International Journal of ChemTech Research
CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.11 No.10, pp 353-360, 2018

UV-Spectrophotometric Estimation of Drotaverine Hydrochloride by Derivative Method in Pharmaceutical Dosage Form

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Abstract : The objective of the study was to develop a UV derivative spectrophotometric i.e.First and second order derivative methods for the determination of drotaverine hydrochloride in pharmaceutical dosage form by using methanol as a solvent. The method was further validated by ICH guidelines. The proposed derivative methods involve the measurement of absorbance at 266 nm for first order and254.7nm for second derivative for the estimation of drotaverine hydrochloride respectively. The linearity of the proposed method was found in the concentration range of 5 to 50 µg /ml (r^2= 0.9999) for first and second order derivative methods respectively. The percentage mean recovery was found to be 100.045 % for first order derivative and 100.02% for second order derivatives methods respectively. The methods were also statistically validated for its linearity, accuracy and precision. Both intra and inter day variations showed less percentage (%) RSD values indicating high grade of precision of this methods.

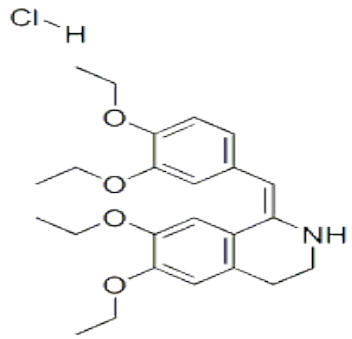
Keywords : UV spectrophotometric estimation, derivative method, drotaverine hydrochloride, methanol.

Introduction

Drotaverine hydrochloride is[(1 - (3, 4 – diethoxybenzylidene) - 6, 7 – diethoxy - 1, 2, 3, 4 tetrahydro isoquinoline) hydrochloride], a benzylisoquinoline derivative. It is a highly potent spasmolytic drug. It shows excellent properties of smooth muscle relaxant. Its antispasmodic activity is due to inhibition of phosphodiesterase enzyme IV. It causes smoothmuscle relaxation by increasing intracellular levels of cyclic adenosine mono-phosphate (cAMP) secondary to inhibition of phosphodiesterase.

According to the literature review several methods has been developed for drug, like spectroscopy, methods[1-7].HPLC[8-11] and miscellaneous[12-18]. The proposed aim of the study was to develop simple, accurate, specific and precise UV spectrophotometric method for the estimation of drug in the bulk and pharmaceutical formulation.

DOI= http://dx.doi.org/10.20902/IJCTR.2018.111044



Structure of drotaverine

Material and Method

Instrument and reagents

Spectral scan was made on a Shimadzu UV-spectrophotometer, model 1800 (Shimadzu, Japan) with spectral band width of 0.5 nm with automatic wavelength corrections by using a pair of 10 mm quartz cells. All spectral measurements were done by using UV-Probe 2.42 software.

Reference standard of drotaverine hydrochloride was obtained from reputed firm with certificate of analysis.

Preparation of standard drug solution

A10 mg standard drotaverine hydrochloride was weighed accurately and transferred to a 10 ml volumetric flask and sonicated with 5 ml methanol for 15 minutes. The volume was made up to the mark with methanolto give a stock solution of drotaverine hydrochloride of concentration 1000 µg /ml. From this solution, 1 ml of solution was pipetted out and transferred into 10 ml volumetric flask. The volume was made up to mark with distilled waterto give a working standard solution of concentration 100 µg/ml.

Estimation from capsules

Twenty tablets were weighed accurately and average weight of powder containing in each tablet was determined. Powder equivalent 10 mg of drotaverine hydrochloride was weighed and transferred in 10 ml of volumetric flask. A 3 ml of methanol added and sonicated for 15 minutes and filtered. The filtrate and washing were diluted up to the mark with methanol to give concentration as 1000µg /ml of drotaverine hydrochloride respectively. From this solution, 1 ml of solution was pipetted out and transferred into 10 ml volumetric flask. The volume was made up to mark with distilled waterto give a working standard solution of concentration 100 µg/ml.

Experimental

Method:

(a)For first order derivative method

For the selection of analytical wavelength, 10µg/ml solution of drotaverine hydrochloride was scanned in the spectrum mode from 350 nm to 200 nm by using distilled water as blank. The first order derivative spectrum was obtained by using derivative mode by UV probe 2.42 software. From the spectrum, the amplitude of the first derivative spectrum was measured at 266 nm.

