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Potentiometric Determination of Fexofenadine Hydrochloride Drug by Fabrication of Liquid Membrane Electrodes

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Abstract

This paper presents a study in the electrochemical methods for the preparation of three new electrodes of Fexofenadine hydrochloride in a polymeric membrane. The first electrode was prepared from ion pair: molybdophosphoric acid reagent and fexofenadine cation with Di-n-butyl phthalate (DBPH), the subsequent electrode was prepared with O-Nitro phenyl octyl ether (NPOE) and the third electrode was set up by Tri-n-butyl phthalate (TBP), respectively as plasticizer for determination of Fexofenadine hydrochloride drug. Two electrodes indicated a Nernstian response with a slope of [57.01, 56.70] mV. decade^{-1} for the first and for the second electrodes individually, with detection limits 5.6×10^{-6} mole.L^{-1} for first electrode and 3.5×10^{-6} mole.L^{-1} for the second electrode and the third electrode gave a non Nernstain response equivalent to 14.30 mV.decade^{-1}. The electrodes FEX -MPA -DBPH, FEX -MPA -NPOE, and FEX -MPA -TBP work adequately over the pH range (2.0-4.5), (2.5-4.0), and (2.0- 4.0) for Fexofenadine hydrochloride electrodes, respectively. The impact of interfering species was insignificant as demonstrated by selectivity coefficient values. The viability of the electrodes FEX -MPA -DBPH, FEX -MPA -NPOE, and FEX -MPA -TBP proceeded in a timeframe (41,36, and 13) days, respectively. The recommended electrodes were successfully used for the determination of Fexofenadine hydrochloride in pure form and pharmaceuticals preparations. This work arrived at excellent outcomes as far as the linearity, and selectivity of the methods.

***Keywords*:** Plasticizer, Selectivity; Fexofenadine Hydrochloride; Sensors; Electrochemistry.

1. Introduction

The expanding interest in chemical observation in environmental assurance, medication and numerous mechanical cycles have made the requirement for sensors with highlights like high selectivity, affectability, dependability, toughness, the feasibility of automation and remote sensing ability. These requests can regularly be fulfilled by ion selective electrodes ISEs, which are generally applied attributable to their straightforwardness, low coast and quick arrangement of analytical outcomes[1].

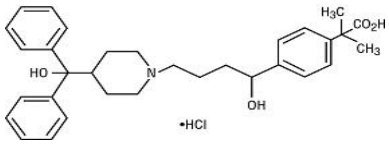

Fig. 1. Structural Formula of Fexofenadine HCl.

Fexofenadine hydrochloride (Fig1) (RS)-2-[4[1-Hydroxy-4-[4-(hydroxy-diphenyl methyl)-1-piperidyl] butyl]phenyl]-2-methylpropanoic acid. white powder, very easily soluble in ethanol and methanol slightly soluble in water [2], with molecular weight 538.1 g/mole effects of accidental negatively disposed rhinitis containing wheezing nose; runny; and watery eyes or red, irritated, or throat tickling of the nose, or top of the mouth in grown-ups.[3, 4]. Fexofenadine hydrochloride is an antihistamine drug utilized in the fix of roughage fever and comparative sensitivity manifestations [5-8]. It was made as a substitution of and substitute to terfenadine, an antihistamine with perhaps authentic contraindications. Fexofenadine hydrochloride, like other second and third-age antihistamines, doesn't clearly cross the blood-frontal cortex limit, thusly causes less laziness than interesting histamine-receptor enemies. It works by being an adversary to the H1 receptor. It has been named as both second-age. moreover, third-age[9].Various chemical

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methods used for determination fexofenadine hydrochloride, spectrophotometer[10-16],titrimetric methods[17] ,high performance liquid chromatography (HPLC)[18-20]. This study, three ion selective electrodes were readied relied upon complex (MPA-FXH) in PVC network and applied these electrodes to assessment Fexofenadine hydrochloride.

2.Experimental

2.1. Apparatus

Potentiometric methods have been done utilizing pH/mv meter (HANNA). Sartorius balance as model 2474 (Germany).

