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FIRST ORDER DERIVATIVE UV SPECTROSCOPIC METHOD DEVELOPMENT AND VALIDATION OF PERINDOPRIL ARGININE IN BULK AND TABLET DOSAGE FORM

Murugan S.[1]*, Vetrichelvan T.[2], Hemamalini R.[3], Jothilakshmi D.[3], Keerthana N.[3], Suvasri P.[3], Keerthana E.[3]

[1]Associate Professor, Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy, Melmaruvathur-603 319, Tamilnadu.
[2]HOD Cum Dean Research, Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy, Melmaruvathur-603 319, Tamilnadu.
[3]Students, Adhiparasakthi College of Pharmacy, Melmaruvathur-603 319, Tamilnadu.

***Corresponding Author: Murugan S.**
Associate Professor, Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy, Melmaruvathur-603 319, Tamilnadu.

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ABSTRACT
A simple UV method was developed for the determination of Perindopril arginine in bulk and tablet dosage form. The method involved in first order derivative. In first order the wavelength selected was 216nm. Calibration curve was linear in the concentration range 10 – 50 µg/ml (R^2 value is 0.9998). The proposed method was successfully applied for the assay of perindopril arginine in bulk and tablet formulation and validated as per ICH guidelines.

KEYWORDS: Perindopril arginine, UV Method, First order derivative.

INTRODUCTION
Perindopril arginine (Figure 1) chemically (2s,3as,7as)-1-[(2s)-2[[(1s)-1-(ethoxy carbonyl)butyl]amino]octa hydro 1H -indole-2-carboxylate L- arginine.[1] It inhibits the angiotensin converting enzyme.[2] Perindopril arginine is rapidly metabolized in liver to perindoprilat, its active metabolite, following oral administration. Perindoprilat is a potent, competitive inhibitor of ACE, the enzyme responsible for the conversion of angiotensin I (ATI) to angiotensin II (AT II).[3]

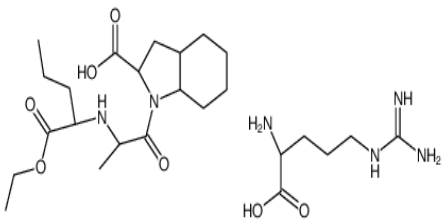

Fig. 1: Chemical structure of Perindopril arginine.

On literature survey, No method was reported for the estimation of Perindopril arginine. So we have developed a novel, simple, rapid, accurate, precise, economical and highly sensitive UV spectrophotometric method (first order derivative method) for estimation of Perindopril arginine in bulk form according to ICH guidelines.[4,5]

MATERIALS AND METHODS
Instrumentation
The instrument used in the present study was Shimadzu double beam UV/Visible spectrophotometer (Model UV-1700) with spectral band width of 1 nm. All weighing was done on electronic balance (Model Shimadzu AUX - 220).

Reagents and Chemicals
Analytically pure sample of Perindopril arginine was supplied by Shanghai Huirui Chemical Technology co.ltd. (China). The tablet dosage form used in this study was Coversyl tablet contains equivalent to 10mg of Perindopril arginine per tablet. The solvent used was distilled water.

Preparation of standard stock solution:
Standard stock solution of Perindopril arginine (10 μg/ml) was prepared by dissolving 10mg Perindopril arginine in 100ml of Distilled water in 100ml volumetric flask with vigorous shaking. From this stock solution, 10ml was withdrawn and diluted to 100ml using Distilled water to get working concentration of 100 μg/ml.

METHOD
FIRST ORDER DERIVATIVE METHOD
In this method, solution of Perindopril arginine (10 µg/ml), was prepared by appropriate dilution of standard stock solution with Distilled water and scanned in the

spectrum mode from 200nm to 400nm. The absorption spectra thus obtained were derivatized for first order. From the first spectra of this drug, wavelength selected for quantitation were 216 nm for Perindopril arginine The first order derivative spectra of Perindopril arginine is shown in Fig.No.2.