(b) For second order derivative method

For the selection of analytical wavelength, 10µg/ml solution of drotaverine hydrochloride was scanned in the spectrum mode from 350 nm to 200 nm by using methanol as blank. The first order derivative spectrum was obtained by using derivative mode by UV probe 2.42 software. From the spectrum, the amplitude of the second derivative spectrum was measured at 254.7 nm.

Preparation of calibration curves

Series of solutions containing 5-50 µg/ ml of drotaverine hydrochloride were used to determine linearity of the proposed method respectively. Solutions were scanned in the spectrum mode and absorbance spectra were converted to first/ second order derivative spectra. The spectra of first order and second order derivatives of drotaverine hydrochloride were given in Fig. 1(a), 1(b) respectively.

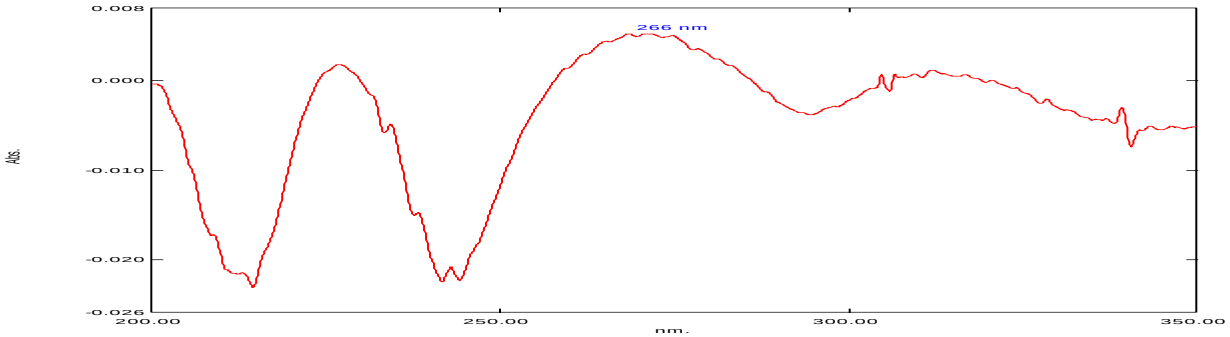


Fig. 1(a):Spectrum of first order derivative of drotaverine hydrochloride in the concentration 10 µg/ ml at 266 nm.

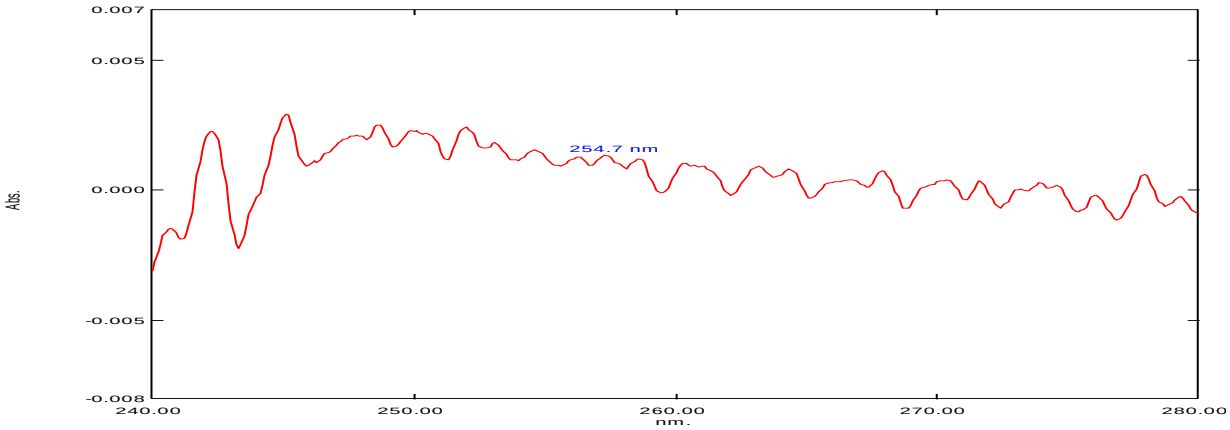


Fig. 1(b): Overlay spectra of second order derivative of drotaverine hydrochloride 10 µg/ ml at 254.7 nm.

After observing the overlain first order and second order derivative spectra of drotaverine hydrochloride, the wave length selected was 266 nm, for first order derivative method and 254.7 nm for second order derivative method. The calibration curves were plotted of amplitude against concentrations [Fig. 2 (a), 2(b)].