2.2. Chemicals and Materials

Pure Fexofenadine hydrochloride was obtained from (The state Company for Drugs Industry and Medical Appliances Samarra), analytical grade molybdophosphoric acid, (chemicals, England), high molecular weight PVC was provided as of U.K. Ltd., tetrahydrofuran solvent (BDH) was supplied , Tri -butyl phosphate ,di- butyl phthalate, O-Nitro phenyl octyl ether as a plasticizers, were provide from Fluka AG. Fexotel (120mg) tablets and Fexodine (120mg) tablets supplied from from pharma International Co.Amman- Jordan.

2.3.Preparation of Standard solutions and Ion pair and liquid membranes for FEX drug.

Stock standard solution (0.1 M) fexofenadine hydrochloride(FEX) by weighting 5.381g with deionized water (100 mL) and a standard solution (0.1M) of Phosphomolybdic acid (PMA) prepared by dissolving 22.5760g of (PMA) in 100 mL of deionized water. Ion pair of fexofenadine-molybdate anion and cation was set up by blending 0.01 M of Fexofenadine hydrochloride with 0.01 M of molybdophosphoric acid. Precipitation as green was constructed, later the precipitation was filtered, then washed a few times with deionized water. Later the liquid membrane was set up by mixing 0.04g of FEX-MPA ion pair with 0.18g of PVC(dissolved in THF). After this progression of disintegration, 0.40g of plasticizers (DBPH,O-NPOE and TBP) was added and set up until a homogenous combination was shaped. The subsequent arrangement was step by step filled a Petri dish [21]of 10 cm distance across and covered with a channel paper. This arrangement was then permitted to vanish for two days at room temperature. The resulting membrane is of 0.3 mm thickness and is sufficient to provide about 10 membranes. Fexofenadine hydrochloride standard solutions (1.00×10^{-6}-1.00×10^{-2}) mol. L^{-1} were arranged precisely. The potentiometric valuations were done utilizing reference electrodes are : Ag/AgCl and Calomel [22]. The potential was measure by the proposed electrodes were documented for every concentration to find the regression equations, to evaluate this drug.

2.4. Study of Experimental Measurements

2.4.1. Influence of pH

pH effect on the response of potential for two Fexofenadine sensors. This was got by addition dilute solution of (0.1 mol. L^{-1}) hydrochloric acid or sodium hydroxide solutions by using (1.00×10^{-3}) mol. L^{-1} solutions of (FEX) drug. The potential values was recorded at each pH regard .

*2.4.2. Evaluation of Selectivity Coefficient*The affectability of the created sensors was concentrated inside seeing some interfering, which might be found with the drug substance. The matched potential method was used to measure selectivity. In this method, the selectivity coefficient is described the movement proportion of the meddling and fundamental that showings a comparable probably variation. The coefficient of selectivity was determined by the Nikolskii–Eisenman Equation:[23, 24]

$$E = E0 + R\,T / ZAF \ln [aI + \Sigma KI,J(aJ)ZI/ZJ]$$

3.Results and Discussion

3.1.FEX –Electrodes Calibration

Two formed electrodes prepared were immersed into a standard solution of the drug (FEX) with a range of concentration was (1.0×10^{-6}-1.0×10^{-1}) mol. L^{-1}, the potential was recorded of every solution, then the graphs of the concentration were drawn between the logarithm of concentration of medication and potential as showed in Fig. 2 . Also, results are indicated in Table 1.

Electrodes FEX-MPA-DBPH and FEX-MPA-NPOE were gave a Nernstain response equal to 57.01, 56.70 mV/ decade thus, due to the excessive mix between the DBPH or NPOE with PVC because of the compatibility of the plasticizer used to the electro active composite in together composition and structure [25]. A small slope value recorded for membrane (FEX- MPATBP) might be ascribed to the type of plasticizer was used TBP, which enclosed a lengthy alkyl chain committed to the group of phosphate which might decreasing ion exchange method between the electro-active(FEX-MPA) and the exterior solution of Fexofenadine[26] Lifetime was 41days for FEX-MPA-DBPH, and 36 days for FEX-MPA-NPOE sensors, the slope of the

regression equation was valued and found to be practically steady, yet after the value of slope was decreased clearly. The third electrode FEX-MPA-TBP was given a non - Nernstain response with lifetime equivalent to 13 days(after 13 day, the slope will be decreased less than 14.3 mV/decade because the material of electrode membrane will be leaching out of the membrane) .

