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RAPID ESTIMATION OF ESCITALOPRAM IMPURITIES IN MULTIPLE BRANDS USING COMPREHENSIVE STABILITY INDICATING RP-HPLC METHOD

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Keywords:

RP-HPLC, Rapid impurity estimation, Escitalopram impurities, Related Substances, Stability indicating method, Application of HPLC

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ABSTRACT: This study aimed regarding application of comprehensive stability-indicating analytical method for estimation of Escitalopram impurities in multiple brands of pharmaceutical dosage forms using reverse phase high-performance liquid chromatography. The comprehensive stability-indicating analytical method applied utilized an isocratic mode with a C18 column. The mobile phase comprised a phosphate buffer and acetonitrile (75:25v/v) at a flow rate of 1.2ml/min. A sample injection volume of 5µL was employed, and eluted analytes were monitored at 240nm. The utilized method was validated following ICH guidelines and found to be simple, specific, highly sensitive, precise, robust, and linear for Escitalopram in the range of 0.16 to 2.4µg/ml. Similarly, for Escitalopram impurities A, B, D, H, L & C, the observed linearity range was 0.25 to7.5µg/ml. Accuracy range was confirmed for Escitalopram from 0.16 to 2.3µg/ml, Escitalopram impurities A, B, H from 0.3 to 8µg/ml, and Escitalopram impurities C, D, and L from 0.5 to 8µg/ml. The solution demonstrated stability for up to 48 Hrs. Additionally, the applied method was proven to be stability-indicating by subjecting drug products to various stress conditions such as acid hydrolysis, base hydrolysis, oxidation, thermal degradation, and photolytic degradation. Major degradation was observed in oxidation and base conditions, along with mass balance, substantiating the method's stability-indicating nature. Furthermore, the method was applied to identify and quantify impurities present in multiple brands of Escitalopram pharmaceutical dosage forms, which includes tablets and solutions, indicating comprehensive application of method to ensure the quality and safety of drug products.

INTRODUCTION: Escitalopram oxalate, chemically known as S-(+)-1-[3-(dimethylamino) propyl]-1-(p-fluorophenyl) - 5 - phthalanarbonitrile oxalate, is an S-enantiomer of racemic citalopram used as an antidepressant to treat major depressive disorder, anxiety disorders, and chronic pain conditions.

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Escitalopram oxalate falls under the category of oral selective serotonin reuptake inhibitors (SSRIs) and has demonstrated high potency in both in vitro and *in-vivo* studies [3]. SSRIs function by inhibiting the reuptake of serotonin into neurons.

According to information from the API vendor, various impurities associated with Escitalopram are generated during the synthesis of the active pharmaceutical ingredient (API) or due to the degradation of the active compound in formulated products. These impurities include Impurity A, B, C, D, H, and L. Impurity A is a process-related impurity generated in basic conditions, while impurity B is a degradation impurity resulting from

hydrolysis. Impurity C is a degradation impurity formed through oxidation, and impurity D is a degradation impurity generated through thermal degradation. Impurity H is considered a probable degradation impurity, and Impurity L is a likely side-reaction impurity, which could form if Des-fluoro CTM-I reacts similarly in the process, leading to the formation of Impurity L.A literature survey uncovered a analytical methods for the estimation of Escitalopram alone [15], Enantiomeric assay tests [4] and the estimation of Escitalopram in combination with other drugs having long run time [2, 3, 5, 10] and [14]. A method specifically reported the analysis of impurities using different columns only same thing not given for sample analysis [1]. The United States Pharmacopeia provides different methods for determining Escitalopram impurities in raw materials and various dosage forms [6] and [7]. The Indian Pharmacopeia offers a method suitable for estimating assay and unknown impurities but is not specified for the estimation of degradation impurities [8]. A method observed for simultaneous assay and impurity estimation [9] and Impurity estimation using chiral column [13]. Based on current knowledge and a literature survey, there is a noticeable absence of a simple, short, and stability-indicating RP-HPLC method for identifying and quantifying Escitalopram impurities. None of the research articles found demonstrate the application of the method on multiple brands of pharmaceutical dosage forms. The objective of the current research is to apply a developed, validated, and stability-indicating RP-HPLC method to multiple brands of Escitalopram for estimating Escitalopram impurities in tablet and solution dosage forms.

