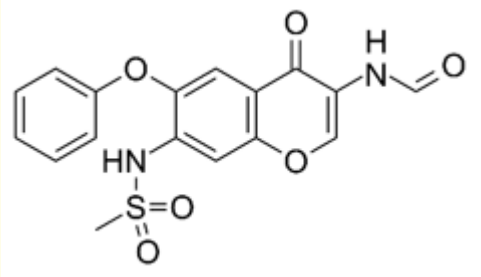

Figure 1: Structure of Iguratimod [7].

Experimental work

Apparatus and instruments

Quantitative analysis of Iguratimod was conducted using a UV–Visible spectrophotometer (Shimadzu UV-mini 1700, Shimadzu Corporation, Kyoto, Japan). The procedure employed an electronic analytical balance (Model AUX220, Shimadzu Ltd., Japan), an ultrasonicator (Trans-O-Sonic, Mumbai, India), 15 mL Tarson tubes, and polyester fibre swabs (Texwipe, USA). Cleaning validation experiments were performed on three substrate surfaces: stainless steel (SS-316) plates (10 × 10 cm^2), borosilicate glass plates (10 × 10 cm^2), and high-density polyethylene (HDPE) plates (10 × 10 cm^2). All instruments, glassware, and accessories were properly calibrated and cleaned prior to use.

Chemicals and reagents

Iguratimod base was procured from Ajanta Pharma (Mumbai, India). Analytical reagent (AR) grade methanol (MeOH) and acetonitrile (ACN) were obtained from Merck India Ltd. Double-

distilled water was freshly prepared in the laboratory and utilized throughout the study.

Determination of wavelength of maximum absorption

A series of Iguratimod standard solutions (2–12 µg/mL) was scanned over the wavelength range of 200–400 nm using methanol as the blank. The spectrum exhibited two characteristic absorption maxima at 257 nm and 325 nm, consistent with previously reported data [8].

Selection of solvent

Solubility screening of Iguratimod was performed in various solvents using the shake-flask approach as previously described. The solubility content was quantified by UV spectrophotometry, and the corresponding spectra were recorded for each solvent system evaluated. Based on solubility and spectral response characteristics, methanol, acetonitrile, and a water: methanol mixture (50:50 v/v) were selected as suitable solvents for subsequent analytical studies [9].

UV spectroscopic cleaning validation method development

Standard and sample preparation

Preparation of diluent and blank (Swabbing Solvent)

Methanol (100%, AR grade) was used as the diluent and swabbing solvent.

Preparation of standard stock solution (100 µg/mL)

Approximately 10 mg of Iguratimod was accurately weighed and transferred into a 100 mL volumetric flask. The analyte was dissolved using 10% of the diluent with sonication and intermittent mixing for approximately 3 minutes. The solution was allowed to equilibrate to room temperature and subsequently diluted to volume with the diluent.

Preparation of working standard solutions (2–12 µg/mL)

Aliquots from the stock solution were quantitatively diluted with the diluent to obtain working standards in the range of 2–12 µg/mL.

Preparation of test tubes and swabs

Clean glass test tubes were washed, dried, and rinsed with the swabbing solvent. Polyester fibre swabs were similarly rinsed and gently squeezed against the test tube walls to remove excess solvent prior to use.

Preparation of blank solution for cleaning validation

Ten milliliters of the swabbing solvent was transferred to a pre-cleaned test tube. A solvent-conditioned swab was placed in the tube and sonicated for 10 minutes. The swab was subsequently squeezed to remove excess solvent. The resulting solution served as the blank, and its UV spectrum was recorded.

Preparation of test solution for cleaning validation

Ten milliliters of the swabbing solvent was added to a pre-cleaned test tube, and the swab was conditioned by brief immersion and squeezing to remove excess solvent. Swabbing was performed following a predefined pattern on three distinct substrate surfaces (Figure 2) [10]. Following sample collection, swabs were placed into the test tube and sonicated for approximately 10 minutes to facilitate drug extraction. Afterward, the swab was squeezed against the test tube wall to recover residual solvent. The solution was filtered through a 0.45 µm membrane filter, and the UV absorbance of the filtrate was recorded.