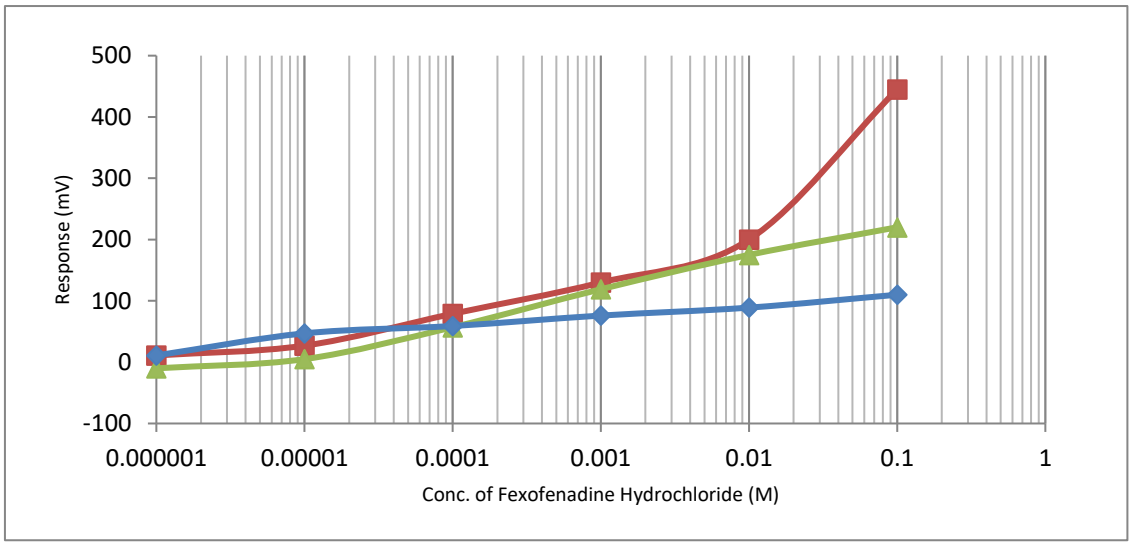

Fig. 2. Calibration curves of Fexofenadine hydrochloride selective electrodes.

3.2.Impact of pH

The impact of pH was studied for the measured potential. The potential was assessed for solution of Fexofenadine hydrochloride using FEX-MPA-NPOE,FEX-MPA-DBPH ,and FEX-MPA-TBP sensors. between pH range (2.0-4.5),(2.5-4.0) and (2.0-4.0) independently.

