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QUANTIFICATION OF ESCITALOPRAM OXALATE IN PHARMACEUTICALS USING UV SPECTROPHOTOMETRY EMPLOYING A CALIBRATION TECHNIQUE AND EVALUATING THE GREENNESS PROFILE

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ABSTRACT

The present work proposes the development of a distinctive methodology and its subsequent testing to quantify the quantity of escitalopram in both formulations and bulk samples. This analytical method is characterized by its sensitivity, precision, and speed. The analytical procedure was conducted using a UV spectrophotometer and a multivariate calibration process. This multivariate calibration method was created based on the correlation relationship between concentration and absorbance has been determined for five distinct wavelengths, including the highest absorption point at 238nm. The strategy was validated according to the ICH Q2 (R1) requirements, employing linear regression equations along with several mathematical and statistical techniques. All the validation parameters specified in the instructions, including accuracy, linearity, and others, have been successfully met. When utilized for routine examination of medications and compositions, this technique demonstrates sensitivity, cost-effectiveness, and produces dependable outcomes. The technique's The greenness values were assessed using the analytical Eco scale, Agree metrics, and Green Analytical Procedure Index.

Keywords: Escitalopram, Multiple variable calibration method, Ultraviolet spectrophotometric, Pharmaceutical Preparation, International Council for Harmonisation regulation, Evaluation

INTRODUCTION

The chemical name for Escitalopram Oxalate is 1-[3-(dimethylamino)propyl]. It has a molecular weight of 324.392 gm/mol.The compound is named -1-(4-fluorophenyl).The compound is named -1,3-dihydro-2-benzofuran-5-carbonitrile.

Escitalopram belongs to the class of tricyclic antidepressant drugs, **[1]** which are medications that have an antidepressant effect by increasing the concentration of monoamines in the synaptic cleft.

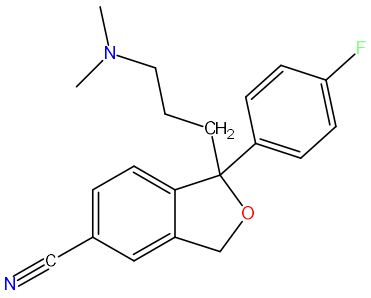

Figure 1: structure of Escitalopram Oxalate

The use of escitalopram for therapy of obsessive-compulsive disorder (OCD) is allowed by the FDA only for individuals who are 10 years old or older. Escitalopram shown superior efficacy in treating OCD compared to sertraline, fluoxetine, and fluvoxamine, as revealed by a meta-analysis. Escitalopram had a 37% higher efficacy in treating the CY-BOCS, which is The Children's Yale-Brown Obsessive-Compulsive Scale is a tool used to assess anxiety and panic attacks in children and adolescents **[2]**. Escitalopram, a very effective serotonin reuptake inhibitor with a diverse range of therapeutic uses, can be utilized as a substitute for fluoxetine because of its extensive therapeutic spectrum. Escitalopram has a higher bioavailability of approximately 80% compared to clomipramine when administered intravenously **[3]**. The pharmacokinetics of Escitalopram indicate that its elimination half-life is around 27-33 hours, which aligns with its recommended once-daily dosing. Stable concentrations are reached within a period of 7-10 days after dosing. Escitalopram exhibits a low degree of protein binding, specifically 56%, and is therefore unlikely to induce interactions with medicines that have a high affinity for protein binding. The substance is extensively disseminated throughout many tissues. The highest concentration of the substance in the bloodstream typically peaks approximately 5 hours after administration. Escitalopram undergoes hepatic metabolism mediated by the enzymes CYP3A4 and CYP2C19, leading to the production of S-desmethyl-citalopram (S-DCT) and S-di-desmethyl citalopram (S-DDCT) **[4]**. Escitalopram has a protein binding rate of around 55-56%, which is considered rather modest. Escitalopram is classified as a BCS class I **[5]** chemical due to its significant permeability and solubility. Based on a comprehensive review of existing research, numerous techniques for detecting escitalopram in biological or

pharmacological forms have been recorded. Several methods for analyzing escitalopram have been described, including LC/MS **[6]**, Bio-Analytical **[7]**, various chromatographic techniques such as HPLC **[8]**, HPLC-UV[9], GC, GC-MS[10], as well as Zero order **[5]** and First order **[3]** spectrophotometry **[11-13]**. There is no multivariate calibration technique (MVC) available for UV spectrophotometry was mentioned for escitalopram. Therefore, the primary objective of the present method is to develop a UV spectrophotometric method. MVC accurately determining the concentration of escitalopram. The application of analytical techniques provides a potent, quick, precise **[2]**, and cost-effective method for quantitatively analyzing investment mixtures under optimal conditions. For each selected wavelength, the amount of light absorbed by a sample (x) can be measured at 228, 233, 238 **[12]**, 243, and 248nm, resulting in the following equations.

