



Optimization of tramadol–PVC membrane electrodes using miscellaneous plasticizers and ion-pair complexes

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ABSTRACT

Effect of the ISE membrane composition on the characteristics of the tramadol–PVC-electrodes has been investigated. The parameters studied include the effect of the plasticizer and the effect of the ion-pair complex. The plasticizers used were 2-nitrophenyl octyl ether (2-NPOE), dioctyl phthalate (DOP), dibutyl phthalate (DBP), tris(2-ethylhexyl) phosphate (TEPh), dioctyl sebacate (DOS), tributyl phosphate (TBPh) and dibutyl butyl phosphonate (DBBPh) and the ion-pair complexes were tramadolium–silicotungstate (TD–ST), silicomolybdate (TD–SM). These electrodes were fully characterized in terms of composition, life span, usable pH range and working concentration range. The results showed that the best combination was TD–ST as the ion-pair complex and DBP as the plasticizer that produced the electrode with favorable characteristics. Another electrode using TD–SM was tested and produced close results. The present electrodes show clear discrimination of tramadol hydrochloride from several inorganic, organic ions, sugars and some common drug excipients. The sensors were applied for determination of tramadol hydrochloride in urine, milk and pharmaceutical preparations using potentiometric determination, standard addition and the calibration curve methods. The results obtained were satisfactory with excellent percentage recovery comparable and sometimes better than those obtained by other routine methods for the assay.

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1. Introduction

Ion-selective electrodes (ISEs) are the chemical sensors of longest history and probably have the largest number of applications [1] such as polymeric membrane-based ion-selective electrodes (ISEs) which have been described for different analytes [2–10].

ISEs were found effective in analysis of pharmaceutical formulations [4,5,10] for their attractive properties of simple design, ease of construction, reasonable selectivity, fast response time, applicability to colored and turbid solutions and possible interfacing with automated and computerized systems [11].

Tramadol HCl (trans-(6)-2-[dimethylamino] methyl)-1-(3-methoxyphenyl) cyclohexanol hydrochloride) (Fig. 1) is a centrally acting analgesic which possesses opioid properties and activates monoaminergic spinal inhibition of pain. It may be administered orally, rectally, intravenously or intramuscularly. Many clinical

studies have evaluated the therapeutic efficacy (analgesic effects) of tramadol in comparison with morphine and other analgesics and found tramadol to be effective for relief of postoperative pain (patient-controlled analgesic, PCA), moderate surgical pain, surgical pain in children, cancer pain control, obstetric pain, osteosynthesis and chronic pain [12].

Methods for estimating tramadol hydrochloride have been described that employ HPLC with UV [13], fluorescence [14], diode array detector [15], and GC with flame ionization detection [16,17].

However, these methods comprise sample manipulations, extraction steps, derivatization reactions that are liable to various interferences as well as being not applicable to colored and turbid solutions. These methods are expensive for they require large infrastructure backup and qualified personnel.

Thus, there is critical need for the development of selective, inexpensive diagnostic tool for the determination of this analyte. Analytical methods based on potentiometric detection with ion-selective electrodes (ISEs) can be considered a good alternative for the attractive characteristics mentioned above.

There are a few reports of potentiometric ISEs based on PVC membrane electrodes [18–21]. We have developed a carbon paste electrode for determination of tramadol [22] with a lower limit of

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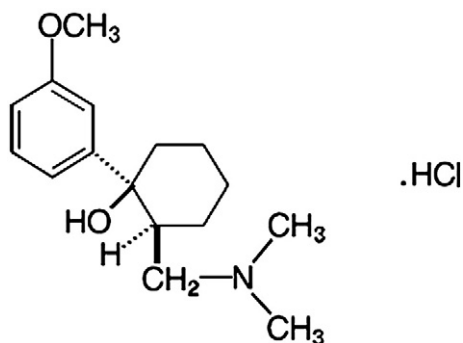


Fig. 1. The chemical structure of tramadol by hydrochloride.

detection by elimination of the internal solution. In this paper we describe an attempt to improve the characteristics of conventional PVC membrane by using various ion-pair complexes of the tramadol cation (TD^+) with silicotungstate, silicomolybdate anion and various plasticizers namely 2-nitrophenyl octyl ether (2-NPOE), dioctyl phthalate (DOP), dibutyl phthalate (DBP), tris(2-ethylhexyl) phosphate (TEPh), dioctyl sebacate (DOS), tributyl phosphate (TBPh) and dibutyl butyl phosphonate (DBBPh) with miscellaneous properties and different concentration of internal solution. Each of these sensors incorporates a certain ion-pair complex as electroactive material in PVC matrix membrane plasticized with dibutyl phthalate (DPB). The results obtained using these PVC-electrodes are comparable to the CPE but better than those reported above for PVC-electrodes. The detection limit was lowered to 2.1×10^{-6} and 5.3×10^{-6} mol L^{-1} , the concentration range was 5.5×10^{-6} – 1.0×10^{-1} and 7.3×10^{-6} – 1.0×10^{-1} mol L^{-1} , the slope was 61.7 ± 0.5 and 60.3 ± 0.8 for TD–ST (electrode 1) and TD–SM (electrode 2) respectively. Furthermore, these sensors showed good selectivity for tramadol in presence of some common excipients. In addition, these electrodes produced reproducible results.

