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RP-HPLC Method Development and Validation of Dronedarone Hydrochloride In Bulk And Dosage Form

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Dronedarone's presence in drugs and dosage formulations has been identified using spectrophotometric and HPLC methods in a number of papers. The study developed a reliable reversed-phase high performance liquid chromatography method to measure dronedarone in bulk medication and tablet formulations. The method uses a UV detector and Openlab EZ chrome software, ensuring accuracy, precision, and robustness in filter study, solution stability, and quantification.

Keywords: Development; Dilsave; Dronedarone; Methanol; RP-HPLC; Validation.

In the pharmaceutical sector, analytical methods validation serves as proof that the procedures are appropriate for the task; these procedures must follow a plan that specifies acceptance limits, performance characteristics, and scopes. It is necessary to validate or revalidate analytical procedures before incorporating them into regular analysis[1]. Chromatography is an analytical method that separates molecules according to structural or compositional variations. Chromatography typically entails passing a sample over a stationary phase inside the apparatus. Due to their interactions and varying affinities for the stationary support, the molecules in the samples will segregate. Analytical chemistry Investigates, detects, and quantifies matter using tools and techniques. In actuality, the analysis may consist solely of separation, identification, or quantification, or it may be paired with another technique[2,3]. Analysis separates the analytes. Analytes are identified through qualitative examination, and the concentration or numerical amount is ascertained through quantitative analysis. Qualitative analysis can determine the presence or absence of a compound, but not its mass or concentration, as they are not quantitative in nature[4].

MATERIAL AND METHODS

Materials

Drug: Dronedarone

Drug is taken from Vidisha analytical.

Reagents: some chemicals and solvents are used,

1. Methanol from Merk
2. Acetonitrile from Merk
3. Water from siddhi laboratory

Instruments:

Instruments that were utilized is UV – visible spectrophotometer

The Jasco Model 550 double beam UV-visible spectrophotometer is a reliable and efficient

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tool for analyzing various types of UV-visible data [6].

HPLC system

Agilent's 1260 Infinity II model number, DEAX02386 pump, and DEACX16446 detector are all in use.

KromasilC18 is a 250 x 4.6 mm, 5 µm column that runs on open lab EZ Chrome software.

Optimal Chromatographic Conditions: Trial No. 4 is regarded as having optimal chromatography, and it looks like this,

Chromatographic Conditions

Column Dimensions: (250 mm x 4.6 mm i.d.) Column Type: Phenomenex C18 5 ìm Temperature of column oven: 40 °C

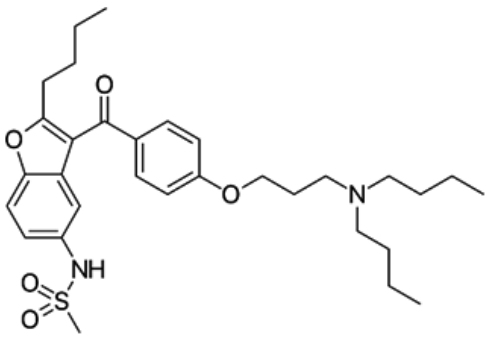
The detector is a UVdetector. 288 nm is the wavelength. Rate of Flow: 1.0 ml/min

Phase of mobility: Methanol: 65:35 water with 0.05% OPA Injection 20 ìl of volume

Sample preparation of Marketed test sample

After being weighed, twenty tablets were moved to a pestle and mortar and ground into a fine powder. Equally combine the ingredients with the butter paper. Once 50 mg of Dronedarone had been weighed out of the powder, it was placed to a 100 mL volumetric flask that had been cleaned and let to dry. After adding 70 milliliters of methanol, the liquid was sonicated by erratic shaking for ten minutes. Allow the solution to reach room temperature after ten minutes, then add methanol to bring the volume up to the proper level. Three to five milliliters of the first filtrate were thrown away after the mixture was filtered using an appropriate 0.45 µ syringe filter.

After adding 20 milligrams of Dronedarone to the mobile phase to dilute the filtered stock



Scheme 1. Structure of Dronedarone[5]

Table 1. Trial of solution with their chromatographic condition of drug dronedarone

Trial	Standard dissolution	Column	Column dimension	Column oven temp.	Detector	wave-length	Flow rate	Mobile phase	Injection volume
1.	Droneda rone 100PPM	Phenomenex C18	(250 mm X4.6 mm i.d.) 5µm	40°C	U.V. Detector	288nm	1.0ml/ min	Methanol: water (70:30)	20µl
2.	Droneda rone 100PPM	Phenomenex C18	(250 mm X4.6 mm i.d.) 5µm	40°C	U.V. Detector	288nm	1.0ml/ min	Acetonitril e: water (70:30)	20µl
3.	Droneda rone 100PPM	Phenomenex C18	(250 mm X4.6 mm i.d.) 5µm	40°C	U.V. Detector	288nm	1.0ml/ min	Methanol: 0.05% OPA in Water (70:30)	20µl
4.	Droneda rone 100PPM	Phenomenex C18	(250 mm X4.6 mm i.d.) 5µm	40°C	U.V. Detector	288nm	1.0ml/ min	Methanol: 0.05% OPA in Water (65:35)	20µl

solution to a volume of 25 milliliters, the mixture was injected, and the chromatograms and outcomes were noted.

