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An innovative validated spectrofluorimetric method for determination of Lisinopril in presence of hydrochlorothiazide; Application to content uniformity testing

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Abstract

A new sensitive and discriminating spectrofluorimetric method has been developed and validated for determination of Lisinopril, one of the angiotensin converting enzyme inhibitors, in its pure bulk form and pharmaceutical tablets. The reaction of Lisinopril with ethylacetoacetate and formaldehyde in acidic buffered medium (pH 3.8) has yielded a pale yellow product that exhibited a high fluorescence measured at 438 nm after excitation at 350 nm. All the experimental parameters affecting the formation and stability of the produced fluorophore were carefully investigated and optimized to give the maximum sensitivity. The fluorescence intensity was directly proportional to the drug concentration in the range of 0.5-4.5 µg/ml with a limit of detection equal to 0.16 µg/ml. The method was successfully applied in the analysis of the commercially available pharmaceutical tablets containing the single drug or its binary mixtures with Hydrochlorothiazide. Furthermore, the developed procedure was adapted for studying the content uniformity test of some dosage forms containing the cited drug.

Keywords: Lisinopril; Spectrofluorimetry; Ethylacetoacetate, Formaldehyde; Pharmaceutical analysis

1.1.Introduction

Lisinopril dihydrate (LIS, Fig. 1) is an angiotensin converting enzyme (ACE) inhibitor which inhibit angiotensin II production leading to preventing vasoconstriction. It is used in the treatment of hypertension and congestive heart failure[1].

The reported analytical methods for the determination of the studied drug included; spectrophotometric [2-11] spectrofluorimetric[10-15], chromatographic [9, 16-25],