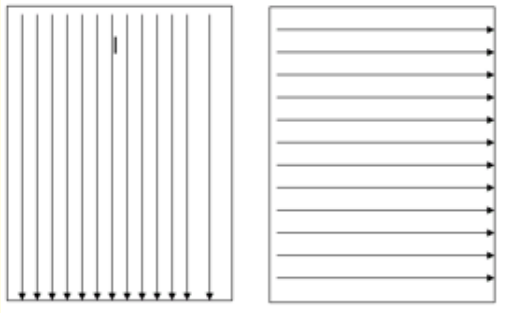

Figure 2: Standard swab sampling pattern for cleaning validation [10].

Formulation analysis (Assay Method)

Ten tablets, equivalent to 25 mg of Iguratimod, were accurately weighed and triturated using a mortar and pestle. The resulting powder was transferred to a 250 mL volumetric flask, and 50 mL of diluent was added. The mixture was sonicated for 5 minutes with intermittent shaking and subsequently allowed to equilibrate to room temperature. The volume was then adjusted to the mark with the diluent. An aliquot of this solution was further diluted with the diluent to obtain a final concentration of 10 µg/mL. The solution was filtered through a 0.45 µm Whatman membrane filter and analyzed at 257 nm to determine the drug content in the formulation.

Solution stability

Solution stability studies were conducted for Iguratimod in both formulation and base forms at predefined time intervals and storage conditions. Stability was assessed over a 96-hour period at room temperature (RT) and under refrigerated conditions (2–8°C). Samples were withdrawn at scheduled intervals and analyzed to evaluate potential degradation and to confirm the stability of the analytical solutions throughout the duration of the study [11].

Method validation

Specificity

Specificity was evaluated by comparing the UV spectra of the blank, standard Iguratimod solution, and Iguratimod sample solution (equivalent to 10 µg/mL). Each solution was prepared independently and analyzed separately to assess potential interference from excipients, diluent components, or swabbing matrices.

Linearity and range

Linearity was assessed over the concentration range of 2–12 µg/mL in methanol. Calibration curves were constructed at 257 nm (n = 6) by plotting absorbance against concentration. Regression analysis was performed to determine the correlation coefficient, and percentage relative standard deviation (RSD) was calculated to evaluate the linear response across the tested range [11].

Method precision

Precision was evaluated in accordance with current ICH guidelines [19]. Precision reflects the degree of reproducibility among a series of closely related analytical measurements and is typically assessed at three levels: repeatability, intraday precision, and intermediate (inter-day) precision [12].

Repeatability

Repeatability was assessed by analyzing six independent Iguratimod sample solutions at distinct concentrations under the same experimental conditions, as prescribed by ICH criteria.

Intraday and inter-day precision

Intraday precision was determined by analyzing three Iguratimod concentrations in triplicate on the same day. Inter-day precision was evaluated by repeating the same experimental procedure on two different days. Precision was expressed in terms of percentage RSD for each concentration level.

Sensitivity

Sensitivity of the method was established through determination of the limit of detection (LOD) and limit of quantitation (LOQ). Both parameters were calculated using regression-derived statistical approaches. The calculated LOQ was experimentally verified by analyzing six replicates at the LOQ level to confirm quantifiability [11].

Accuracy (Recovery Study)

Accuracy was evaluated by recovery studies conducted at three concentration levels corresponding to 80%, 100%, and 120% of the LOQ, yielding working concentrations of 0.96 µg/mL, 1.20 µg/mL, and 1.44 µg/mL, respectively. Recovery experiments were performed on three substrate surfaces—SS-316 plate, borosilicate glass plate, and HDPE plate—to assess surface-related recovery during cleaning validation. After swabbing, each swab was placed into a 10 mL test tube, the volume was adjusted to 10 mL with diluent, and the solution was sonicated for 10–15 minutes. Samples were subsequently analyzed to determine percentage recovery.