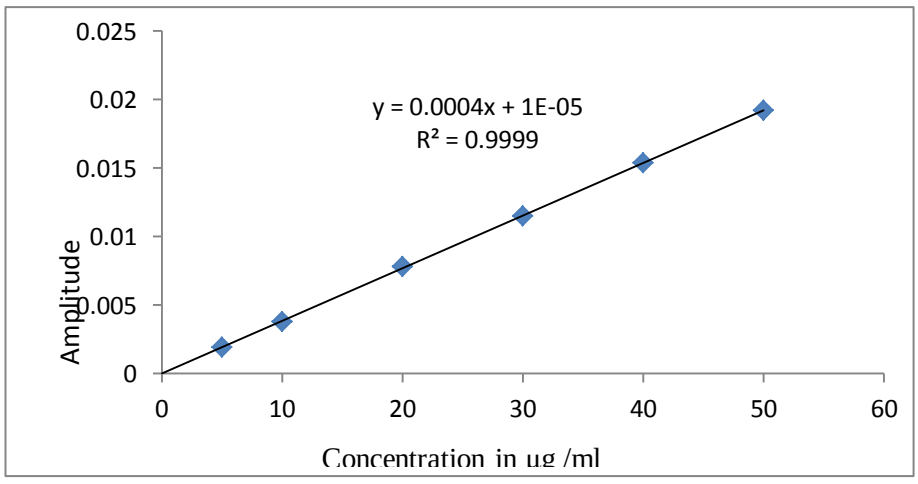


Fig.2 (a): Calibration curve of first order derivative method in the concentration range of 2-14 µg/ml.

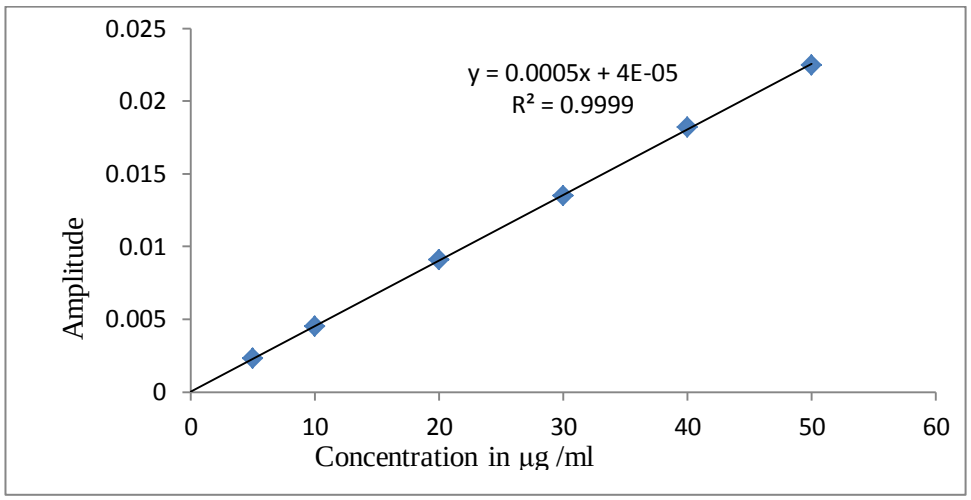


Fig.2 (b): **Calibration curve of second order derivative method in the concentration range of 2-14 µg/ml.**

Results of the analysis are given in table 1.

Table 1: Values of results of optical and regression of drugs

Parameter	First order derivative method	Second order derivative method
Detection Wavelength (nm)	266	254.7
Beer Law Limits (µg/ml)	5-50	5-50
Correlation coefficient(r^2)	0.9999	0.9999
Regression equation (y=b+ac)		
Slope (a)	0.0004x	0.0005x
Intercept (b)	$1x\ 10^{-5}$	$4x\text{-}10^{-5}$

Estimation from pharmaceutical formulation

Powdered from twenty tablets were collected and weighed accurately and average weight of powder from each tablet was determined. Powder equivalent to 10 mg of drotaverine hydrochloride was weighed and transferred in 10 ml of volumetric flask. A 3 ml of methanol was added and sonicated for 15 minutes and filtered. The filtrate and washing were diluted up to the mark with methanol to give concentration as 1000µg /ml of drotaverine hydrochloride respectively. A 1 ml of such solutions was diluted with distilled water to 10 ml. It was scanned in the range of 200-350 nm against distilled water as blank. The absorbance spectra were converted to first and second order derivative spectra. Calculations were done as per the equations. The concentrations of drotaverine hydrochloride present in capsules were calculated by substituting the values of absorbance in linearity equations.

(a) For first order derivative method Y = 0.0004x + 1E-05
(b) For second order derivative method Y = 0.0005x + 4E-05

Method Validation

These methods were validated according to ICH guidelines.