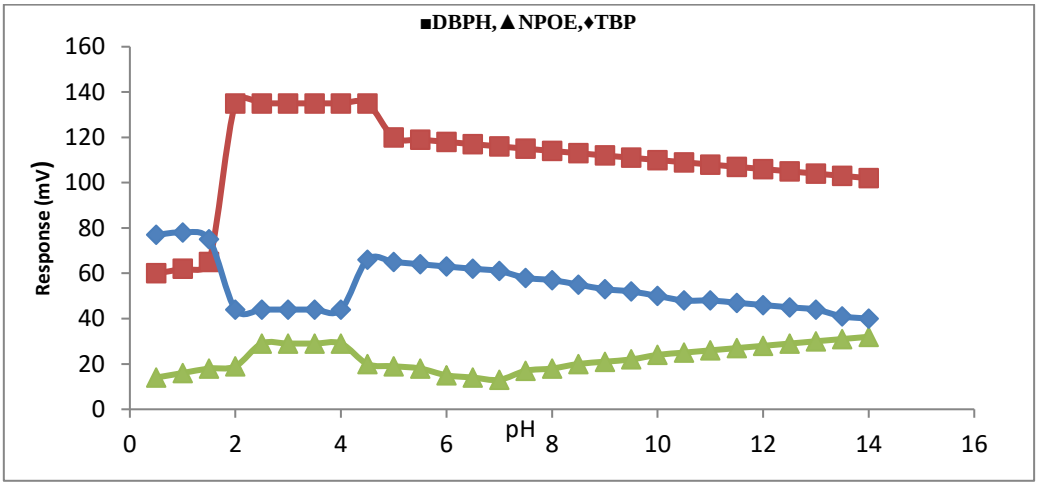

Fig.3. Range of pH for Fexofenadine hydrochloride selective electrodes at 10^{-3}M of Fexofenadine hydrochloride solution.

From Fig.3 noticed that the potential remains stable when pH regard more than 4.5 a saw decline in potential was found. It was discovered that there is wide scope of pH for the two sensors (I and II).

Table 1

The Value of parameters for Fexofenadine hydrochloride selective electrodes.

Parameters	Electrode I FEX-MPA-DBPH	Electrode II FEX-MPA-NPOE	Electrode III FEX-MPA-TBP
Slope (mV/decade)	57.01	56.70	14.30
Limit of detection (M)	5.6×10^{-6}	3.5×10^{-6}	3.9×10^{-6}
Correlation Coefficient	0.9938	0.9987	0.9958
Linear range (mol.L^{-1})	8.0×10^{-6}-1.0×10^{-1}	1.31×10^{-5}-1.0×10^{-2}	2.5×10^{-5}-1.0×10^{-1}
Working pH range	2.0-4.5	2.5-4.0	2.0-4.0
Regre. Eq. Y = mX + b	Y=24.755 ln(x)+308.5	Y=24.624ln(x)+286.2	Y=6.2104 ln(x)+117.8
Lifetime (day)	41	36	13

3.3. Selectivity of FEX Electrodes

The response of the suggested sensors inside seeing interfering substances was thought of, the potentiometric of selectivity coefficients were recorded to evaluate the selectivity of the electrodes for the fundamental drug particle (FEX) if there should be an occurrence of sensor I and sensor II, within the sight of the interfering substances which may exist in the medication concentration. As demonstrated in Table 2.

Table 2

Values of Selectivity Coefficient calculated by Nikolskii–Eisenman Equation for Fexofenadine hydrochloride selective electrodes at (10^{-3} M).

Interfering Species	I	II
K^{+1}	1.3218×10^{-1}	2.9150×10^{-1}
Li^{+1}	2.9819×10^{-1}	9.8816×10^{-1}
Cl^{-1}	4.9120×10^{-1}	3.1730×10^{-1}
Br^{-1}	1.6156×10^{-1}	9.4503×10^{-1}
Cu^{+2}	5.8123×10^{-2}	3.4290×10^{-2}
Zn^{+2}	7.5632×10^{-2}	8.0931×10^{-2}
SO_4^{-2}	5.9430×10^{-2}	7.9210×10^{-2}
Fe^{+3}	9.0543×10^{-3}	5.9317×10^{-3}
Al^{+3}	2.0932×10^{-3}	5.1102×10^{-3}
Glucose	3.2178×10^{-4}	3.1820×10^{-4}
Fructose	1.1098×10^{-4}	9.3129×10^{-4}
Starch	3.1226×10^{-4}	1.1298×10^{-4}

3.4. Potentiometric measurements of FEX samples

The constructed sensors identified using the reference electrode (Ag/AgCl) were dipped freely in the sample solution. The subsequent potential was recorded; the comparing concentration was evaluated from the regression equations for every sensor. The outcomes were contrasted and the outcomes acquired by other electrodes of Fexofenadine hydrochloride were readied. Four techniques were applied by utilizing Fexofenadine hydrochloride selective electrodes, utilizing direct, standard addition (SAM), multi standard addition methods (SAMS) and titration method, the outcomes were recorded in Table 3,4 and Fig. 4,5,6,7,8 and 9 shows the potentiometric techniques for Fexofenadine hydrochloride electrodes. For the determination of Fexofenadine hydrochloride in drug tablets (Fexotel, Fexodine), potentiometric method of direct was applied as documented in Table 5 by using the electrode contain DBPH as a plasticizer. The average recovery for (FEX-DBPH-MPA) in tablets was calculated around 97.08% by calculating an average of 3 readings for every sample.