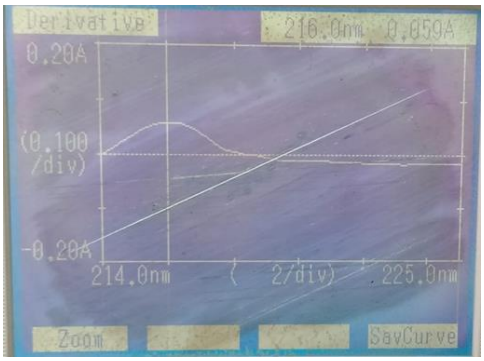

Fig. 2: The first order derivative spectra of Perindopril arginine.

Analysis of Marketed Tablet Formulation

Weighed accurately 20 tablets. The average weight of tablet were found and powered. The tablet powder equivalent to 10mg of Perindopril arginine was weighed and transferred into 100ml volumetric flask and add minimum quantity of distilled water and sonicate for 15min. Finally made upto the volume with distilled water to get 100µg/ml. The content was filtered through the Whatman filtered paper no:41 from the clear solution further pipetted out 2ml of filtrate and transferred into 10ml of volumetric flask added distilled water and made upto to get 20 µg/ml of perindopril arginine. The zero order derivative is converted into first order derivative. The wavelength selected for first order derivative was 216nm. This procedure was repeated for 6 time.

Validation

The proposed methods were validated as per ICH guidelines.

Linearity

The aliquots of five different concentration ranging 10-50 µg/ml were prepared and calibration curve was plotted between concentration vs absorbance (first order derivative)**.** The linearity was calculated by the least square regression method and calculated optical parameter.

Accuracy

Accuracy is the nearness between the expected value and the value formed. It is determined by applying the method to sample to which known amount to analyte has been added. In this case to evaluate the accuracy of the developed method. Successive analysts (n=6) for three different concentration. For each concentration the procedure was repeated for six time and calculate the percentages RSD value.

Precision

The reproducibility of this method was determined by analyzing tablet (Intra-day assay precision) at different time intervals on same day in triplicates and (Inter-day assay precision) on three different days.

RESULT AND DISCUSSION

Coversyl tablet formulation containing 10mg of Perindopril arginine was selected for estimation. From the linearity, the nominal concentration of Perindopril arginine i.e., 20 µg/ml was prepared for about six times and the absorbance of the each solution was measured at 216 nm in first order derivative method. The percentage purity found in tablet dosage form was 100.16. The % RSD values were found to be 0.0145. Hence the method has good precision and the results of analysis were shown in Table 01. Accuracy study of the developed UV spectrophotometer method shows that the percentage recovery ranged from 99.53□ to 100.27□ Lower % RSD values indicated that the developed UV spectrophotometric method was more accurate and the results were shown in Table 02.

Table 1: Results of Analysis of Tablet.

Sample	Sample number	Label claim (mg/tab)	Amount present (mg/tab)*	% Purity (% w/w)	Mean purity (% w/w)	SD	% RSD
Perindopril arginine	1	10	10.0	100.00	100.16	1.4617	0.0145
	2	10	9.90	99.00			
	3	10	9.80	98.01			
	4	10	10.09	100.99			
	5	10	10.19	101.98			
	6	10	10.09	100.99			

Table 2: Results of Recovery Studies for formulation.

Sample	% Concentration	Sample amount (µg/ml)	Amount spiked (µg/ml)	Recovered amount (µg/ml)	Average % Recovery	SD	% RSD
Perindopril arginine	50	20	10	29.85	99.53	1.0638	0.01068
	100	20	20	39.86	96.67	0.6753	0.0067
	150	20	30	50.13	100.273	0.6361	0.00634

CONCLUSION

The proposed UV spectrophotometric method (First order derivative) employed here proved to be simple, economical, rapid, precise and accurate. Thus these can be used for routine estimation of Perindopril arginine in tablet dosage form.

ACKNOWLEDGMENT

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