$A_{\lambda 238} = a \times C_X + k1$ …… (1)

$A_{\lambda 239} = b \times C_X + k2$…… (2)

$A_{\lambda 240} = c \times C_X + k3$ …….. (3)

$A_{\lambda 241} = d \times C_X + k4$ …… (4)

$A_{\lambda 242} = e \times C_X + k5$ …… (5)

While as,

- A_λ= The measurement of the amount of light absorbed by the sample
- a, b, c, d, e = The slope of the linear regression functions of a sample;
- k_1, k_2, k_3, k_4, k_5 = Y-intercept of the linear regression;
- C_X = Sample concentration

The five equations described above can be organized in the following manner:

$A_T = a \times C_X + b \times C_X + c \times C_X + d \times C_X + e \times C_X + K_T$….(6)

The aforementioned equation may be reduced even more to

$A_T = C_X (a+b+c+d+e) + K_T$……. (7)

While as,

- A_T = Total of the acquired absorbances
- K_T = The sum of intercepts in a regression equation.

Use the formula to quantify the concentration of analyte X in a solution.

$$Cx = \frac{A_T - K_T}{(a+Ab+c+d+e)} \quad \text{……(8)}$$

Evaluation techniques of greenness

According to "The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)" states that the eco analytical scale **[14]** awards Penalty points are assigned based on the combination of signal words.and pictograms. The analytical eco scale technique takes into account every reagent, including its type, quantity, potential occupational exposure, energy depletion, and waste. A starting score of 100 points is decreased by penalty points.

Analytical eco-scale = 100 - total penalty points ……. (9)

An additional illustration is the the Green Analytical Procedure Index (GAPI) is comprised of five pentagons and showcases a unique color pattern. The pictogram for each phase of an analytical method has a three-tiered system of evaluation for color coding. GAPI utilizes the colors green, yellow, and red to represent the levels of minimum, moderate, and major environmental damage associated using the analytical technique, respectively. In 2018, J. Potka-Wasylka delivered concise, precise, and enlightening coverage on GAPI **[15]**. Specialized Software is utilized to measure and evaluate the level of environmental friendliness during the second evaluation phase using AGREE metrics **[16]**. The software produces a circular shape with numerals on the edges arranged in a clockwise direction, spanning from 1 to 12. The visuals depict the 12 tenets of green analytical chemistry. The results of these 12 principles are evaluated on a scale ranging from 0 to 1, based on the supplied facts and their significance. The dimension ranges from 1 to 12. On this scale, the color red represents a value of zero, the color dark green symbolizes a numerical value of one or a value very close to one, and yellow represents a value that is in between. The twelve principles are integrated with the core to create a numerical score that measures the degree of environmental friendliness.

MATERIALS AND METHODS:

Chemicals and solvents employed:

- Methanol
- ESCITALOPRAM OXALATE® TABLETS – (Label claim – 10 mg), manufactured by Sun Pharma Laboratories Pvt. Ltd, The medication formulations that were marketed were obtained on a regional basis.

Solubility:

- Readily dissolving in methanol, dimethyl sulfoxide (DMSO) and methylene chloride.

Equipments:

- UV-Vis double beam Spectrophotometric (Lab India UV-3092).
- Electronic balance (SHIMADZU AY-220H).
- Ultra-sonicator (model 160T, The barton-Australia).

METHOD DEVELOPMENT:

Choices of Solvent

Methanol, employed as the solvent throughout the analysis to dissolve the medicine, was found to be highly soluble.

Setting up of Standard solution

The drug component was diluted in methanol to form the escitalopram standard stock solution, with a concentration of 10

mg per 10 mL. We modified the concentration of this solution to a range of 7-13g/mL and employed it for subsequent analysis.

Preparation of sample solution

Precisely measuring 10mg of escitalopram, it was then transferred into a 10ml volumetric flask. Following the addition of 10ml of methanol, the mixture underwent sonication for a duration of 20 minutes. The final volume obtained was 10 ml, with a concentration of 10000 micrograms per milliliter. The resulting mixture was later diluted with the solvent to generate concentrations ranging from 7 to 13 µgmL-1.

Measurement of λ_{max}

The escitalopram working standard solutions were compared to methanol as the reference solution using a spectrophotometer. The comparison was done across the wavelength range of 200 to 400 nm. Methanol, which exhibits maximum absorption at 238 nm, was used as the reference solution. The MVC method's wavelength was positioned precisely between these absorption maxima, specifically at 228, 233, 238, 243, and 248nm.

METHOD VALIDATION

The linearity, accuracy, and precision of the suggested approach were validated using the guidelines set by the International Council for Harmonisation (ICH) **[17]**.

Linearity

The stock solution was diluted with methanol to achieve concentrations ranging from 7 to 13 µg mL-1. These concentrations were subsequently utilized to assess the linearity and spectrum area of escitalopram. The absorbance of linear solutions was measured and analyzed using the MVC method at the chosen wavelength.

