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Research Paper

Method Development and Validation of Desidustat in Solid Dosage Form by RP-HPLC Method

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ABSTRACT

Desidustat is a novel oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor used for the treatment of anemia associated with chronic kidney disease. It acts by stabilizing hypoxia-inducible factors, thereby stimulating endogenous erythropoietin production and improving iron metabolism. A new simple, precise, accurate, sensitive, and rapid RP-HPLC method was developed and validated for the estimation of Desidustat in pharmaceutical solid dosage form. Desidustat was chromatographed on an Inertsil ODS-3V, 150 mm × 4.6 mm ID, 5 µm column using a mobile phase consisting of Acetonitrile:Water (75:25, v/v) under isocratic conditions. The mobile phase was pumped at a flow rate of 1.0 mL/min and the analyte was detected at 232 nm using a UV detector. The retention time of Desidustat was satisfactory with good peak symmetry. The detector response was linear in the concentration range of 10–50 µg/mL with a correlation coefficient greater than 0.999. The developed method was validated according to ICH Q2(R1) guidelines for accuracy, precision, linearity, specificity, robustness, limit of detection, and limit of quantification. The intra-day and inter-day precision studies showed %RSD values less than 2.0%, indicating good precision of the method. The percentage recovery of the drug was within acceptable limits, confirming the accuracy of the proposed method. The developed RP-HPLC method was found to be simple, economical, reproducible, and suitable for routine quantitative analysis of Desidustat in tablet dosage forms in quality control laboratories

INTRODUCTION

The development of sound analytical methods is of supreme importance during the process of drug discovery, product release, and development, culminating in marketing approval. The objective of analytical method development is to optimize and validate a method for the drug product from the developmental stage of the formulation. Validation demonstrates that processes involved in

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drug development, production, and analytical testing can be performed in an effective and reproducible manner (1,2).

High Performance Liquid Chromatography (HPLC) is one of the most widely used analytical techniques. Chromatography is a separation technique involving mass transfer between stationary and mobile phases. In HPLC, a liquid mobile phase is used to separate the components of a mixture as they pass through a packed column under high pressure. Separation depends on differences in interaction between analytes and the stationary phase. By choosing suitable mobile and stationary phases, HPLC can separate a wide variety of compounds with high versatility and reliability (3,4).

Desidustat is a novel oral hypoxia-inducible factor prolyl hydroxylase inhibitor used for the treatment of anemia associated with chronic kidney disease. It works by stabilizing hypoxia-inducible factors, stimulating endogenous erythropoietin production, and improving iron metabolism. Because only limited analytical methods were available for this drug, there was a need for a simple, rapid, and validated RP-HPLC method suitable for routine pharmaceutical analysis (5,6).

The present study was designed to develop and validate an RP-HPLC method for Desidustat in solid dosage form according to ICH guidelines (1).

MATERIALS AND METHODS

Materials

Desidustat reference standard and marketed tablet formulation were used in the study. The marketed product mentioned in the thesis is Rystat 100 tablet. HPLC-grade acetonitrile, water, and other reagents used in the study were of analytical or chromatographic grade.

Instrumentation

Chromatographic analysis was carried out using an HPLC system equipped with UV detection. The column used was Inertsil ODS-3V, 150 mm × 4.6 mm ID, 5 µm. The detection wavelength selected for analysis was 232 nm.

Chromatographic Conditions

The optimized chromatographic conditions were:

- Column: Inertsil ODS-3V, 150 mm × 4.6 mm, 5 µm.
- Mobile phase: Acetonitrile:Water (75:25, v/v).
- Mode: Isocratic.
- Flow rate: 1.0 mL/min.
- Detection wavelength: 232 nm.
- Retention time: approximately 2.63 min.
- Run time: approximately 9 min.

Placebo preparation:

Sr. No.	Ingredients	Role	Qty (mg)
1	Lactose	Filler	80
2	Starch	Binder	5
3	Magnesium stearate	Lubricant	5
4	Talc	Glidant	5
5	crospovidone	Disintegrants	5
Total			100 mg

Method Development

Different trial chromatographic conditions were evaluated to obtain a sharp, symmetrical peak with acceptable system suitability parameters. The final conditions were selected based on retention time, peak shape, resolution, and reproducibility. The method was then optimized for routine assay of Desidustat in tablet dosage form.

Method Validation

The method was validated according to ICH Q2(R1) guidelines for the following parameters:

- Specificity.
- Linearity.
- Range.
- Accuracy.
- Precision.
- Limit of detection.
- Limit of quantitation.
- Robustness.
- System suitability.

LINEARITY AND RANGE:

Sr. No.	Level (%)	mL of stock solution	Diluted to with Mobile phase (mL)	Desidustat Concentration (µg/mL)
1	50%	1.0	10	5.00
2	75%	1.5	10	7.50
3	100%	2.0	10	10.00
4	125%	2.5	10	12.50
5	150%	3.0	10	15.00

Accuracy levels details: Refer Following table for each sample:

Level (%)	API (mg)	Placebo	Diluted to (mL)	Volume taken(mL)	Diluted to (mL)	Conc (µg/mL)
50	50.10	202.6	100	0.2	20	5.01
	50.20	202.4	100	0.2	20	5.02
	49.90	202.3	100	0.2	20	4.99
100	100.00	202.1	100	0.2	20	10.00
	100.20	203.1	100	0.2	20	10.02
	100.50	204.2	100	0.2	20	10.05
150	150.10	202.5	100	0.2	20	15.01
	149.80	201.8	100	0.2	20	14.98
	150.00	203.2	100	0.2	20	15.00

Precision (Repeatability) Sample details are as follows:

Sample	Powder wt (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
Sample 1	301.6	100	0.2	20
Sample 2	302.5	100	0.2	20
Sample 3	301.9	100	0.2	20
Sample 4	303.2	100	0.2	20

Sample 5	302.5	100	0.2	20
Sample 6	302.8	100	0.2	20

Intermediate Precision Sample details are as follows:

Sample	Powder wt. (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
Sample 1	301.6	7026532	97.15	301.6
Sample 2	302.5	7115290	98.08	302.5
Sample 3	301.9	7095268	98.00	301.9
Sample 4	303.2	7142518	98.23	303.2
Sample 5	302.5	7095237	97.80	302.5
Sample 6	302.8	7056238	97.17	302.8

Sample Preparation

Tablet samples were prepared according to the procedure described in the thesis. The sample solution was filtered and analyzed under the optimized chromatographic conditions. Placebo and blank solutions were also prepared for specificity assessment.

RESULTS System Suitability

The system suitability parameters met the acceptance criteria. The method provided a satisfactory retention time, good peak symmetry, and acceptable chromatographic performance for routine analysis. The thesis acceptance limits for system suitability included theoretical plates greater than 2000, capacity factor less than 1, resolution greater than 1.5, tailing factor less than 2, and %RSD less than 2.

Specificity

Blank and placebo chromatograms showed no interference at the retention time of Desidustat, demonstrating the specificity of the method. The analyte peak was well resolved and free from co-eluting peaks.

Linearity

The detector response was linear in the concentration range of 10–50 µg/mL. The calibration curve showed a correlation coefficient greater than 0.999, indicating excellent linearity.

Accuracy

Accuracy was evaluated at 50%, 100%, and 150% levels. The percentage recovery values were within acceptable limits, confirming that the method is accurate for tablet analysis.

Precision

Repeatability, intra-day precision, and inter-day precision studies showed %RSD values below 2.0%, indicating that the method is precise and reproducible.

Robustness

The method remained unaffected by small deliberate variations in flow rate, mobile phase composition, and temperature, demonstrating robustness.

Assay

The assay of the marketed tablet formulation showed satisfactory recovery and confirmed the suitability of the proposed method for routine quality control analysis.

