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RP-HPLC METHOD DEVELOPMENT AND VALIDATION OF DESVENLAFAXINE SUCCINATE MONOHYDRATE IN TABLET DOSAGE FORM

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ABSTRACT

The objective of this work was to develop and validate simple, rapid and accurate chromatographic method for determination of Desvenlafaxine succinate in solid dosage form. This RP-HPLC method was based on Reversed Phase High Performance Liquid Chromatography, on Kromasil C-18, (250 mm × 4.6 mm, 5.0 µm) , using Acetonitrile: Ammonium Phosphate buffer (pH 3.0) (70:30 v/v) as the mobile phase, at a flow rate of 1 mL/min at ambient temperature. Quantification was achieved by UV detection at 220 nm over a concentration range of 20-160 µg/mL for Desvenlafaxine succinate. The mean retention time for Desvenlafaxine succinate was found to be 2.44 min. The amount of Desvenlafaxine succinate estimated as percentage label claim was found to be 99.67.

Key words: RP-HPLC, Desvenlafaxine succinate, marketed formulation.

1. INTRODUCTION

Desvenlafaxine succinate is a newer antidepressant drug, which is chemically 1-[(1RS)-2-(Dimethylamino)-1-(4-hydroxyphenyl) ethyl] cyclohexanol succinate monohydrate. Desvenlafaxine succinate is a structurally novel SNRI (serotonin - norepinephrine reuptake inhibitor) useful for the treatment of MDD (major depressive disorder). Desvenlafaxine (O-desmethyl venlafaxine) is the major active metabolite of the antidepressant venlafaxine, a medication used to treat major depressive, generalized anxiety and panic disorders. Desvenlafaxine succinate is not official in any pharmacopoeia.

Literature survey revealed that few methods of HPLC and most of were by UV spectrophotometric and some LC-MS methods were reported for the estimation of Desvenlafaxine Succinate in human plasma and all reported methods for the estimation of Desvenlafaxine Succinate were gave retention time 5-6 min. In the present investigation, I report the Methods for Determination of Desvenlafaxine Succinate in Tablet Dosage form.

2. MATERIALS AND METHODS

2.1 Materials: Pharmaceutical grade of Desvenlafaxine succinate was kindly gifted from Religare Pharma, Nasik. The commercially available marketed tablet Desnilla OD 50 (Mankind) containing 50 mg Desvenlafaxine was used and it was procured from the local market. All the solvents and chemicals used were Water, Dibasic ammonium phosphate , Phosphoric acid , Acetonitrile are of HPLC grade were used in the present investigation from Merk, fine chemicals, Mumbai.

2.2 Method

2.2.1 Instrument: Chemito HPLC system isocratic (model LC-6600) having UV detector and column heater. Data collection and analysis were performed using LC Solution software. Separation was achieved on Kromasil C-18 (250 mm × 4.6 mm, 5.0 µ). The column was supported Inertsil ODS C 18 (250 mm × 4.6 mm, 5 µ) . The peaks were checked with the UV detector.All weighing were done on electronic balance Essae FB200. pH meter used for adjusting pH was Digital pH Meter pH System Equiptronics EQ-611 and ultrasonicator of make PCi was used for study.

2.2.2 Buffer preparation: Accurately weigh and transfer about 660 mg of Dibasic ammonium phosphate dissolved in 1000 ml with water. Adjust the pH 3.0 with phosphoric acid

2.2.3 Preparation of mobile phase : Mix Acetonitrile and buffer in the ratio of 70:30 v/v solutions.

2.2.4 Preparation of Diluent: Mobile phase is used as Diluent.

2.2.5 Preparation of standard stock solution Accurately weigh and transfer about 75.84 mg of Desvenlafaxine succinate monohydrate (Equivalent. to 50 mg of Desvenlafaxine)in 50 ml of volumetric flask add 30 ml with diluent sonicate for 5 min,cool and make up to the mark with diluent.Diluent 5 ml of this solution to 50ml with diluent.

2.2.6 Preparation of Sample solution: Weigh 20 tablets and determine its average weight. Crush 20 tablets to fine powder and mix thoroughly. Weigh powder equivalent to 50 mg of Desvenlafaxine in to 50 ml volumetric flask, dissolve by 30 ml of diluent, sonicate for 20-25 minutes, cool and make up the volume up to the mark with diluent and filter through 0.45 µ membrane filter discarding first few ml.Dilute 5 ml of this solution 50 ml with diluent.