Quantification and Detection limits

The Limits of Detection (LOD) and Limits of Quantification (LOQ) for escitalopram were determined by analyzing the slope of the calibration curve and the standard deviation of responses at a specific wavelength.

$$\text{LOD} = \frac{3.3 \text{ x standard deviation}}{\text{Slope}} \quad \ldots\ldots\ldots (10)$$

$$\text{LOQ} = \frac{10 \text{ x standard deviation}}{\text{Slope}} \quad \ldots\ldots\ldots (11)$$

Precision

The precision's repeatability was assessed by intraday and interday evaluations. An escitalopram solution with a concentration of 10 µgmL-1 was utilized to assess different levels of precision. Repeatability was assessed by examining six solutions at five distinct wavelengths. The ability to absorb of the constructed solutions was measured thrice

at different time intervals on the same day to assess intervariation. An additional three days were utilized to address intravariation by measuring absorbance.

Accuracy (15)

The precision of the escitalopram method was assessed using sample solutions with concentrations of 80%, 100%, and 120% of the previously examined samples. The recovery values were subsequently estimated as percentages.

Assay

Measure the weight and grind into a fine powder. There are 10 tablets. Precisely measure an amount of the tablet powder that is approximately equal to 50mg of escitalopram. Then, add 25 ml of methanol to the powder and subject it to sonication for a duration of 10 minutes. Add an adequate amount of methanol and bring the total volume up to 50mL. The previously produced solution is subjected to filtration and then mixed with methanol in order to Attain a concentration of 10 micrograms per milliliter (µg/mL) of methanol. The concentration of escitalopram is determined by quantifying the absorption value of the resulting solution at an identified wavelength of 238 nm.

RESULTS AND DISCUSSION

The Escitalopram reference solution was initially analyzed using a spectrophotometer and its wavelength range spans from 200 to 400 nm. The escitalopram spectrum has a peak wavelength of 238 nm. The UV spectra of both the reference compounds and the test samples of escitalopram was determined by utilizing methanol as a reference and setting the wavelength at 238nm for maximum variability control (MVC).

Linearity

The results on the repeatability of the established approach for escitalopram were resolved within the amount present varies from 70 to 130 percent for a solution with a concentration 10g mL-1 (7 to 13 μgmL^{-1}), in accordance with ICH Q2 R1 requirements. In **Figure 3,** the linearity spectrum of escitalopram is depicted. By estimating the calculation of the quantity of light reflected by a substance of reference diluted solutions at five distinct wavelengths (228,233,238,243,248), the calibration curve was produced. **Table 1** displays the recorded outcomes in a tabulated format. All of the standard curves were found to be linear within the selected concentration range. **Figure 4-8** and **Table 2** illustrate the calibration graphs and perform regression analysis, accordingly.