Results and Discussion

Analytical method development

Wavelength determination

Standard Iguratimod solutions (2–12 µg/mL) were examined to determine the wavelength of maximum absorption. Spectral scans were recorded over the range of 200–400 nm, and distinct absorption maxima were observed at 257 nm and 325 nm. The UV spectrum for the standard Iguratimod solution is shown in Figure 3. Although both wavelengths exhibited measurable absorbance, 257 nm was selected as the analytical wavelength due to superior response characteristics and a higher coefficient of determination (R^2) relative to 325 nm.

Solubility determination

Solubility studies were performed in various solvents, and corresponding UV spectra were recorded. The solvents assessed included water: methanol (50:50 v/v), methanol, and acetonitrile.

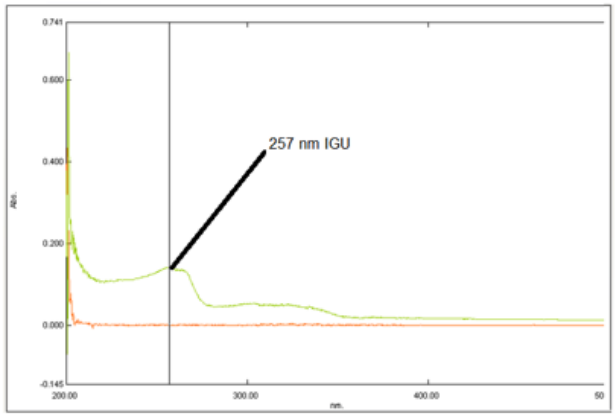

Figure 3: UV Calibration curve of Iguratimod showing maximum absorbance (λ max) at 257 and 325 nm.

Comparative solubility data are presented in Figure 4 and Table 1. Methanol demonstrated the most favorable solubility and spectral characteristics; therefore, it was selected as the diluent for subsequent analytical and validation studies.

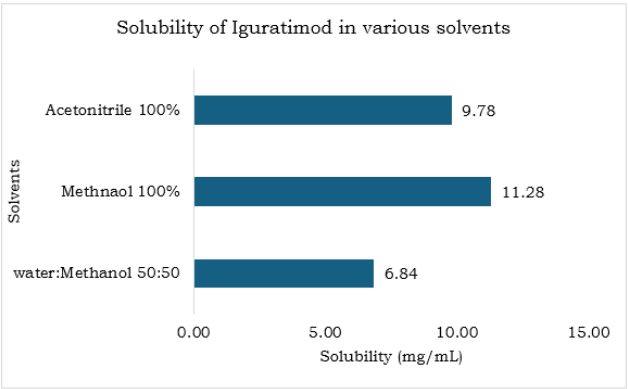

Figure 4: Solubility data for Iguratimod in different solvent.

Sr. No.	Solvent	Solubility of Iguratimod (mg/mL)
1	Water: Methanol 50:50	6.84
2	Methanol 100%	11.28
3	Acetonitrile 100%	9.78

Table 1: Solubility of Iguratimod in different solvents.

Analytical method validation

Specificity

The specificity of the method was assessed using Iguratimod solution (10 **µg**/mL) scanned at 257 nm in methanol. The blank, standard, and sample spectra were analyzed independently and compared using a UV spectrophotometer. No interfering peaks were observed at the analytical wavelength, as illustrated in Figures 5 and 6. These findings confirm that the method is specific for Iguratimod and suitable for quantitative analysis.

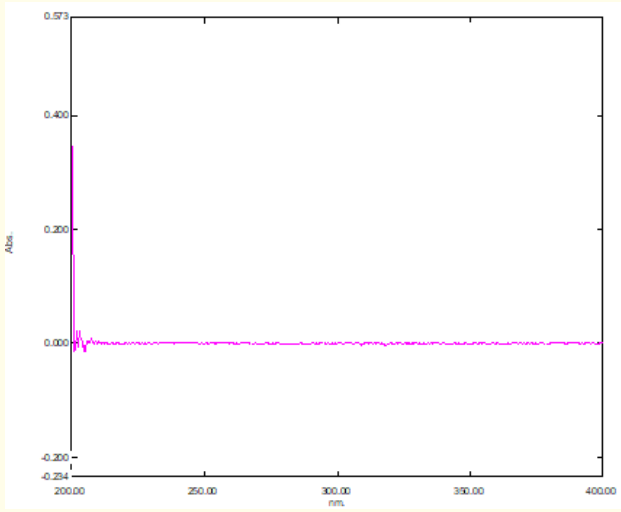

Figure 5: Blank spectra of Iguratimod in MeOH.

