



International Journal of Research and Development in Pharmacy & Life Science

An International open access peer reviewed journal

ISSN (P): 2393-932X, ISSN (E): 2278-0238

Journal homepage: <http://ijrdpl.com>



Original Article

A new analytical method development and validation for the estimation of Midodrine HCl by UV and HPLC

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Keywords: HPLC, UV, Midodrine hydrochloride, method development, Validation

Article Information:

Received: May 19, 2018;

Revised: June 25, 2018;

Accepted: July 01, 2018

Available online on:

15.07.2018 @ <http://ijrdpl.com>



[http://dx.doi.org/10.21276/IJRDPL.2278-0238.2018.7\(4\).3060-3070](http://dx.doi.org/10.21276/IJRDPL.2278-0238.2018.7(4).3060-3070)

ABSTRACT: Two simple, accurate, sensitive and precise reverse phase-high performance liquid chromatographic and U.V. assay method for estimation of Midodrine hydrochloride (MD) was developed in tablet formulation. The chromatographic separation was performed on Thermo C18, (250 mm X 4.6 mm, 5 μm) column. The mobile phase consists of water: acetonitrile (30:70 v/v) pH adjust 3.5 with TEA was delivered at a flow rate of 1.0 ml/min and UV detection at 272 nm. The retention time of the drug was found to be 3.89 min. The developed method was found to be linear in a concentration range of 5-25 μg/ml of the drug ($r^2 = 0.999$). The low value of % RSD indicates reproducibility of the methods. The low value of LOD and LOQ suggests the sensitivity of the method. Thus, this method can be used for routine analysis of Midodrine hydrochloride formulation and to check the stability of bulk samples.

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INTRODUCTION

Every year many new drugs and newer drug combinations enter the pharmaceutical area. The analytical methods for these new and first timer drugs are mostly confined only to the manufacturing company. However, availability of multiple analytical methods for the same drug/drug combinations in their formulations is always advantageous.

Moreover, development of such methods helps in training the analysts for skillfully handling the sophisticated analytical instruments and the way for research approach. Reference literature and general survey reveals that similar work of development of UV and HPLC methods for new drugs and their combinations introduced in the market is continuously underway in many academic institutions. The present work is also planned on similar lines [1,2].

The non-availability of analytical methods till now for the concurrent analysis of single and multi-component formulations made it worthwhile to pursue the present research work. It was also planned to validate the developed methods as per ICH guidelines.

Hence, they offer wide area for research activity with relatively minimum chances of exactly repetitive work. The pharmaceutical dosage forms are widely present with multiple active components i.e. in combined dosage forms. This has opened new task for analyst for simultaneous estimation of Midodrine hydrochloride in marketed formulation.

Therefore, in proposed project, to attempt to develop New, simple, accurate, cost effective and precise method for analysis of drugs in marketed formulation and validate them [2-4].

METHODS

Characterization and identification of midodrine hydrochloride [3-7]

Physiochemical characteristics

Description- Solid, off white powder.

Melting point- M.P. of the drug was 200-203°C found through Melting point apparatus.

Solubility- Solubility of Midodrine hydrochloride was established by I.P. method.

Chemicals and solvents

Table 1: Chemicals and Solvents Used

S. No.	Chemicals	Manufacturer
1.	Midodrine HCl	Working standard, API Grade
2.	Methanol (AR Grade)	Solvent Merck Ltd., India
3.	Methanol (HPLC)	Merck Ltd., India
4.	Water (HPLC)	Merck Ltd., India

Instruments & Equipment:

For UV method:

Absorbance measurements were made on UV-Visible spectrophotometer Lab India, model is 3000+ with 1cm quartz cell. For weighing, Wensar (max 1g, sensitive = 0.01 mg) balance was used.

For HPLC method:

The HPLC system consisted of a Waters isocratic System UV detector. Model no. 784. The software used was Data Ace, Separation was achieved on a reverse C₁₈ (250mm×4.6mm 5µm).

Marketed formulation of Midodrine hydrochloride

Proamatine 5 mg tablets

Midodrine hydrochloride 5mg

Determination of solubility

Solubility of Midodrine hydrochloride was performed in different solvents.

Estimation of midodrine hydrochloride by spectrophotometry [6-11]:

Area under curve method:

Determination of λ_{max} of Drug

Standard solution (10µg/ml) of pure Midodrine hydrochloride was prepared. The pure drug solution was scanned on UV spectrophotometer, which showed maximum absorbance at 272.0 nm.