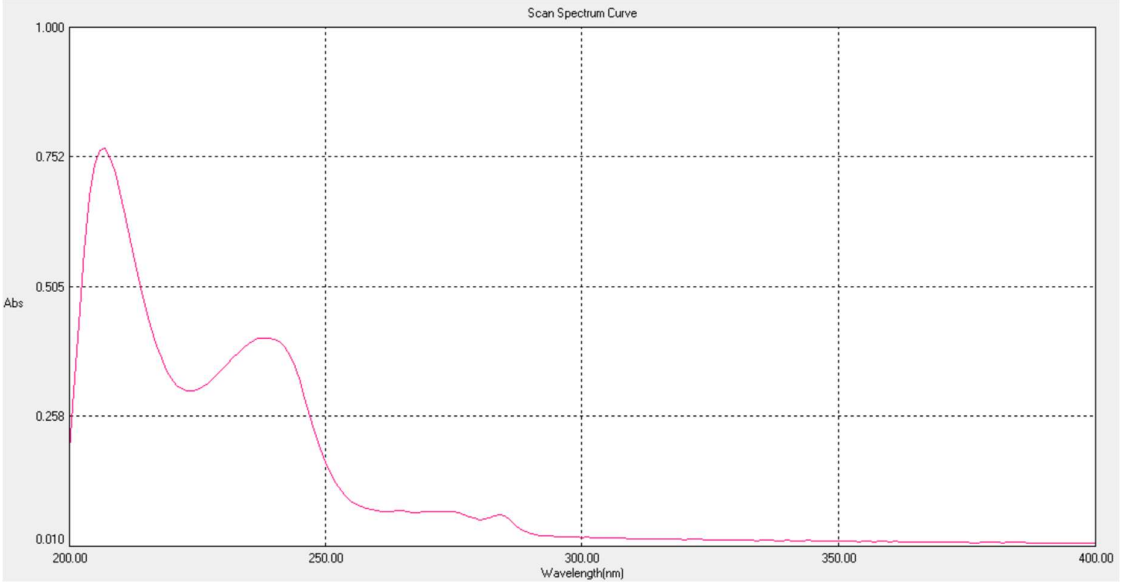

Figure 2: **Displays the usual spectra of escitalopram at 10 µg mL^{-1}**

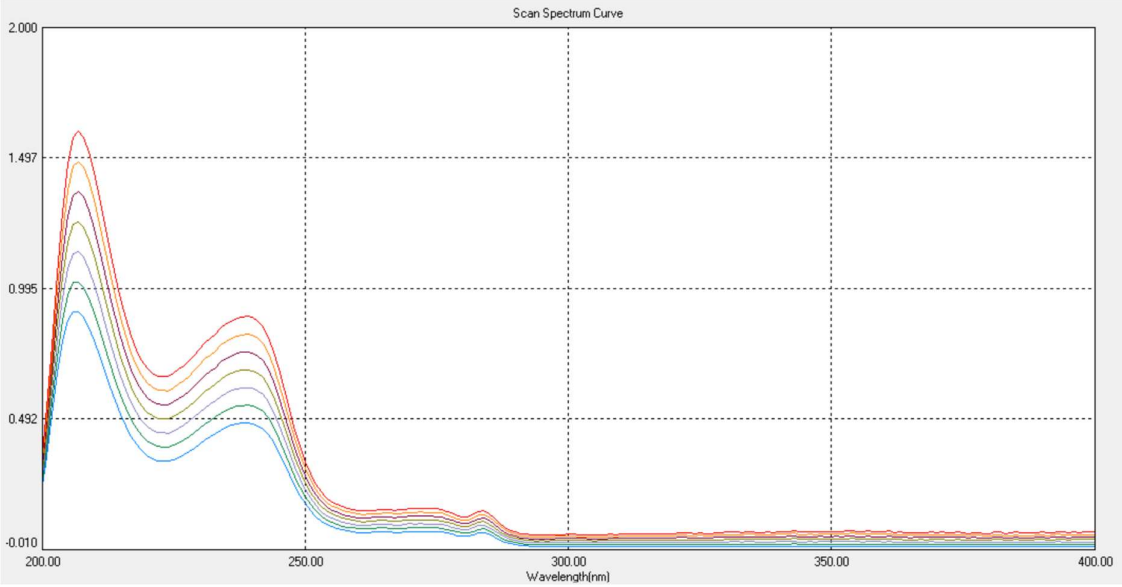

Figure 3: Linearity spectrum of clomipramine (7-13 µg mL^{-1}) using Methanol as a blank

Table 1: Multivariate UV calibration data at five selected wavelengths

Concentration (µgmL^{-1})	228nm	233nm	238nm	243nm	248nm
7	0.367	0.437	0.476	0.433	0.236
8	0.425	0.500	0.541	0.496	0.271
9	0.484	0.562	0.612	0.558	0.303
10	0.538	0.628	0.681	0.619	0.343
11	0.600	0.686	0.745	0.684	0.379
12	0.658	0.755	0.817	0.746	0.414
13	0.716	0.818	0.885	0.809	0.450