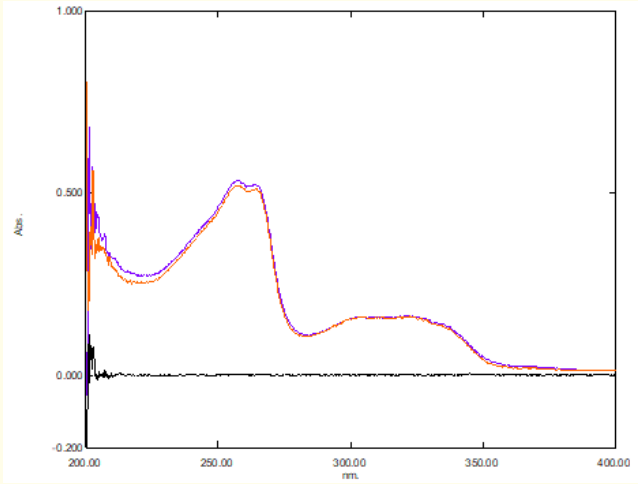

Figure 6: Overlay of Blank, Standard and Sample 10µg/mL solution spectrum of Iguratimod.

Linearity and range

Linearity was evaluated across six calibration levels within the range of 2–12 µg/mL at both 257 nm and 325 nm (Tables 2 and 3). Calibration plots of absorbance versus concentration demonstrated a linear response at both wavelengths, consistent with Beer–Lambert's law (Figures 7, 8 and 9). Regression analysis was performed using the least squares method, and the statistical significance of the regression was evaluated by one-way ANOVA ($P < 0.05$), as summarized in Table 5. The corresponding regression parameters are presented in Table 4.

Conc (µg/mL) (n = 6)	Average absorbance ± SD	RSD
2	0.141 ± 0.0006	0.45
4	0.228 ± 0.0010	0.78
6	0.317 ± 0.0015	0.47
8	0.416 ± 0.0012	0.29
10	0.516 ± 0.0021	0.40
12	0.613 ± 0.0015	0.24

Table 2: Calibration curve Iguratimod at 257 nm (2-12 µg/mL).

Conc (µg/mL) (n = 6)	Average absorbance ± SD	RSD
2	0.048 ± 0.0009	1.86
4	0.075 ± 0.0012	1.56
6	0.094 ± 0.0013	1.35
8	0.127 ± 0.0010	0.83
10	0.145 ± 0.0024	1.67
12	0.173 ± 0.0022	1.25

Table 3: Calibration curve of Iguratimod at 325 nm (2-12 µg/mL).

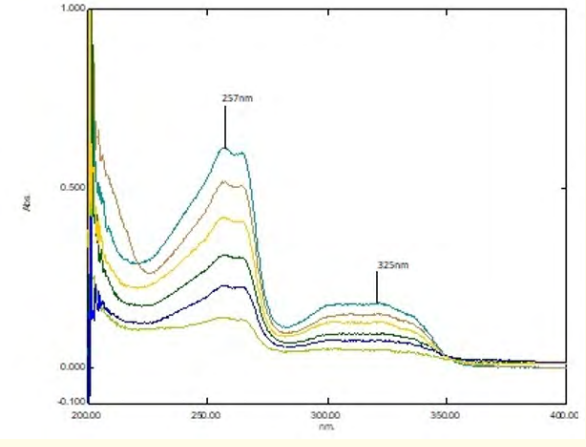

Figure 7: Overlay spectrum of Iguratimod (2-12 µg/mL) in methanol.