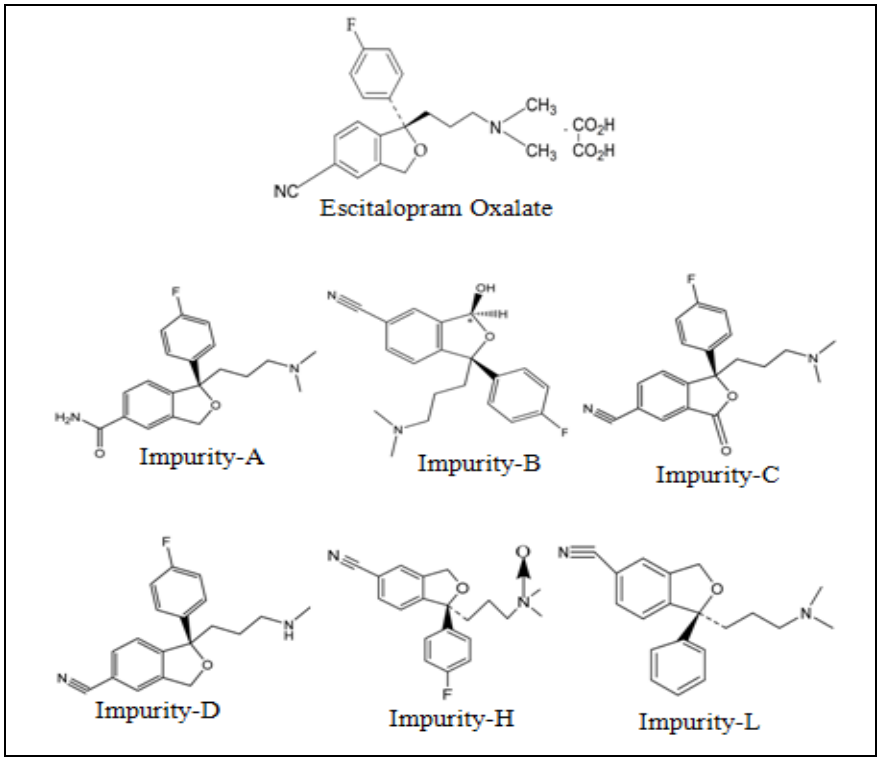

FIG. 1: CHEMICAL STRUCTURE OF ESCITALOPRAM AND ESCITALOPRAM IMPURITIES

MATERIALS AND METHOD:

Drugs and Reagents: Escitalopram Oxalate (purity 99.4%) Procured from Sigma-Aldrich, Laramie WY-USA, A standard grade Escitalopram impurity-A, B, C,s D and H was procured from CRO Splendid Lab Pvt Ltd, Pune, India. Furthermore, Impurity-L procured from Synthink Research chemicals, Pune, India. Escitalopram oral drops and its placebo solution were received as gift samples from a pharmaceutical industry. Escitalopram tablets procured from Mumbai- India market and a global placebo for tablet dosage forms, comprising inactive ingredients such as talc, croscarmellose sodium, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, and polyethylene glycol, were received as gift samples from pharmaceutical industry. Additionally, all reagents and solvents utilized in the study were of analytical grade.

Instrumentation, Chromatographic Conditions and Preparation of Solutions: The analysis was performed using Shimadzu prominence-i LC-2030C series dual wavelength UV detector and Thermo scientific dionex ultimate 3000 PDA-HPLC system, which was equipped with a quaternary pump, auto sampler, and column compartment. The instruments were monitored using chromeleon 7.2.10 ES chromatography.

TABLE 1: OPTIMIZED CHROMATOGRAPHIC CONDITION

Column	Ascentis express C18-150 mm x 4.6 mm, 2.7 µm particle size
Flow rate	1.2 mL/minute
Injection volume	5 µL
Column oven temperature	40ºC
Auto sampler temperature	25ºC
Run time	15-minute
Mode	Isocratic
Wavelength	240nm

Mobile Phase: Prepared a mixture of phosphate buffer pH 7.0 and acetonitrile in the ratio of 75:25v/v. The buffer was prepared by dissolving 6.8g potassium dihydrogen phosphate in 1000mL of water, to this solution 5ml of triethylamine was added, and the pH was adjusted to 7.0 using diluted orthophosphoric acid which is then filtered through a 0.45µm membrane filter.

Diluent: Prepared a mixture of water and methanol in a ratio of 50:50v/v.

Preparation of Standard and Impurity Identification Solution:

Escitalopram Oxalatestandard Solution: To prepare the Escitalopram Oxalate standard solution, 20mg of the Escitalopram oxalate was weighed and transferred into a 200ml volumetric flask. It was dissolved and diluted to the mark using a diluent. Additionally, 2ml of this solution was further diluted to 10ml in a volumetric flask, subsequently; 2ml of the latter solution was diluted into a 20ml volumetric flask using similar diluent and mixed and used for final analysis (Conc. 2µg/ml).

Escitalopramimpurity Identification Solution: For the preparation of Escitalopram impurity solutions, 2.5mg of Impurity A, B, C, D, H, and L were individually weighed and transferred into 50ml of volumetric flasks. The substances were dissolved and diluted up to the mark using a diluent, Subsequently, 1ml of each solution was diluted into 20ml volumetric flasks using the diluent and mixed well for subsequent analysis (Conc. 5µg/ml).

Preparation of Sample Solution:

Preparation of Sample Solution for Escitalopram Oral Drop: To prepare the oral drop solution, a sample was mixed and transferred using dropper equivalent to 20mg of Escitalopram oxalate into a 20mL of volumetric flask, added 8ml of diluent, and the mixture was vortexed for 5 minutes. The volume was adjusted up to the mark in the volumetric flask using the same diluent. The solution was then filtered through a 0.45µm nylon Millipore filter by discarding initial 2mL of filtrate (Conc. 1000µg/ml).

Preparation of Test Solution for Escitalopram Tablets: Weighed 10-tablets determined its average weight than crushed the tablets into powdered form and weighed a powdered sample equivalent to 20mg of Escitalopram oxalate transferred into a 20mL of volumetric flask, added 8mL of diluent, and the mixture was vortexed for 5 minutes. The volume was adjusted up to the mark in the volumetric flask using the same diluent. The solution was then filtered through a 0.45µm nylon Millipore filter by discarding initial 2mL of filtrate (Conc. 1000µg/ml).