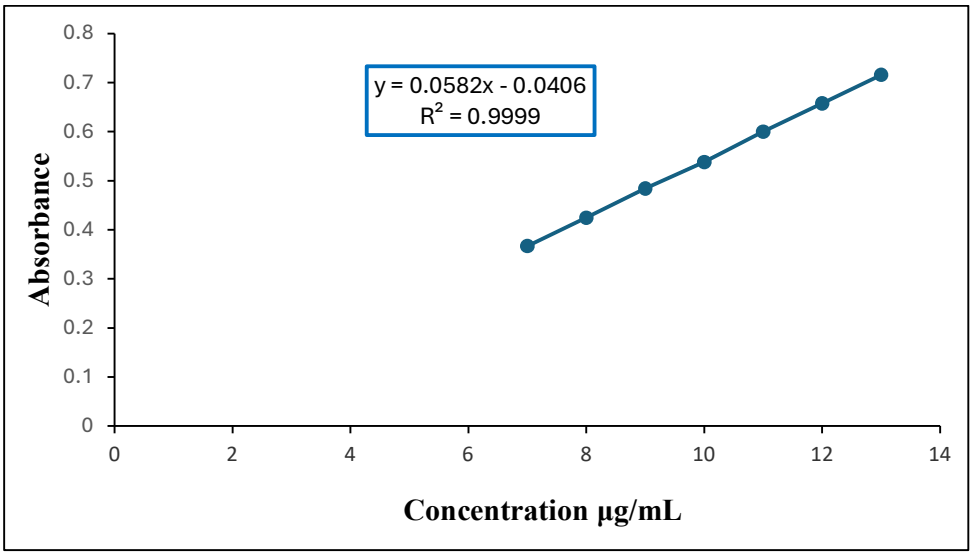

Figure 4: Calibration curve at 228nm

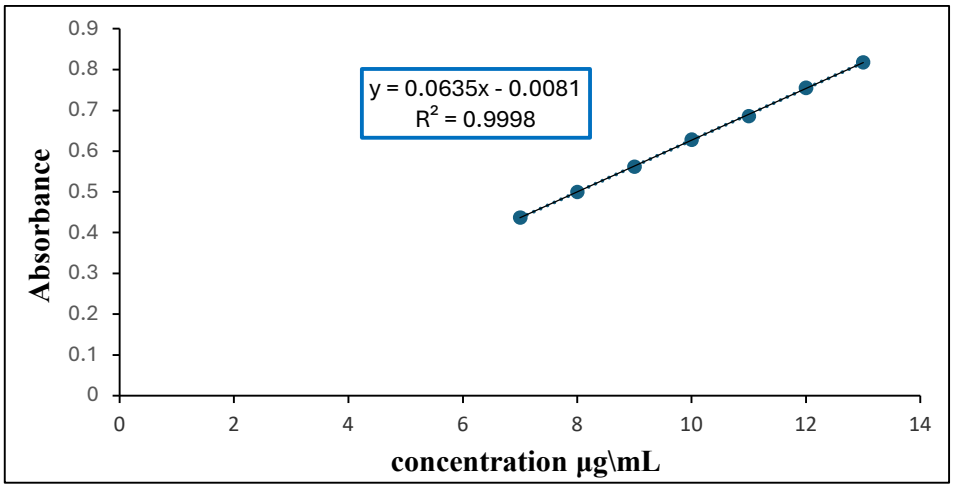

Figure 5: Calibration curve at 233nm

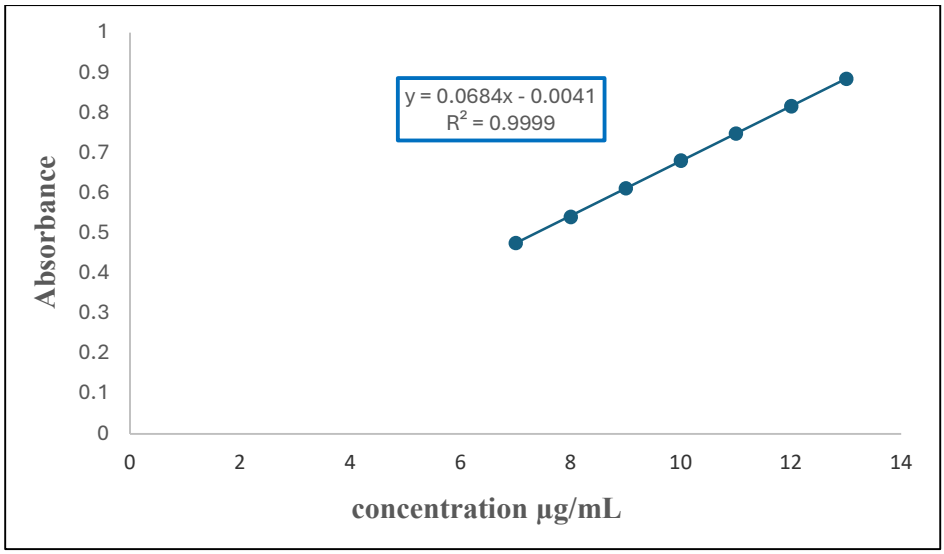

Figure 6: Calibration curve at 238nm

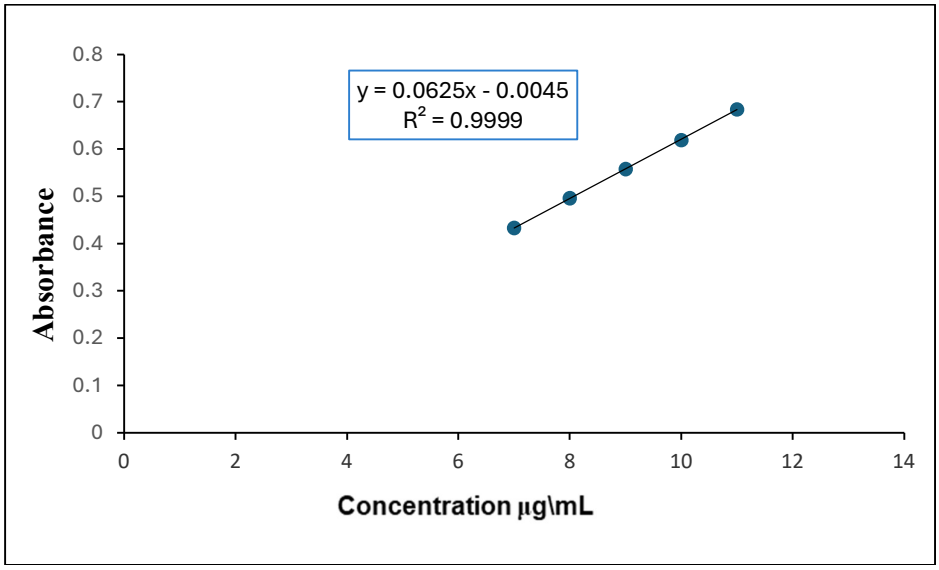

Figure 7: Calibration curve at 243nm

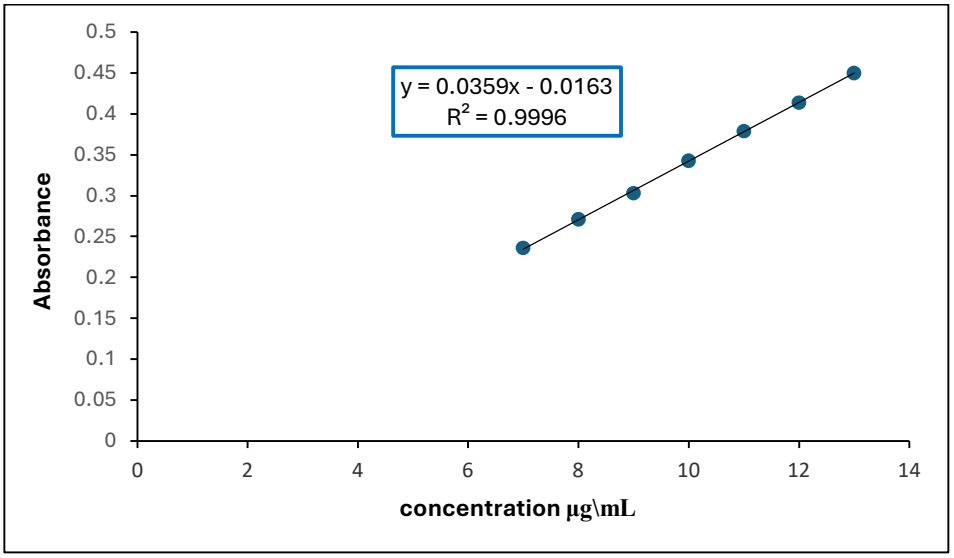

Figure 8: Calibration curve at 248nm

Table 2: Linearity data shows statistical parameters at the selected wavelengths

Wavelength(nm)	Regression equation	Slope	Intercept	R^2	LOD (µg mL^{-1})	LOQ (µg mL^{-1})
228	y = 0.0582x - 0.0406	0.05817	-0.0406	0.9999	0.08774	0.26588
233	y = 0.0635x - 0.0081	0.0626	-0.0081	0.9998	0.11471	0.34763
238	y = 0.0684x - 0.0041	0.0686	-0.0041	0.9999	0.05975	0.18106
243	y = 0.0625x - 0.0045	0.0626	- 0.0045	0.9999	0.05400	0.09897
248	y = 0.0359x - 0.0163	0.0358	- 0.0163	0.9996	0.15889	0.48150

Limit of Detection and Limit of Quantification

The linearity slope was employed for calculating the LOD and LOQ for escitalopram, and many sample studies have supported this method. The average of all the absorbance was used to compute the LOD for escitalopram, which was found to be 1.4132 µg mL^{-1}. The average of all the absorbances was used to compute the LOQ for escitalopram, The concentration was determined to be 4.2826 µg mL-1.

Precision

Figure 9 Displays the spectral precision of the escitalopram system. **Figure 10** depicts the eescitalopram interday precision spectra. **Figure 11** for escitalopram depicts the intraday precision spectra. For escitalopram, the percentage RSD of the system's intraday and interday precision was calculated. It was discovered to be less than 2%, demonstrating the precision of the approach method. Comparing the results acquired from other accuracy approaches, the suggested method exhibits good precision.