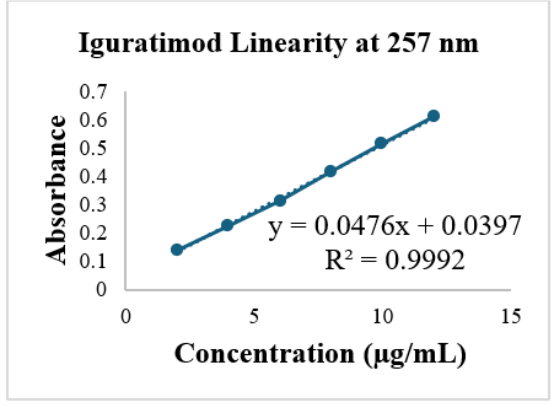

Figure 8: Calibration curve of Iguratimod at 257 nm.

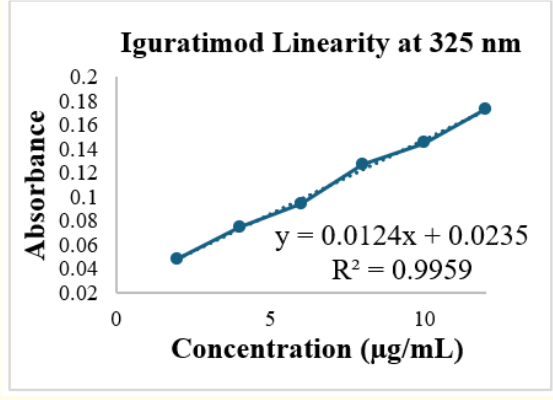

Figure 9: Calibration curve of Iguratimod at 325 nm.

Parameters	Iguratimod	
Wavelength (nm)	257	325
Range (µg/mL)	2-12 (µg/mL)	2-12 (µg/mL)
Regression equation (y = mx+c) slope (m) Intercept (c)	Y = 0.04575x+0.0397 0.04575 0.0397	Y = 0.0124x+0.0235 0.0124 0.0235
Correlation coefficient (r^2)	0.9992	0.9959

Table 4: Summary of Linear Regression.

Model	df	SS (sum of squares)	MS (Mean Square)	F	Significance F
Regression	1	0.158222629	0.158222629	4842.138152	2.55552E-07
Residual	4	0.000130705	3.26762E-05		
Total	5	0.158353333			

Table 5: Analysis of the ANOVA results for the Iguratimod calibration curve at 257 nm.

Analytical solution stability

Solution stability studies indicated that Iguratimod standard and sample solutions remained stable throughout the evaluated period. Percentage recovery values ranged from 95.63% to 100%, with RSD values below 2%. As summarized in Table 6, both standard and sample solutions exhibited stability for up to 72 hours at room temperature and up to 96 hours under refrigerated storage (2–8°C).

Studies	Conditions	Time (Hour)	Absorbance (n = 2) ± SD	RSD	Recovery (%)
Standard Solution	Room Temperature	0	0.515 ± 0.0007	0.14	100.00
		24	0.514 ± 0.0014	0.28	99.90
		48	0.511 ± 0.0014	0.28	99.32
		72	0.507 ± 0.0042	0.84	98.54
		96	0.496 ±0.0021	0.43	96.31
	2-8°C	0	0.515 ± 0.0007	0.14	100.00
		24	0.514 ± 0.0014	0.28	99.90
		48	0.513 ± 0.0007	0.14	99.61
		72	0.509 ± 0.0021	0.42	98.83
		96	0.505 ± 0.0014	0.70	98.15
Sample Solution	Room Temperature	0	0.515 ± 0.0007	0.14	100.00
		24	0.513 ± 0.0014	0.28	99.71
		48	0.511 ± 0.0021	0.42	99.22
		72	0.506 ± 0.0049	0.98	98.25
		96	0.492 ± 0.0014	0.29	95.63
	2-8°C	0	0.515 ± 0.0007	0.14	100.00
		24	0.513 ± 0.0021	0.41	99.61
		48	0.511 ± 0.0014	0.28	99.32
		72	0.507 ± 0.0042	0.84	98.45
		96	0.507 ± 0.0070	0.29	98.45

Table 6: Solution Stability of Iguratimod in Sample and Standard Solution.