2.2.7 Chromatographic Conditions: The detailed chromatographic conditions are shown in Table 1.

Table: 1 chromatographic condition

Parameter	Value
Column	Kromasil C-18, (250 mm × 4.6 mm, 5.0
Mobile Phase	Acetonitrile: Buffer (70:30v/v)
Flow rate	1.0 mL min^{-1}
Run time	5 min
Injection volume	20 µL
Detection wavelength	220 nm
Diluent	Mobile Phase

2.2.8 System Suitability: Separation variable was set and mobile phase was allowed to saturate the column at 1.0 ml/min. After complete saturation of column, five replicates of working standard of Desvenlafaxine Succinate Monohydrate were injected. The results of system suitability shown in table 2.

Table: 2. Results of System suitability parameters

Parameter	Desvenlafaxine Succinate Monohydrate
Area	5358.758
% RSD	0.27
Theoretical plates	2767
Retention time	2.5
Peak Tailing	1.647

3. METHOD VALIDATION

3.1 Analysis of Standard Solution: Weigh accurately about 75.84 mg of Desvenlafaxine Succinate Monohydrate(Equivalent to 50mg of Desvenlafaxine) in to 50 ml volumetric flask, add 30 ml of diluent and sonicate for 5 min. Make up the volume with diluent . Dilute 5 ml of

the above solution to 50 ml with diluent and mix.A typical chromatogram obtained from a standard solution is shown in "Fig. 1".

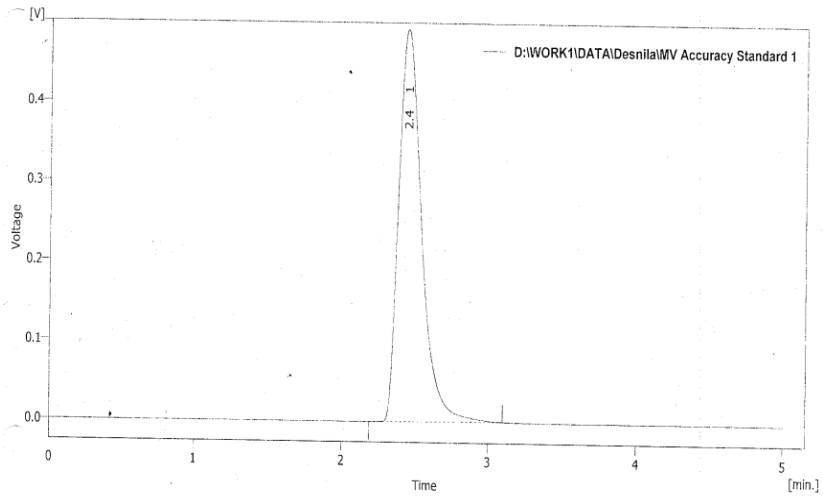

Fig. 1.Chromatogram of standard Desvenlafaxine Succinate Monohydrate

3.2 Analysis of Formulation: Weigh 20 tablets and determine its average weight. Crush 20 tablets to fine powder and mix thoroughly.

Weigh powder equivalent to 50 mg of Desvenlafaxine in to 50 ml volumetric flask, dissolve by 30 ml of diluent, sonicate for 20-25 minutes, cool and make up the volume up to the mark with diluent and filter through 0.45 µ membrane filter discarding first few ml.Dilute 5 ml of this solution 50 ml with diluent. A typical chromatogram obtained from formulation is shown in "Fig. 2".