Experimental Procedure:

Preparation of Standard Stock Solution

10mg of Midodrine hydrochloride was weighed accurately and transferred to a 10ml volumetric flask, and the volume was adjusted to the mark with the diluent water, to give a stock solution of 1000ppm.

Preparation of Working Standard Solution

From stock solutions of Midodrine hydrochloride 1 ml was taken and diluted up to 10 ml. From this solution 0.5, 1.0, 1.5, 2.0 and 2.5 ml solutions were transferred to 10ml volumetric flasks and make up the volume up to 10 ml with water gives standard drug solution of 5, 10, 15, 20, 25 g/ml concentration.

Preparation of the calibration curves of the drug

The standard drug solutions were taken absorbance 3 times and the mean area of drug was calculated and plotted against the concentration of the drug. The regression equation was found out by using this curve. A typical spectrum and the calibration curve were obtained.

Preparation of analysis of tablet formulation

20 tablets were weighed and ground to a fine powder. Tablet powder equivalent to 10 mg Midodrine hydrochloride was weighed and transferred to a 10 ml volumetric flask and volume was made up to 10 ml with diluents (water) to obtain concentration of 1000µg/ml. Resultant solution was filtered through Whatmann filter paper.

1 ml of filtrate was taken in 10 ml volumetric flask and volume was made up to 10 ml with diluent to obtain concentration of 100µg/ml. Further 1.0 ml of this solution was taken and diluted up to 10 ml obtain final concentration of 10 µg/ml. Absorbance of the sample solutions at 272.0 nm was measured and from the absorbance values, the concentration of drugs in the sample solution was determined by using calibration curve $Y=mx+c$.

Validation

Linearity

Linearity of analytical procedure is its ability (within a given range) to obtain test, which are directly proportional to absorbance of analyte in the sample. The calibration plot was constructed after analysis of five different (from 5 to 25 g/ml) concentrations and area for each concentration were recorded three times, and mean absorbance was calculated.

The regression equation and correlation coefficient of curve and the standard curve of the drug is shown in figure.

Accuracy

Recovery studies were performed to validate the accuracy of developed method. To pre-analyzed sample solution, a definite concentration of standard drug (80%, 100%, and 120%) was added and then its recovery was analyzed.

Precision

(A) Repeatability

Standard dilutions were prepared, and three replicates of each dilution were analyzed in same day for repeatability and results were subjected to statistical analysis. Standard dilutions were prepared, and three replicates of each dilution were analyzed in different days and by different analysts. Statistical analysis was carried out.

(B) Intermediate Precision

(a) Day to Day

(b) Analyst to Analyst

The intermediate precision expresses with in laboratories variation: different days, different analysts, different equipment etc. The standard dilution was prepared, and three replicates of each dilution were analyzed by different analysts for all the developed methods.

LOD (Limit of Detection):

The Limit of Detection (LOD) is the smallest concentration of the analyte that gives the measurable response. LOD was calculated using the following formula.

$$LOD = 3.3 (\sigma / S)$$

Where, S = slope of calibration curve, σ = standard deviation of the response.

6.6.5 LOQ (Limit of Quantitation):

The Limit of Quantification (LOQ) is the smallest concentration of the analyte, which gives a response that can be accurately quantified. LOQ was calculated using the following formula.

$$LOQ = 10 (\sigma / S)$$

Where, S = slope of calibration curve, σ = standard deviation of the response.

Analytical method development by HPLC[11-14]:

Mobile Phase Selection:

Initially to estimate Midodrine hydrochloride number of mobile phase in different ratio were tried. Taking into consideration the system suitability parameter like RT, Tailing factor, No. of theoretical plates and HETP, the mobile phase found to be most suitable for analysis was Water (pH adjust 3.5 with TEA):

Acetonitrile in the ratio of (20:80v/v). The mobile phase was filtered through 0.45 μ filter paper to remove particulate matter and then degassed by sonication. Flow rate employed for analysis was 1.0 ml/min at the λ_{max} 272nm.

Selection of wavelength:

100 mg of Midodrine hydrochloride was weighed accurately and transferred to a 100 ml volumetric flask, and the volume was adjusted to the mark with the mobile Water (pH adjust 3.5 with TEA): Acetonitrile in the ratio of (20:80v/v). From above solutions of 0.1 ml was transferred to 10 ml volumetric flasks and make up the volume up to mark. Resulting solution was scanned over UV range (200-400nm), maximum absorbance was found at Lambda max 272nm.