Method Validation: The optimized method underwent validation following ICH guidelines Q2R2 [11], encompassing specificity, limit of detection, limit of quantification, linearity-range, accuracy, precision, robustness, filter study, and solution stability study. The validation parameters are detailed in our previously published study, affirming the reliability of the method for its intended application refer@ IJARESM, Volume 12, Issue 2, Feb-2024 [12].

Force Degradation Study (FD Study): The Forced Degradation study serves as a crucial tool for evaluating and confirming the specificity of an analytical method. It helps to identify and quantify the potential degradation products, contributing to the understanding of degradation pathways and intrinsic molecule stability. Optimization of degradation behavior involved acid hydrolysis,

alkali hydrolysis, oxidation, thermal and photolytic stress conditions, revealing degradation and mass balance observations, particularly in basic and oxidation conditions. Further details on the FD study can be found in our previously published study refer@ IJARESM, Volume 12, Issue 2, Feb-2024 [12].

Application: The method described above was implemented across seven distinct brands of oral dosage forms, which were available both in tablet and solution formulations. This comprehensive application aimed to assess the suitability and versatility of the method across different pharmaceutical dosage forms. Sample preparation procedure for both tablet and solution dosage forms refer above section Preparation of Sample Solution. This specific procedure provided details on the preparation of sample solutions, ensuring consistency and accuracy in the analysis of various pharmaceutical formulations. By applying the method to a range of dosage forms, the study sought to validate its robustness and applicability in diverse pharmaceutical product matrices.

RESULTS AND DISCUSSION:

System Suitability Criteria: The system suitability criteria were established by analyzing six replicates of the standard solution. This assessment involved evaluating the %RSD (Relative Standard Deviation) of the area response, asymmetry of the Escitalopram peak, and the theoretical plates. The %RSD of the area response ensures consistency in the measurement of peak areas across replicates, indicating the precision of the method. Asymmetry reflects the shape and symmetry of the Escitalopram peak, and theoretical plates assess the efficiency of the chromatographic separation.

Meeting the acceptance limits for these criteria demonstrates the reliability and robustness of the analytical method for accurate and reproducible analysis of Escitalopram impurities in the given conditions. The observed retention time for Escitalopram is 11.547, impurity-A, B, D, H, L and C are 2.673, 4.552, 6.735, 7.760, 8.862 and 9.605 respectively. Refer figure 2 to 6 for specimen chromatogram of blank, placebo, standard and impurity solution.

TABLE 2: RESULTS OF SYSTEM SUITABILITY CRITERIA

Sr. no.	Area of Escitalopram	Asymmetry	Theoretical plates
1	17.937	1.20	19039
2	18.002	1.22	18915
3	17.740	1.22	19164
4	17.987	1.21	18781
5	17.891	1.21	19044
6	17.739	1.21	19284
Average (n=6)	17.883	1.21	19038
standard deviation	0.1	Note: RSD- Relative standard deviation	
%RSD	0.6		
Limit	% RSD ≤ 5%,	≤ 2	≥2000

