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Research Article

VISIBLE SPECTROSCOPIC ESTIMATION AND VALIDATION OF MIDODRINE HYDROCHLORIDE IN BULK AND PHARMACEUTICAL DOSAGE FORMS BY USING $KMnO_4$

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ABSTRACT

A simple, sensitive, accurate visible spectroscopic method has been developed for the quantitative estimation of Midodrine hydrochloride in bulk and pharmaceutical dosage forms. The method was mainly based on the formation of violet colour chromogen with potassium permangate in acidic condition or medium. The produced colour was measured at wavelength maximum of 570 nm against reagent blank. The proposed method was showing linearity in the concentration range of 1-5 µg/mL. The developed method was validated statistically for its linearity, accuracy and precision as per FDA guidelines.

KEYWORDS: *Visible spectroscopy, Midodrine Hydrochloride.*

INTRODUCTION

Midodrine Hydrochloride is chemically (+-)-2-amino-N-(beta-hydroxy-2,5-dimethoxyphenethyl) acetamide1-(2',5'-Dimethoxyphenyl)-2-glycinamidoethanol2-Amino-N-(2,5-dimethoxy-beta-hydroxyphenethyl)acetamideDL-N1-(beta-Hydroxy-2,5-dimethoxyphenethyl)glycinamid. Its empirical formula is C12H18N2O4. It is an alpha$_1$-agonist, and exerts its actions via activation of the alpha-adrenergic receptors of the arteriolar and venous vasculature, producing an increase in vascular tone and elevation of blood pressure. It is official in U.S.P. Literature survey reveals that there is no visible spectrophotometric method has been reported for the estimation of Midodrine Hydrochloride in bulk and pharmaceutical dosage forms. In the present investigation, an attempt has been made to develop a simple, economical and validated visible spectroscopic method with greater precision, accuracy and sensitivity for the estimation of Midodrine Hydrochloride in bulk and pharmaceutical dosage forms [1, 2].

EXPERIMENTAL METHODS

The pure standard of Midodrine Hydrochloride was obtained as a gift sample from Aurabindo Pharmaceuticals, Hyderabad. The purity of the standard was found to be 99.97 %. (SPECTRO 2080 Plus) UV/VIS double beam spectrophotometer with 1 cm matched quartz cells was used for spectral measurements. All the chemicals used for performing the work were of AR grade from S.D. Fine Chem., Mumbai. The potassium permanganate solution, methanol, concentrated sulphuric acid and Midodrine hydrochloride tablets was employed for this study [3].

1. Preparation of working standard:

Accurately weighed quantity of drug, equivalent to 100 mg was dissolved in few mL of methanol and the volume was made up to 100 mL with methanol to get the concentration about 1000 µg/mL (stock-1). From the above stock solution 1 mL was taken and made up to the volume to 100 with methanol to get the concentration about 100 µg/mL (stock-2) [4].

2. Preparation of solution of marketed formulation:

20 Tablets of Midodrine Hydrochloride were weighed and the average weight of tablets was determined. The tablets were powdered and the powder equivalent to 100 mg of drug was dissolved in the 100 mL of methanol to get the concentration about 1000 µg/mL (stock-1). From the above stock solution 1 mL was taken and made up to the volume to 100 with methanol to get the concentration about 100 µg/mL (stock-2) [5].

3. Assay of marketed formulation:

From above stock solutions of both standard and sample were taken as a series of aliquots of drug solution ranging from 0.1-0.5 mL and transferred into a five cleaned test tubes, to this added 4 mL of potassium permanganate reagent solution and 2 mL of concentrated sulphuric acid, finally made up the volume with distilled water to 10 mL to get the concentrations about 1-5 µg/mL. The produced green colour

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was measured for absorbance at the wavelength maximum of 570 nm against reagent blank. The calibration curve was constructed, that showed good linearity in range of 1-5 µg/mL [6].

RESULTS AND DISCUSSION

The optimum conditions were established by varying each parameter at a time and keeping the other constant by observing the effect produced on absorbance of the coloured species. Various parameters was optimized before starting the development of the method like concentration of reagent, volume of reagent added, the time required for absorbance of prepared solutions (stability of colour),volume of sulphuric acid added and linearity range were optimized. The optical characteristics and precision of method was given in Table-1. The regression equation was calculated by method of least squares for calibration curve. A good linear relationship (r = 0.9998) was observed between drug concentration and absorbance. The regression equation found to be Y = 0.0299 X-0.02679 (where Y = absorbance of the drug, X = concentration of drug). The accuracy of the method found by analyzing the five replicate sample of the known concentration of the drug [7].