Formula for % Assay calculation

$$\%\,\text{Assay} = \frac{\text{Dronedarone Spl area}}{\text{Dronedarone Std avg area}} X \frac{\text{Dronedarone STD wt (mg)}}{20} X \frac{0.5}{25} X \frac{100}{\text{Tablet sample weight (mg)}}$$

$$\frac{25}{1} X \frac{\text{Avg wt of tablet (mg)}}{\text{Label claim of Dronedarone}} X\ Factor\ X\ 100$$

Validation of RP-HPLC Method

The Dronedarone estimate method has been validated for certain parameters in accordance with ICH guidelines.

Filtration study

An analytical procedure's filtration investigation evaluates a filter's compatibility with the sample, its deposition on the filter bed, and interference from extraneous components[7].

Stability of analytical solution

The stability analysis was conducted on both the test sample and standard solution in a typical laboratory setting, evaluating the solution under standard lighting conditions after 12 and 24 hours[8].

Specificity

Specificity is the ability to accurately detect an analyte in the presence of expected components.

The next step is to prepare and inject the solution to demonstrate the method's specificity[9].

(Peak purity for test sample and standard solution checked)

Table 2. The sample was prepared in duplicate and the summary of the preparation process is provided below

Sample	Sample (mg)	Diluted to (mL)	Volume taken	Diluted to (mL)
Sample 1	96.7	100	1	25
Sample 2	97.2	100	1	25

Table 3. Linearity levels preparation

Sr. No.	Level (%)	mL of stock solution	Diluted to with mobile phase (mL)	Dronedarone Concentration (µg/mL)
1	10%	0.4	10	2.00
2	50%	2.0	10	10.00
3	100%	4.0	10	20.00
4	125%	5.0	10	25.00
5	150%	6.0	10	30.00

Table 4. Accuracy levels

Level (%)	Dronedarone HCl Std (mg)	Placebo (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)	Dronedarone Concentration (µg/mL)
50	26.8	43.9	100	1	25	10.07
	26.9	43.7	100	1	25	10.10
	26.7	44.2	100	1	25	10.03
100	53.4	44.1	100	1	25	20.06
	53.3	43.8	100	1	25	20.02
	53.4	44.3	100	1	25	20.06
150	79.9	43.9	100	1	25	30.01
	80.1	43.7	100	1	25	30.09
	80.0	44.1	100	1	25	30.05

• Blank (diluent: mobile phase)
• Placebo
• The standard dronedarone solution
• Sample solution for tablet testing[10].

Linearity and range

Preparation of linearity solution

Linearity refers to an analytical procedure's ability to produce test results proportionate to the analyte concentration within a given range, with five linearity levels tested[11].

Linearity Dronedarone stock solution

20 milliliters of methanol were used to dissolve 21.30 milligrams of Dronedarone hydrochloride, which is equal to 20 milligrams of Dronedarone. To create 50 mL, 2.5 ml of the stock solution were further diluted with mobile phase[12]. (Parts per million of 50)

Determination

The mean area was calculated after each level was administered three times. The calibration curve was plotted as mean area on the y-axis against analyte concentration in µg/mL on the X- axis based on the results.

Acceptance criteria

NLT 0.98 is the correlation coefficient. Interception: To be documented Slope: To be reported

1). Limit of Detection (LOD) and Limit of Quantitation (LOQ) Detection limit

The detection limit of an analytical

Table 5. Precision (Repeatability) Sample details are as follows

Sample No.	Test powder material (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
1	97.2	100	1	25
2	96.9	100	1	25
3	97.3	100	1	25
4	97.1	100	1	25
5	96.8	100	1	25
6	97.4	100	1	25

Table 6. Intermediate Precision Sample details are as follows

Sample No.	Test powder material (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
1	96.9	100	1	25
2	97.2	100	1	25
3	96.8	100	1	25
4	97.4	100	1	25
5	97.1	100	1	25
6	97.3	100	1	25

Table 7. Color, odour and appearance of Drug

Sr. No	Name	Colour, odour and appearance of drug
1	Dronedarone hydrochloride	White, odorless and Crystalline powder

Table 8. Melting point of Drug

Sr.No.	Name	Melting point std. value (°C)	Melting point observed (°C)
1	Dronedarone hydrochloride	142-146 °C	144-148 °C

technique refers to the lowest concentration of analyte in a sample that can be identified but may not always be accurately measured[13].

