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Spectrophotometric determination of nifedipine in pharmaceutical formulations, serum and urine samples via oxidative coupling reaction

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Abstract Two rapid, simple, sensitive and selective spectrophotometric methods have been developed for the quantitative estimation of nifedipine in pharmaceutical formulations and different human body fluids (serum and urine). The proposed methods are based on the reduction of the nitro group to amino group of the drug. The resulting amine was then subjected to proposed methods. Method A is based on the oxidation followed by coupling of nifedipine with 3-methyl-2-benzothiazolinone hydrazone (MBTH) in presence of ferric chloride (FeCl_3) to form green colored chromogen at 685 nm. Method B is based on the formation of oxidative coupling reaction between the corresponding drug and brucine – NaIO_4 to form violet colored chromogen at 546 nm. The procedures described were applied successfully to the determination of the compound in their dosage forms and body fluids. The results showed that the proposed procedures compared favorably with reference method are satisfactory sensitive, accurate and precise. The optical characteristics such as Beer's law limits, molar absorptivity, Sandell's sensitivity and various statistical data are reported. The results of the analysis for the two methods have been validated statistically and by recovery studies.

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1. Introduction

Nifedipine is chemically known as dimethyl-1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl) pyridine-3,5 dicarboxylate. (Fig. 1 A) It is pharmacologically a selective L-type calcium channel antagonist (Matrindale the Extra Pharmacopoeia, 2002). It causes coronary vasodilation and increases coronary blood flow. It reduces the total peripheral vascular resistance, for which it is widely used in the treatment of hypertension angina pectoris, various other cardiovascular disorders and Reynaud's phenomenon (Sorkin et al., 1985; Kahan et al., 1981; Hardman et al., 1996). It is mainly used in the treatment of diuretics and ACE (Tripathi K.D.) inhibitors

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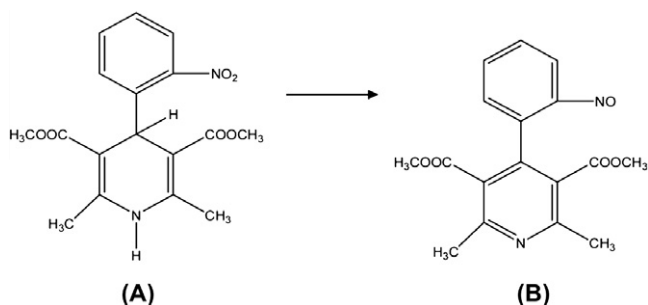


Figure 1 Chemical structures of (A) Nifedipine (B) Nitro phenyl pyridine.

although calcium channels antagonists are still favored as primary treatment for older black patients – sub lingual. Nifedipine has previously been used in hypertensive emergencies. It has a very low bioavailability, and it is photosensitive and thermally unstable. This compound, when exposed to daylight and certain wavelengths or artificial light readily converts to a nitro phenyl pyridine derivative (NFPD) (Fig. 1B) (Henry, 1980; Miller, 1987; Stone et al., 1980). Blood pressure diabetes and LDL cholesterol are casual risk factors for cardiovascular diseases (CVD) and their combined effects make this disease common. A pill containing different active ingredients (Polly Pill) to overcome these factors is more beneficial than the common pills with only one, interns of cost and patient compliance. Nifedipine is a common prescribed active ingredient for CVD. Nifedipine, a highly non polar compound, is absorbed completely from the gastrointestinal tract, predominately from the Jejunum, but has a very low bioavailability mainly due to presystemic metabolism. Following absorption, nifedipine is further metabolized in the small intestine and liver to more polar compounds which are primarily eliminated by the kidney (Dokladaiova et al., 1982; Schellens et al., 1991; Kleinbloesem et al., 1984). Nifedipine is a photolabile compound, undergoing oxidative biotransformation in human body into pharmacologically inactive metabolites (Dokladaiova et al., 1982; Suzuki et al., 1985; Ohkubo et al., 1992).