Selection of Separation Variable:

Standard drug solution of Midodrine hydrochloride was prepared in different mobile phase and chromatograph was recorded by using different column (5 and 10 μ m) at different chromatographic condition like different flow rate and temperature. Considering the theoretical facts and after several trials separation variables were selected which were constant during whole experiment.

System Suitability Parameters:

Separation variables were set, and mobile phase was allowed to saturate the column at 1.00 ml/min. After complete saturation of column, three replicates of working standard of Midodrine hydrochloride 10 μ g/ml was injected separately. Peak report and column performance report were recorded for all chromatogram.

Preparation of Standard Stock Solution:

10mg of Midodrine hydrochloride was weighed accurately and transferred to separate 10ml volumetric flask, and the volume was adjusted to the mark with Acetonitrile to give a stock solution of 1000ppm.

Preparation of Working Standard Solution:

From stock solutions of Midodrine hydrochloride 1 ml was taken and diluted up to 10 ml. from this solution 0.5, 1.0, 1.5, 2.0, 2.5 ml solutions were transferred to 10ml volumetric flasks and make up the volume up to 100 ml with Acetonitrile, gives standard drug solution of 5, 10, 15, 20, 25 μ g/ml concentration.

Preparation of the Calibration Curves of the Drug:

Standard drug solutions were injected 3 times and the mean peak area of drug was calculated and plotted against the concentration of the drug. The regression equation was found out by using this curve.

Analysis of tablet formulation[15-17]:

Assay of Tablet formulation:

20 tablets were weighed and ground to a fine powder. Tablet powder equivalent to 10 mg Midodrine hydrochloride was weighed and transferred to a 10 ml volumetric flask and volume was made up to 10 ml with Acetonitrile to obtain concentration of 1000 μ g/ml. Resultant solution was filtered through Whatmann filter paper. 1 ml of filtrate was taken in 10 ml volumetric flask and volume was made up to 10 ml with diluents (Acetonitrile) to obtain concentration of 100 μ g/ml. Further 1.0 ml of this solution was taken and diluted up to 10 ml obtain final concentration of 10 μ g/ml.

The amounts of Midodrine hydrochloride in Tablet formulation was calculated by extrapolating the value of area from the calibration curve. Analysis procedure was repeated six times with Tablet formulation.

Validation:

Linearity:

Linearity of analytical procedure is its ability (within a given range) to obtain test, which are directly proportional to area of analyte in the sample. The calibration plot was constructed after analysis of five different (from 5 to 25 μ g/ml) concentrations and areas for each concentration were recorded three times, and mean area was calculated. The regression equation and correlation coefficient of curve are given, and the standard calibration curve of the drug is shown in fig. From the mean of AUC observed and respective concentration value, the response ratio (response factor) was found by dividing the AUC with respective concentration.

Accuracy:

Recovery studies were performed to validate the accuracy of developed method. To pre-analyzed sample solution, a definite concentration of standard drug (80%, 100%, and 120%) was added and then its recovery was analyzed.

Precision:

(A) Repeatability

Standard dilutions were prepared, and three replicates of each dilution were analyzed in same day for repeatability and results were subjected to statistical analysis. Standard dilutions were prepared, and three replicates of each dilution were analyzed in different days and by different analysts. Statistical analysis was carried out.

(B) Intermediate Precision

(a) Day to Day

(b) Analyst to Analyst

The intermediate precision expresses with in laboratories variation: different days, different analysts, different equipment etc. The standard dilution was prepared, and three replicates of each dilution were analyzed by different analysts for all the

developed methods. The statistical analysis method was carried out and the data is presented.

Robustness:

As per ICH norms, small, but deliberate variations, by altering the pH and / or concentration of the mobile phase were made to check the method capacity to remain unaffected. The effect of change in pH of mobile phase, flow rate, mobile phase ratio on the retention time, theoretical plates, area under curve and percentage content of Midodrine hydrochloride was studied.