Quantitation limit

The quantitation limit of an analytical technique is the lowest concentration in a sample that can be accurately identified, and LOD and LOQ are computed in accordance with ICH Q2R1 recommendations[14].

The calibration curve was utilized to determine the residual standard deviation of a regression line, and the LOD and LOQ were determined using the following formula[15].

$$LOD = 3.3\ \sigma / S$$
$$LOQ = 10\ \sigma / S$$

Were,

σ = represents the regression line's residual standard deviation. S = Slope of regression line

2). Accuracy (% Recovery)

The analytical procedure's accuracy is determined by the degree of agreement between the discovered and recognized value, with a working concentration of 50-50% and three copies of each accuracy level[16].

Table 9. Solubility study of Dronedarone hydrochloride

Sr. No.	Name of Solvent	Observation	Conclusion	Summary
1	Water	Drug Particles seen after sonication	Drug was not foundsoluble in water.	The stock solution is prepared using methanol as a diluent.
2	Methanol	No Drug Particles seen after sonication.	Drugwas found soluble in methanol.	

Table 10. Optimized Chromatographic Conditions

Parameter	Description
Mode	Isocratic
Column Name	Phenomenex C18, 250mm*4.6mm, 5µ
Detector	UV Detector
Injection Volume	20 il
wavelength	288nm
Column Oven temp	40ºC
Mobile Phase	Methanol: 0.05% OPA in Water (65:35 % V/V)
Flow Rate	1.0 ml/min
Run time	8 minutes

Table 11. Results for System Suitability Test of Dronedarone

Sr. no	Standard solution	Area	Asymmetry	Theoretical plates
1	Standard 1	8442067	1.21	7058
2	Standard 2	8463658	1.21	7043
3	Standard 3	8456980	1.21	7047
4	Standard 4	8420621	1.21	7064
5	Standard 5	8476790	1.21	7069
Mean		8452023	1.21	7056
STD Dev.		21555.49178		
% RSD		0.26		

Accuracy levels details

Refer Following table for each sample

Acceptance criteria

1. The mean recovery and the percentage recovery for every sample should fall between 98 and 102%.
2. The recommended relative standard deviation is no more than 2.0%.

Precision

Analytical method precision refers to the agreement between measurements from multiple samplings of a homogenous test, with intermediate precision and repeatability being the two types[17].

Repeatability

Acceptance criteria

Each sample's 90% to 110% as well as the average assay value RSD percentage: NMT 2% for the six-sample assay

Intermediate precision

Analysis is done on a different day to confirm that the results are repeatable. Using the

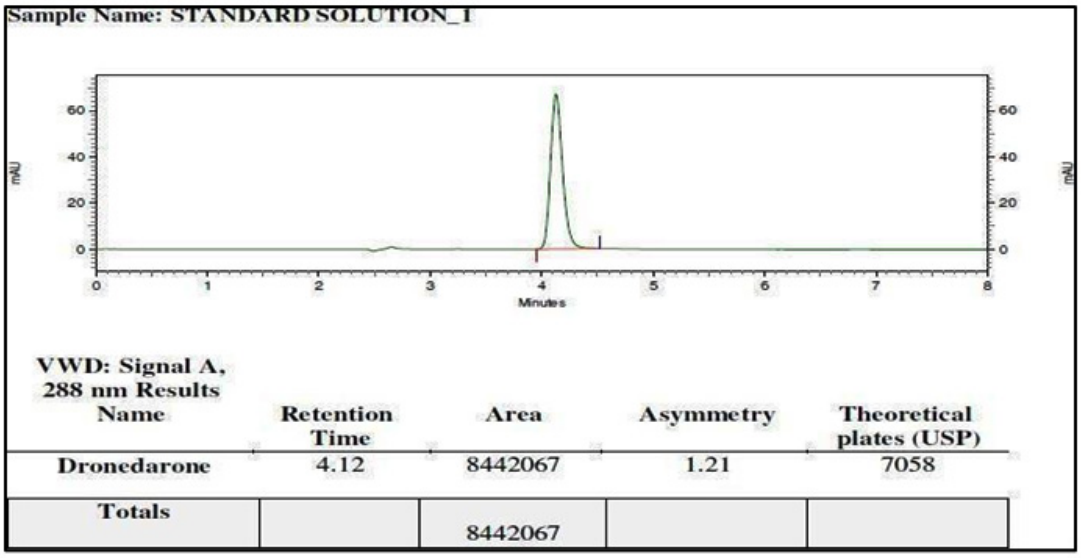


Fig. 1. The standard solution 1 of the system suitability solution is a typical chromatogram

Table 12. Dilsave tablet assay result

Assay results of Dilsave 400mg tablet sample	Area	% Assay	Mean Assay
Sample 1	8269685	98.06	98.50
Sample 2	8386850	98.94	

Table 13. Result of filter study

Results of Filter study Sample description	Area	% Absolute difference
Unfiltered	8453581	NA
0.45 µ PVDF filter	8416258	0.44
0.45 µ Nylon filter	8432560	0.25

Table 14. Results of Solution stability

Sample solution time point	Area	% Absolute difference	Standard solution timepoint	Area	%Absolute difference
Initial	8449658	NA	Initial	8465823	NA
12 Hours	8425260	0.29	12 Hours	8443582	0.26
24 Hours	8401704	0.57	24 Hours	8428060	0.45

same process as the Repeatability parameter, six samples were created[18].