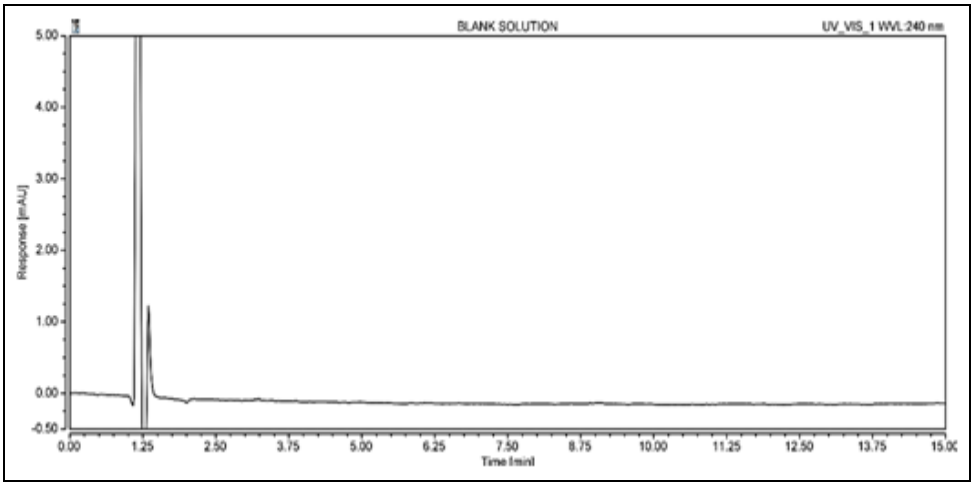

FIG. 2: REPRESENTATIVE CHROMATOGRAM OF BLANK SOLUTION

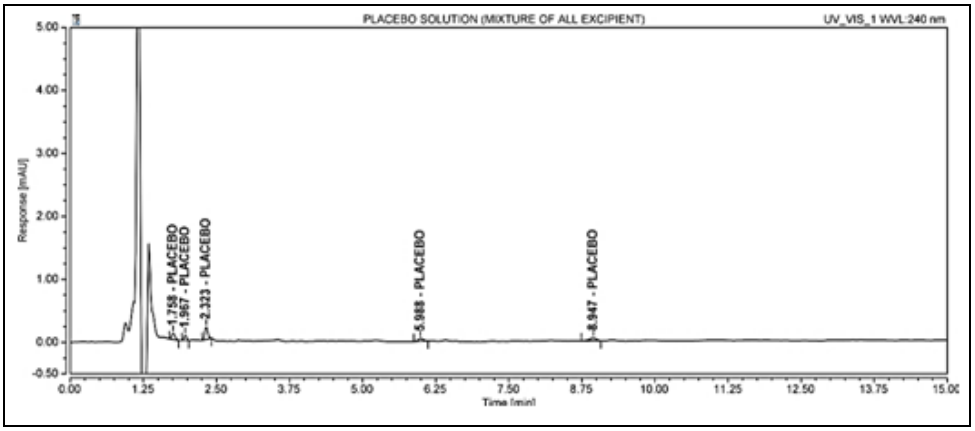

FIG. 3: REPRESENTATIVE CHROMATOGRAM OF PLACEBO SOLUTION FOR TABLET DOSAGE FORM

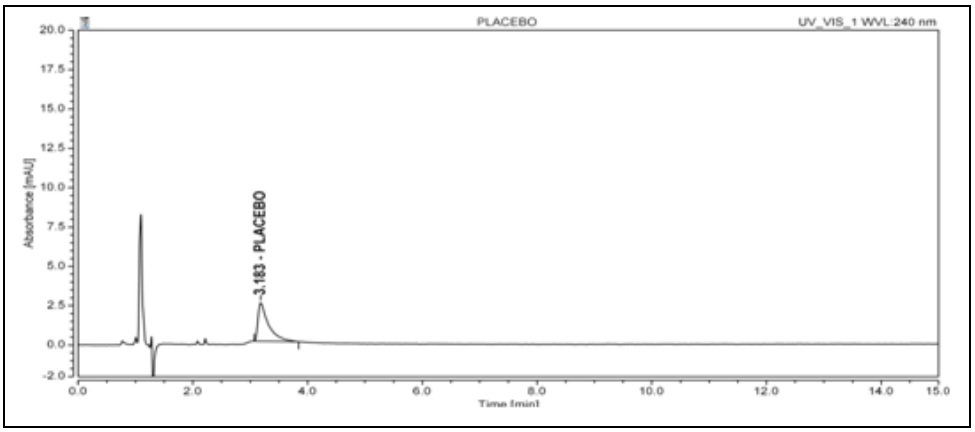

FIG. 4: REPRESENTATIVE CHROMATOGRAM OF PLACEBO SOLUTION FOR ORAL SOLUTION DOSAGE FORM

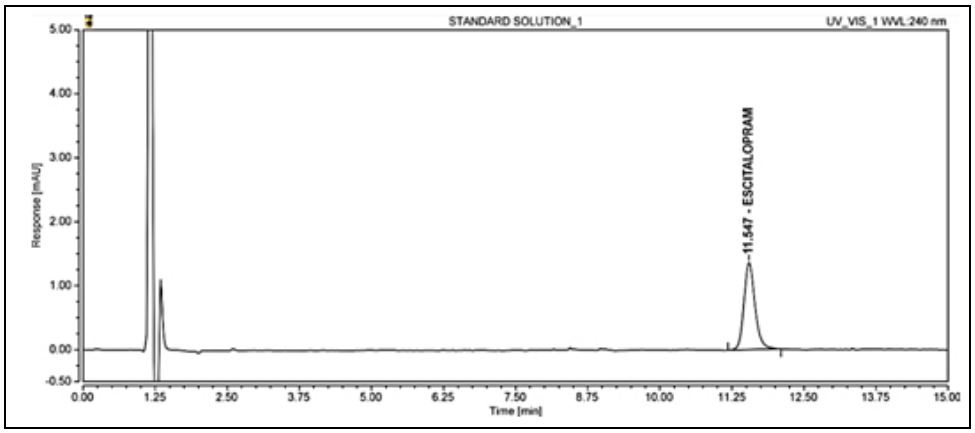

FIG. 5: REPRESENTATIVE CHROMATOGRAM OF ESCITALOPRAM STANDARD SOLUTION

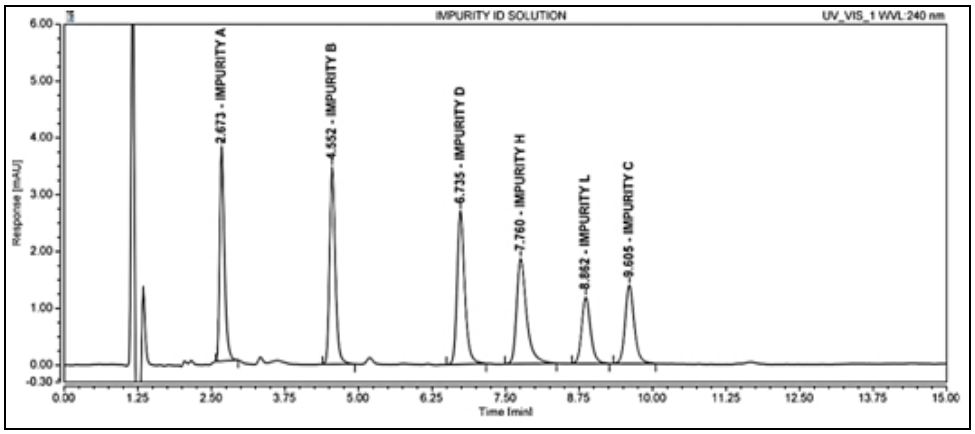

FIG. 6: REPRESENTATIVE CHROMATOGRAM OF IMPURITY IDENTIFICATION SOLUTION

Application of Method on Different Pharmaceutical Products: Seven different samples of pharmaceutical products were analyzed using optimized method condition, the observed chromatograms and results of each analyzed sample in tabulated form given as below.

