

## NEWER SPECTROPHOTOMETRIC METHOD OF DETERMINATION FOR LISINOPRIL DOSAGE FORMS

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Received: 19 May 2011, Revised and Accepted: 26 June 2011

### ABSTRACT

A simple, precise, accurate, spectrophotometric method is developed for determination of Lisinopril in dosage forms. The complex formed after reacting with Lisinopril and fluorescein in methanolic media, showed the absorption maxima at 227nm. Linearity was observed in the range of 2 µg to 11 µg, with regression coefficient of 0.9984, RSD is 0.5138. Tablet dosage form was estimated, and percentage recovery was 98-100%. The effect of temperature, concentration of coupling agent and the time of reaction completion were studied. The method was validated for linearity, precision, accuracy, specificity and recovery studies. The values found were within the specified limits.

**Keywords:** Lisinopril, Condensation, Fluorescein, Spectrophotometric method.

### INTRODUCTION

Lisinopril is ACE inhibitor which is a popular antihypertensive agent<sup>1-4</sup>. The analytical methods reported in the official books for the determination of Lisinopril are potentiometric titration and HPLC. Various spectrophotometric methods based on reaction between Lisinopril and different reagents including ninhydrin, chloranil, dichlone and acetylacetone with formaldehyde, phenylhydrazine have been described and comparative study of these methods was revealed by Basavaiah K and coworkers were remarked<sup>5-17</sup>.

The first, second derivative spectrophotometric, spectrofluorometric and fluorimetric methods were reported for the single or multi-component dosage forms. The chromatographic methods of analysis

such as micellar electrokinetic chromatography and gas liquid chromatography have been described. The other methods such as Capillary electrophoresis/fluoroimmunoassay, radioimmunoassay and fluoroenzymatic assay have also been reported<sup>18-30</sup>.

Present study was carried to develop new; accurate, precise, specific and simple fluorimetric method to determine the Lisinopril in pure form or in formulation. Lisinopril coupled with fluorescein<sup>20</sup> in methanolic media to convert the Lisinopril to a more sensitive form and was subjected to spectrophotometric determination at  $\lambda_{max}$  227 nm. Observations have displayed linearity with Beer's range of 2 µg to 11 µg, the effect of the factors like temperature, reaction duration, concentration of coupling reagent were studied and developed method was validated as per the ICH guidelines.

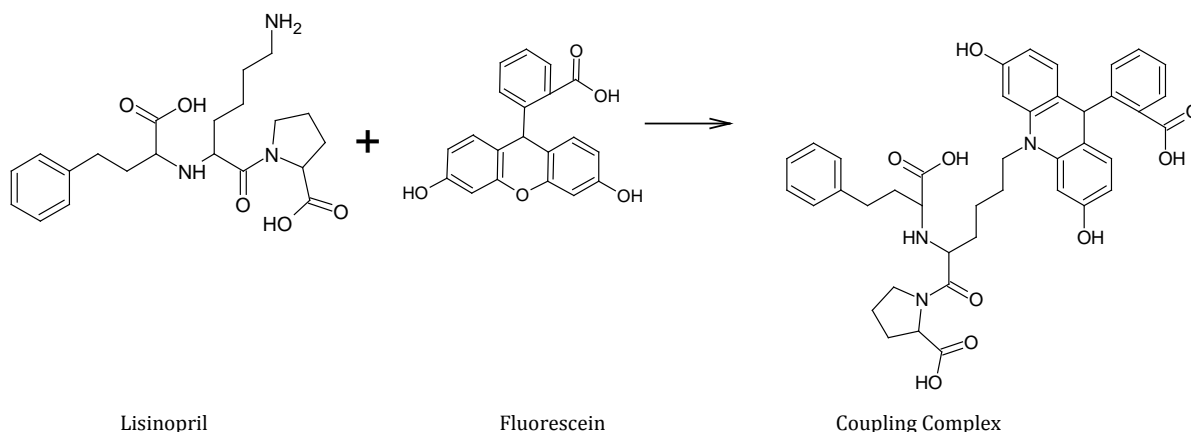


Fig. 1: Proposed reaction pathway for Lisinopril and fluorescein complex formation

Table 1: Statistical observations of developed method

Parameter	Observation
Linearity range, µg/ml	2 - 11 µg/ml
Relative Standard Deviation	0.513831
Slope (b)	13.27438
Intercept (a)	0.91016
Correlation co-efficient	0.999814
Percentage of recovery	98-100

Equation of linearity for % Relative Intensity = Slope x Concentration + Intercept

The method was compared with standard method and statistically expressed.