Acceptance criteria

90% to 110% for each sample and the average assay value

Percentage RSD for six samples of intermediate precision assay: NMT 2

% RSD for each of the 12 samples: 6 tests for intermediate precision and 6 tests for repeatability; NMT 2% for test outcomes.

Robustness

Robustness is a statistic that conveys how reliable an analytical procedure is under typical operating conditions and how resistant it is to tiny, intentional changes in method parameters[19].

Determination: The Blank and Standard solutions were injected using a variety of chromatographic conditions, as shown below[20].

a) Variation of ±10% in the flow rate. (± 0.1 ml/min)
b) Temperature of the column oven has changed. (± 2ºC)
c) Wavelength variation (± 3 nm).

RESULTS

Preliminary characterization and identification of drug

Color, odour and appearance

Selection of solvent

Methanol was selected as the solvent for dissolving Dronedarone hydrochloride.

DISCUSSION

System suitability test

System Suitability Acceptance Criteria

1. The analyte peak area's relative standard deviation in standard chromatograms shouldn't be more than 2.0%.
2. There should be at least 2000 theoretical plates of analyte peak in standard chromatograms.
3. The analyte peaks' tailing factor (asymmetry) in standard chromatograms should be less than 2.0.

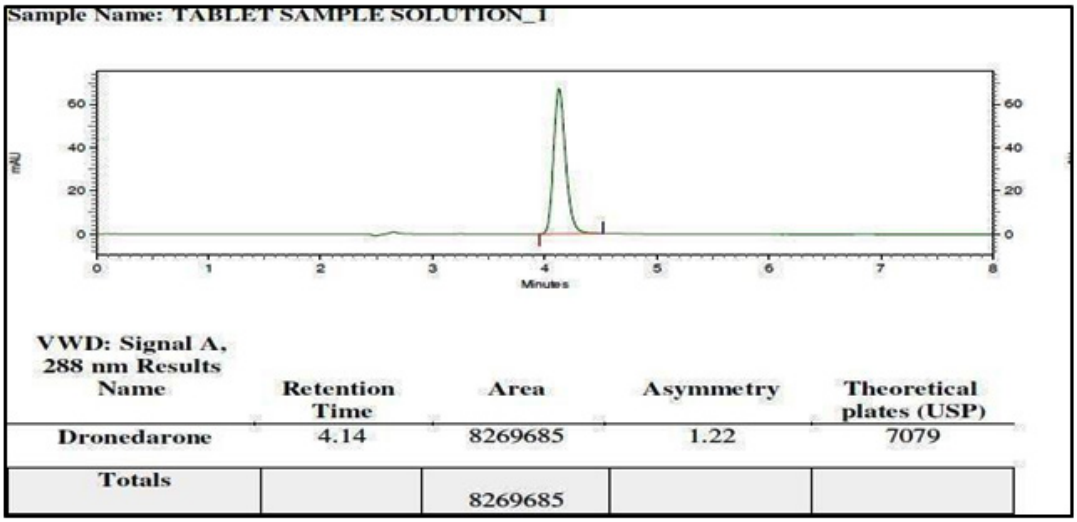


Fig. 2. Typical chromatogram Dilsave 400 mg Tablet sample

Table 15. Results of specificity description

Results of specificity description	Observation
Blank	Due to blank, there is no interference at R.T. of Dronedarone
Placebo	No placebo-induced interference at R.T. of Dronedarone
Standard solution	The highest purity was 0.987.
Test solution	The highest purity was 0.981.

Data interpretation

As can be seen from the data given above, the procedure conforms to the requirements for system appropriateness. Therefore, it may be said that the intended analysis can be conducted using the chromatographic method.

Analysis of Marketed Test samples (Assay): Dilsave 400 mg Tablet:

Weight of 20 tablets = 15.5060 gm.