RESULTS AND DISCUSSION

Identification and characterization of drug

Results of melting point

Results: Melting point of midodrine hydrochloride found 200-203°C

Result of FTIR of Midodrine hydrochloride

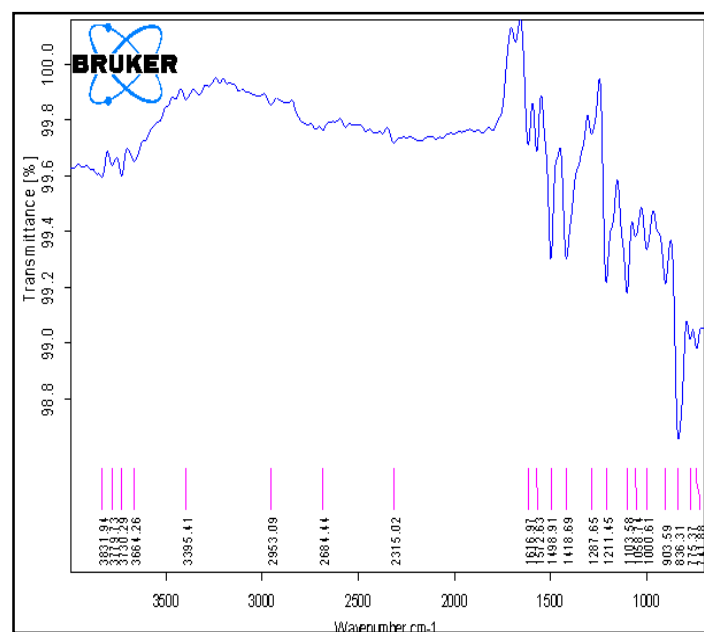


Figure 1: FT-IR of Midodrine hydrochloride

Results of solubility study

Table 2: Solubility of Midodrine hydrochloride

S. No.	Solvent	Solubility
1	Water	Soluble
2	0.1 N HCl	Soluble
3	Methanol	Freely Soluble
4	Ethanol	Freely Soluble
5	0.1 N NaOH	Slightly Soluble
6	Phosphate buffer 7.2	Soluble

Determination of λ_{max} of Drug

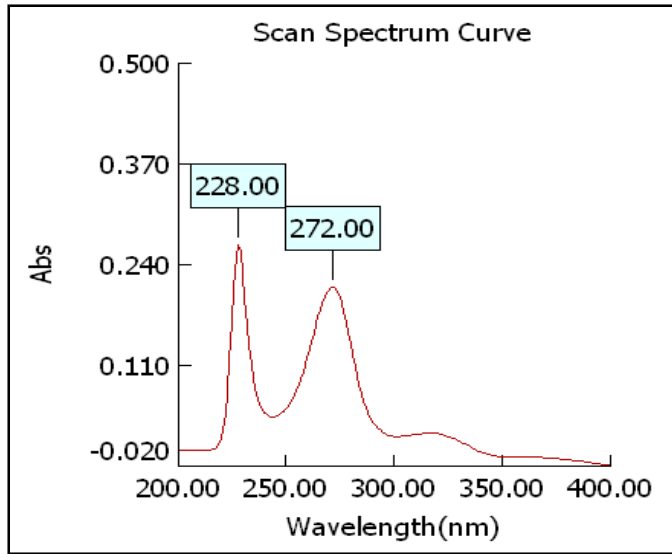


Figure 2: Selection of λ_{max} of Midodrine hydrochloride

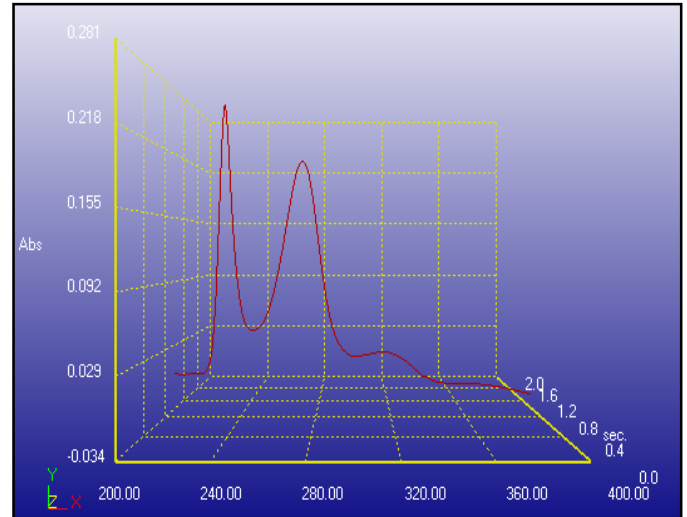


Figure 3: 3D spectra of λ_{max} of Midodrine hydrochloride

Preparation of the calibration curves of the drug using AUC method

Table 3: Linearity of Midodrine hydrochloride

Conc. ($\mu\text{g/mL}$)	0	5	10	15	20	25
Rep.1	0	9.14	18.45	22.4	29.07	37.8
Rep.2	0	9.15	18.43	22.41	29.05	37.7
Rep.3	0	9.18	18.42	22.39	29.06	38.05
Mean	0	9.15667	18.4333	22.4	29.06	37.85
S.D.	00	0.02082	0.01528	0.01	0.01	0.18028
R.S.D%	000	0.22734	0.08287	0.04464	0.03441	0.47629