Method precision

Repeatability, LOQ-level repeatability, and intermediate precision results are presented in Tables 7, 8, and 9, respectively. In all cases, the percentage RSD remained below 2.0%, demonstrating that the method meets precision requirements and is suitable for routine quality control analysis [11].

Replicates 10 µg/mL (n = 6)	Absorbance
1	0.516
2	0.512
3	0.514
4	0.518
5	0.516
6	0.516
Mean ± SD	0.515 ± 0.0020
RSD	0.40

Table 7: Repeatability (Mimod).

Conc. (µg/mL) (n = 3)	Mean absorbance ± SD	RSD
2	0.142 ± 0.0012	0.82
6	0.315 ± 0.0015	0.49
10	0.613 ± 0.0006	0.09

Table 8: Intra-day precision for Iguratimod (Mimod).

Conc. (µg/mL) (n = 3)	Mean absorbance ± SD	RSD
2	0.141 ± 0.0010	0.71
6	0.311 ± 0.0020	0.64
10	0.624 ± 0.0040	0.65

Table 9: Inter-day precision for Iguratimod (Mimod).

Sensitivity: Limit of detection (LOD) and limit of quantification (LOQ)

The LOD and LOQ for Iguratimod were calculated using Equations 1 and 2 based on statistical parameters derived from regression analysis. The values of σ and s are provided in Table 10 and Table 11. The theoretical LOD and LOQ values were determined to be 0.39 µg/mL and 1.20 µg/mL, respectively, for the SS-316 surface (Figure 10).

LOD = 3.3 σ/S---- Equation (1)

LOQ = 10 σ/S---- Equation (2)

R^2	0.9992
Standard Error (σ)	0.005
Observations	6
Intercept	0.039
X variable (s)	0.047
LOD	0.39 µg/mL
LOQ	1.20 µg/mL

Table 10: Iguratimod Regression statistics for LOD and LOQ.

Replicates (n = 6)	Absorbance
1	0.097
2	0.098
3	0.099
4	0.101
5	0.098
6	0.102
Mean ± SD	0.099 ± 0.0019
RSD	1.96

Table 11: LOQ repeatability at 1.20 µg/mL on SS-316s slab (Mimod).

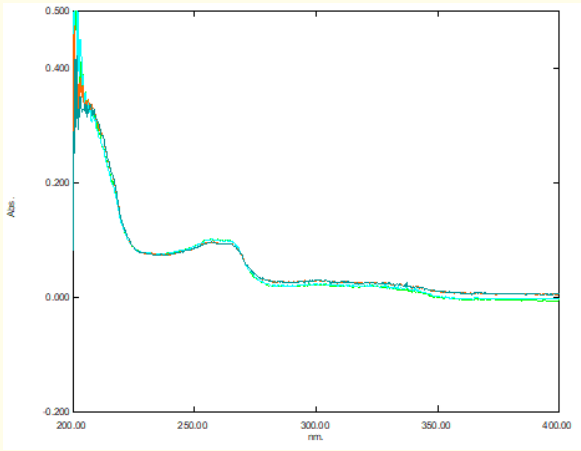

Figure 10: Iguratimod LOQ precision of 1.20 µg/mL at 257nm (n = 6) (SS-316s slab).

Where:

σ = standard deviation of the y-intercepts from six calibration curves

S = mean slope of the six calibration curves [13].

Accuracy (Recovery Study)

Accuracy was assessed using recovery studies conducted on SS-316 plates, borosilicate glass plates, and HDPE plates. Percent recovery was calculated using Equations 3 and 4. The developed method demonstrated recovery values within acceptable limits across all surfaces, ranging from 96.24% to 99.13% for SS-316, 97.67% to 98.19% for borosilicate glass, and 96.22% to 99.15% for HDPE, with RSD values below 2% (Table 12, 13 and 14).