Table 3: Results by potentiometric methods for (FEX-DBPH-MPA) electrode.

	Results by potentiometric methods			
Sample	Direct	SAM	SAMS	Titration
1×10^{-3}	0.9751×10^{-3}	0.9866×10^{-3}	0.9682×10^{-3}	0.98630×10^{-3}
%RSD	0.73	1.46	-	-
%Rec	97.51	98.66	96.82	98.63
%RE	-2.49	-1.34	-3.18	-1.37
1×10^{-4}	0.9651×10^{-4}	0.97765×10^{-4}	0.9813×10^{-4}	0.9871×10^{-4}
%RSD	1.06	0.425	-	-
%Rec	96.51	97.76	98.13	98.71
%RE	-3.49	-2.24	-1.87	-1.29

*n=5

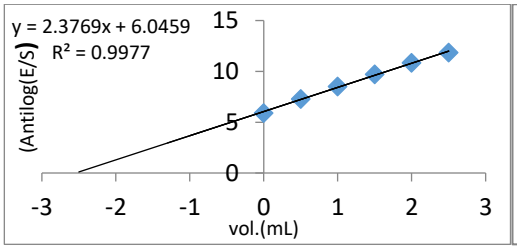

Fig 4. Antilog(E/S) vs. volume of Fexofenadine hydrochloride at 10^{-3}M with using(FEX-DBPH-MPA) electrode.

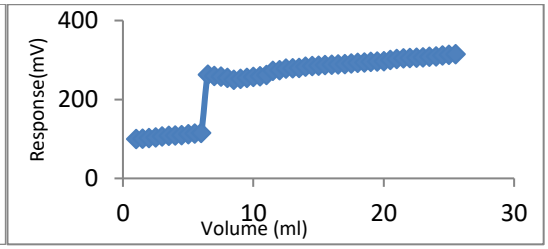

Fig 6. Potentiometric titration of Fexofenadine hydrochloride at 10^{-3}M with using(FEX-DBPH-MPA) electrode.

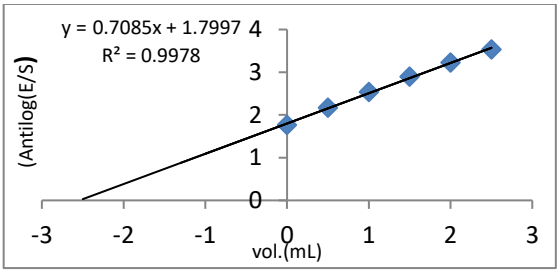

Fig 5. Antilog(E/S) vs. volume of Fexofenadine hydrochloride at 10^{-4}M with using(FEX-DBPH-MPA) electrode.

Table 4: Results by potentiometric methods for (FEX- NPOE-MPA) electrode(.NPOE-MPA) electrode

	Results by potentiometric methods			
Sample	Direct	SAM	SAMS	Titration
1×10^{-3}	0.9732×10^{-3}	0.9906×10^{-3}	0.9941×10^{-3}	0.9835×10^{-3}
%RSD	0.78	0.62	-	-
%Rec	97.32	99.06	99.41	98.35
%RE	-2.68	-0.94	-0.59	-1.65
1×10^{-4}	0.9758×10^{-4}	0.9895×10^{-4}	0.9814×10^{-4}	0.9823×10^{-4}
%RSD	0.79	0.65	-	-
%Rec	97.58	98.95	98.14	98.23
%RE	-2.42	-1.05	-1.86	-1.77

*n=5

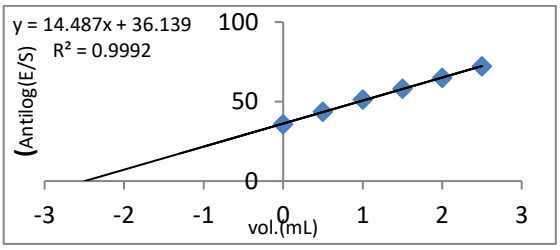

Fig 7. Antilog(E/S) vs. volume of Fexofenadine hydrochloride at 10^{-3}M with using(FEX-NPOE-MPA) electrode**.**