It is likely that the different combination of these plasticizers and ion-pair complexes made it possible to attain results that are much better than those reported.

2. Experimental

2.1. Reagents

2-nitrophenyl octyl ether (2-NPOE), dioctyl phthalate (DOP), dibutyl phthalate (DBP), tris(2-ethylhexyl) phosphate (TEPh), dioctyl sebacate (DOS), tributyl phosphate (TBPh) dibutyl butyl phosphonate (DBBPh), silicotungstic acid (STA), silicomolybdic acid (SMA) were purchased from Sigma-Aldrich (CH-9471 Buchs-Germany). High molecular weight poly (vinylchloride) (PVC) was obtained from Sigma-Aldrich and (Sigma-Aldrich, CH-9471 Buchs-Italy). Tramadol hydrochloride TDCI was obtained from Pharmacare LTD company (Ramallah-Palestine). The pharmaceutical preparations containing TDCI (Tramal, tablets, capsules, drops and ampoules) were obtained from local drug stores.

2.2. Apparatus

Potentiometric and pH measurements were made with a Pocket pH/mV Meters, pH315i (Wissenschaftlich-Technische Werkstätten GmbH (WTW)-Germany) under stirring conditions at room temperature (25.0 ± 1.0 °C).

The performance of the electrodes was investigated by measuring the emfs of TD solutions with a concentration range of 10^{-7} – 10^{-1} M by serial dilution. Each solution was stirred and the potential reading was recorded when it became stable. The potential is plotted as a

logarithmic function of TD cation activities which are calculated from the Debye–Hückel equation

$$\log \gamma = -0.511 Z^2 \left[\mu^{1/2} \left(1 + 1.5 \mu^{1/2} \right) - 0.2 \mu \right]$$

that is applicable to any ion, where μ is the ionic strength and Z the charge [23]. It is believed that the activity of the ions in very dilute solutions is equal to the concentration as the activity coefficients are equal to unity. The measurements presented here are made in dilute solutions so one can safely consider that the response of the electrode is acceptable and it was found repeatable.

2.3. Preparation of ion-pair

The ion-pair complexes tramadolium–silicotungstate (TD–ST) and silicomolybdate (TD–SM) were prepared [5] by adding a hot solution of 50 mL of 0.01 M TDCI to 12.5 mL of 0.01 M of one of silicotungstic acid (STA) or silicomolybdic acid (SMA). The precipitates that formed were filtered off, washed thoroughly with distilled water, dried at room temperature and ground to fine powders. These ion-pair complexes were used as the active substances for preparing the PVC membrane electrodes of tramadol hydrochloride.

2.4. Preparation of the electrodes

The membranes were prepared as previously described by Thomas and co-workers [24]. In each case, after curing, a small disk (7.5 mm) was punched from the cast film and mounted on the body of a homemade electrode body. The electrodes TD–ST and TD–SM were filled with a solution that is 10^{-1} mol NaCl L^{-1} and 10^{-3} mol TDCI L^{-1} and preconditioned by soaking in 10^{-3} mol TDCI L^{-1} .

2.5. Selectivity coefficient determination

The Separate Solution Method (SSM) and the Matched Potential Method (MPM) [25] are employed to determine the selectivity coefficients, $\log K_{\text{Drug}, J^{z+}}^{\text{pot}}$, of the potentiometric sensors towards different species.

In the SSM, the potential of a cell comprising a working electrode and a reference electrode is measured in two separate solutions, one containing the drug ions, E_1 , and the other containing the interferent ions (J), E_2 , and S is the slope of the calibration graph.

These values were used to calculate the selectivity coefficient from the following equation:

$$\log K_{\text{Drug}, J^{z+}}^{\text{pot}} = \frac{E_2 - E_1}{S} + \log[\text{Drug}] - \log[J^{z+}]^{1/2}$$

Potentiometric selectivity factors of the electrode were evaluated by applying the matched potential method (MPM). According to this method, the activity of (TD) was increased from $a_{\text{TD}^+} = 1.0 \times 10^{-5}$ M (reference solution) to $a_{\text{TD}^+} = 5.0 \times 10^{-5}$ M, and the changes in potential (ΔE) corresponding to this increase were measured. Next, a solution of an interfering ion of concentration a_j in the range 1.0×10^{-1} – 1.0×10^{-2} M was added to new 5.0×10^{-5} M reference solution until the same potential change (ΔE) was recorded. The selectivity factor, for each interferent was calculated using the following equation:

$$\log K_{\text{TD}^+, J^{z+}}^{\text{pot}} = \frac{\bar{a}_{\text{TD}^+} - a_{\text{TD}^+}}{a_j}$$

Where the a_j is the activity of the added interferent.

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