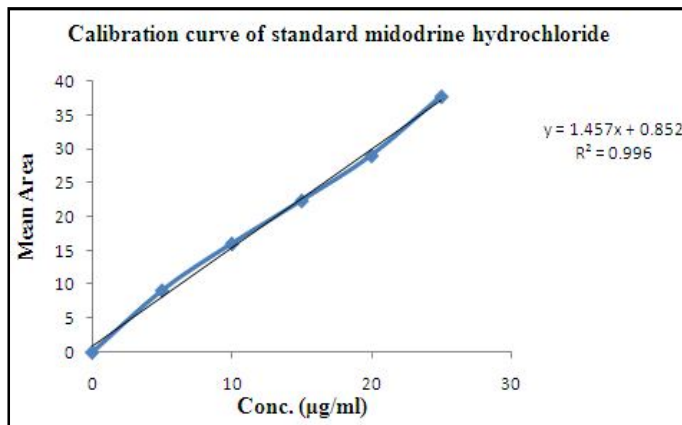


Figure 4: Calibration curve of standard midodrine hydrochloride

Regression Equation

$Y = mx + c$,

Slope- $M = 1.457$

intercept - $C = 0.852$

$r^2 = 0.996$

Table 4: Result of Optical Parameter of Midodrine hydrochloride

S. No.	Parameters	Observation
1.	λ_{max}	272.0 nm
2.	Ber's law limit ($\mu\text{g/mL}$)	5-25
3.	Regression equation	$Y = 1.457x + 0.852$
4.	Correlation Coefficient (r^2)	0.996

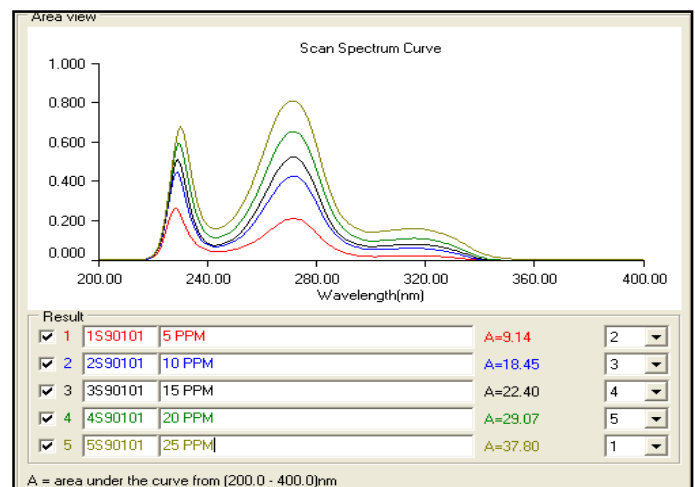


Figure 5: Linearity of standard Midodrine hydrochloride AUC method

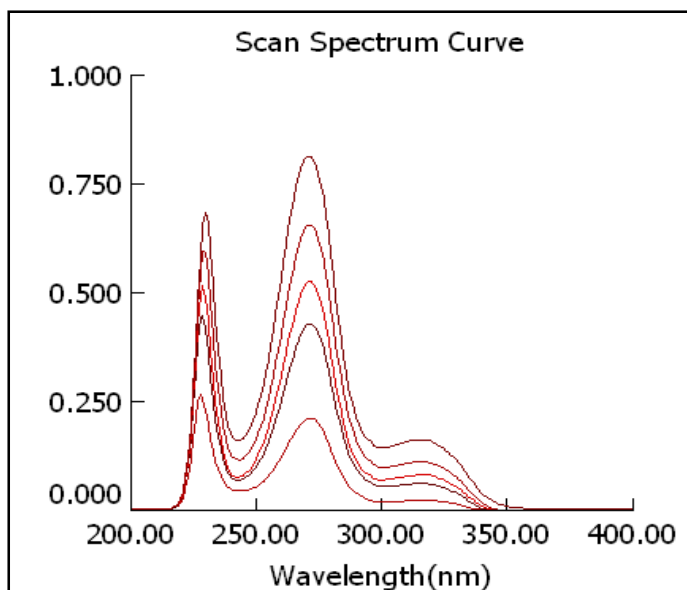


Figure 6: Spectra of linearity of standard Midodrine hydrochloride

Result of Analysis of Tablet formulation

Table 5: Assay of Tablet Formulation

Brand Name	MIDODRINE HYDROCHLORIDE		
	Label Claim	% Found	% Purity
Proamatine	5mg	4.98mg	99.60