SS-316s PLATE						
% Spiked Level	**Replicate Number**	**Spiked amount (µg/mL)**	**Amount Recovered (µg/mL)**	**% Recovery**	**Mean (n = 3) % Recovery ± SD**	**RSD**
80	1	0.96	0.97	99.13	98.40 ± 1.26	1.28
	2		0.93	96.95		
	3		0.95	99.13		
100	1	1.2	1.16	97.69	98.27 ± 1.82	1.85
	2		1.20	100.32		
	3		1.16	96.81		
120	1	1.44	1.37	95.27	96.24 ± 1.68	1.75
	2		1.41	98.19		
	3		1.37	95.27		

Table 12: Accuracy/ Recovery in SS-316s Plate slabs at LOQ 1.2µg/mL (Mimod)

HDPE plastic plate						
% Spiked Level	**Replicate Number**	**Spiked amount (µg/mL)**	**Amount Recovered (µg/mL)**	**% Recovery**	**Mean (n = 3) % Recovery ± SD**	**RSD**
80	1	0.96	0.93	96.95	96.22 ± 1.26	1.31
	2		0.91	94.76		
	3		0.93	96.95		
100	1	1.2	1.20	100.32	99.15 ± 1.01	1.02
	2		1.18	98.56		
	3		1.18	98.56		
120	1	1.44	1.37	95.27	96.24 ± 0.84	0.88
	2		1.39	96.73		
	3		1.39	96.73		

Table 13: Accuracy/ Recovery in HDPE Plastic Plate slabs at LOQ 1.2 µg/mL (Mimod).

Borosilicate glass plate						
% Spiked Level	Replicate Number	Spiked amount (µg/mL)	Amount Recovered (µg/mL)	% Recovery	Mean (n = 3) % Recovery ± SD	RSD
80	1	0.96	0.93	96.95	97.67 ± 1.26	1.29
	2		0.93	96.95		
	3		0.95	99.13		
100	1	1.2	1.16	96.81	97.98 ± 1.01	1.03
	2		1.18	98.56		
	3		1.18	98.56		
120	1	1.44	1.41	98.19	98.19 ± 1.46	1.49
	2		1.39	96.73		
	3		1.43	99.64		

Table 14: Accuracy/Recovery in Borosilicate Glass Plate Slabs at LOQ 1.2 µg/mL (Mimod).

Amount Recovered: Y = MX + C ----------Equation (3)

% Recovery = (Amount Recovered/Amount Spiked) × 100 ----------Equation (4)

Where:

Y = absorbance

M = slope

X = concentration

C = intercept

Assay of Iguratimod in marketed formulation (Mimod)

Ten commercial tablets of Iguratimod (Mimod) were accurately weighed and triturated to obtain a quantity equivalent to 100 mg of Iguratimod. The powder was transferred to a 250 mL volumetric flask, 50 mL of diluent was added, and the mixture was sonicated for 5 minutes with intermittent stirring. After cooling to room temperature, the solution volume was adjusted to 250 mL to obtain a concentration of 400 µg/mL. From this stock, 5 mL was transferred to a 20 mL volumetric flask and diluted to yield 100 µg/mL. A final working solution of 10 µg/mL was prepared and analyzed at 257 nm (Figure 11). The assay values ranged from 98.47% to 99.94%, with an RSD less than 2%. The assay results are summarized in Table 15.

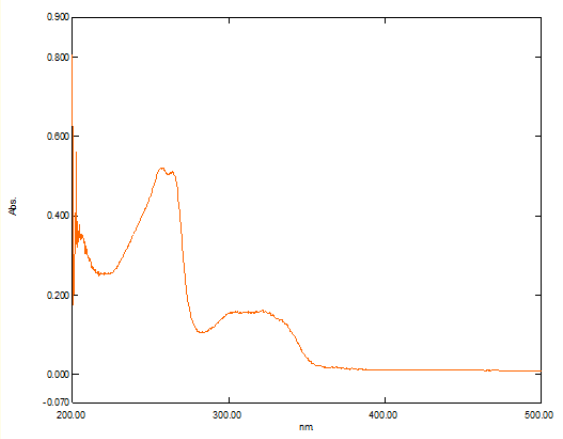

Figure 11: Assay of mimod at 10 µg/mL at 257 nm.