Sample Solution-1(Escitalopram Tablets, Label Claim 10mg): The observed average weight (n=10) of Escitalopram tablets was 130.702mg. The sample weight 262.83mg was taken for analysis, which is equivalent to 20mg of Escitalopram the result indicates that all the analytes were well separated and can be identified and quantified, refer **Fig. 7** for its representative chromatogram and **Table 3** for detailed results.

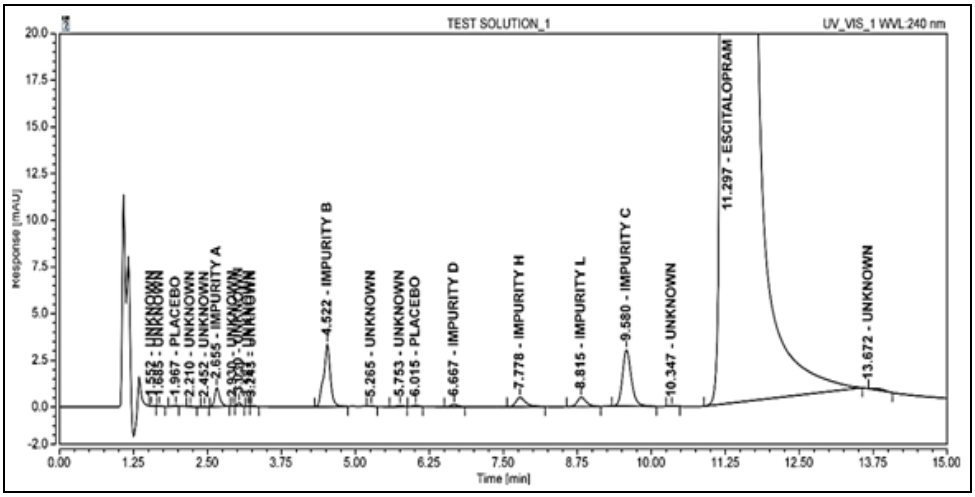

FIG. 7: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-1

TABLE 3: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-1

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.297	1	9463.24	-
			Known Impurities		
2	Impurity-A	2.655	0.24	6.068	0.182
3	Impurity-B	4.522	0.40	22.539	0.677
4	Impurity-D	6.667	0.59	0.967	0.026
5	Impurity-H	7.778	0.69	5.651	0.176
6	Impurity-L	8.815	0.78	5.179	0.150
7	Impurity-C	9.580	0.85	31.243	1.433
			Unknown Impurities		
8	Unknown-1	1.552	0.14	0.06	0.001
9	Unknown-2	1.685	0.15	0.095	0.001
10	Unknown-3	2.210	0.2	0.109	0.001
11	Unknown-4	2.452	0.22	0.08	0.001
12	Unknown-5	2.930	0.26	0.152	0.001
13	Unknown-6	3.030	0.27	0.897	0.008
14	Unknown-7	3.243	0.29	0.222	0.002
15	Unknown-8	5.143	0.46	0.065	0.001
16	Unknown-9	5.265	0.47	0.201	0.002
17	Unknown-10	5.753	0.51	0.515	0.004
18	Unknown-11	10.347	0.92	0.151	0.001
19	Unknown-12	13.672	1.21	0.95	0.008

(RT-Retention time, RRT-Relative retention time)

Sample Solution-2 (Escitalopram Tablets, Label Claim 10mg): The observed average weight (n=10) of Escitalopram tablets was 116.29mg. The sample weight 232.07mgwas taken for analysis which is equivalent to 20mg of Escitalopram the result indicates that all the analytes present in sample were well separated and can be identified and quantified, refer **Fig. 8** for its representative chromatogram and **Table 4** for detailed results.