Results of Validation Parameters

Results of Accuracy

Table 6: Recovery Studies for Accuracy of Tablet formulation

Level of Recovery (%)	80	100	120
Amount Present	10	10	10
	10	10	10
	10	10	10
Amount of Std.Added	8	10	12
	8	10	12
	8	10	12
Amount Recovered	7.99	10.01	11.98
	8.02	10.05	11.99
	8.01	10.04	12.01
% Recovery	99.875	100.1	99.833
	100.25	100.5	99.917
	100.125	100.4	100.083

Table 7: Statistical Validation of Recovery Studies

Level of Recovery (%)	Drug	% Recovery	Standard Deviation*	% RSD
80	Midodrine hydrochloride	100.08	0.191	0.191
100	Midodrine hydrochloride	100.33	0.308	0.207
120	Midodrine hydrochloride	99.94	0.127	0.127

*Denotes average of three determinations

Result of Precision

(A) Repeatability

Table 8: Results of analysis Data of Tablet Formulation

Drug	Label claim	Amount found*	Label claim(%)	S.D.	% RSD
Midodrinehydrochloride	5 mg	4.98	99.60	0.215	0.245

(B) Intermediate Precision (Inter-day and Intra-day precision)**Table 9: Intra-day and Inter-day precision**

Intra-day Precision		Inter-day Precision	
	% Label Claim		% Label Claim
After 1hr	99.98	First day	98.89
After 2hr	99.85	Second day	98.75
After 3hr	99.52	Third day	98.12
Mean	99.783	Mean	98.587
SD	0.237	SD	0.410
% RSD	0.238	% RSD	0.416

(C) Analyst to Analyst**Table 10: Result of Analyst to Analyst Precision**

Analyst	Label claim (mg)	Amount found* (mg)	Label claim (%)	S.D.	% RSD
1.	5	4.99	99.80	0.125	0.126
2.	5	4.98	99.60	0.105	0.145

Results of LOD and LOQ**Table 11: Results of LOD and LOQ**

S.NO.	Parameter	Results
1.	LOD	0.120 µg/ml
2.	LOQ	0.360 µg/ml

Results of HPLC method**Mobile Phase Selection****Table 12: Mobile Phase selection**

Mobile phase	Ratio(v/v)	Flow rate	Conclusion
Water: Methanol	50:50	1.0ml/min	Poor resolution
Methanol: Acetonitrile	50:50	1.0ml/min	Peak Broadening
Water (pH adjust 3.5 with TEA): Acetonitrile in the ratio of (20:80v/v)	20:80	1.0ml/min	Good resolution

Taking into consideration the system suitability parameter like RT, Tailing factor, No. of theoretical plates and HETP, the mobile phase found to be most suitable for analysis was Water (pH adjust 3.5 with TEA): Acetonitrile in the ratio of (20:80v/v) in the ratio of 20:80.

The mobile phase was filtered through 0.45 µ filter paper to remove particulate matter and then degassed by sonication. Flow rate employed for analysis was 1.0 ml/min

Selection of Separation Variable**Table 13: Selection of Separation Variable**

Variable	Condition
Column	
Dimension.	250mm x 4.60mm
Particle Size	5 µ
Bonded Phase	Octadecylsilane (C ₁₈)
Mobile Phase	
Water (pH-3 with TEA)	20
ACN	80

Flow rate	1 ml/min
Temperature	Room temp.
Sample Size	20 µl
Detection wavelength	272.0 nm
Retention time	
Midodrine hydrochloride	3.89 ± 0.3 min

System Suitability Parameters:

Table 14: Result of System Suitability Parameters for Midodrine hydrochloride

System suitability Parameter →	RT	AUC	Theoretical plates	Tailing factor
Rep-1	3.89	1825.658	2565	1.05
Rep-2	3.85	1830.458	2570	1.03
Rep-3	3.90	1840.256	2565	1.02
Mean	3.86	1832.124	2566.667	1.033
S.D.	0.05	7.440	2.887	0.015