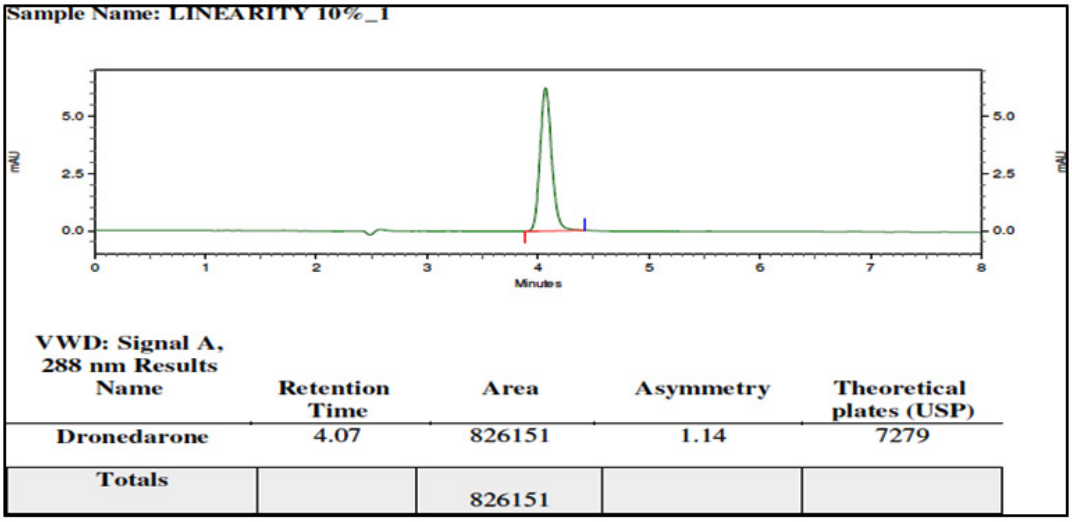
Average weight of tablet = 15.5060 /20 = 0.7753 gm. = 775.3 mg

Acceptance criteria:

The assay found should fall within the 90-110% range.

Data interpretation:

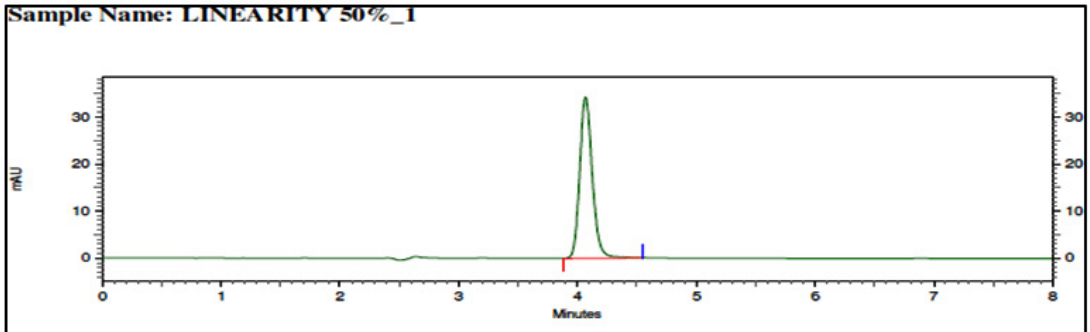
Based on the aforementioned findings, it can be said that the sample can be utilized for validation because the assay result for the chosen commercial test sample is within the acceptable range.



VWD: Signal A, 288 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Dronedarone	4.07	826151	1.14	7279
Totals		826151		

Fig. 3. Typical chromatogram of Linearity 10%



VWD: Signal A, 288 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates(USP)
Dronedarone	4.07	4208075	1.16	7266
Totals		4208075		

Fig. 4. Typical chromatogram of Linearity 50%

Validation of RP-HPLC Method

Filtration study

The analytical technique's filtration inquiry assesses the filter's compatibility with the sample, deposition on the filter bed, and interference from extraneous components on a tablet test sample.

Acceptance criteria

The absolute difference between filtered samples and unfiltered samples is calculated using NMT 2.0.

Data interpretation

PVDF and Nylon filters are both suitable for use as they meet the requirements for filter studies. Since nylon showed smaller absolute difference than PVDF filter, we chose to utilize it.

Solution stability

The stability analysis was conducted on both test and standard samples in a typical laboratory setting, examining the solution after six, twelve, and twenty four hours under standard laboratory lighting.