Accuracy

To ascertain the accuracy of proposed methods, recovery studies were carried out by standard addition method different levels. Percentage recoveries for drotaverine hydrochloride were 100.016 % and 100.11 % to 100.02 % for first order and second order derivatives respectively. (Table2).

Table 2(a): Statistical evaluation of the data subjected to accuracy for first order derivative method

Amount of Sample Added in (µg/ml)	Amount of Standard Added in (µg/ml)	Total amount recovered (µg/ml)	Percentage recovery(%)	Standard deviation	Percentage of relative standard deviation (C.O.V.)
10	0	9.933	99.33	0.03638	0.3663
10	10	20.1934	100.967	0.1494	0.7402
10	20	29.9479	99.7271	0.1825	0.6101
10	30	40.052	100.13	0.1804	0.4504
				Mean=0.1371	Mean=0.1371

Table 2(b): Statistical evaluation of the data subjected to accuracy for second order derivative method

Amount of Sample Added in (µg/ml)	Amount of Standard Added in (µg/ml)	Total amount recovered in (µg/ml)	Percentage recovery(%)	Standard deviation	Percentage of relative standard deviation (C.O.V.)
10	0	10.04348	100.4348	0.03074	0.3061
10	10	19.9068	99.5341	0.171	0.8592
10	20	30.2173	100.103	0.15	0.4995
10	30	39.5652	99.844	0.2725	0.6823
				Mean=00.1560	Mean=0.1560

Linearity

The linearity of measurement was evaluated by analyzing different concentration of the standard solutions of drotaverine hydrochloride. For both the methods concentration range was found to be 5-50 µg/ml for drotaverine hydrochloride respectively.

Precision

The method precision was established by carrying out the analysis of powder blend from tablets containing40 mg of drotaverine hydrochloride. The assay was carried out for the drugs by using proposed analytical method in six replicates. The values of relative standard deviation were0.4976 % for first order derivative method and 0.3253 % for second order derivative method in respectively indicating the sample repeatability of the methods. The results obtained are tabulated in table 3.

Table 3: Statistical evaluation of the data subjected to method of precision

Sr. .No.	Sample No.	% Assay	
		First order derivative method	Second order derivative method
1	1	98.95833	100.2174
2	2	100.2632	100.4339
3	3	100.2625	100.00
4	4	99.7382	99.568
5	5	100.2625	100.2169
6	6	99.4764	100.432
Mean % assay		99.8268	100.1449
%R.S.D.		0.4976	0.3253

Intra-day precision was estimated by assaying capsules powder blend containing 4 mg of drotaverine hydrochloride. The assay was carried out for the drugs by using proposed analytical method in six replicates. The results were average for statistical evaluation.

Inter-day precision was estimated by assaying capsules powder blend containing 4 mg of drotaverine hydrochloride for three consecutive days (i.e. 1st, 3rd and 5th days). The statistical validation data for intra and inter day precision is summarized in table 4.

Table 4: Summary of validation parameter for intra-day and inter-day

Sr. No.	Parameters	First order derivative method	Second order derivative method
1	Intra-day precision (N=3)amount found ± % R.S.D.	100.263% 0.3663	100.217% 0.3061
2	Inter-day precision (N=3)amount found ± % R.S.D.	98.953% 0.6101	99.534% 0.8592

Both intra- day and inter-day precision variation found to be less in % RSD values. It indicates high degree of precision of the methods.

Result and discussion

The developed derivative spectrophotometric methods for determination of drotaverine hydrochloride in capsules formulation were found to be simple and convenient for the routine analysis of drug. The proposed methods are accurate, precise and reproducible. It is confirmed from validation data as given in tables 1 to 4. The % RSD was found to be less than 1, which indicates validity of method. Linearity was observed by linear regression equation methods for drotaverine hydrochloride in different concentration range. The correlation coefficient of these drugs was found to be close to 1.00, indicating good linearity figure 2 (a) and 2 (b).

The assay results obtained by proposed method is shown in table 2 are in good agreement. Hence proposed methods can be used for routine analysis of the drug in pharmaceutical dosage form. Methods are simple, accurate, precise, reliable, rapid, sensitive, reproducible and economical. They are validated as per ICH guidelines.

Conclusion

The proposed methods are simple, precise, accurate and rapid for the determination of drotaverine hydrochloride in pharmaceutical dosage form. These methods can be adopted as an alternative to the existing methods. It can be easily and conveniently adopted for routine quality control analysis.

Acknowledgement

Authors express sincere thanks to the principal of D.G. Ruparel College, Dr. Tushar Desai, for encouragement and providing laboratory facility

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