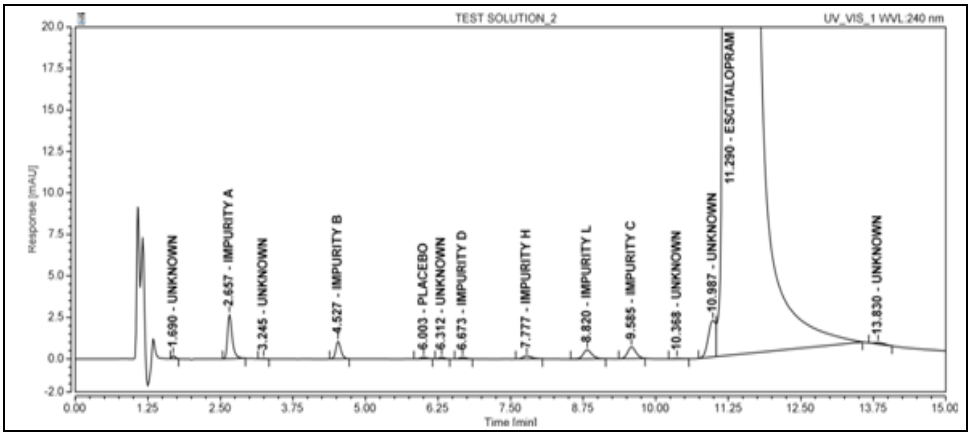

FIG. 8: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-2

TABLE 4: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-2

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.290	1.00	9964.68	-
			Known Impurities		
2	Impurity-A	2.657	0.24	15.24	0.461
3	Impurity-B	4.527	0.40	6.752	0.204
4	Impurity-D	6.673	0.59	0.713	0.019
5	Impurity-H	7.777	0.69	1.967	0.062
6	Impurity-L	8.820	0.78	5.68	0.166
7	Impurity-C	9.585	0.85	7.595	0.351
			Unknown Impurities		
8	Unknown-1	1.690	0.15	0.686	0.006
9	Unknown-2	3.245	0.29	0.126	0.001
10	Unknown-3	6.312	0.56	0.684	0.006
11	Unknown-4	10.368	0.92	0.291	0.003
12	Unknown-5	10.987	0.97	19.052	0.167
13	Unknown-6	13.830	1.22	1.018	0.009

Sample Solution-3 (Escitalopram Tablets, Label Claim 10mg): The observed average weight (n=10) of Escitalopram tablets was 134.48mg. The sample weight 262.83mg for analysis was taken, which is equivalent to 20mg of Escitalopram the result indicates that all the analytes were well separated and can be identified and quantified, refer **Fig. 9** for its representative chromatogram and **Table 5** for detailed results.

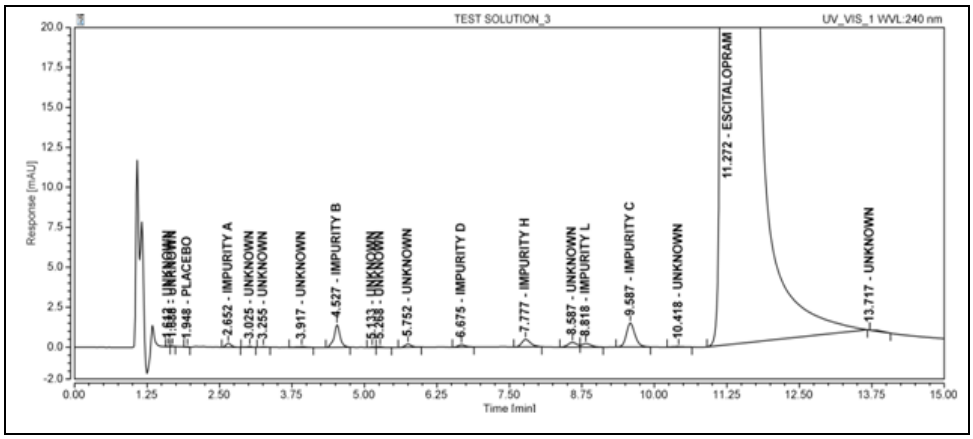

FIG. 9: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-3

TABLE 5: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-3

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.272	1.00	11313.88	-
			Known Impurities		

2	Impurity-A	2.652	0.24	1.615	0.050
3	Impurity-B	4.527	0.40	10.391	0.321
4	Impurity-D	6.675	0.59	1.136	0.031
5	Impurity-H	7.777	0.69	4.957	0.159
6	Impurity-L	8.818	0.78	2.442	0.073
7	Impurity-C	9.587	0.85	15.378	0.726
Unknown Impurities					
8	Unknown-1	1.612	0.14	0.059	0.001
9	Unknown-2	1.688	0.15	0.073	0.001
10	Unknown-3	3.025	0.27	0.311	0.003
11	Unknown-4	3.255	0.29	0.186	0.002
12	Unknown-5	5.133	0.46	0.188	0.002
13	Unknown-6	5.268	0.47	0.312	0.003
14	Unknown-7	5.752	0.51	1.479	0.013
15	Unknown-8	8.587	0.76	3.145	0.028
16	Unknown-9	13.717	1.22	0.565	0.005

Sample Solution-4 (Escitalopram Tablets, Label Claim 10mg): The observed average weight (n=10) of Escitalopram tablets was 165.07mg. The sample weight 336.66mg for analysis was taken, which is equivalent to 20mg of Escitalopram the result indicates that all the analytes were well separated and can be identified and quantified, refer **Fig. 10** for its representative chromatogram and **Table 6** for detailed results.