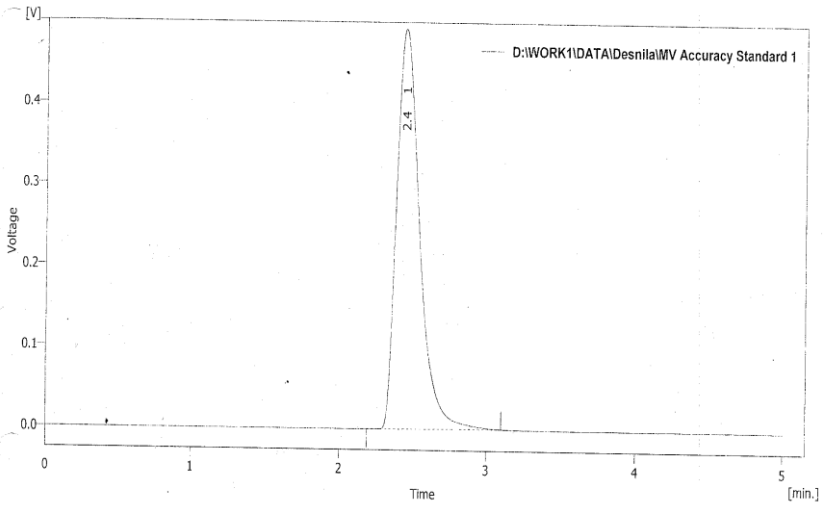

Fig. 2. Chromatogram of the Formulation consisting Desvenlafaxine

The assay of Tablet was established with present chromatographic condition developed and it was found more accurate and precise.Assay results of formulation are shown in Table 3.

Table: 3. Assay results of Desvenlafaxine

Sr. No.	Lable Claim (mg)	Area	% Found
1	50	5564.126	100.59
2	50	5457.752	99.52
3	50	5411.325	99.10
4	50	5449.441	99.37
5	50	5550.700	100.78
6	50	5443.608	99.26
	Average		99.77
	SD		7.36
	%RSD		0.14

3.3 Validation: The newly developed method was validated according to the ICH guidelines with respect to specificity, linearity, accuracy, precision and robustness. System suitability was established by injecting standard solution. The chromatograms were checked for the appearance of any extra peaks. No chromatographic interference from the tablet excipients was found. Method precision was determined using six-independent test solutions. The accuracy of the method was evaluated with the recovery of the standards from excipients. Three different quantities of the authentic standards were prepared. The mixtures were analyzed using the developed HPLC method. Linearity test solutions were prepared. To determine the robustness of the method, the final experimental conditions were purposely altered and the results were examined. The flow rate was varied by (±) 0.2 mL min-1, the percentage of mobile phase was varied by (±) 2%, column temperature was varied by (±) 50C, pH was varied by (±) 0.2 pH unit.

a. Specificity

The diluents, Placebo and Standard solution were prepared and injected. The obtained results are presented in the Result Table 4.Complete separation of Desvenlafaxine Succinate Monohydrate was noticed in presence of placebo/ Diluent. Chromatogram obtained from a diluent & placebo are shown in "Fig. 3" & "Fig.4".

Table: 4. Results of specificity

Name Of Solution	R.T. (Min.)
Diluent	Straight Line
Placebo	Straight Line
Standard	Standard peak observed at 5 min.