Solubility study Desidustat

Sr. No.	Name of Solvent	Observation	Conclusion	Summary
1	Water	Drug Particles seen after sonication	Drug was not found soluble in water.	DMSO used as a diluent for preparing stock solution.
2	Methanol	Drug Particles seen after sonication	Drug was not found soluble in methanol.	
3	Ethanol	Drug Particles seen after sonication	Drug was not found soluble in Ethanol.	
4	Acetonitrile	Drug Particles seen after sonication	Drug was not found soluble in Acetonitrile	
5	0.1 N HCl	Drug Particles seen after sonication	Drug was not found soluble in 0.1 N HCl.	
6	0.1 N NaOH	Drug Particles seen after sonication	Drug was not found soluble in 0.1 N NaOH	
7	DMSO	No Drug Particles seen after sonication	Drug was found soluble in DMSO.	

1) Blank Solution1:

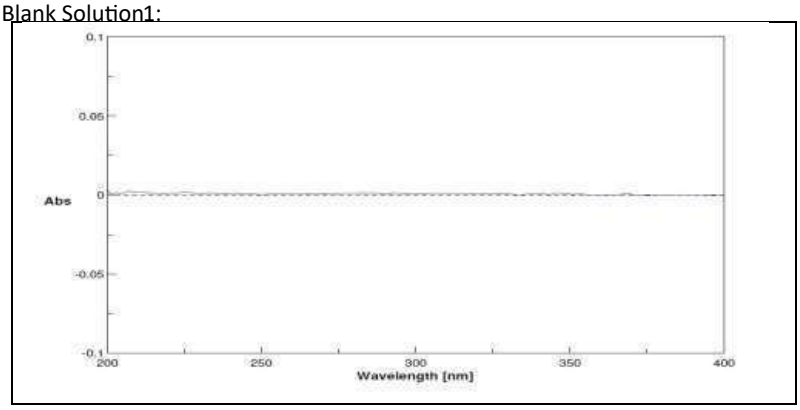


Fig. UV spectrum of Solution 1 as blank

2) Desidustat STD solution: (10 PPM)

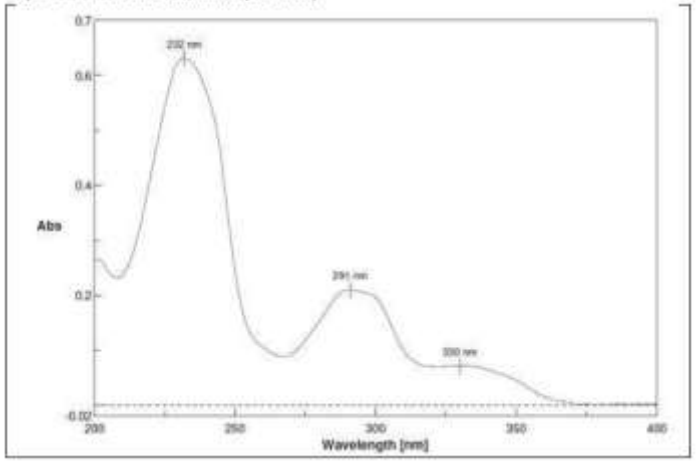


Fig. UV spectrum of Desidustat (10 PPM)

Optimization of HPLC method Trial 1:

Chromatogram:

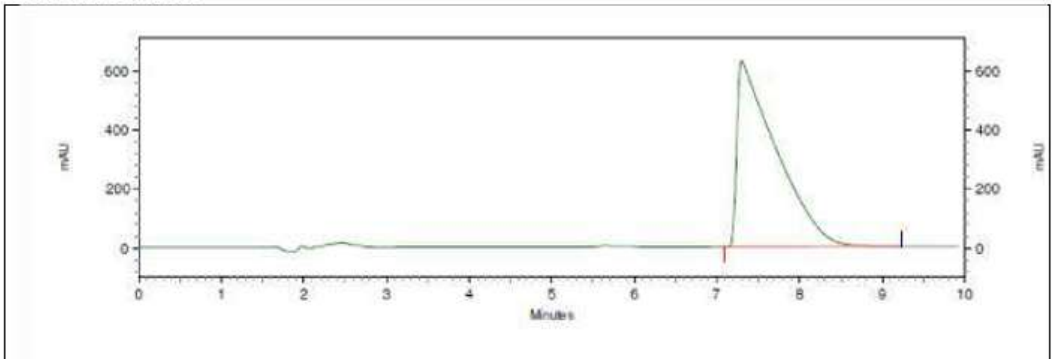


Fig. Typical chromatogram of Trial 1

Chromatogram:

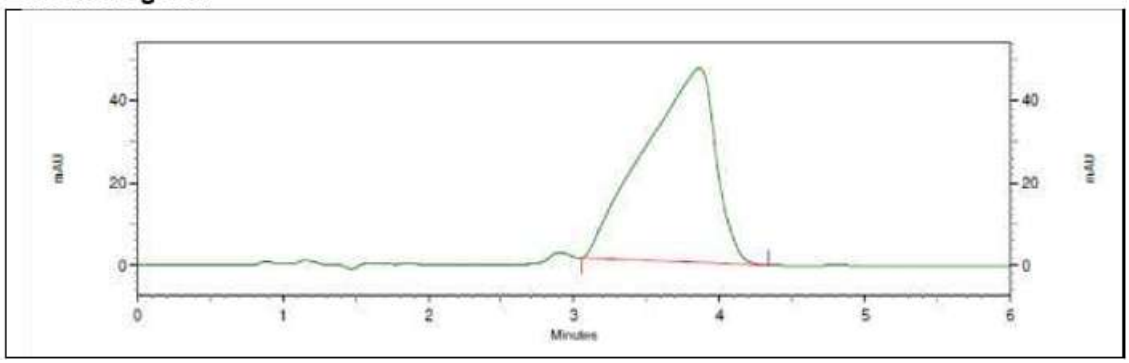


Fig. Typical chromatogram of Trial 2 Trial 3:

Chromatogram:

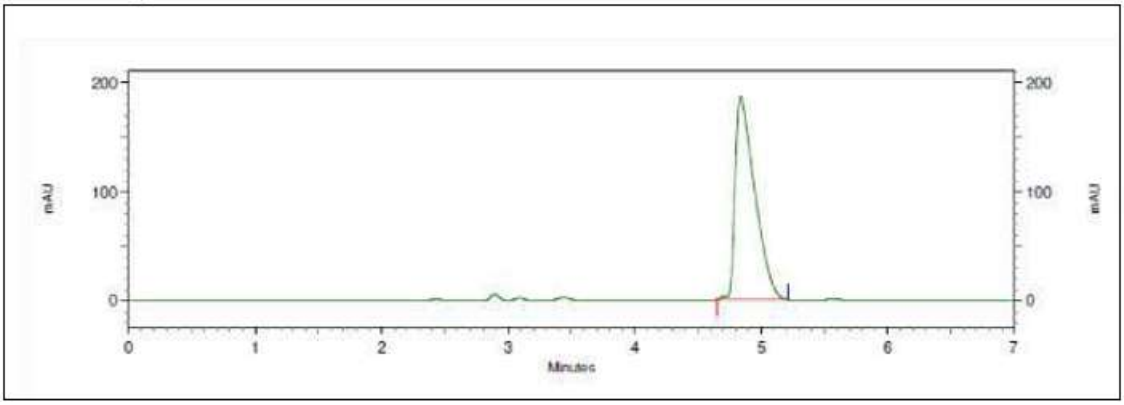


Fig. Typical chromatogram of Trial 3 Trial 4:

Chromatogram:

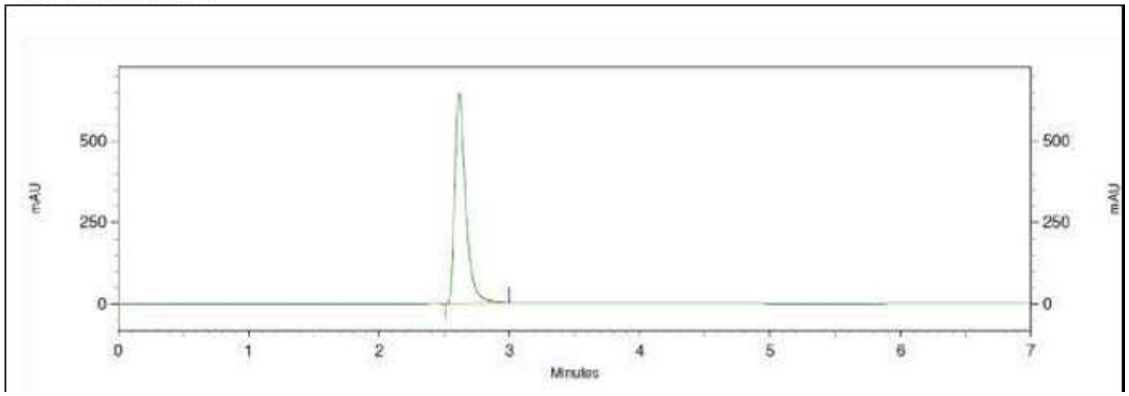


Fig. Typical chromatogram of Trial 4

Conclusion: From the observations of trials first to four, it was concluded that chromatographic conditions in trial four gives better peak, good retention time and tailing factor therefore chromatographic conditions in trial four was used for method validation

Table. Optimized Chromatographic Conditions

Parameter	Description
Mode	Isocratic
Column Name	Inertsil ODS-3V, 150 mm X 4.6mm ID, 5µm
Detector	UV Detector
Injection Volume	20 µl
Wavelength	232 nm
Column Oven temp	40ºC
Mobile Phase	Acetonitrile :Water (75:25 %V/V)
Flow Rate	1.0 ml/min
Diluent	Stock solution: DMSO followed by methanol Final dilution: Mobile phase
Run time	6 Minutes

8.4. System suitability test

Sr No.	Standard solution	Area	Asymmetry	Theoretical plates
1	Standard_1	7256521	1.32	6240
2	Standard_2	7249562	1.32	6249
3	Standard_3	7244851	1.32	6251
4	Standard_4	7259532	1.31	6243

5	Standard_5	7250268	1.32	6261
	Mean	**7252147**	**1.32**	**6249**
STD Dev		**5854.797**		
% RSD		**0.08**		

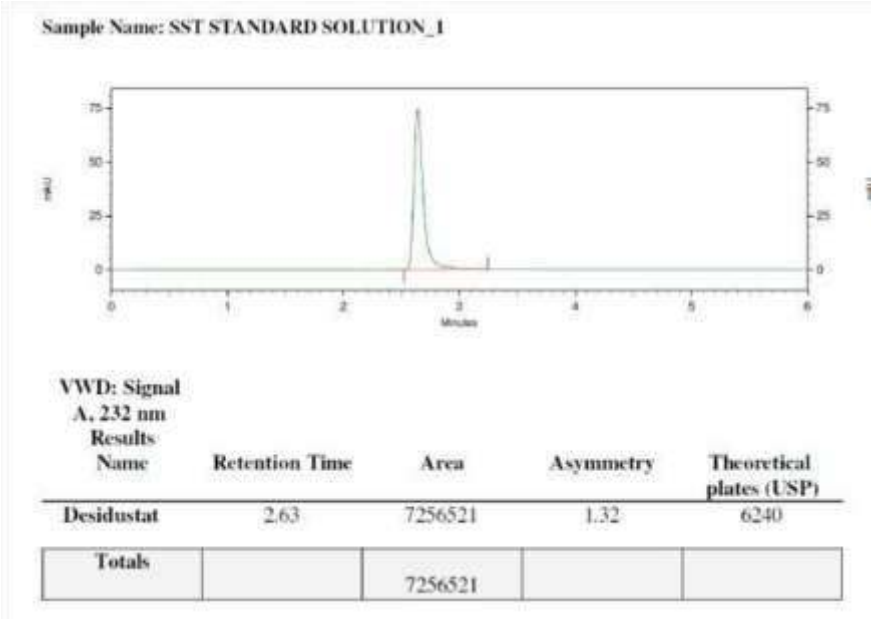
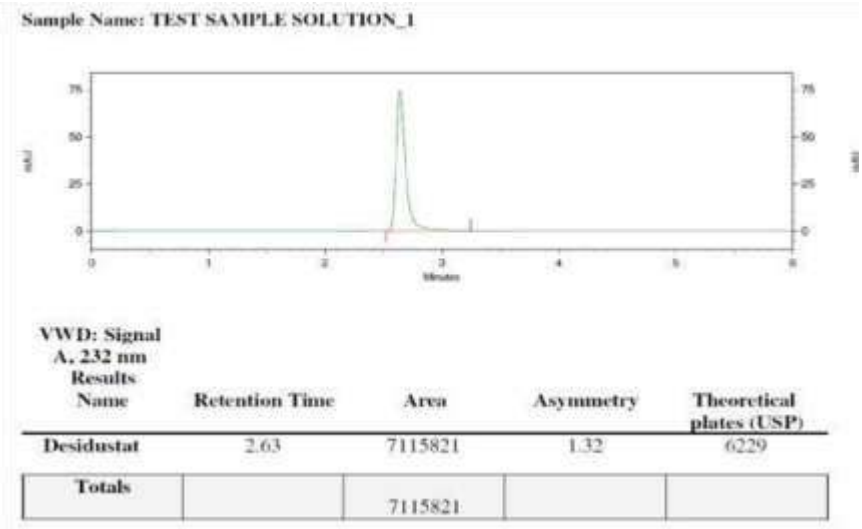


Fig. Typical chromatogram Standard solution 1 of system suitability solution



Analysis of Marketed Test samples (Assay)

a) Rytstat100mg Tablet: Weight of 20 tablets = 6.0480gm

Average weight of tablet = 6.0480 /20 =0.3024gm = 302.4mg

Table. Assay results of Rytstat 100Tablet

Sample	Area	% Assay	Assay
Sample 1	7115821	98.06	98.42
Sample 2	7156532	98.78	

Fig. Typical chromatogram Tablet sample_1

1) % Assay found should be in the range of 90-110%.

Data interpretation:

From the above results, it can be concluded that the assay result is within the limit for selected marketed test sample and sample can be used for validation.

8.6. VALIDATION OF RP-HPLC METHOD

1) FILTRATION STUDY:

Filtration study of an analytical procedure checks the interference of extraneous components from filter, deposition on filter bed and compatibility of filter with sample. Performed on tablet test sample.

Table. Results of Filter study

Sample description	Area	% Absolute difference
Unfiltered	7169532	NA
0.45 µ PVDF filter	7123568	0.64
0.45 µ Nylon filter	7145829	0.33

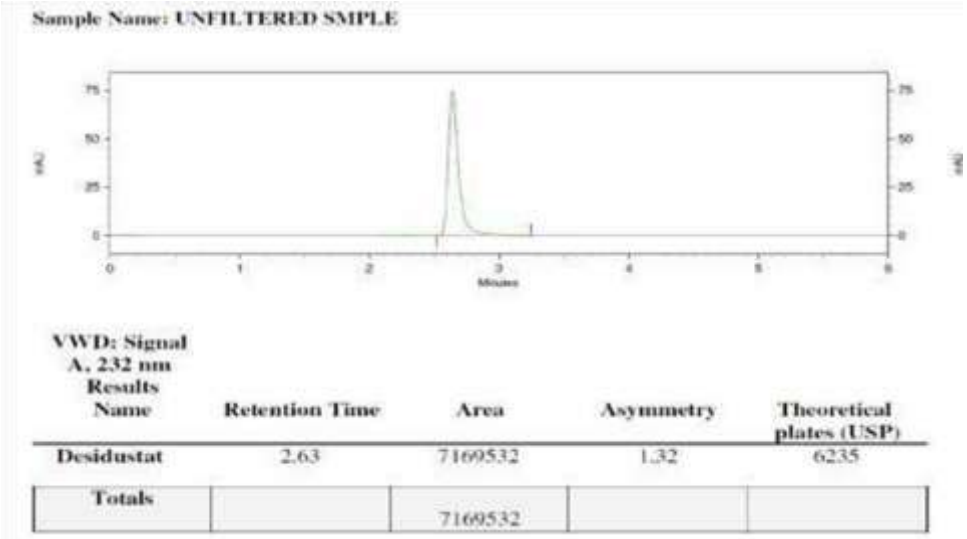
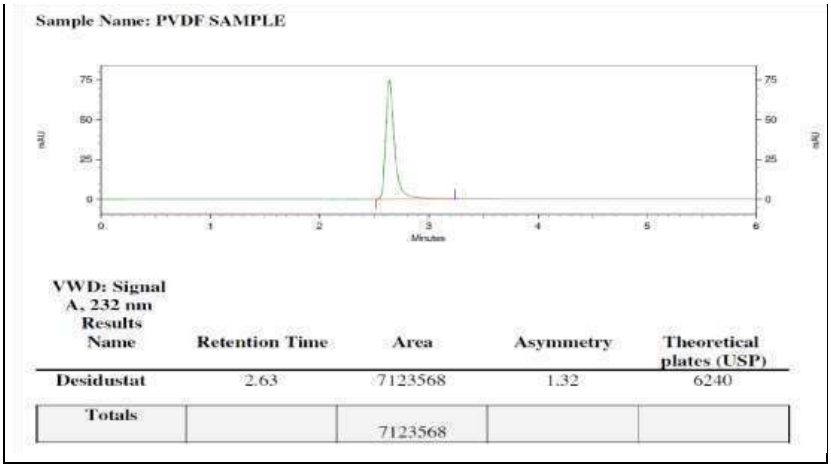