Linearity and Calibration Graph

Table 15: Result of Linearity of Midodrine hydrochloride

Std. Conc. µg/ml	0	5	10	15	20	25
1	0	918.251	1825.658	2725.658	3665.568	4552.13
2	0	915.458	1830.458	2730.458	3680.458	4540.13
3	0	910.457	1840.256	2740.569	3675.587	4520.26
Mean	0.00	914.722	1832.124	2732.228	3673.871	4537.502
SD	0.000	3.949	7.440	7.612	7.592	16.096
%RSD	0.000	0.432	0.406	0.279	0.207	0.355

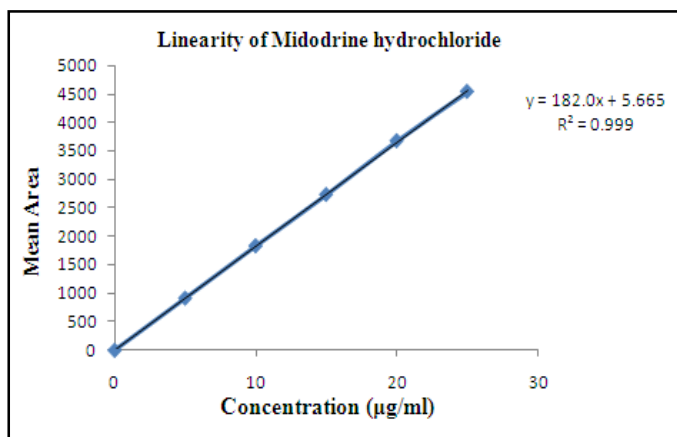


Figure 7: Calibration Graph of Midodrine hydrochloride

Regression Equation

$Y = mx + c,$

$Y = \text{AUC}$

$m = \text{slope} = 182.0$

$X = \text{Conc. in } \mu\text{g/ml}$

$c = \text{Intercept} = 5.665$

$r^2 = 0.999$

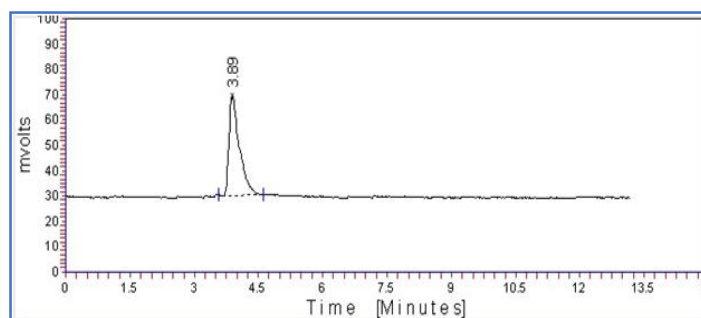


Figure 8: Chromatogram of Midodrine hydrochloride

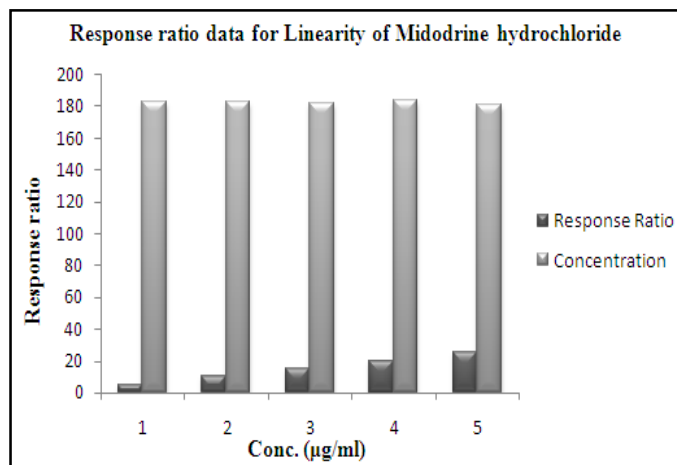


Figure 9: Response Ratio Curve of Midodrine hydrochloride

Assay of Tablet Formulation

Table 16: Result of Analysis for Midodrine hydrochloride in Tablet Formulation

Std Conc. µg/ml	Midodrine Hydrochloride (mg)	
	5	
Rep-1	4.98	
Rep-2	4.99	
Rep-3	4.95	
% found*		
Rep-1	99.60	
Rep-2	99.80	
Rep-3	99.00	
Mean	99.467	
SD	0.416	
% RSD	0.419	