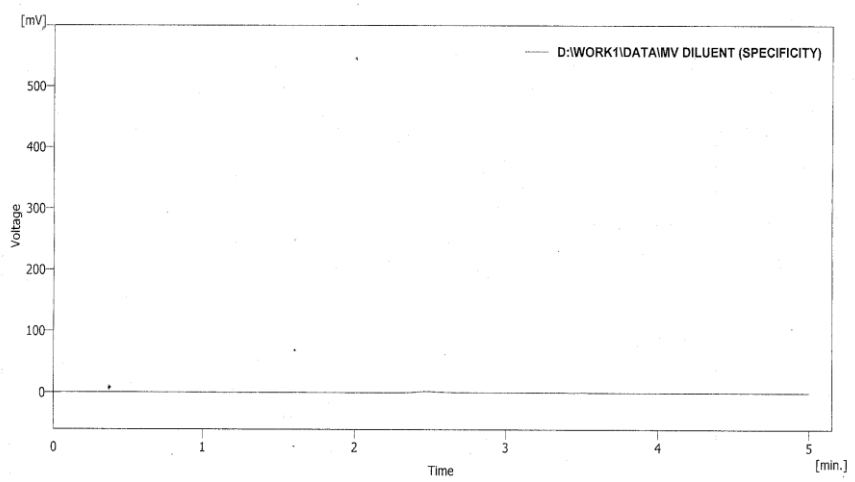

Fig. 3. Chromatogram of the Diluent

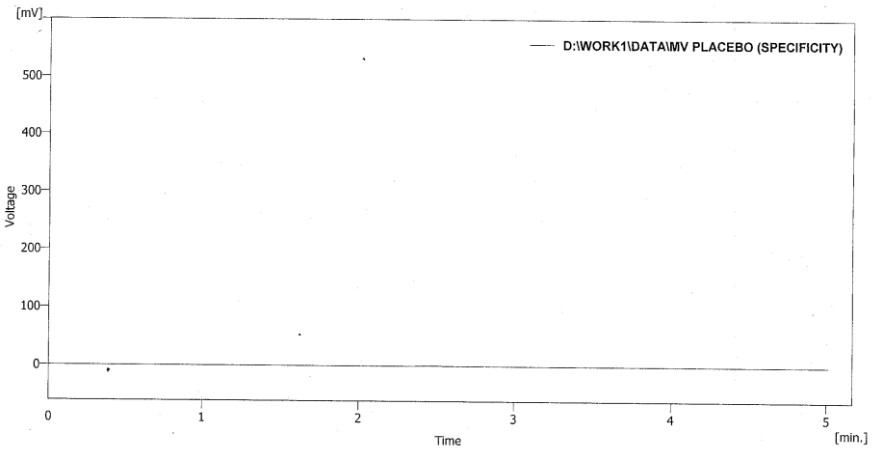

Fig.4. Chromatogram of the Placebo

Based on obtained results it is concluded that there is no interference observed due to diluents and placebo at the retention time of main peak (2.5) in standard solution.

b. Linearity

For the construction of calibration curves, eight calibration standard solutions were prepared over the concentration range. Linearity was determined for Desvenlafaxine in the range of 20

- 160 µg/ ml. The correlation coefficient ('r2') values were 0.999. The linearity results are shown in table 5.And Linearity curve of Desvenlafaxine is shown in "Fig.5".

Table: 5. Linearity of Desvenlafaxine Succinate Monohydrate

Sr. No.	Sample Identity	Conc. in µg/ml	Area
1	20%	20	1143.518
2	40%	40	2287.036
3	60%	60	3430.554
4	80%	80	4660.096
5	100%	100	5517.590
6	120%	120	6649.576
7	140%	140	7882.196
8	160%	160	8948.144
	Intercept		1122
	Correlation coefficient		0.999

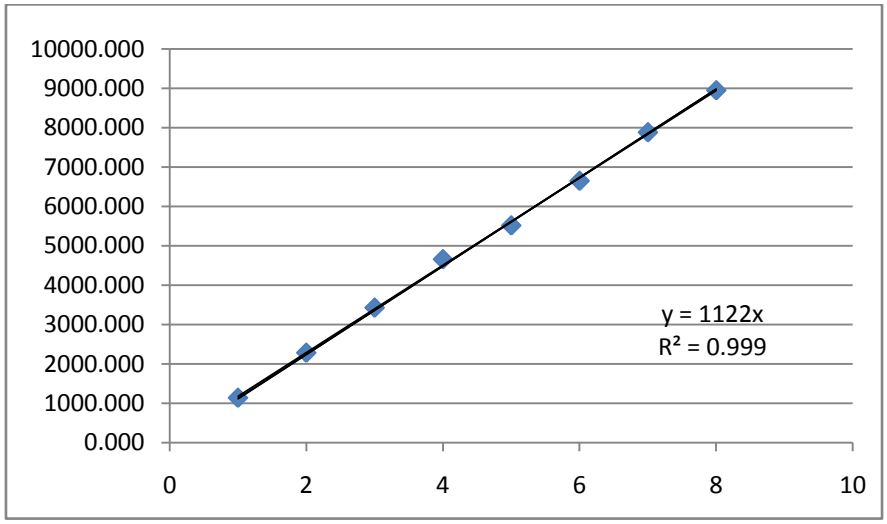

Fig.5. Linearity curve of Desvenlafaxine

c. Precision

1. System Precision To check the system precision , desvenlafaxine succinate working standard solution was prepared as follows and peak response measured in six replicates. The mean and relative Standard deviation was calculated. The results are presented in the following result Table 6. Weigh accurately about 75.84 mg of Desvenlafaxine Succinate Monohydrate (Equivalent to 50mg of Desvenlafaxine) in to 50 ml volumetric flask, add 30

ml of diluent and sonicate for 5 min. Make up the volume with diluent .Dilute 5 ml of the above solution to 50 ml with diluent and mix**.**

Table: 6 System Precision of Desvenlafaxine

Sr.No.	Area
1	5433.411
2	5440.237
3	5436.191
4	5441.103
5	5422.810
6	5444.449
Mean	5436.367
Std.Dev.	7.6849
% RSD	0.14

2. Repeatability

The assay method was carried out on six test preparation from the same sample for Desvenlafaxine Succinate and the percentage assay were calculated. The mean and relative standard deviation of the results was calculated and the obtained results are presented in Table 7

