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Use of picric acid and iodine as electron acceptors for spectrophotometric determination of lansoprazole through a charge-transfer complexation reaction

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Abstract

This article describes the development of two simple and selective spectrophotometric methods for the determination of lansoprazole (LAN), an irreversible proton pump inhibitor, in both pure drug and capsule formulations. The methods are based on the formation of charge-transfer (CT) complexes between LAN an electron donor and either picric acid or iodine as an electron acceptor. The intensely coloured products formed were quantified based on the absorption bands at 410 nm for picric acid (method A) and 360 nm for iodine (method B). The accuracy and precision of the methods were evaluated on intra-day and inter-day bases. Beer's law is obeyed in the concentration ranges of 2–32 and 0.8–12.0 μg/ml LAN for method A and method B, respectively. The molar absorptivity values, limits of detection (LOD) and limits of quantification (LOQ) have also been reported. The reaction stoichiometry for both methods was evaluated by Job's method of continuous variation and was found to be 1:1 (LAN: picric acid and LAN: iodine). The proposed methods were successfully applied to the determination of LAN in capsules with good accuracy and precision and without a detectable interference from common excipients. A statistical comparison of the methods revealed that there is no significant difference between the official method and the proposed methods.

Keywords: Lansoprazole; Spectrophotometry; Picric acid; Iodine; CT complex; Pharmaceutical analysis

1. Introduction

Lansoprazole (LAN), which is chemically known as 2-[[[3-methyl-4-(2,2,2 trifluoroethoxy) pyridine-2-yl]methyl]sulfinyl]-1*H*-benzimidazole, is widely used as an anti-ulcer drug (proton pump inhibitor) through inhibition of H^+, K^+-ATP-ase in gastric parietal cells [1]. The drug assay is listed in the monograph of the United States Pharmacopoeia (USP) [2] and the British Pharmacopoeia (BP) [3]. The USP describes a high-performance liquid chromatographic method and the BP recommends

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a potentiometric titration of LAN with NaOH in a 4:1 ethanol:water mixture.

Several methods have been reported for the determination of LAN in pharmaceutical formulations, including high-performance liquid chromatography (HPLC) [4–17], ultra-performance liquid chromatography (UPLC) [18–21], high-performance thin-layer chromatography (HPTLC) [22,23], liquid chromatography/tandem mass spectrometry (LC–MS) [24], capillary electrophoresis [25,26], polarography [27–29], voltammetry [30], UV spectrophotometry [31–38], flow-injection analysis (FIA) [12,39], kinetic spectrophotometry [40,41], spectrofluorimetry [42,43] and fluorimetry [33]. Although those methods are sensitive, some of them are time-consuming, complicated, and require expensive instrumentation. In particular, chromatographic methods necessitate judicious control of the pH of the medium. Therefore, visible spectrophotometry remains the technique of choice because it is sensitive, economical, rapid and easily manageable.

A number of colour formation reactions utilizing different reagents have been employed for the visible spectrophotometric determination of LAN in pharmaceuticals [4,12,40,44–56]. The reported methods are based on complexation and oxidative coupling [44], formation of a charge-transfer complex [4,45], redox followed by complexation or colour bleaching [46–49], bromination [50], ion-pair complexation reaction [51–55] and coupling with diazotized p-nitroaniline [56]. However, most of the reported visible spectrophotometric methods suffer from one or more disadvantages, such as poor sensitivity [4,44,45], a narrow range of determination [47–50], use of a heating step [44,48], and use of an extraction step [52–55], as shown in Table 1.

The present work describes two rapid and simple visible spectrophotometric methods for the determination of LAN by exploiting its basic nature and electron-donating property. This determination is based on a charge-transfer complexation of LAN with either picric acid as a π-acceptor or iodine as a σ-acceptor. Iodine has been used for the spectrophotometric determination of LAN based on a charge-transfer complexation reaction in a chloroform medium [45]. In the present study, the same reaction in a dichloromethane medium was found to be very rapid and far more sensitive with a wide linear dynamic range. The proposed methods utilizing picric acid and iodine as reagents in dichloromethane were successfully applied to the determination of LAN, in either its pure form or in capsules, with good accuracy and precision.

2. Experimental

2.1. Instrument

A Systronics model 106 digital spectrophotometer provided with 1-cm matched quartz cells was used for all absorbance measurements.

2.2. Materials

Pharmaceutical-grade LAN with a certified purity of 99.80% was obtained from Cipla Ltd., Bangalore, India. The following pharmaceutical preparations were purchased from commercial sources and subjected to analysis: Lan-15 (15 mg LAN per capsule) and Lan-30 (30 mg LAN per capsule) from Intas Pharmaceuticals, Dehradun, India; Lanzol-15 and Lanzol-30 from Cipla Ltd., Sikkim, India.

2.3. Reagents and chemicals

All reagents and solvents used were of analytical-reagent grade. Picric acid (0.4%, w/v) (S.D. Fine Chem. Ltd., Mumbai, India) and iodine (0.1%, w/v) (Loba Chemie, Mumbai, India) solutions were prepared in dichloromethane (DCM) (Merck, Mumbai, India) and kept in the dark when not in use.

2.4. Stock solution of LAN

Using a 100-ml calibrated flask, a 100-ml stock solution (100 μg/ml LAN) was prepared by dissolving an accurately weighed 10 mg aliquot of the pure drug in DCM. This solution was further diluted with DCM to obtain working concentrations of 40.0 and 20.0 μg/ml LAN for use as standards in methods A and B, respectively.

2.5. Sample preparation

2.5.1. Capsules

The contents of 20 capsules were combined, mixed, weighed accurately and ground to a powder. A portion of the powder equivalent to 5 mg of LAN was accurately weighed and transferred into a 50-ml calibrated flask. Then, 30 ml of DCM was added to the flask, and the container was shaken thoroughly for 15–20 min to extract the drug into the liquid phase. Finally, the solution was diluted to the mark with the same solvent, mixed well and filtered using Whatman No. 42 filter paper. An aliquot of the filtrate (100 μg/ml LAN) was further diluted with DCM to obtain working concentrations of