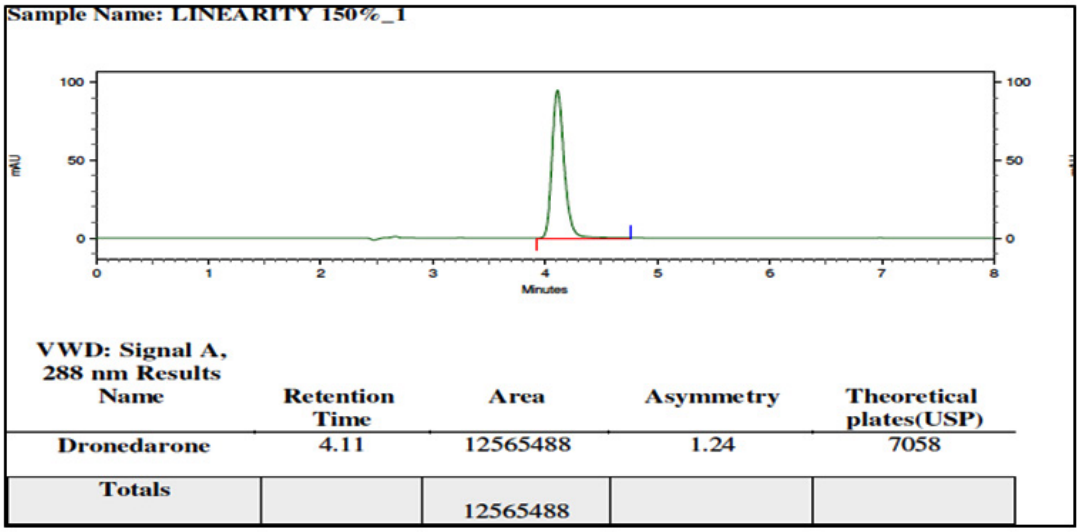


Fig. 5. Typical chromatogram of Linearity 150%

Table 16. Linearity data for dronedarone level

Linearity Data for Dronedarone Level	Concentration (µg/mL)	Area	Mean	% RSD
10%	2.00	826151 827692 825207	826350	0.152
50%	10.00	4208075 4213620 4219894	4213853	0.140
100%	20.00	8439096 8427679 8450680	8439152	0.136
125%	25.00	10413175 10438940 10420807	10424307	0.127
150%	30.00	12565488 12540843 12578304	12561545	0.152

Acceptance criteria

NMT 2.0's absolute stability solution differs from the first solution in percentage terms.

Data interpretation

Testing and standard solutions were proven to be steady for a whole day. Therefore, you can use both solutions for up to 24 hours.

Table 17. Data of linearity of Dronedarone:

Sr no.	Parameter	Result value	Acceptance criteria
1	Beer's linearity range	2.0 -30.0 µg/mL	NA
2	Correlation coefficient (R2)	0.99996	NLT 0.98
3	Intercept	13759.060	To be report
4	Slope	418334.9181	To be report
5	% RSD for area at each level	NA	NMT 2.0