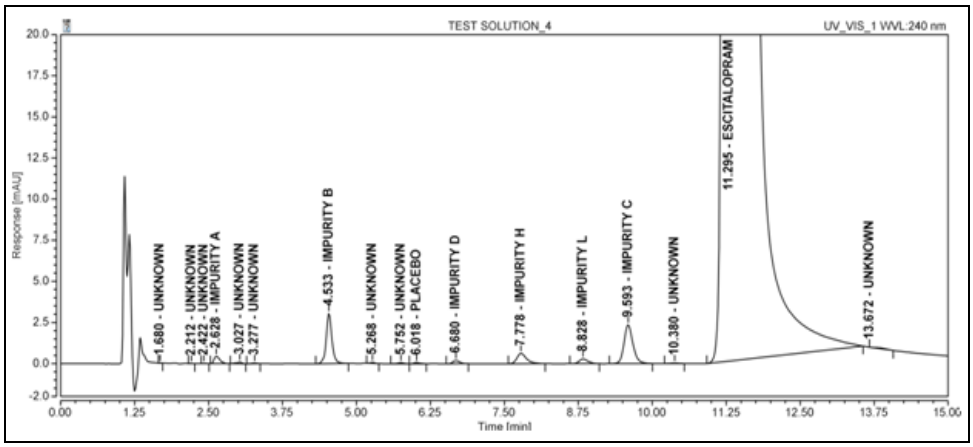

FIG. 10: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-4

TABLE 6: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-4

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.295	1.00	10467.81	-
Known Impurities					
2	Impurity-A	2.628	0.23	3.127	0.093
3	Impurity-B	4.533	0.40	20.622	0.611
4	Impurity-D	6.68	0.59	1.623	0.042
5	Impurity-H	7.778	0.69	7.135	0.219
6	Impurity-L	8.828	0.78	3.03	0.087
7	Impurity-C	9.593	0.85	24.59	1.112
Unknown Impurities					
8	Unknown-1	1.680	0.15	0.026	0.0002
9	Unknown-2	2.212	0.20	0.035	0.0003
10	Unknown-3	2.422	0.21	0.087	0.001
11	Unknown-4	3.027	0.27	0.641	0.006
12	Unknown-5	3.277	0.29	0.241	0.002
13	Unknown-6	5.268	0.47	0.295	0.003
14	Unknown-7	5.752	0.51	0.452	0.004
15	Unknown-8	10.380	0.92	0.293	0.003
16	Unknown-9	13.672	1.21	0.579	0.005

Sample Solution-5 (Escitalopram Tablets, Label Claim 10mg): The observed average weight (n=10) of Escitalopram tablets was 144.58mg. The sample weight 289.47mg for analysis was taken, which is equivalent to 20mg of Escitalopram the result indicates that all the analytes were well separated and can be identified and quantified, refer **Fig. 11** for its representative chromatogram and **Table 7** for detailed results.

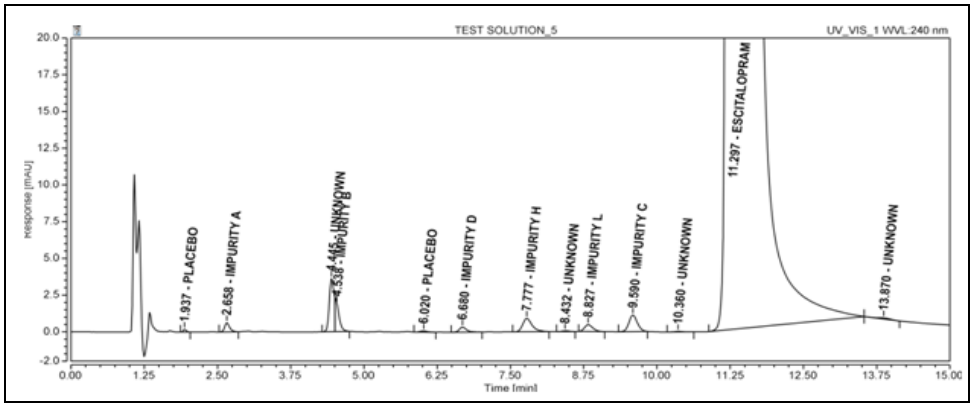

FIG. 11: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-5

TABLE 7: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-5

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.297	1	10196.67	-
		Known Impurities			
2	Impurity-A	2.658	0.24	3.67	0.111
3	Impurity-B	4.445	0.39	30.775	0.929
4	Impurity-D	6.680	0.59	2.79	0.074
5	Impurity-H	7.777	0.69	10.338	0.323
6	Impurity-L	8.827	0.78	4.769	0.139
7	Impurity-C	9.590	0.85	11.795	0.543
		Unknown Impurities			
8	Unknown-1	1.690	0.15	0.236	0.002
9	Unknown-2	3.027	0.27	0.151	0.001
10	Unknown-3	3.260	0.29	0.196	0.002
11	Unknown-4	5.258	0.47	0.154	0.001
12	Unknown-5	5.738	0.51	0.255	0.002
13	Unknown-6	8.432	0.75	0.41	0.004
14	Unknown-7	10.36	0.92	0.376	0.003
15	Unknown-8	13.672	1.21	0.772	0.007

Sample Solution-6 (Escitalopram Tablets, Label Claim 10mg): The observed average weight (n=10) of Escitalopram tablets was 165.88mg. The sample weight 330.42mg for analysis was taken, which is equivalent to 20mg of Escitalopram the result indicates that all the analytes were well separated and can be identified and quantified, refer **Fig. 12** for its representative chromatogram and **Table 8** for detailed results.