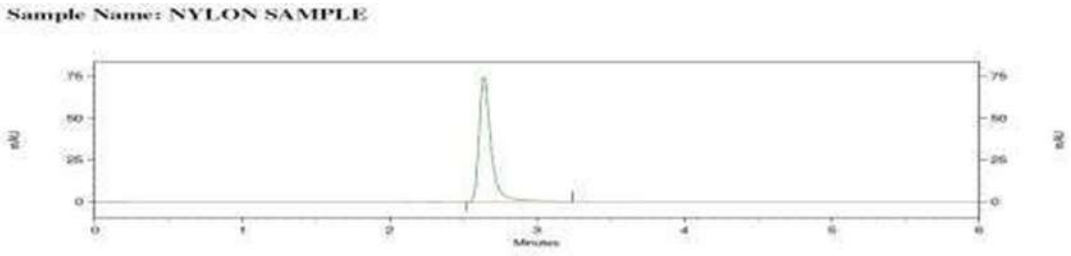
Fig.No. Typical chromatogram of unfiltered sample



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.63	7123568	1.32	6240
Totals		7123568		

Fig. Typical chromatogram of sample filtered through 0.45µ PVDF filter



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.62	7145829	1.31	6251
Totals		7145829		

Fig. Typical chromatogram of sample filtered through 0.45µ Nylon filter Acceptance criteria:% Absolute difference of filtered samples NMT 2.0 w.r.t. Unfiltered sample.

Table. Results of Solution stability

le solution			ard solution		
point		solute differen	cpoint		solute differenc
	60			24	
urs	29		urs	09	
urs	51		urs	53	

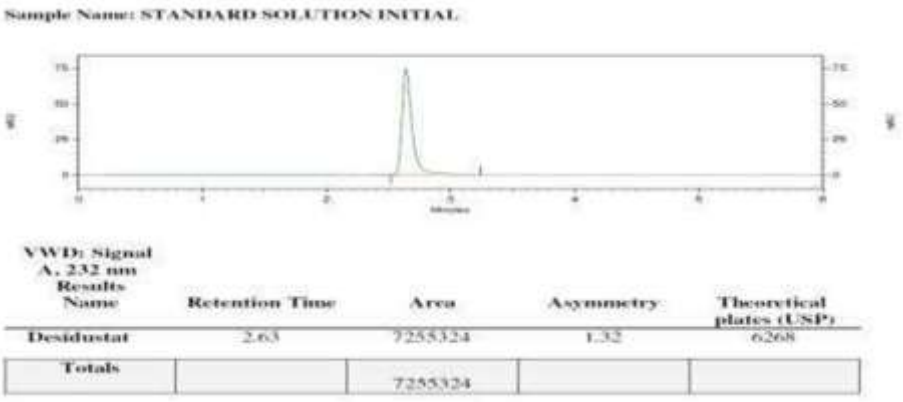


Fig. Typical chromatogram of Standard solution Initial

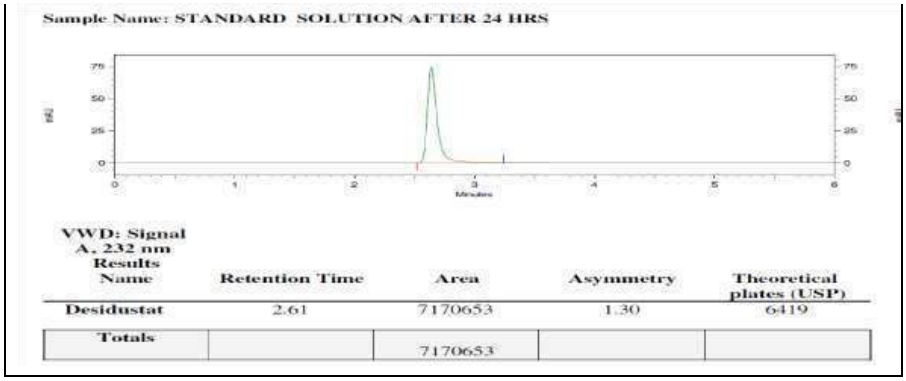


Fig. Typical chromatogram of Standard solution After 24 Hrs

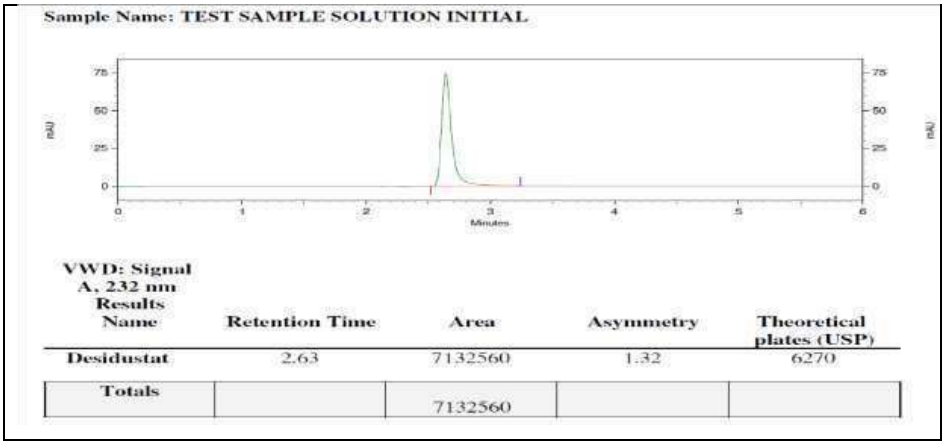


Fig. Typical chromatogram of Test solution After 24 Hrs

Table. Results of Specificity

Description	Observation
Bank	o interference at R.T. of Desidustat due to blank
pacebo	o interference at R.T. of Desidustat due to placebo

Chromatograms:

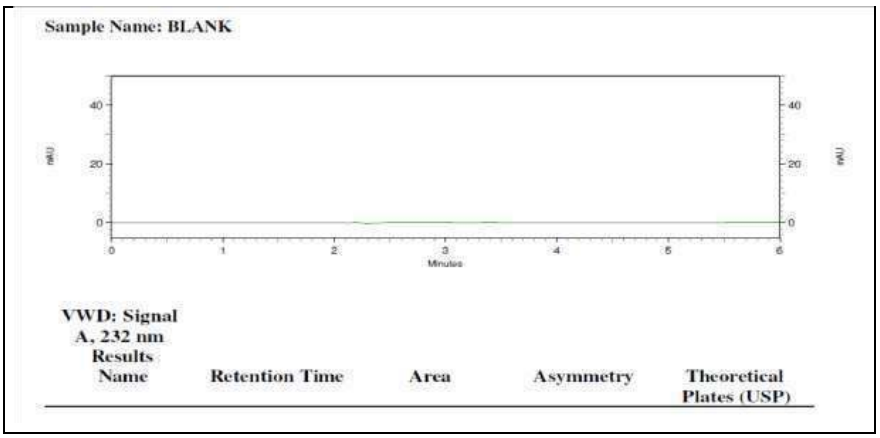


Fig. Typical chromatogram of Blank solution

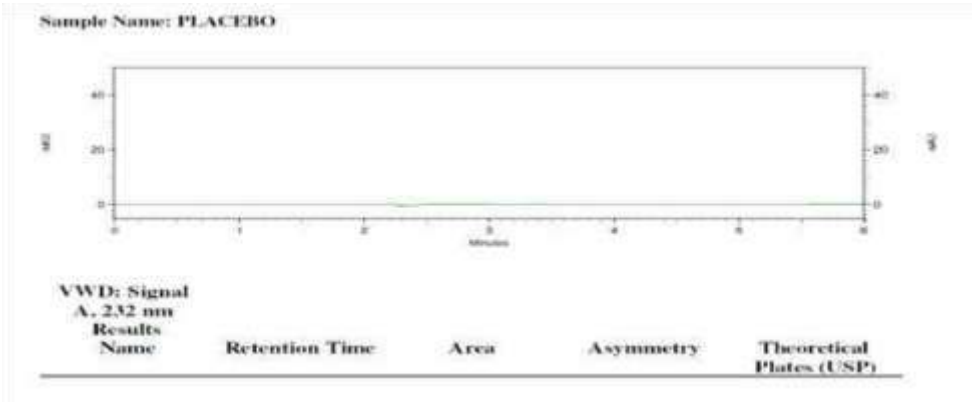


Fig. Typical chromatogram of Placebo solution Acceptance criteria:

Blank: There should be no Interference at R.T. of Desidustat

Placebo: There should be no Interference at R.T. of Desidustat

Data interpretation: Blank and placebo were not having interference at R.T. of Desidustat. Hence developed chromatographic method passed the criteria for specificity.

Table. Linearity Data for Desidustat

Level	Conc (µg/mL)	Area	Mean	% RSD
50%	5.00	3636532	3639304	0.068
		3640129		
		3641251		
75%	7.50	5469539	5473308	0.108
		5480126		
		5470259		
100%	10.00	7265239	7255977	0.190

		7240152		
		7262539		
		9023561		
		9050129		
125%	12.50	9042535	9038742	0.151
		10823561		
		10842153		
150%	15.00	10825865	10830526	0.094

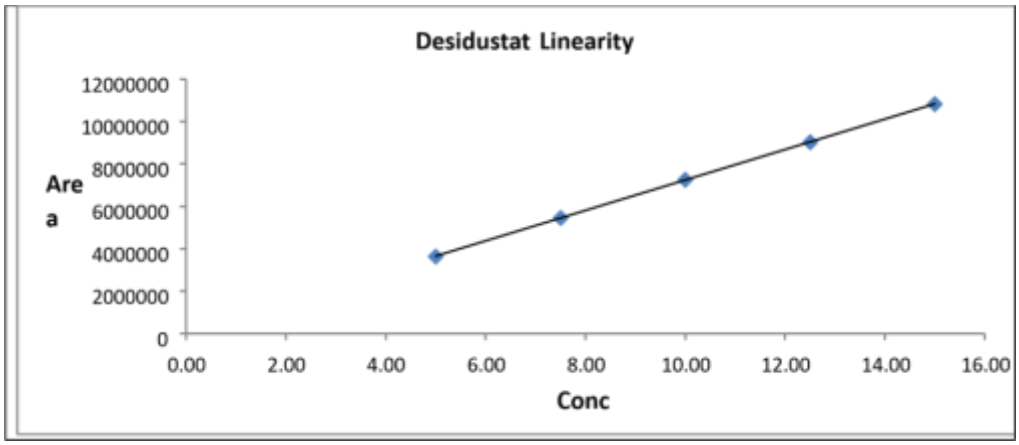
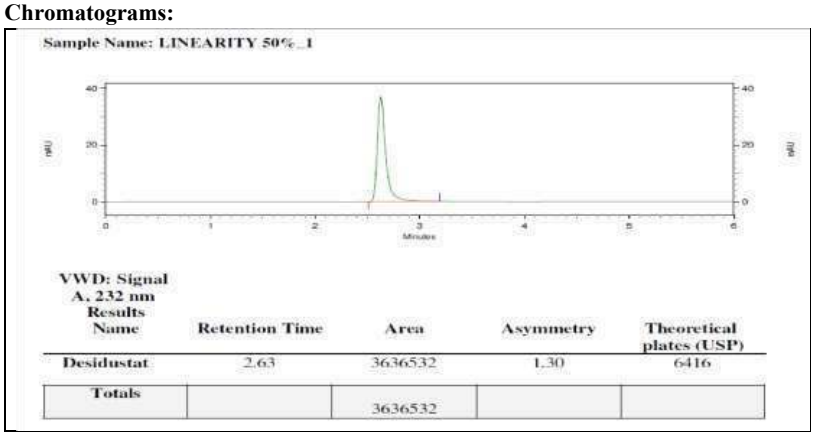


Fig. Calibration curve of Desidustat

Table. Data of linearity of Desidustat:

Sr no.	Parameter	Result value	Acceptance criteria
1	Beer's linearity range	5.00-15.00 µg/mL	NA
2	Correlation coefficient (R^2)	0.99999	NLT 0.98
3	Intercept	68420.20	To be report
4	Slope	717915.12	To be report
5	% RSD for area at each level	NA	NMT 2.0

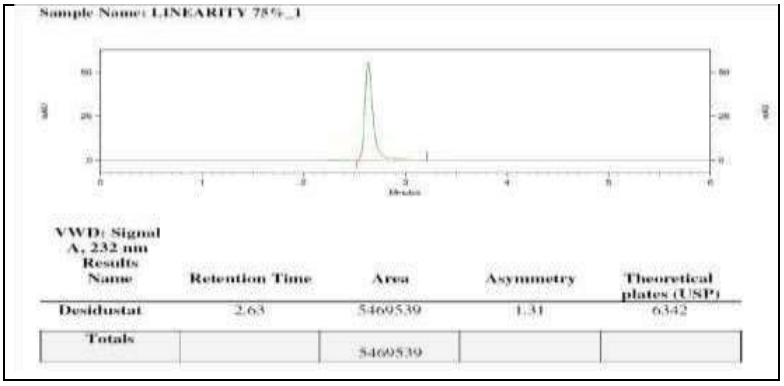
Chromatograms:



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.63	3636532	1.30	6416
Totals		3636532		

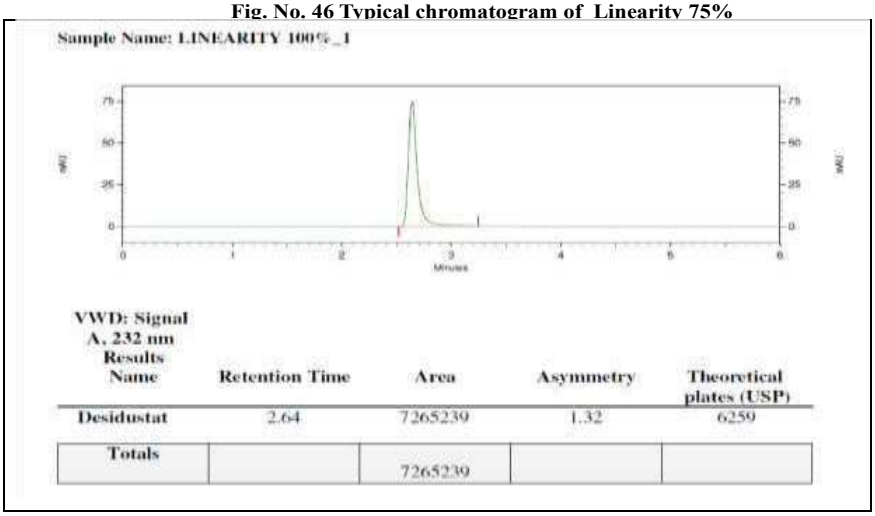
Fig. Typical chromatogram of Linearity 50%



