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ORIGINAL ARTICLE

Novel and validated titrimetric method for determination of selected angiotensin-II-receptor antagonists in pharmaceutical preparations and its comparison with UV spectrophotometric determination

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Abstract A novel and simple titrimetric method for determination of commonly used angiotensin-II-receptor antagonists (ARA-IIs) is developed and validated. The direct acid base titration of four ARA-IIs, namely eprosartan mesylate, irbesartan, telmisartan and valsartan, was carried out in the mixture of ethanol:water (1:1) as solvent using standardized sodium hydroxide aqueous solution as titrant, either visually using phenolphthalein as an indicator or potentiometrically using combined pH electrode. The method was found to be accurate and precise, having relative standard deviation of less than 2% for all ARA-IIs studied. Also, it was shown that the method could be successfully applied to the assay of commercial pharmaceuticals containing the above-mentioned ARA-IIs. The validity of the method was tested by the recovery studies of standard addition to pharmaceuticals and the results were found to be satisfactory. Results obtained by this method were found to be in good agreement with those obtained by UV spectrophotometric method. For UV spectrophotometric analysis ethanol was used as a solvent and wavelength of 233 nm, 246 nm, 296 nm, and 250 nm was selected for determination of eprosartan mesylate, irbesartan, telmisartan, and valsartan respectively. The proposed titrimetric method is simple, rapid, convenient and sufficiently precise for quality control purposes.
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1. Introduction

Many of the active components of pharmaceutical preparations are of organic origin and contain acidic or basic groups. Such compounds can be successfully determined in their pharmaceutical preparations using titrimetric methods. The purpose of this work was to develop a simple, accurate, reproducible and rapid titrimetric method for the determination of commonly used angiotensin-II-receptor antagonists

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(ARA-IIs) such as eprosartan mesylate (I), irbesartan (II), telmisartan (III) and valsartan (IV), and applying it to the pharmaceutical dosage forms. These compounds contain either carboxylic acid group or tetrazole ring or both which act as an acidic centre and form the basis for acid–base reactions during titration. The structural formulae of these ARA-IIs are given in Fig. 1.

These ARA-IIs are safe and effective agents in the treatment of hypertension and heart failure, either alone or in conjunction with diuretics. They have been proposed as alternatives to the more traditional angiotensin converting enzyme (ACE) inhibitors because they selectively block the angiotensin type 1 (AT1) receptor, which is responsible for vasoconstriction, and salt and water retention. The angiotensin type 2 (AT2) receptor, which is thought to have cardioprotective effects and inhibitory effects on growth, is left unaffected [1–6].

Several methods that are reported for ARA-IIs compounds estimation include enzyme-linked immunosorbent assays (ELISAs) for the determination of telmisartan in human blood plasma [7], spetrofluorimetric for the determination of valsartan in human urine [8], colorimetric method [9], and UV-derivative spectrophotometric [10] for the determination of ARA-II in bulk and in tablets. Tatar and Saglik [11] compared UV- and second derivative-spectrophotometric and high-performance liquid chromatographic methods for the determination of valsartan in pharmaceutical formulation. Also, capillary electrophoresis (CE), capillary electrochromatography (CEC), micellar electrokinetic capillary chromatography (MEKC) and capillary zone electrophoresis (CZE) methods have also been reported [12–16]. High-performance liquid chromatography has been the major technique used in the determination of these compounds in different matrices with UV [17–24], fluorimetric [25–27] or mass spectrometry (MS) detections [28–30]. Validated methods which allow the determination of a single drug [31–39] or combination of ARA-IIs with hydrochlorothiazide or some of their metabolites [40–43] in urine, plasma and in pharmaceutical formulations [44] have also been published.

Although chromatographic techniques have been suggested for the determination of ARA-IIs, it requires high skilful operator and expensive instrument. In addition, most of the described procedures require expensive instrumental setup. So, there is a need to develop a simple, reliable, rapid and economical method for the determination of ARA-IIs in pharmaceuticals.

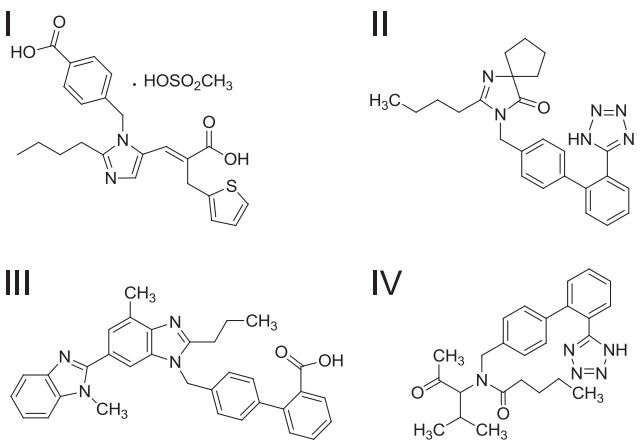

Figure 1 Structural formulae of angiotensin-II-receptor antagonists: (I) Eprosartan mesylate, (II) Irbesartan, (III) Telmisartan and (IV) Valsartan.

No titrimetric method for determination of ARA-IIs has been found in literature. In this paper, the validated titrimetric method is described for the determination of ARA-IIs in pharmaceuticals. The method is based on the titration of the drug solution in neutral ethanol:water mixture (1:1) with aqueous NaOH to a phenolphthalein end point or potentiometric equivalence point. In this paper the proposed titrimetric method is a very simple technique and adoptable for routine analysis to determine the content of ARA-IIs at milligram level in the quality control laboratories.

Because of unavailability of pharmacopial method for some of these ARA-IIs, UV spectrophotometric method has been developed for statistical comparison with results obtained by proposed titrimetric method. A comparison of results obtained by the proposed titrimetric method and those obtained by UV method shows good statistical correlation.

2. Materials and methods

2.1. Apparatus

A Jenway 3020 digital pH meter equipped with a combined pH-electrode was used throughout the study. All titrations were carried out manually. A shimadzu UV–visible recording spectrophotometer (model UV2501 PC) with 1 cm matched quartz cells was used for spectrophotometric analysis.

2.2. Reagents and materials

Eprosartan mesylate, valsartan, and telmisartan were obtained from Glenmark Pharmaceutical Ltd. Sinnar, Nasik, India; and irbesartan was obtained from Cadila Healthcare Ltd., Ahmedabad, India. These ARA-IIs were chemically pure laboratory working standards having purities of 99.8%, 99.4%, 99.6% and 99.3%. Sodium hydroxide, ethanol, potassium hydrogen phthalate, and phenolphthalein powder were obtained from Merck, India and S.D's Lab Chem & Industries, Bombay. Teveten (eprosartan mesylate), Karvea (irbesartan), Telsartan (telmisartan) and Diovan (valsartan) tablets were obtained from a local pharmacy. All chemicals were of analytical reagent grade unless otherwise stated, and doubly distilled deionised water was used throughout.

Sodium hydroxide (*0.01 M*): Accurately 0.2 g of the pure NaOH (Merck, India) was dissolved in doubly distilled water. The solution was made up to 500 mL with the same water and standardized [45].

Phenolphthalein indicator (*0.5%*): It was prepared by dissolving 500 mg of the pure phenolphthalein powder (S.D's Lab Chem & Industries, Bombay) in 50 mL alcohol and diluting to 100 mL with doubly distilled water.

2.3. Procedures

2.3.1. Potentiometric titration

Accurately weighed quantities (2.0–10.0 mg) of four ARA-IIs, namely eprosartan mesylate, irbesartan, telmisartan and

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