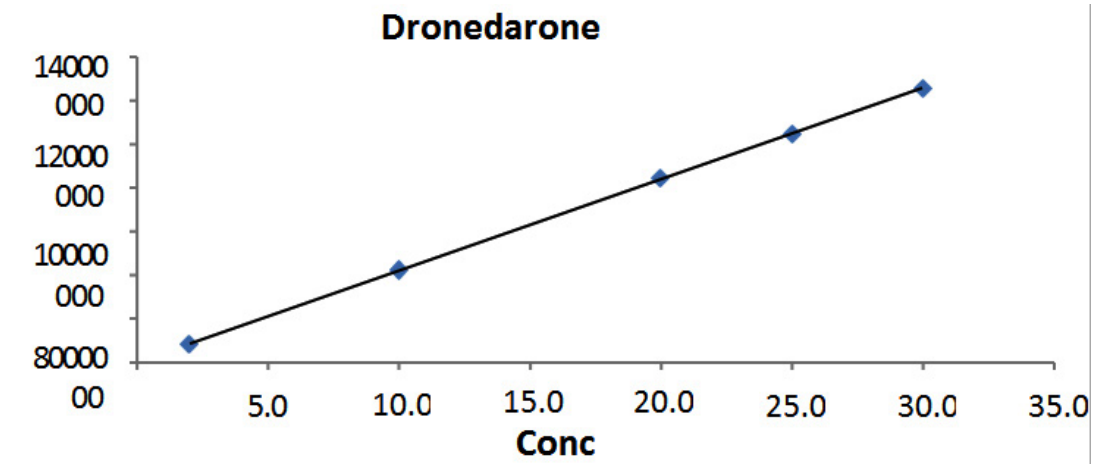


Fig. 6. Calibration curve of Dronedarone

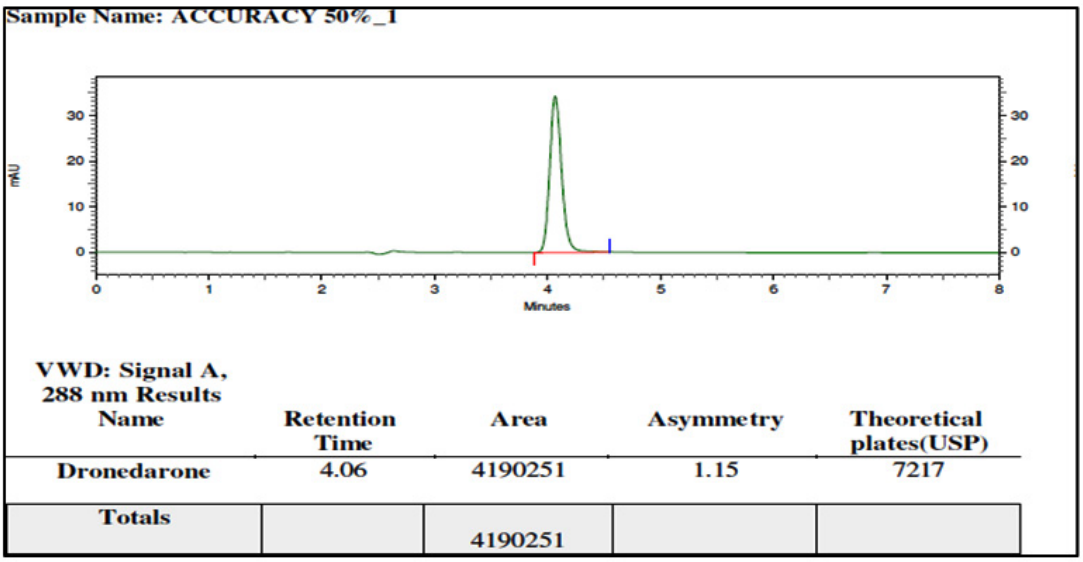


Fig. 7. Typical chromatogram of Accuracy 50%

Specificity

Specificity is the ability to accurately detect an analyte in the presence of expected components.

A standard solution was prepared and injected to ensure peak purity.

Acceptance criteria:

Blank: There shouldn't be any disruption at Dronedarone's R.T. Placebo: At R.T. of Dronedarone, there shouldn't be any interference. Sample solutions for testing and standards: Maximum purity: 0.95 NLT

Interpretation of the data

The chromatographic technique for Dronedarone met specificity requirements, with both standard and test solutions' purity peaks within acceptable bounds, without interference from blank or placebo.

Linearity and Range

Linearity is an analytical method's ability to produce test results directly proportional to the concentration of the analyte in the samples.

The respective linear equation for Dronedarone

$Y = M X + C$

$Y = 418334.9181 x + 13759.060$

Table 18. Result and statistical data of Accuracy of Dronedarone

Level (%)	Area	Recovered conc (µg/mL)	Added conc (µg/mL)	% Recovery	Mean Recovery	% RSD
50	4190251	9.92	10.07	98.51	98.94	0.589
	4250485	10.06	10.10	99.60		
	4183840	9.90	10.03	98.70		
100	8490256	20.09	20.06	100.15	99.27	0.858
	8330475	19.71	20.02	98.45		
	8411823	19.90	20.06	99.20		
150	12564057	29.73	30.01	99.07	99.07	0.636
	12679430	30.00	30.09	99.70		
	1250160	29.58	30.05	98.44		

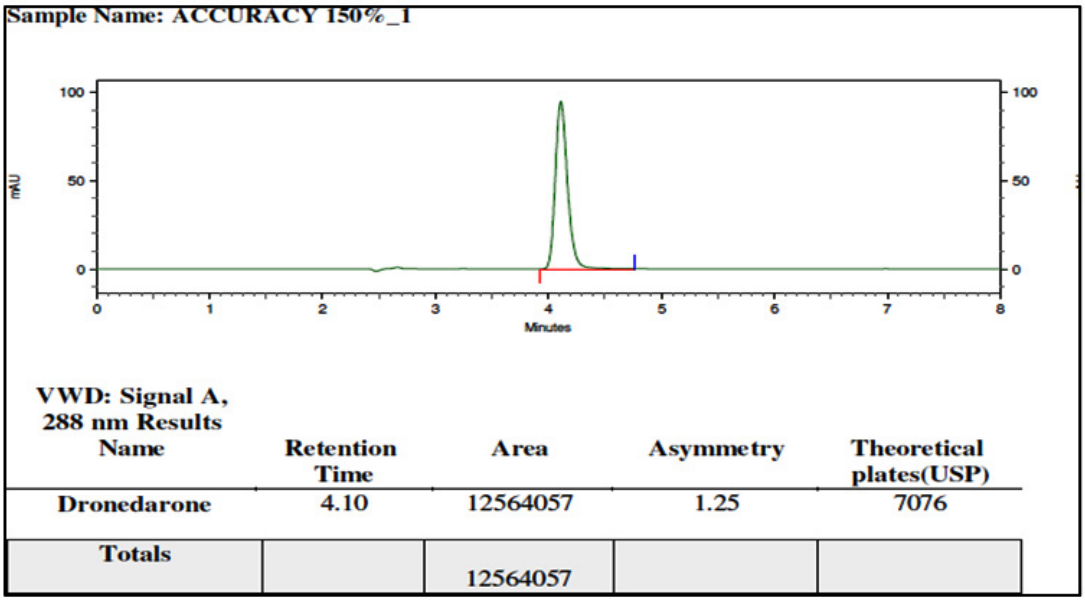


Fig. 8. Typical chromatogram of Accuracy 150%

Table 19. Result of Intra- day and Inter- Day Precision for Dronedarone test sample assay

