Journal of Pharmaceutical and Biomedical Analysis 48 (2008) 57–61

Contents lists available at ScienceDirect

Journal of Pharmaceutical and Biomedical Analysis

journal homepage: www.elsevier.com/locate/jpba

Characteristics of new composite- and classical potentiometric sensors for the determination of pioglitazone in some pharmaceutical formulations

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ARTICLE INFO

Article history:
Received 4 March 2008
Received in revised form 28 April 2008
Accepted 30 April 2008
Available online 7 May 2008

Keywords:
Pioglitazone HCl
Sodium tetraphenylborate
Phosphomolybdic acid
Phosphotungstic acid
PVC
Potentiometry

ABSTRACT

The construction and electrochemical response characteristics of poly(vinyl chloride) membrane sensors for pioglitazone HCl (PG) are described. The sensing membranes incorporate ion association complexes of pioglitazone cation and sodium tetraphenylborate (NaTPB) (sensor 1) or phosphomolybdic acid (PMA) (sensor 2) or phosphotungstic acid (PTA) (sensor 3) as electroactive materials. The sensors display a fast, stable and near-Nernstian response over a relative wide pioglitazone concentration range (1×10^{-2} to 10^{-6} M), with cationic slopes of 55.0 ± 0.5, 58.0 ± 0.5 and 53.0 ± 0.5 mV per concentration decade over a pH range of 1.0–5.0. The sensors show good discrimination of pioglitazone from several inorganic and organic compounds. The direct determination of 2.5–3900.0 μg/ml of pioglitazone show an average recovery of 98.5, 99.0 and 98.4% and a mean relative standard deviation of 1.6, 1.5 and 1.7% at 100.0 μg/ml for sensors 1, 2 and 3, respectively. The proposed sensors have been applied for direct determination of pioglitazone in some pharmaceutical preparations. The results obtained by determination of pioglitazone in tablets using the proposed sensors are comparable favorably with those obtained using the HPLC method. The sensors have been used as indicator electrodes for potentiometric titration of pioglitazone.

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1. Introduction

Pioglitazone hydrochloride [(±)-5-[[4-[2-(5-ethyl-2-pyridinyl) ethoxy] phenyl] methyl]-2,4-]thiazolidinedione hydrochloride (Fig. 1). Pioglitazone HCl is an oral antidiabetic agent that acts primarily by decreasing insulin resistance. Pharmacological studied indicate that PG improve sensitivity to insulin in muscle and adipose tissue and inhibits hepatic gluconeogenesis. Pioglitazone HCl improves glycaemic control while reducing circulating insulin levels. Fasting and postprandial glycaemic controls are improved in patients with type 2 diabetes mellitus. The decreased insulin resistance produced by PG results in lower blood glucose concentrations, lower plasma insulin levels and lower HBA_{1c} values [1,2].

Various method cited in literature for its determinations involve, high performance liquid chromatography (HPLC) [3–9], HPLC/MS [10], HPLC/MS/MS [11], capillary electrophoresis (CE) [8] and second derivative spectrometry [9]. However, most of these methods involve time-consuming procedures, derivatization and/or sophisticated instruments.

Recent years have seen an upsurge of interest in the application of sensors in the field of medicinal analysis [12–15]. This can be explained by the good analytical performances in terms of selectivity and accuracy, low detection limit, wide concentration range and relatively limited financial investment. For our knowledge till now no potentiometric membrane sensors for PG have been published. The proposed sensors are based on the use of PVC membrane sensor of pioglitazone–tetraphenylborate or pioglitazone–phosphomolybdate or pioglitazone–phosphotungstate as electroactive materials. The present work describes the construction and evaluation of novel PVC electrochemical sensors for the sensitive and selective determination of pioglitazone in its pharmaceutical preparations. The proposed methods are successfully applied for the determination of PG in some pharmaceutical formulation.

2. Experimental

2.1. Apparatus

All potentiometric measurements were made at 25 ± 1 °C unless otherwise stated using an Orion pH/mV meter (model 330) using pioglitazone membrane sensors in conjunction with an Orion double junction Ag/AgCl reference electrode (model 90-02) containing 10% (w/v) potassium nitrate in the outer compartment. Adjustment of pH was made with a combined Ross glass pH electrode (Orion 81-02) for all pH measurements.

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doi:10.1016/j.jpba.2008.04.029

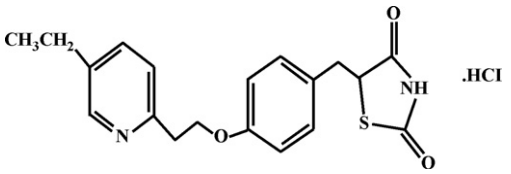

Fig. 1. Chemical structure of pioglitazone hydrochloride.

2.2. HPLC system

A Waters HPLC (Milford, MA, USA) system consisting of a binary solvent delivery pump (model 1525), an auto sampler (model 717), a dual wavelength absorbance detector (model 2487), and a computer having Empower software was used. A validation method for the determination of PG in pharmaceutical dosage form was used [8]. The analysis was performed using a reversed phase C18 (150 mm × 4 mm, 3 μm). The mobile phase consisted of a mixture of aqueous 10 mM potassium dihydrogen phosphate–acetonitrile (50:50, v/v) adjusted to a pH 6.0 with 0.1 M KOH at a flow rate of 1.0 ml/min. The UV detector was set at 225 nm. A calibration graph was constructed using standard PG solution. The data obtained with this method was utilized to compare the proposed potentiometric method using the developed sensors.