Table: 7. Repeatability of Desvenlafaxine

Sample No.	Area	Wt. of Sample	Avg. Wt. in mg	% Assay
Sample 1	5564.126	232	230	100.59
Sample 2	5457.752	230	230	99.52
Sample 3	5411.325	229	230	99.10
Sample 4	5449.441	230	230	99.37
Sample 5	5550.700	231	230	100.78
Sample 6	5443.608	230	230	99.26
Mean				99.87
% RSD				0.76

3. **Intermediate Precision**

The analysis was carried out as described in the Repeatability. Different Analyst has carried out this analysis on different days using different columns and the obtained results are presented in Table 8, Table 9 and Table 10.

Table: 8. Intermediate Precision

Conditions	Analyst I	Analyst II
Date Of Analysis	6/12/13	7/12/13
Name Of Analyst	A	B
HPLC Used	LC6600	LC6600
Column Used	RPPL/CL/ 012	RPPL/CL/ 014

Table: 9. Intermediate Precision(Assay Result of Analyst II)

Test	Sample Area	Mean	% Assay
Desvenlafaxine Succinate	5582.911	5589.857	99.78
	5596.802		

Table: 10. Intermediate Precision(Comparative Results)

	Desvenlafaxine Succinate
% Assay Mean in Repeatability	99.87 %
% Assay in Intermediate Precision	99.78 %
% RSD	0.06 %
Absolute Difference in assay of analyst I & II	0.09%

Table: 11 Accuracy (recovery) of Desvenlafaxine Succinate Monohydrate

Sr. No.	Sample Identity	Amount added in mg	Area	Amount recovered in mg	% Recovered
1	80%- Set -1	61.06	4472.459	61.06	100.65
2	80%- Set- 2	61.06	4475.055	61.10	100.71
3	80%- Set -3	61.06	4471.159	61.04	100.62
4	100%- Set -1	75.84	5340.119	75.22	99.19
5	100%- Set -2	75.84	5362.698	75.54	99.61
6	100%- Set -3	75.84	5348.496	75.33	99.34
7	120%- Set -1	91.00	6089.949	90.66	99.63

8	120%- Set -2	91.00	6089.827	90.66	99.63
9	120%- Set -3	91.15	6122.890	91.15	100.17
				Average	99.678
				SD	0.5582741
				%RSD	0.56

d. Accuracy

Recovery studies were performed by adding 60.67mg, 75.84 mg and 91.00 mg of Desvenlafaxine Succinate Monohydrate in placebo (80,100 and 120 % of quantification concentration) . The resulting sample solutions were injected and chromatograms were recorded. At each of the levels, three determinations were performed and results were obtained. The results obtained are shown in Table 11

Table:12. Robustness study of Desvenlafaxine Succinate

Parameter	Variation	Area of Standard	Area of Sample	% Assay	% RSD	R.T	Theoretical Plates
Flow rate (mL min^{-1}) (± 0.2 mL)	0.8	5249.231	5271.147	99.88	0.47	2.5	2759
	0.8	5286.547				2.5	2783
	0.8	5296.321				2.5	2663
	0.8					2.5	2754
	1.0	5491.258	5423.457	98.84	0.08	2.4	2983
	1.0	5487.546				2.4	3089
	1.0	5482.973				2.4	2959
	1.0					2.4	3183
	1.2	5563.478	5561.111	100.26	0.79	2.2	3213
	1.2	5579.423				2.2	2990
	1.2	5496.987				2.2	3383
	1.2					2.2	2923
pH (± 0.2 unit)	2.8	5498.564	5463.269	99.20	0.47	2.4	2859
	2.8	5536.248				2.4	3383
	2.8	5487.268				2.4	2763
	2.8					2.4	2754
	3.0	5586.589	5542.471	99.74	0.80	2.4	3383
	3.0	5578.124				2.4	2859
	3.0	5454.235				2.4	3159
	3.0					2.4	3183
	3.2	5516.351	5514.341	100.12	0.33	2.4	3213
	3.2	5520.104				2.4	2860
	3.2	5487.205				2.4	3383
	3.2					2.4	2923

e. Robustness

Robustness of the method was determined by making slight changes in the chromatographic conditions as per ICH guidelines. It was observed that there were no marked changes in the chromatograms, which demonstrated that the RP-HPLC method developed and System suitability parameters were found to be within acceptable limits. Results are shown in Table 12 indicating that the test method was robust for all variable conditions. Hence the method was sufficiently robust for normally expected variations in chromatographic conditions.