Conclusion

This study presents a validated, rapid, and cost-effective UV spectrometric method for the cleaning validation and quantitative determination of Iguratimod on various pharmaceutical equipment material surfaces. The developed method demonstrated excellent specificity, linearity, precision, accuracy, and sensitivity in accordance with the International Council for Harmonisation guideline Q2(R2). The method was successfully applied for residue analysis on stainless steel, borosilicate glass, and high-density

Sr. No	Drug Recovered (µg/mL)	% Assay	% Assay ± SD (n = 6)	RSD
1	9.85	98.47	98.96 ± 0.65	0.69
2	9.95	99.52		
3	9.99	99.94		
4	9.87	99.68		
5	9.89	98.89		
6	9.83	98.26		

Table 15: Assay of Iguratimod formulation at 10 µg/mL (mimod).

polyethylene surfaces, as well as for the assay of Iguratimod in marketed tablet formulations. Owing to its simplicity, reproducibility, and economical nature, the proposed method is suitable for routine application in pharmaceutical cleaning validation studies involving Iguratimod (Table 16).

Parameters	Result
Wavelength	257 nm
Diluent	Methanol (100%)
Specificity	No interference observed
Linearity	
Range	2-12µg/mL
Wavelength 325 nm (R^2)	0.9959
Wavelength 257 nm (R^2)	0.9992
Analytical Solution Stability	
Room temperature	72 Hr (Sample and Standard Solution)
2-8° C of Standard solution	96 Hr (Sample and Standard Solution)
Precision (RSD)	
Repeatability 10 µg/mL (n = 6)	0.50 ± 0.002
Repeatability 10 µg/mL (n = 6)	0.09 ± 0.002
Intra-day (n = 3)	0.51 ± 0.002
Inter-day (n = 3)	0.45 ± 0.001
LOD	0.39 µg/mL
LOQ	1.20 µg/mL
Accuracy/% Recovery for Cleaning Validation	
SS-316s plate	95.27-100.32%
HDPE plate	95.27-100.32%
Borosilicate glass plate	96.73-99.64%
% ASSAY (n = 6)	
Iguratimod formulation (Mimod)	98.26-99.94%

Table 16: Summary table of cleaning validation.

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Conflict of Interest

The authors declare that there are no conflicts of interest.

Bibliography

1. United States FDA. "Guide to Inspections: Validation of Cleaning Processes". FDA, (1993).
2. FDA. "Current Good Manufacturing Practice (CGMP) Regulations". U.S. Food and Drug Administration, (2020).
3. Tanaka, Y. "Iguratimod: A Review of its Pharmacological Profile and Clinical Efficacy in Rheumatoid Arthritis". *Clinical Medicine Insights: Arthritis and Musculoskeletal Disorders* (2019).
4. Qiu J., *et al*. "Determination of Iguratimod in Tablets by HPLC and HPTLC". *Journal of Pharmaceutical Analysis* (2018).
5. Gao X., *et al*. "Cleaning Validation Study of Iguratimod Residues Using HPLC". *Journal of Chromatographic Science* (2020).
6. ICH. "Validation of Analytical Procedures: Q2(R2)". International Council for Harmonisation (2022).
7. Kawai S., *et al*. "Iguratimod, a Novel Disease-Modifying Antirheumatic Drug, from Basic Research to Clinical Application". *Inflammation and Regeneration* 31.2 (2011): 151-160.
8. Zhang Y., *et al*. "UV Spectrophotometric Determination of Iguratimod". *Asian Journal of Chemistry* (2017).
9. Shakeel F., *et al*. "Shake-Flask Solubility Determination Method in Pharmaceutical Analysis". *Journal of Solution Chemistry* (2012).
10. Fourman GL and Mullen MV. "Determining Cleaning Validation Acceptance Limits for Pharmaceutical Manufacturing Operations". *Pharmaceutical Technology* (1993).
11. International Council for Harmonisation (ICH). "ICH Q2(R2): Validation of Analytical Procedures". ICH Harmonised Guideline (2022).
12. Rogado S. "Concepts of Precision and Accuracy in Analytical Chemistry". *Journal of Analytical Methods*.
13. Miller JC and Miller JN. "Statistics and Chemometrics for Analytical Chemistry, (LOD/LOQ equations reference)".