2.3. Reagents and materials

All chemicals used were of analytical reagent grade unless otherwise stated and doubly distilled water was used throughout. Polyvinyl chloride powder (PVC) high molecular weight, dibutyl sebacate (DBS), dioctyl phthalate (DOP), *o*-nitrophenyl octylether (NPOE), tetrahydrofurane (THF) of purity >99% were obtained from Aldrich Chemical Company and pioglitazone HCl was obtained from Tekeda Chemical Industrial Ltd., Oska, Japan. NaTPB, PMA and PTA were obtained from BDH. Actos tablets containing 15 and 30 mg of PG were obtained from local Pharmacy. The stock solution of 1×10^{-2} M pioglitazone–HCl was prepared by dissolving the appropriate amount of PG in 100 ml of aqueous acidic solution (0.5 M). The standard PG solution were prepared 1×10^{-3} to 1×10^{-6} by diluting the appreciate amount in double distilled water. Phosphate buffer solution of pH 3.0 was prepared by mixing appropriate amount of 0.1 M NaH_2PO_4 with 0.1 M H_3PO_4.

2.4. Preparation of the PG-PVC membrane sensors

Upon the addition of 25 ml of 1×10^{-2} M of pioglitazone HCl solution to equal amount of 1×10^{-2} M NaTPB or 75 ml of 1×10^{-2} M of PG to 25 ml each of phosphomolybdic or phosphotungstic acid, a whit or green or whitish precipitate of PG-TPB or PG-PM or PG-PT were formed, respectively. The precipitate was filtered off through a Whatman filter paper No. 42, washed with cold deionized water until no chloride ion was detected into the washing solution. The precipitate was dried under vacuum for 48 h, then grinded to a fine powder in mortar, forming ion-pairs complex. Elemental analysis confirmed the formation of 1:1 or 3:1 or 3:1 complexes of PG-TPB or PG-PM or PG-PT, respectively. 10 mg portions of the prepared ion associate complexes were thoroughly mixed with 190 mg PVC powder, 350 mg of DBS or DOP or NPOE and 5 ml THF in glass Petri dishes (5 cm diameter). After the constituents being well mixed, the solvent has been allowed to evaporate overnight while the sensing membranes have been formed. The PVC master membranes were sectioned with a cork borer (10 mm diameter) and glued to a polyethylene tube (3 cm length, 8 mm I.D.) using THF [16,17]. Laboratory made electrode bodies were used, which consisted of a glass tube, to which the polyethylene tube is attached at one end and filled with internal reference solution (equal volumes of 1×10^{-2} M aqueous solution of PG and KCl). Ag/AgCl internal reference electrode (1.0 mm diameters) was used. The indicator electrode was conditioned by soaking in a 1×10^{-2} M aqueous PG solution for 1 h and stored in the same solution when not in use.

2.5. Procedure

The pioglitazone PVC membrane sensors were calibrated by immersion in conjunction with the reference electrode in a 50 ml beaker containing 9.0 ml of phosphate buffer of pH 3.0. Then 1.0 ml aliquot of PG solution was added with continuous stirring, to give final PG concentration ranging from 1×10^{-2} to 1×10^{-6} M and the potential was recorded after stabilization to ±0.5 mV. A calibration graphs were then constructed by plotting the recorded potentials as a function of -log[PG]. The resulting graphs were used for subsequent determination of unknown pioglitazone concentration.

2.6. Determination of pioglitazone in the pharmaceutical dosage forms

Ten tablets of Actos (15 or 30 mg of pioglitazone) were accurately weighed and crushed and mixed in a mortar. An appropriate amount (30 mg of pioglitazone powder, from each) was weighed, transferred to a 100 ml beaker and dissolved in acidic water solution (0.5 M), sonication for about 15 min and completed to the mark with the same acidic solution. A 5.0 ml aliquot of this solution was transferred to 50 ml standard flask, the pH was adjusted to 3.0 using phosphate buffer and completed to the mark with water. The potential of the solution was measured using PG-sensors in conjunction with an Orion Ag/AgCl double junction reference electrode. The potential of the stirred solution was recorded after the signal stabilization (±1 mV/min) and the concentration was calculated from the previous calibration graph under identical experimental conditions from standard solutions of PG.

Alternatively, the potentials displayed by pioglitazone test solution before and after the addition of a 1.0 ml aliquot of 1×10^{-3} M pioglitazone were measured. The change in the potential readings was recorded and used to calculate the unknown pioglitazone concentration in the test solution using the standard addition technique [18].

Reconstituted powder: one mixture was prepared with a known amount of pioglitazone powdered and other components such as starch, lactose and magnesium stearate. The accuracy of the potentiometric determination of PG in this powdered was checked by evaluation the recovery.

3. Results and discussion

Sodium tetraphenylborate, phosphomolybdic acid, phosphotungstic acid were tested as ion-pairing agent for the preparation of an electroactive ion association complexes for PG. Sparingly soluble complexes of PG-TPB or PG-PM or PG-PT have been instantaneously formed upon the addition of PG solution to solutions of NaTPB or PMA or PTA, respectively. The dry powder of the formed ion-pairs is used for the construction of new pioglitazone ion selective electrodes. The elemental analysis showed that the composition of the complex is 1:1 or 3:1 or 3:1 for PG-TPB or PG-PM or PG-PT, respectively. Plastic membranes were prepared by using a casting solution of (1.82:34.45:63.64) ion-pair, PVC and DBS or DOP or NPOE as plasticizer, respectively.

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