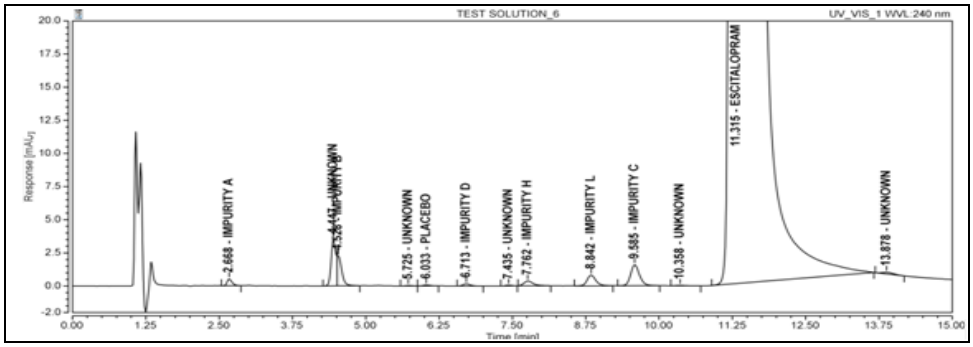

FIG. 12: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-6

TABLE 8: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-6

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.315	1	10179.46	-
Known Impurities					
2	Impurity-A	2.668	0.24	3.19	0.097
3	Impurity-B	4.528	0.40	12.235	0.371
4	Impurity-D	6.713	0.59	1.469	0.039
5	Impurity-H	7.762	0.69	3.893	0.122
6	Impurity-L	8.842	0.78	8.487	0.249
7	Impurity-C	9.585	0.85	16.633	0.770
Unknown Impurities					
8	Unknown-1	3.012	0.27	0.312	0.003
9	Unknown-2	4.447	0.39	19.931	0.175
10	Unknown-3	7.435	0.66	0.415	0.004
11	Unknown-4	10.358	0.92	0.339	0.003
12	Unknown-5	13.878	1.23	1.608	0.014

Sample Solution-7(Escitalopram Oral Solution, Label Claim 20mg): The observed weight per mL of Escitalopram oral solution was 0.9905g per mL, the sample was analyzed using 1.02302g weight, which is equivalent to 20mg of Escitalopram the result indicates that all the analytes were well separated and can be identified and quantified, refer **Fig. 13** for its representative chromatogram and **Table 9** for detailed results.

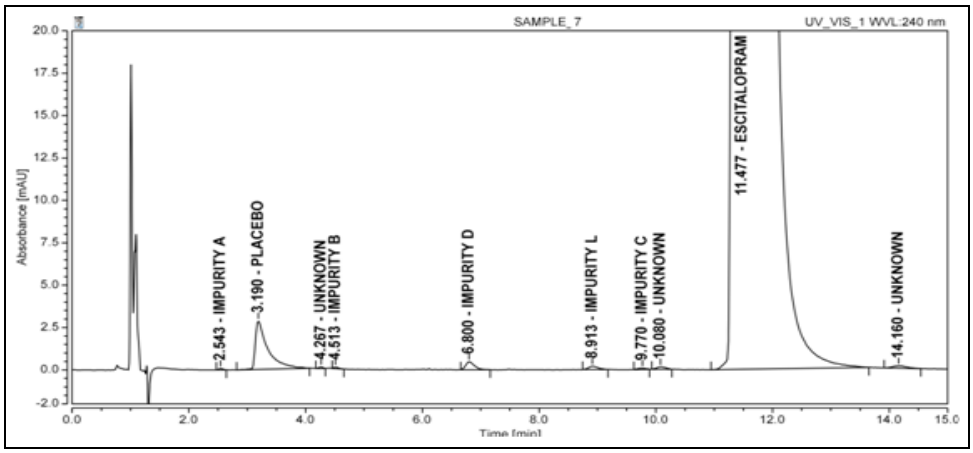

FIG. 13: REPRESENTATIVE CHROMATOGRAM OF SAMPLE SOLUTION-7

TABLE 9: RESULTS OBTAINED THROUGH SAMPLE SOLUTION-7

Sr. no.	Analyte	RT	Observed RRT	Area	% Impurity
1	Escitalopram	11.477	1.00	12285.71	-
Known Impurities					
2	Impurity-A	2.543	0.22	0.495	0.01
3	Impurity-B	4.513	0.39	0.490	0.01
4	Impurity-D	6.800	0.59	5.023	0.12
5	Impurity-H	ND	ND	NA	NA
6	Impurity-L	8.913	0.78	2.243	0.06
7	Impurity-C	9.770	0.85	0.743	0.03
Unknown Impurities					
8	Unknown-1	4.267	0.37	0.486	0.00
9	Unknown-2	10.080	0.88	1.611	0.01
10	Unknown-3	14.160	1.23	2.412	0.02

(ND-Not detected, NA-Not applicable)

CONCLUSION: The newly developed RP-HPLC method is highly comprehensive and suitable to monitor many potential impurities present in tablet and oral solution dosage forms of multiple escitalopram pharmaceutical products during research and development. The developed method

has been determined to be novel, short, simple, selective, precise, linear, accurate, robust, and stability-indicating for the identification and quantification of Escitalopram impurities in multiple brands of drug products. Additionally, it is well-suited for quality control analysis, playing a crucial role in ensuring the quality and safety of pharmaceutical dosage forms one can use this method for estimation of mentioned potential impurities in tablets as well as oral solution dosage forms.

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CONFLICTS OF INTEREST: Nil

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