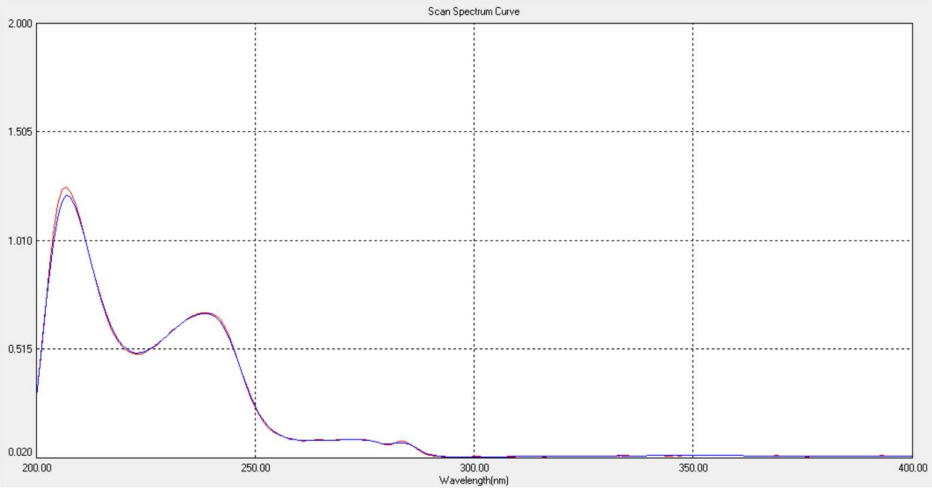

Figure 9: System precision overlay spectra of clomipramine

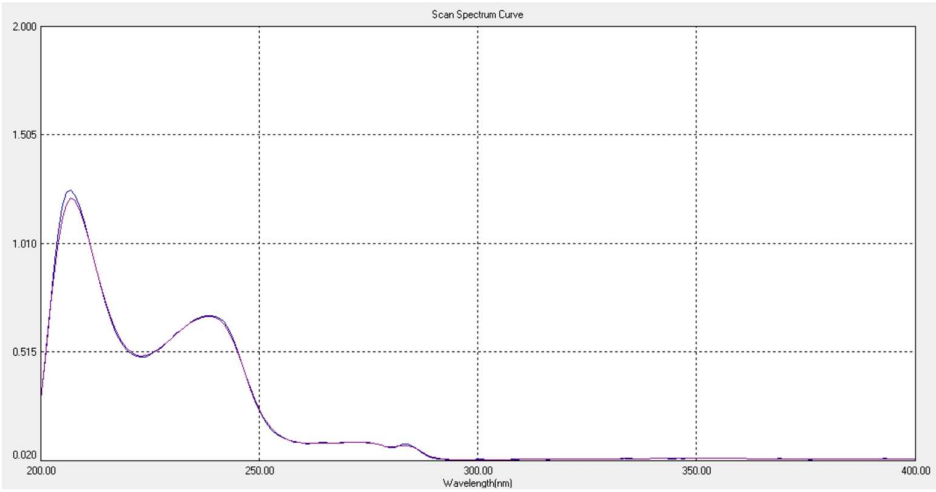

Figure 10: Interday precision overlay spectra of Escitalopram

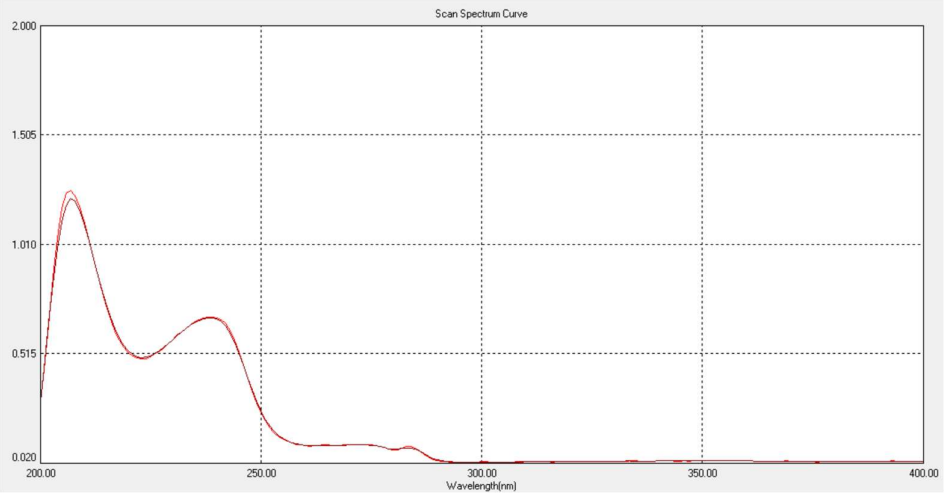

Figure 11: Intraday precision overlay spectra of Escitalopram

Accuracy

Figure 12 are presented the spectrum overlay for escitalopram, were verified to ensure precision at 80, 100, and 120%. The escitalopram findings are displayed in **Table 3**, and it was determined that the results were within acceptable bounds.

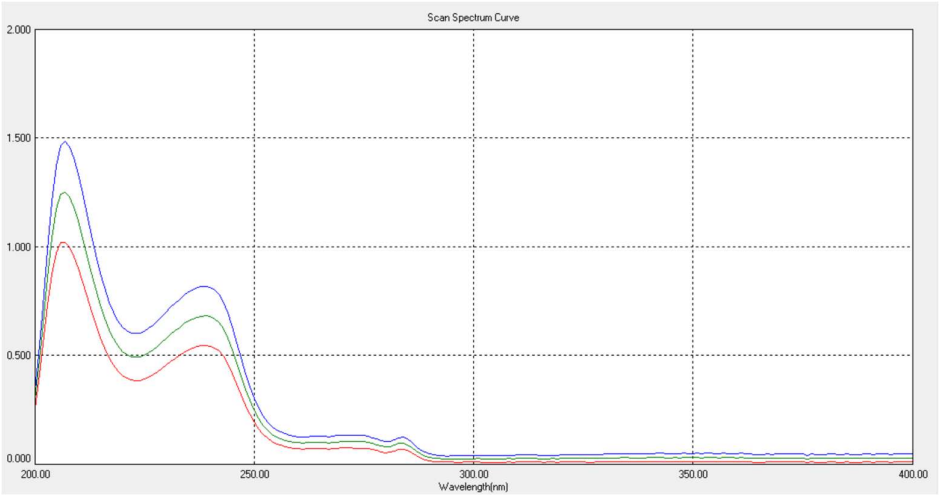

Figure 12: Overlay spectra of accuracy of clomipramine 80, 100, 120 % raising

Table 3: Recovery Studies

Wavelength (nm)	Amount present (µg mL^{-1})	Amount added (µg mL^{-1})	Absorbance	Amount recovered (µg mL^{-1})	% Recovery
228	5	4	0.484	7.97	99.63
		5	0.538	9.95	99.50
		6	0.6	11.98	99.83
233	5	4	0.562	7.99	99.88
		5	0.628	9.98	99.80
		6	0.686	11.96	99.67
238	5	4	0.612	7.99	99.88
		5	0.681	9.99	99.90
		6	0.745	11.97	99.75
243	5	4	0.558	7.95	99.38
		5	0.619	9.84	98.40
		6	0.684	11.92	99.33
248	5	4	0.303	7.94	99.25
		5	0.343	9.89	98.90
		6	0.343	11.94	99.50