4. RESULT AND DISCUSSION

4.1 RESULT

The present work was aimed to develop an analytical method determination of Desvenlafaxine Succinate monohydrate and its validation.The details of Formulation Taken for analysis are shown in Table 13.

Table: 13. Formulation Taken for analysis

Drug	Strength	Batch no	Company
Desvenlafaxine Succinate	50 mg	PLD1002	Mankind

After considering the solubility and spectral features of the drug, mobile phase was selected as diluent and after a number of trials ACN: buffer (pH 3.0) in the ratio of 70:30 was selected as mobile phase. The details selection of mobile phase are shown in Table 14.

Table: 14. Selection of Mobile Phase

Mobile Phase	Observation	Result
Methanol	Low resolution	Mobile phase rejected.
Buffer: Acetonitrile (50:50 v/v)	Very low resolution	Mobile phase rejected
Buffer: Acetonitrile (65:35 v/v)	Poor resolution	Mobile phase rejected
Acetonitrile: Buffer (70:30 v/v)	Good resolution	Mobile phase accepted

The UV detector response of Desvenlafaxine Succinate was studied and the best wavelength was found to be 220 nm showing highest sensitivity.

HPLC determinations of this drug was carried out by maintaining following chromatographic conditions throughout the method. The details of chromatographic conditions for analysis are shown in Table 14.

Table: 14 Chromatographic condition

Parameter	Value
Column	Kromasil C-18, (250 mm × 4.6 mm, 5.0 µm)
Mobile Phase	Acetonitrile: Buffer (70:30v/v)
Flow rate	1.0 mL min^{-1}
Run time	5 min
Column Temperature	25^0C
Injection volume	20 µL
Detection wavelength	220 nm
Diluent	Mobile Phase

For determination of Desvenlafaxine Succinate monohydrate series of mixed standards were prepared in different concentration 20 -160 µg/ ml.

The developed method is validated for following parameters.

a. Linearity

b. Accuracy

c. Precision

d. Robustness

a. Linearity

The results of linearity analysis indicates that the drug components are linear with respect to the concentration range mentioned in the Table 15

Table: 15 Statistical Data of Linearity

Data for Linearity	Desvenlafaxine Succinate monohydrate
Correlation Coefficient (r^2)	0.999
Y-Intercept	1122
Linearity Range (µg/mL)	20 - 160

b. Accuracy

Accuracy was studied by standard addition method and result show that the percent recovery was found within the acceptable limit, data is shown in Table 16

Table: 16 Statistical data of accuracy

Statistical data	Desvenlafaxine Succinate monohydrate
Assay % Mean	99.67 %
SD	0.5582741
%R.S.D.	0.56

c. Precision

Precision was determined to assure the repeatability of the method. The R.S.D. was found less than 2.0% results are shown in Table 17

Table: 17 Statistical data of precision

	Desvenlafaxine Succinate
% Assay Mean in Repeatability	99.87
% Assay in Intermediate Precision	99.78
% RSD	0.06
Absolute Difference	0.09

d. Robustness

To determine the robustness of the method, the final experimental conditions were purposely altered. The flow rate was varied by (±) 0.2 mL min-1, the percentage of mobile phase was varied by (±) 2%, pH was varied by (±) 0.2 pH unit. and results of the same are shown in Table 17

Table: 18 Statistical data of Robustness

Parameter	**Variation**	**Area of Standard**	**Area of Sample**	**% Assay**	**% RSD**	**R.T**	**Theoretical Plates**
Flow rate (mL min $^{-1}$) (± 0.2 mL)	0.8	5249.231	5271.147	99.88	0.47	2.5	2759
	0.8	5286.547				2.5	2783
	0.8	5296.321				2.5	2663
	0.8					2.5	2754
	1.0	5491.258	5423.457	98.84	0.08	2.4	2983
	1.0	5487.546				2.4	3089
	1.0	5482.973				2.4	2959
	1.0					2.4	3183
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	1.2	5579.423				2.2	2990
	1.2	5496.987				2.2	3383
	1.2					2.2	2923
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	3.2	5487.205				2.4	3383
	3.2					2.4	2923

Table : 19 Column Response.