Repeatability	Sample	Test Sample (mg)	Area	% Assay
	Sample 1	97.2	8330682	98.28
	Sample 2	96.9	8430648	99.76
	Sample 3	97.3	8306720	97.89
	Sample 4	97.1	8352358	98.63
	Sample 5	96.8	8478516	100.43
	Sample 6	97.4	8315835	97.90
	Mean	98.82		
	STD DEV	1.050195		
	% RSD	1.063		
Intermediate precision (Inter-Day)	Sample 1	96.9	8482361	100.38
	Sample 2	97.2	8313504	98.07
	Sample 3	96.8	8242860	97.64
	Sample 4	97.4	8413692	99.05
	Sample 5	97.1	8283025	97.81
	Sample 6	97.3	8467921	99.79
	Mean	98.79		
	STD DEV	1.131106		
	% RSD	1.145		
Repeatability Plus Inter-day	Mean	98.803		
	STD DEV	1.04069		
	% RSD	1.053		

Table 20. Result of Robustness study of Dronedarone

Change in Parameter	R.T.	Standard area	Asymmetry	Theoretical plates
Wavelength by +3 NM (291 NM)	4.05	7938226	1.22	7289
Wavelength by -3 NM (285 NM)	4.03	7844385	1.19	7281
Flow rate by +10% (1.1 mL/min)	3.66	7336241	1.18	6743
Flow rate by -10% (0.9 mL/min)	4.48	9010416	1.21	7566
Column oven temp by +2ºC (42 ºC)	4.13	8410892	1.23	6936
Column oven temp by -2ºC (38 ºC)	4.12	8435691	1.21	7083

Where, x = concentration of Analyte in µg/mL y = is area of peak.
M = Slope C=Intercept

CONCLUSION

The Dronedarone demonstrated a linear response within the 2.0-30.0 ìg/ml range, with a regression value within the limit.
Limit of Detection (LOD) and Limit of Quantitation (LOQ):
ó = 40611.40658 (Residual standard deviation of a regression line) s = 418334.9181
Detection limit (LOD):
LOD = 3.3 ó / S
LOD = 3.3 x 40611.40658 / 418334.9181
LOD = 0.320 µg/mL
Quantitation limit (LOQ):
LOQ = 10 ó / S
LOQ = 10 x 40611.40658 / 418334.9181
LOQ = 0.971 µg/mL
5) ACCURACY (RECOVERY):
An analytical method's accuracy is determined by its closeness to the true value, achieved by applying the method to samples with known analyte amounts.
Overall Recovery: 99.09 %
% RSD for Overall Recovery: 0.627
Acceptance criteria
The recovery rate for each level and overall recovery ranges from 98.0 to 102.0%. The percentage RSD for each level and overall recovery

rate for NMT 2.0 is provided.

Data interpretation

The analytical procedure's recovery was found to be within acceptable criteria at all three levels, and the recovery was not affected by changes in analyte concentration.

Precision

The precision of an analytical method refers to the agreement among individual test results when applied to multiple samplings of a homogenous sample, usually expressed as standard deviation or relative standard deviation.

Acceptance criteria

% Assay

The mean assay value for precision (6 samples), intermediate precision (6 samples), and precision plus intermediate precision (12 samples) ranges from 90-110%.

% RSD

The NMT 2.0 was utilized to calculate the % RSD for precision, intermediate, and precision plus intermediate precision samples.

Data interpretation

The method was found tobe precise and reproducible, with the % Assay and % RSD falling within the acceptance limit.

Robustness

An analytical method's robustness signifies its ability to withstand minor parameter changes, indicating its reliability during normal usage.

The following modifications have been made under the category of Robustness.

• Change in Wavelength
• Change in flow rate
• Change in column oven temperature

Acceptance criteria

The system suitability acceptance criteria for chromatography should not be failed.

Data interpretation

The system suitability test results were found to be within the limits, indicating a robust analytical method.

Conclusion

The current work's objective was to create a suitable, accurate, precise, and simple RP-HPLC method.

A survey of the literature revealed that several methods for quantifying dronedarone in bulk or prescription dosage forms have been reported.

In the current work, a new, sensitive, and suitable reversed-phase high performance liquid chromatography method was developed and validated in order to determine dronedarone in bulk dosage form. The developed RP-HPLC technique resolved the analyte using an isocratic procedure.

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Conflict of interest

The authors do not have any conflict of interest.

Data Availability Statement

This statement does not apply to this article.

Ethics Statement

This research did not involve human participants, animal subjects, or any material that requires ethical approval.

Informed Consent Statement

This study did not involve human participants, and therefore, informed consent was not required.

Clinical Trial Registration

This research does not involve any clinical trials**.**

Authors contribution

Rutika B. waghchaure: Data collection, writing original draft, methodology Shivraj P. Jadhav: Project administration, Analysis, writing review and editing Khemchand R. surana: Visualization; Darshan S. sonawane: Data collection, editing of data. Sunil K. Mahajan: Resource and supervision.

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