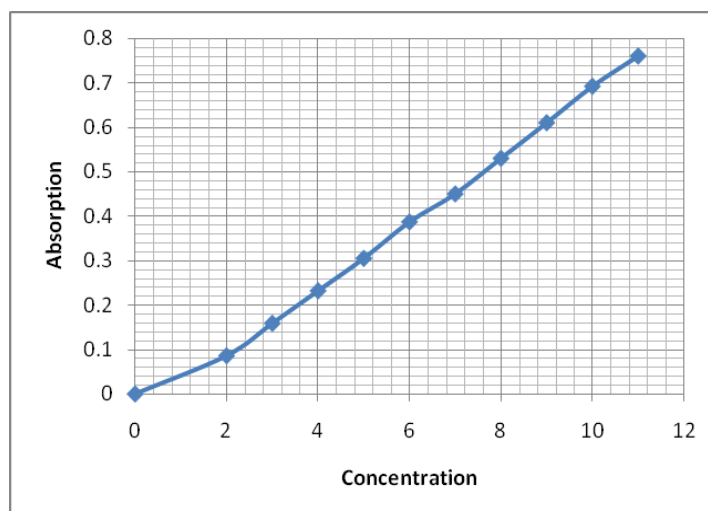


Fig. 2: Linearity curve of spectrophotometric determination

## MATERIALS AND METHODS

### Instrumentation

A double beam Elico SL 159 UV-visible spectrophotometer with recording software Spectral treats SL 159 was used. The wavelength range used for scanning speed was 200 nm to 800 nm. The absorption of test and reference solutions was recorded in 1-cm borosilicate cells.

### Materials and reagents

Lisinopril dihydrate standard drug was procured from the Unimark Pharmaceuticals Ltd, Vapi, Gujarat, India, and certified to contain 99.3%. All the chemicals, solvents and reagents used in the study were of analytical grade. The three different marketed formulations of brand names Listril 5mg, Lipril 10 mg and Lisiril 5mg were used for sample estimation.

### Standard solutions and calibration graphs

Lisinopril of 100 mg was transferred to 100 ml volumetric flask. Add 50 ml methanol and shake well to dissolve, and then fluorescein of 0.07526 mg was added. The mixture was shaken and heated to 50°C for 5 min, cooled to room temperature and then final volume was made with methanol. This will be used as standard solution. Various volumes are transferred to 50 ml volumetric flask to prepare the dilutions in the range of 2-11 µg/ml. The absorbance was measured at 227 nm using methanol as blank.

### Procedure for estimation of commercial Tablets

Weigh accurately 20 tablets of Lisinopril and ground to fine powder. The tablet powder equivalent to 100 mg was weighed and 50 ml of methanol was added, shaken and filtered with Whatman filter paper No.42 into 100 ml volumetric flask. Add 0.07526 gm of fluorescein, stirred well and heated the mixture for 5 min at 50°C. The final volume was made with methanol. This solution was used as sample stock solution to prepare different unknown concentrations in 50 ml volumetric flasks and absorbance was measured at 227 nm.

## RESULTS AND DISCUSSION

The lisinopril coupled with fluorescein to produce complex in methanol was used for spectrophotometric estimation. The spectrophotometric method developed was validated as per ICH guidelines for the parameters such as precision, accuracy, specificity and ruggedness. The analytical data on statistical calculation shows the relative standard deviation 0.513831, correlation coefficient was 0.999814, the percentage recovery was 98-100 and method was compared with standard method the data found to be within specified limit (Table 1). Thus the developed method can be applied for routine analysis of Lisinopril and formulations.

## ACKNOWLEDGEMENT

Authors are thankful to Unimark Pharmaceuticals Vapi Gujarat for generously providing the drug sample. We express our gratitude to Shri. G. D. Patil secretary Shri Warana Vibhag Shikhsan Mandal Warananagar for continuous support.

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