Parameter	Column C8	Column C18
Retention Time	4.657	2.448
Area	5851.605	5397.235
Peak	Sharp	Sharp

Table: 20. Summary of validation parameter

Validation parameters		Acceptable Limit	Results
Linearity (r2)		Linear , $r^2 \geq 0.99$	0.999
Precision (%RSD)		RSD NMT 2 %	0.76
Repeatability			
Accuracy by recovery study (%found)		98 % -102%	99.67 %
Robustness(%RSD)	Variation		
Flow rate (mL min ^{1})	0.8	RSD NMT 2 %	0.47
	1.0		0.08
	1.2		0.79
pH (± 0.2 unit)	2.8		0.47
	3.0		0.80

	3.2	RSD NMT 2 %	0.33
Tablet Analysis (% Found)			99.77 %

4.2 DISCUSSION

Selection of Wavelength: The UV detector response of Desvenlafaxine Succinate was studied and the best wavelength was found to be 220 nm showing highest sensitivity.

Selection of Mobile Phase: Initially to estimate Desvenlafaxine Succinate number of mobile phases in different ratios were tried as mentioned below, taking into consideration the system suitability parameters like RT, tailing factor, No. of theoretical plates and HETP, the mobile phase found to be most suitable for analysis was ACN: buffer (pH 3.0) in the ratio of 70:30.

Selection Of Column: First C-8 (250 mm × 4.6 mm, 5 µm) was used for analysis. Then Kromasil C-18 (150 mm × 4.6 mm, 5 µm) was used. On comparing the response of both the columns we found that Kromasil C-18 (250 mm × 4.6 mm, 5 µm) column was the most suitable one, since it produced symmetrical peaks with very good sensitivity .Column C18 gives peak at 2.447 min while Column C8 gives peak at 4.657 at same mobile phase . Hence we concluded that C18 is less expensive than C8 as it required less mobile phase and give peak at less retention time .Column response is shown in Table 19

Methanol individually, Methanol and buffer in mixture are used for the study but it did not give good resolved peaks. The effect of changing the ratio of organic modifier on the selectivity and retention times of the test solutes was investigated using mobile phases containing Buffer and ACN in different concentration. Therefore ACN was the organic modifier of choice giving symmetrical narrow peaks. Ratio less than 10 % of organic resulted in peaks with more tailing, whereas ratios higher than 50 % resulted in decreased resolution.

Effect of Flow Rate The effect of flow rate on the formation of peak of the compound was studied and a flow rate of 1 ml min-1 gives for good separation in a reasonable time.

Effect of Temperature

The effect of Temperature on the formation, separation and resolution was studied by varying the Temperature from 20-300C; we found that there was no change in peak response at decided temperature range.

The correlation coefficient for linearity of Desvenlafaxine Succinate is nearby to 1 within the working range which shows the good linearity. As the precision, accuracy and robustness are

concern the maximum RSD found was to be less than 2. Hence all the validation parameters are within the acceptable limit. So, method can be used for the routine analysis of Desvenlafaxine Succinate.

5. CONCLUSION

Modern medicines for human use are required to comply with specific standards and regulation set forth by the concerned authorities. The efficacy and safety of medicinal products can only be assured by analytical monitoring of its quality.

Therefore, the quality control laboratory is considered as the backbone of the pharma industries with ever-increasing need for the development of analytical techniques for drug formulation.

In the present research work, a successful attempt was made for determination of Desvenlafaxine Succinate in Tablet dosage form by High Performance Liquid Chromatography (HPLC). The method was developed by experimentation, based on literature survey and ascertained by statistical parameter of sampling. The simplicity, rapidity, reproducibility and economy of the proposed method completely fulfill the objective of this research work.

In the present work, application of RP-HPLC for analysis of selected drug formulation was successfully attempted using Chemito LC-6600.

The developed RP-HPLC method was validated for simultaneous estimation of Desvenlafaxine Succinate using linearity, accuracy, precision and robustness. The %RSD for all parameters was found to be less than two, which indicates the validity of method and assay results obtained by this method are in fair agreement.

Desvenlafaxine Succinate good resolution, which can be well understood, looking at the validation data for the developed method are given in Table 20 as follows

The proposed method is simple, accurate and precise for the determination of Desvenlafaxine Succinate from Tablet. Hence it can be employed for routine quality control of Tablet containing this drug.

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13. Regalagadda Mallikarjuna*1, Nanda Kishore Agarwal1, Prem Kumar Bichala2, Sukhen som3 Method Development And Validation For The Simultaneous Estimation Of

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