Marketed formulation of assay

Using the proposed spectrophotometric method, The amount of escitalopram in the contents of the tablet was examined. The UV absorption spectra of a Marketing medication was tested Threefold. During the process of extraction and filtration, the pharmaceutical formulation exhibited exceptional analytical recovery values remained stable. The **Table 4** presents the findings.

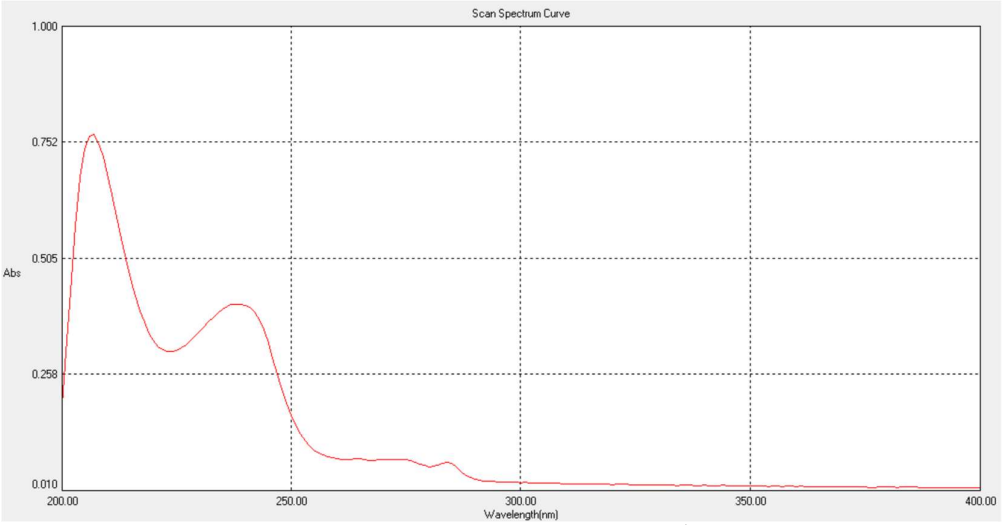

Figure 13: UV spectrum of standard clomipramine (10µg mL^{-1}) using water as a blank

Table 4: Assay of Escitalopram

Label claim (mg)	Amount estimated (mg)	% Assay
10	9.96	99.60
10	9.98	99.20
10	9.98	99.80
Average	9.95	99.53
SD		0.3055
% RSD		0.3069

Assessment of Environmental Sustainability

The outcomes of the suggested approaches greenness methodology were assessed. Analytical scale findings are displayed in **Table 6**, whereas agree and GAPI metrics data are provided in **Figures 14 and 15**.

Table 6: Summary of Eco scale penalty points for the proposed method

Description	Penalty points	Total Penalty Points	Score
Methanol	12	12	88
Instrument	0		
Occupational hazard	0		
Waste	0		

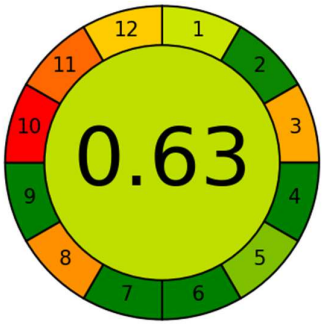

Figure 15: Agree metrics output for the proposed method.

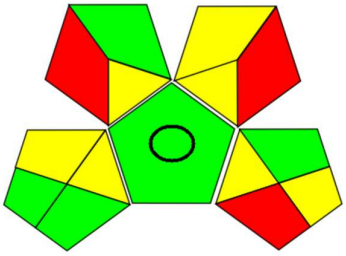

Figure 14: GAPI Pictogram for the proposed method.

CONCLUSION

By assessing a variety of validation criteria, the recently developed spectrophotometric approach for measuring escitalopram has been verified and found to be within permitted limits as specified by the International Council for Harmonisation (ICH) guidelines. The measurement escitalopram The tablet formulation demonstrated sensibility, reliability, and efficiency and reproducible using the described approach. There is no text provided. We highly recommend utilizing the suggested methodology for regular study on escitalopram in pharmaceutical formulations since it offers greater precision compared to current UV spectrophotometric methods and incorporates an easy mathematical approach.

STATEMENT OF ETHICS

There are no animal or human participants used in this study's trials.

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DISPUTE OF INTEREST

There are no financial interests that could be at odds with this content.

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No financing has been reported.

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