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.63	5469539	1.31	6342
Totals		5469539		

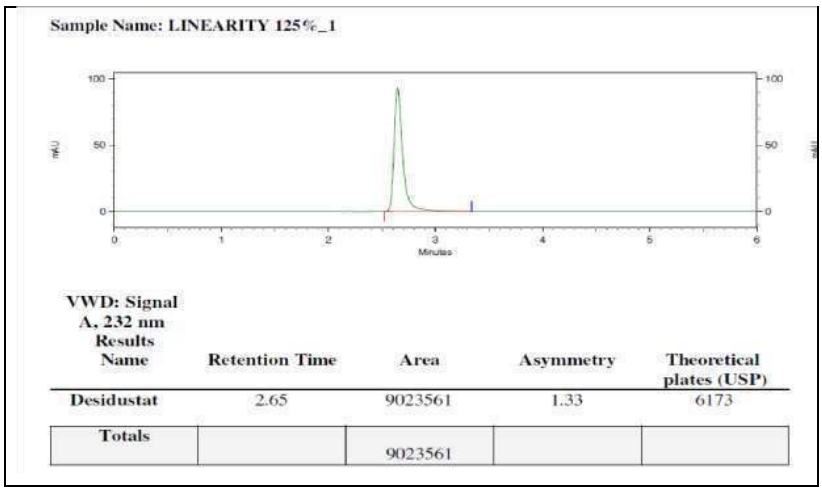
Fig. No. 46 Typical chromatogram of Linearity 75%



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.64	7265239	1.32	6259
Totals		7265239		

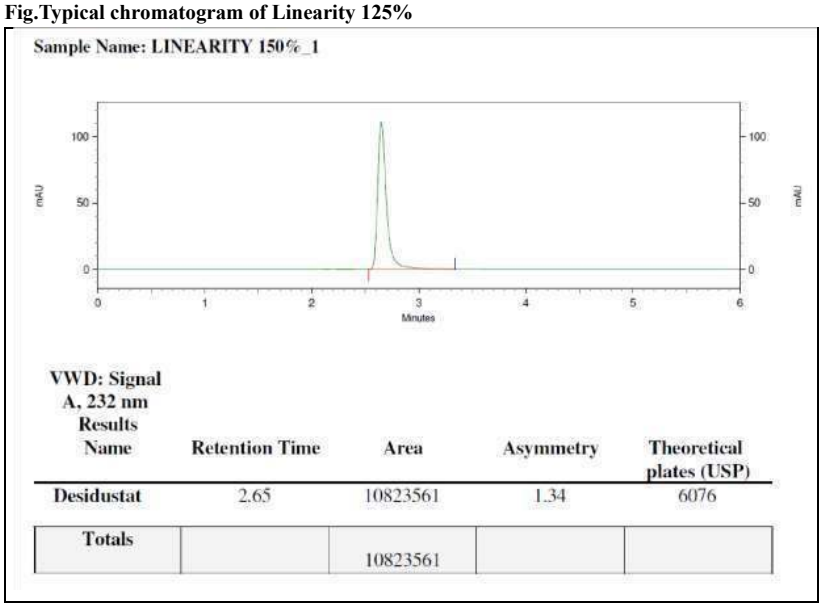
Fig. No. 47 Typical chromatogram of Linearity 100%



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.65	9023561	1.33	6173
Totals		9023561		

Fig.Typical chromatogram of Linearity 125%



VWD: Signal A, 232 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Desidustat	2.65	10823561	1.34	6076
Totals		10823561		

Fig. Typical chromatogram of Linearity 150% Conclusion:

From the calibration curve it was concluded that the Desidustat shows linear response in the range of 5.0015.00µg/ml. The Regression value was found well within the limit.

Limit of Detection (LOD) and Limit of Quantitation (LOQ):

σ = 14985.08 (Residual standard deviation of a regression line)

S = 717915.12(Slope)

Detection limit (LOD):

LOD = 3.3 σ / S

LOD = 3.3 x 14985.08/ 717915.12

LOD = 0.07µg/mL

Quantitation limit (LOQ):

LOQ = 10 σ / S

LOQ = 10 x 14985.08/ 717915.12

LOQ = 0.21µg/mL

ACCURACY (RECOVERY):

Table. Result and statistical data of Accuracy of Desidustat

Level (%)	Area	Recovered conc (µg/mL)	Added conc (µg/mL)	% Recovery	Mean Recovery	% RSD
50	3645109	5.03	5.01	100.40	100.13	0.461
	3652109	5.04	5.02	100.40		
	3605231	4.97	4.99	99.60		
100	7256204	10.01	10.00	100.10	100.33	0.492
	7269568	10.02	10.02	100.00		
	7350256	10.14	10.05	100.90		
150	10850268	14.96	15.01	99.67	100.42	0.728
	10913562	15.05	14.98	100.47		
	11000135	15.17	15.00	101.13		

Overall Recovery: 100.30 %

% RSD for Overall Recovery: 0.513

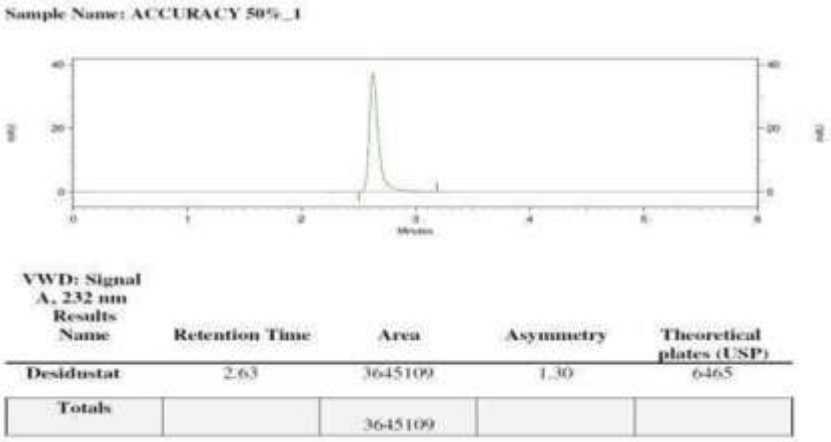


Fig. Typical chromatogram of sample 1 of Accuracy 50%

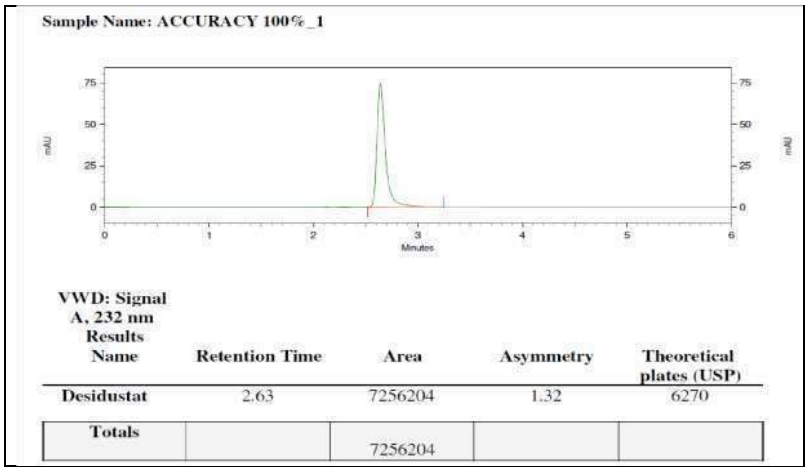


Fig. Typical chromatogram of sample 1 of Accuracy 100%

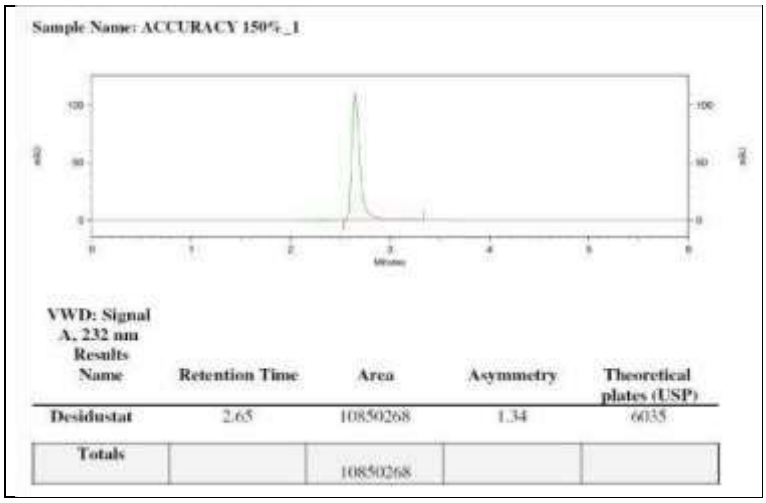


Fig. Typical chromatogram of sample 1 of Accuracy 150% Acceptance criteria:

% Recovery for each level and overall recovery: 98.0 to 102.0%
% RSD for each level and overall recovery: NMT 2.0

Data interpretation: Recovery of analytical procedure was found well within acceptance criteria at all 3 levels. % Recovery not get hampered by changed in analyte concentration.

PRECISION

Precision of an analytical method is the degree of agreement among individual test results when the procedure is applied repeatedly to multiple samplings of a homogenous sample. Precision of an analytical method is usually expressed as standard deviation or relative standard deviation. Precision was performed on Test sample.

Table No.Result of Intra- day and Inter- Day Precision for Desidustat test sample

	Sample	Test Sample (mg)	Area	% Assay
Repeatability	Sample 1	301.6	7026532	97.15
	Sample 2	302.5	7115290	98.08
	Sample 3	301.9	7095268	98.00
	Sample 4	303.2	7142518	98.23
	Sample 5	302.5	7095237	97.80
	Sample 6	302.8	7056238	97.17
	Mean			**97.74**
	STD DEV			**0.4690**

	% RSD			**0.480**
Intermediate precision (Inter-Day)	Sample 1	302.6	7100521	97.84
	Sample 2	302.5	7156223	98.64
	Sample 3	302.9	7058621	97.17
	Sample 4	302.1	7110532	98.14
	Sample 5	301.9	7125368	98.41
	Sample 6	302.4	7112539	98.07
	Mean			**98.05**
	STD DEV			**0.5108**
	% RSD			**0.521**
Repeatability Plus Inter-day	**Mean**			**97.892**
	STD DEV			**0.4942**
	% RSD			**0.505**

Chromatograms:

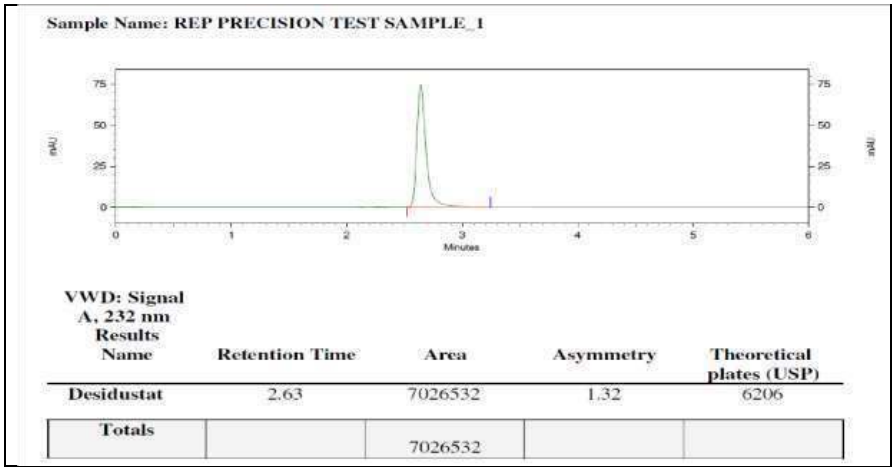


Fig. Typical chromatogram of Repeatability precision (Sample 1)

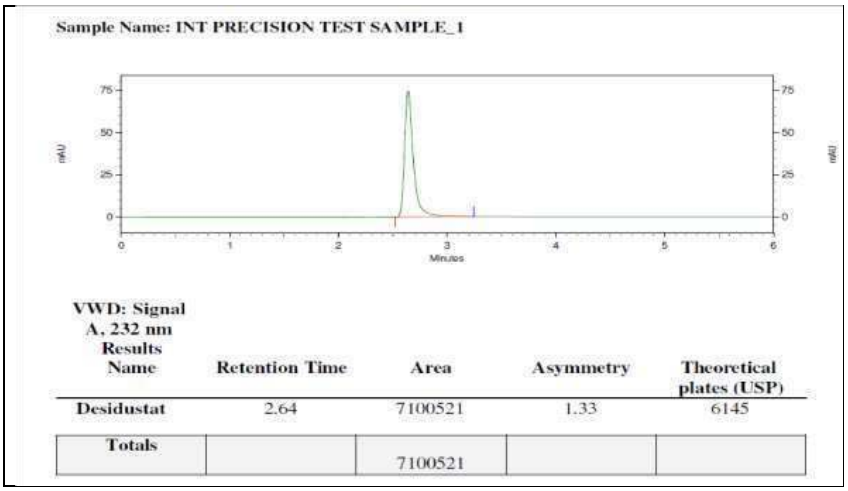


Fig. Typical chromatogram of Inter-day precision (Sample 1)

Acceptance criteria:

% Assay: % Assay value for each sample (Individual sample) and mean assay value for precision (6 samples), mean assay value intermediate precision (6 samples), and mean assay value for precision plus intermediate precision sample (12 samples): 90-110%

% RSD: % RSD for precision study samples (6 samples), Intermediate precision study samples (6 samples) and precision plus intermediate precision sample (12 samples): NMT 2.0 Data interpretation:

% Assay and % RSD was found well within acceptance limit and hence method is precise (Reproducible).

ROBUSTNESS:

The robustness of an analytical method is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Table. Result of Robustness study:

Change in Parameter	R.T.	Standard area	Asymmetry	Theoretical plates
Wavelength by +3 NM (234 NM)	2.63	7080253	1.33	6312
Wavelength by -3 NM (230NM)	2.63	6893238	1.32	6085
Flow rate by +10% (1.1mL/min)	2.40	6520125	1.37	5953
Flow rate by -10% (0.9mL/min)	2.92	7953201	1.36	6742
Column oven temp by +2ºC (42 ºC)	2.63	7210539	1.31	5928
Column oven temp by -2ºC (38 ºC)	2.64	7256861	1.32	6082

Chromatograms:

A. Change in Wavelength by +2 NM:

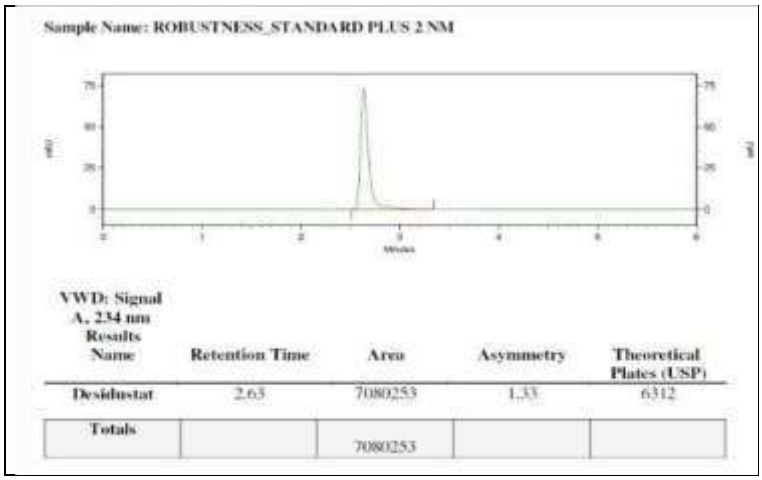


Fig. Typical chromatogram of Standard +2 NM

B. Change in Wavelength by -2 NM:

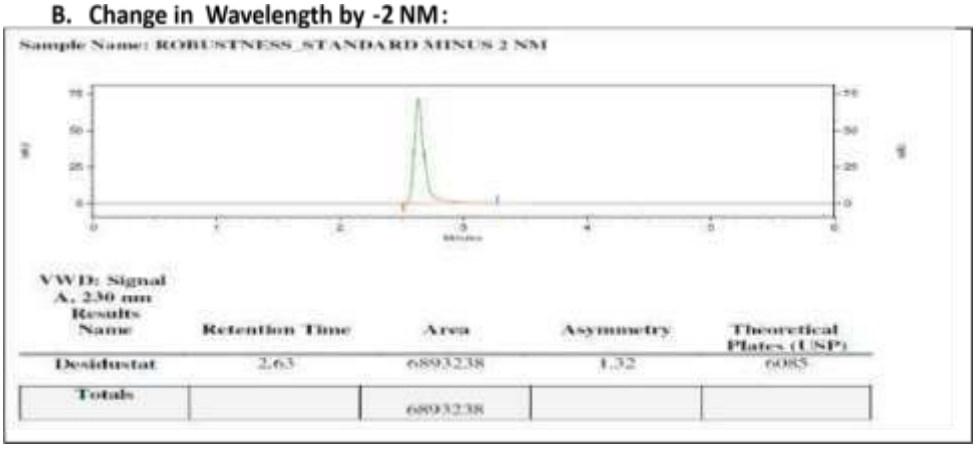


Fig. Typical chromatogram of Standard -2 NM C.

Change in Flow rate by + 10% (1.1 mL/min)

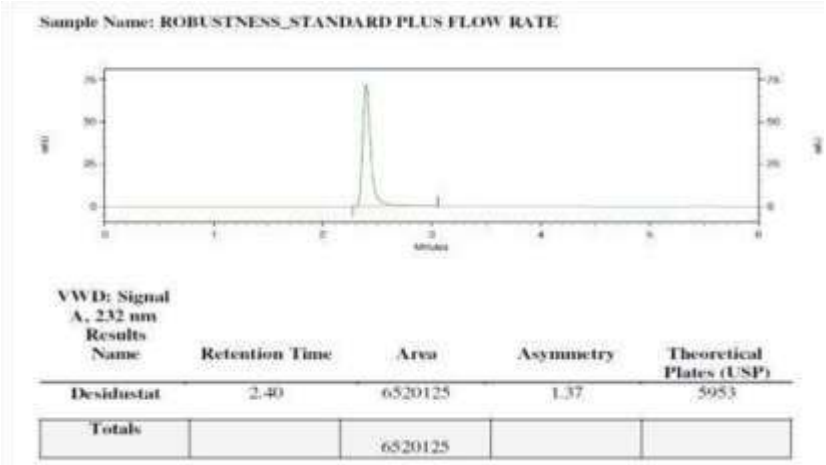


Fig. Typical chromatogram of Standard +10% F.R.

D. Change in Flow rate by - 10% (0.9 mL/min)

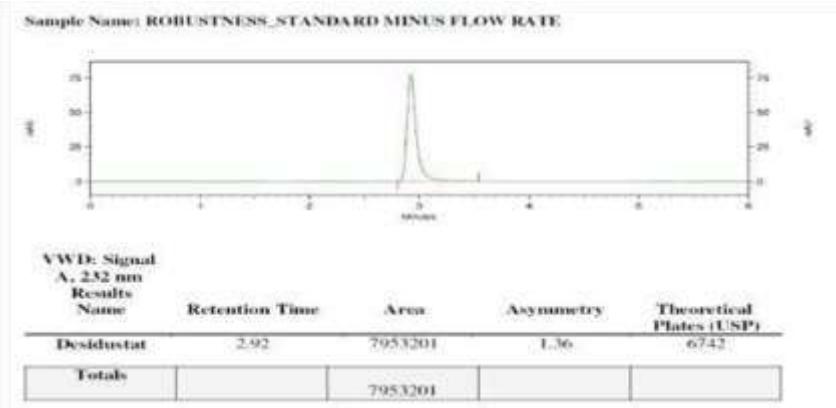


Fig. Typical chromatogram of Standard -10% F.R.

E. Change in Column Oven temperature by +2°C:

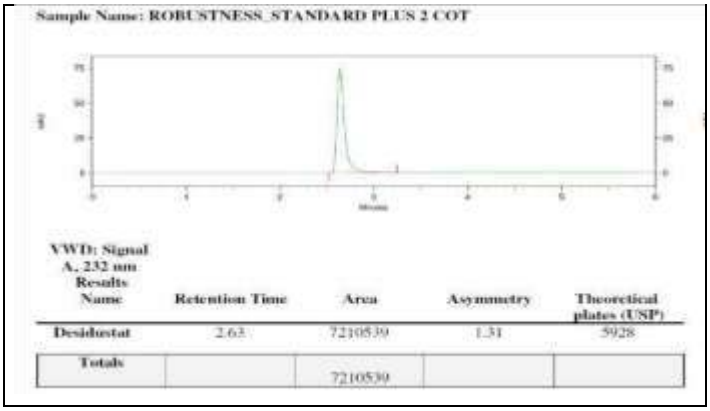


Fig. Typical chromatogram of Standard +2°C C.O.T.

F. Change in Column Oven temperature by -2°C:

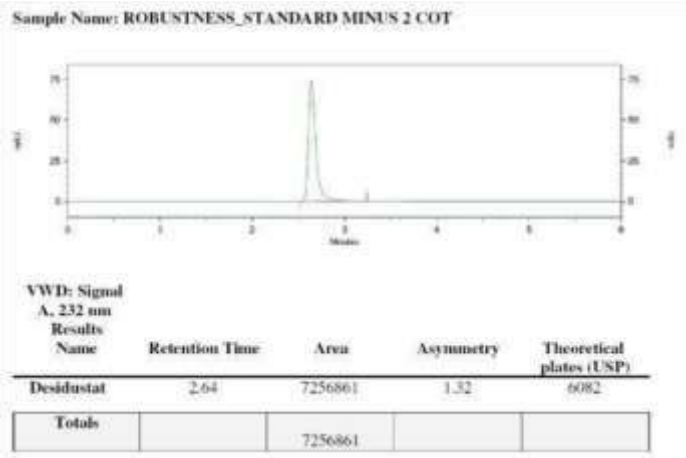


Fig. Typical chromatogram of Standard -2°C C.O.T.

Acceptance criteria:

Chromatography (System suitability) acceptance criteria should not get failed.

Data interpretation: From the above results, it was concluded that the system suitability test results was found well within the limit

DISCUSSION

The present RP-HPLC method was developed successfully for the estimation of Desidustat in solid dosage form. The selected column and mobile phase combination produced a sharp peak with a short retention time, which is advantageous for routine analysis. The use of Acetonitrile:Water (75:25, v/v) under isocratic conditions simplified the procedure and reduced analysis time.

The method showed excellent linearity over the selected concentration range, confirming that detector response was directly proportional to analyte concentration. The low %RSD values obtained in precision studies demonstrate that the method is reliable and reproducible. Accuracy values within acceptable recovery limits further support the suitability of the method for quantitative analysis.

Specificity testing confirmed that excipients and blank samples did not interfere with the analyte peak, which is important for tablet formulation analysis. Robustness studies showed that minor variations in analytical parameters did not significantly affect the results, indicating that the method is rugged enough for routine laboratory use. Overall, the method is simple, economical, and suitable for routine quality control analysis of Desidustat tablets in pharmaceutical laboratories.

CONCLUSION

A rapid, accurate, precise, and validated RP-HPLC method was successfully developed for the estimation of Desidustat in solid dosage form. The method complies with ICH Q2(R1) requirements and demonstrated excellent linearity, precision, accuracy, specificity, and robustness. Because of its simplicity and reproducibility, the method is suitable for routine analysis of Desidustat in pharmaceutical quality control laboratories.

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