The literature has reported some methods for nifedipine determination in biological fluids, which included gas chromatography, high performance liquid chromatography with either UV detection or electrochemical detection, fluorescence procedures, first derivative spectroscopy, Voltammetric method and LC–MS combining a simple liquid–liquid extraction (Kondo et al., 1980; Sheridan et al., 1989; Jankowski et al., 1994; Suzuki et al., 1985; Ozattin et al., 2002). Additionally, the methods reported to quantify nifedipine in bulk and in pharmaceuticals formulation involved a variety of analytical techniques such as high performance thin layer chromatographic, liquid chromatographic, gas chromatographic, polarographic, micellar electro kinetic chromatography, electro analytical and spectrophotometric methods (Patravale et al., 2000; Rahman et al., 2004; Rahman and Hoda, 2002; Karadi et al., 2000; Tu et al., 1995; Dumitrescu et al., 2001; Richter et al., 1997; Beaulieu et al., 1991; Kalieswari et al., 2002; Kasture and Ramteke, 2005; Milenovic et al., 2008; Rodríguez et al., 2008; Hemmateenejad et al., 2009).

Surprisingly, according to the best of our knowledge few spectrophotometric methods for the determination of nifedi-

pine in pharmaceutical formulations, body fluids and other additives were reported. The present study documents an accurate, sensitive, rapid, selective and reproducible visible spectrophotometric assay which meets an accepted analytical validation. Spectrophotometry is the technique of choice even today in the laboratories of research, hospitals and pharmaceutical industries due to its low cost and inherent simplicity.

2. Experimental

2.1. Apparatus

Shimadzu UV–visible double beam spectrophotometer (model 2450) with 1 cm matched quartz cells was used for all the spectral measurements.

2.2. Materials and reagents

All chemicals and reagents were of analytical grade and water was always double distilled water.

- (1) Nifedipine was kindly supplied by Novartis Pharmaceuticals Ltd. Mumbai, India its Purity was found to be 100.024 ± 0.84 .
- (2) Brucine solution (Loba, 0.2%; 5.067×10^{-3} M): prepared by dissolving 200 mg of Brucine in 100 ml distilled water.
- (3) NaIO₄ solution (BDH, 0.2%; 9.35×10^{-3} M): prepared by dissolving 200 mg of sodium metaperiodate in 100 ml distilled water and standardized iodometrically.
- (4) H₂SO₄ solution (Qualigens, 2.3 M): Prepared by diluting 6.38 ml of 18 M H₂SO₄ to 100 ml with distilled water.
- (5) MBTH (Merck, 0.2%): Prepared by dissolving 200 mg in 100 ml distilled water.
- (6) FeCl₃ (Merck, 0.5%): Prepared by dissolving 500 mg in 100 ml distilled water.
- (7) Pharmaceutical formulations: Nicardia retard – 10 mg nifedipine per tablet (Local market Tirupati).

Calciguard – 10 mg and Adalat retard – 10 mg nifedipine per tablet (Novartis Pharmaceuticals Ltd., Mumbai, India).

2.3. Reduction of nitro group in Nifedipine (Olajire Aremu and Offiong Edet, 2009; Tulasamma and Venkateswarlu, 2009)

100 mg of nifedipine pure or equivalent tablet powder was accurately weighed and dissolved in 20 ml of methanol. This solution was treated with 10 ml of 5 N HCl and 0.5 g of Zinc powder was added in the portions, while shaking and refluxed at 80 °C for 10 min. The solution was filtered using a Whatman filter paper 41 to remove the insoluble matter and the volume was made up to 100 ml with methanol to get the concentration 1 mg/ml.

2.4. Preparation working standard solution

The resulting amine from the above solution 10 ml was taken into 100 ml volumetric flask and made up to the mark with methanol to get the concentration $100 \mu\text{g ml}^{-1}$ and dilution was carried out to the further working standards.

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