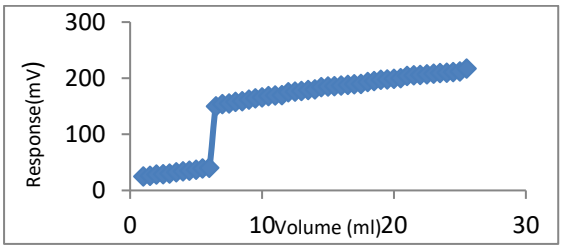

Fig 9. Potentiometric titration of Fexofenadine hydrochloride at 10^{-3}M with using(FEX-NPOE-MPA) electrode.

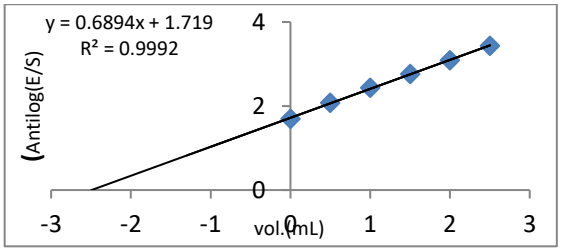

Fig 8. Antilog(E/S) vs. volume of Fexofenadine hydrochloride at 10^{-4}M with using(FEX-NPOE-MPA) electrode.

Table 5
Sample analysis for tablets using the Fexofenadine hydrochloride selective electrode based on DDBH plasticizer using the direct potentiometric method.

Pharmaceutical tablets	Fexotel (120mg) tablets	Fexodine(120mg) tablets
Concentration of FXE(prepared)	1×10^{-3}	1×10^{-3}
Concentration of FXE(found)	0.9765×10^{-3}	0.9651×10^{-3}
%Rec	97.65	96.51
%Er	-2.35	-3.49

*n=3

3.5. Comparison Study

The potentiometric properties with respect to detection limit, selectivity, impact of pH, straight range, and lifetime of the Fexofenadine hydrochloride electrodes were contrasted and those revealed for Fexofenadine hydrochloride ion selective electrodes were recorded in Table 6. Depended on this comparison study, Fexofenadine hydrochloride electrodes offered potentiometric properties practically identical now and again (Limit of detection, slope, influence of pH, linear range, and life of time) with those detailed in written works. Accordingly, the benefits offered by the Fexofenadine potentiometric electrodes close to electrodes of Fexofenadine hydrochloride recently detailed in writing for this drug include high sensitivity, scope of pH, lifetime, detection limit, and linearity.

Table 6: Comparison between potentiometric characters of different Fexofenadine hydrochloride electrodes.

Parameters	FEX-MPA-DBPH	FEX-MPA-NPOE	Reference[26]	Reference[27]
Slope (mV/decade)	57.01	56.70	62.3 ± 0.7	$- 59.23 \pm 0.05$
Linear range (mol.L^{-1})	8.0×10^{-6}-1.0×10^{-1}	1.31×10^{-5}-1.0×10^{-2}	1×10^{-2} -2.5×10^{-6}	1.0×10^{-2}-1.0×10^{-5}
Limit of detection(mol.L^{-1})	5.6×10^{-6}	3.5×10^{-6}	1.3×10^{-6}	1.4×10^{-8}
Working pH range	2.0-4.5	2.0-4.5	5.0 – 8.0	5.5-8.0
Lifetime(day)	41	36	-	69

4. Conclusion

This work was in the field of electrochemical for the evaluation of Fexofenadine hydrochloride drug to give critical results the extent that discovery limit, long lifetime, with selectivity. The results showed that the progressed technique was exact, precise, touchy for the assurance of the drug as unadulterated structure and drug concentrations. In light of the results, it will in general be offered an incredible and adaptable scientific strategy just as a huge direct powerful reach, with moderately ease instrumentation for the affirmation of drug, so we propose using this sort of electrodes in the investigation of medication.

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