Table No. 1: Optimum characteristics

S. No.	Conditions	Optimum range	Conditions in procedure
1.	Concentration of $KMnO_4$ solution	0.1%	0.1%
2.	Volume of reagent	1ml	1ml
3.	Stability of color	2.5-3.5min	2.5min
4.	Beer's law limit	10-50 mcg/ml	10-50mcg/ml

Table No. 2: Optimum Concentration of $KMnO_4$ Reagent (Drug Concentration is 50 µg/ml)

Volume of Reagent	Absorbance		
	0.025%of $KMnO_4$reagent	0.05%of $KMnO_4$ reagent	0.1% of $KMnO_4$ reagent
1ml	0.043	0.164	**0.253**
2ml	0.121	0.226	**0.380**
3ml	0.138	0.249	**0.373**
4ml	**0.146**	**0.261**	**0.351**

Table No. 3: Stability of color complex

S.no	Time (min)	Absorbance
1	0	0.156
2	0.5	0.189
3	1	0.228
4	1.5	0.311
5	2	0.341
6	2.5	0.347
7	3	0.347

Table No. 4: Determination of Accuracy of Midodrine Hydrochloride

Drug	Concentration of sample (µg/mL)	Level of Addition (%)	Amount of drug added (µg/mL)	Amount* recovered (µg/mL)	%Recovery* ± S.D
Midodrine Hcl	25	80	20	20.004	100.02±0.24
	25	100	25	24.998	99.99 ± 0.26
	25	120	30	30.002	100.01 ±0.04

Table No. 5: Precision results of Midodrine Hydrochloride

Concentration of drug taken (µg/mL)	Concentration found * (µg/mL)	%R.S.D
25	24.999 ±0.567	0.19

Table No. 6: Results of intermediate Precision of Midodrine Hydrochloride

Conc of Drug (µg/ml)	Average absorbance in intraday studies** (µg/ml)			Average absorbance in intraday studies** (µg/ml)		
25	Sess-I	Sess-II	Sess-III	1st day	3rd day	5th day
	0.121	0.124	0.119	0.121	0.112	0.125
	SD : 0.0006			SD : 0.0005		
	%RSD : 0.170			%RSD : 0.142		

Table No. 7: Validation Parameters of Midodrine Hydrochloride by UV method

Correlation coefficient	**0.999**
Molar absorptivity (lit.mol^{-1}cm^{-1})	3.124×10^3
LOD	3.84 µg/ml
LOQ	11.52 µg/ml
Assay (n=6)	99.992%

Table No. 8: Summary of assay results

Drug/brand name	Labeled amount	Amount found*	% Assay*
ProAmatine	25 mg	24.998 mg	99.992
Gutron	25mg	24.978mg	99.952

SUMMARY

The present study was carried out to develop a simple, sensitive, accurate and more precise UV Spectrophotometric method for estimation of Midodrine Hydrochloride in bulk & pharmaceutical dosage forms. The %purity of was calculated by using regression equation method and it was found to be 99.992%. A good linear relationship was observed between Concentration vs Absorbance of standard solution in the range of 10-50 µg/ml. The drug obeys Beer's law with a correlation coefficient of 0.999. The Midodrine Hydrochloride sample solution was analyzed by proposed UV Spectrophotometric method for finding out intra & inter day variations showed a low coefficient of variation. It indicates that the proposed UV method was highly precise. By spiking various concentrations ranging about 75%, 100%, 125% into previously analyzed sample, the amount of drug recovered was calculated and it was in the range 99.99% – 100.02%. It indicates that the proposed method was highly accurate. Based on the standard deviation, slope, limit of detection and limit of quantification values for Midodrine Hydrochloride were calculated and found to be within the acceptance limits. The lowest possible concentrations can be determined by the proposed method.

CONCLUSION

It can be concluded that the proposed method for estimation of Midodrine Hydrochloride is simple, convenient, accurate, sensitive and reproducible. It can be successfully used for routine analysis of the drug in bulk and tablet as an alternative to existing HPLC methods.

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