*Each reading is mean reading of three batch of formulation

Validation of Developed Method:

Linearity

Table 17: Response Ration Data for Linearity of Midodrine hydrochloride

Replicates	Concentration (µg/ml)	Mean AUC	Response Ratio
Rep-1	5	914.722	182.9444
Rep-2	10	1832.124	183.2124
Rep-3	15	2732.228	182.1485
Rep-4	20	3673.871	183.6936
Rep-5	25	4537.502	181.5001
Mean		182.699	
S.D.		0.873	
R.S.D.		0.478	

Result of Accuracy

Table 18: Recovery Studies of Formulation

Level of Recovery (%)	80	100	120
	Midodrine hydrochloride	Midodrine hydrochloride	Midodrine hydrochloride
Amount present (mg)	10	10	10
	10	10	10
	10	10	10
Amount of Std. added (mg)	8	10	12
	8	10	12
	8	10	12
Amount recovered (mg)	8.01	9.99	12.01
	8.02	9.98	12.01
	7.99	9.99	12.03
% Recovery	100.125	99.90	100.08
	100.25	99.80	100.08
	99.875	99.90	100.25

Table 19: Statistical Validation of Recovery Studies

Level of Recovery (%)	Drug	% Recovery	StandardDeviation*	% RSD
80	Midodrine hydrochloride	100.083	0.191	0.191
100	Midodrine hydrochloride	99.87	0.058	0.058
120	Midodrine hydrochloride	100.139	0.096	0.096

*Denotes average of three determinations

Result of precision

(A) Repeatability

Table 20: Results of analysis Data of Tablet Formulation

Drug	Label claim	Amount found*	Label claim(%)	S.D.	% RSD
Midodrine hydrochloride	5 mg	4.98 mg	99.60	0.325	0.345

(B) Intermediate Precision- (Inter-day and Intra-day Precision)

Table 21: Intra-day and Inter-day Precision

	Intra-day Precision		Inter-day Precision	
	% Label Claim Midodrinehydrochloride		% Label Claim Midodrine hydrochloride	
After 1hr	99.89	First day	98.98	
After 2hr	99.85	Second day	98.01	
After 3hr	99.54	Third day	97.85	
After 4hr	99.21			
After 5hr	99.10			
After 6hr	99.05			
Mean	99.440	Mean	98.98	
SD	0.374	SD	98.01	
% RSD	0.377	% RSD	97.85	

(C) Analyst to Analyst

Table 22: Analyst to Analyst

Analyst	Label claim	Amount found*	Label claim (%)	S.D.	% RSD
1	5 mg	4.95	99.00	0.165	0.169
2	5 mg	4.96	99.20	0.185	0.186

Result of Robustness

Table 23: Result of Robustness of Formulation

Compound	% RSD in Normal	Changed Condition n= 6	
Temperature		- 5 °C	+ 5 °C
Midodrine hydrochloride	0.99	1.25	1.22
Flow rate		(-10%)	(+10%)
Midodrine hydrochloride	0.68	1.12	1.05
Mobile phase ratio		- 2 %	+ 2 %
Midodrine hydrochloride	0.96	0.99	1.05

CONCLUSION

This U.V. Spectrophotometric and HPLC method is quite simple, accurate, precise, reproducible, and sensitive. The U.V. and HPLC method has been developed for quantification of Midodrine Hydrochloride in tablet formulation. The method was successfully validated as per ICH guidelines Q2 (R1). The validation procedure confirms that this is an appropriate technique for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound. The accuracy of the method was checked by recovery experiment performed at three different levels i.e., 80%, 100% and 120%. The % recovery was found to be in the range 99.00%–101.00%.

The low values of % RSD are indicative of the accuracy and reproducibility of the method. The precision of the method was studied as an intra-day, inter-day variations and repeatability. The % R.S.D. value less than 2 indicate that the method was precise. Ruggedness of the proposed method was studied with the help of two analysts. The above method was a rapid and cost-effective quality-control tool for routine analysis of drug in bulk and in pharmaceutical dosage form.

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How to cite this article:

Dhote V, Jain P and Jain V. A new analytical method development and validation for the estimation of Midodrine HCl by UV and HPLC. *Int. J. Res. Dev. Pharm. L. Sci.* 2018; 7(4):3060-3070. doi: 10.13040/IJRDP.L.2278-0238.7(4).3060-3070.

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