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Non-aqueous Potentiometric Estimation of Drugs Paracetamol and Aceclofenac in Double Component Pharmaceuticals

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Abstract

Non-aqueous potentiometric estimation of drugs paracetamol and aceclofenac in double component pharmaceuticals by the use of solvent isopropyl alcohol and titrant potassium hydroxide in isopropyl alcohol has been performed using a pair of platinum and saturated calomel electrodes. Drugs paracetamol and aceclofenac are distinctly acidic in nature. In medicines, there is wide use of these drug combinations. Non-aqueous potentiometric titration method has been found to be very much suitable and most accurate for assay of double component pharmaceuticals. Results obtained are comparable to those obtained by method given in Indian Pharmacopoeia (IP).

Keywords : Non-aqueous, potentiometric, paracetamol, aceclofenac, pharmaceuticals

INTRODUCTION

Non-aqueous potentiometric estimation by the use of different electrode pairs was reported in some communications[1-3]. Various techniques, methods were suggested for the determination of combination drugs. These are mostly deals with separation of components present in drug followed by estimation of individual components with suitable technique. Estimation of combination drugs can be performed by different methods given in pharmacopoeias[4-6]. Estimation of combination drugs paracetamol-barbitone, paracetamol-salicylamide, paracetamol-aspirin by differentiating potentiometric titrations have been reported earlier[2,7-9]. Estimation of double and triple component mixtures of drugs paracetamol-aceclofenac and paracetamol-aceclofenac-chlorzoxazone have been found to be performed earlier by the techniques viz. spectrophotometry and chromatography[10,11]. Determination of paracetamol-aceclofenac combination drug by non-aqueous potentiometric titration using a pair of platinum and saturated calomel electrodes and solvent isopropyl alcohol was not so far reported. Both the drugs paracetamol and aceclofenac are distinctly acidic in nature, so owing to their hydrolysis, these could not be titrated directly with aqueous alkali. Again basic titrants are superior to the alkoxide solvents, which are more susceptible to the atmospheric moisture and carbondioxide.

For estimation of double component pharmaceuticals, here simple, precise method is given which will help the analysis of raw materials and products for quick check of spurious drugs that are feared to penetrate the markets. Present work deals with the non-aqueous potentiometric estimation of drugs paracetamol and aceclofenac in double component pharmaceuticals using a pair of platinum and saturated calomel electrodes and solvent isopropyl alcohol, without prior separation of drug components.

MATERIAL AND METHODS

Digital potentiometer (Equiptronics, EQ-602) was used to perform all titrations. Platinum and saturated calomel electrodes were used as an indicator and reference electrode respectively. For weighing the chemicals and drugs, Precisa-310-M (±0.001 g) balance was used. All chemicals and solvents used were of AR grade. Solvents were purified and made anhydrous by standard methods[12]. During estimation, titrants were protected from atmospheric moisture and carbondioxide. Drugs selected for given study are of pharmaceutical nature and obtained from pharmaceutical laboratories. These drugs are included in pharmacopoeias[6-8].

For the present study, ten tablets of the same batch of paracetamol-aceclofenac combination pharmaceuticals were weighed accurately and powdered. Powder equivalent to 325 mg of paracetamol and 100 mg of aceclofenac was accurately weighed. It was treated with 50 ml of isopropyl alcohol and stirred vigorously to dissolve active component of the tablets. Binding agents and fillers remained insoluble. Common additives present in tablets are calcium carbonate, glucose, lactose, starch, gum etc. and are mostly insoluble in isopropyl alcohol. Solutions were filtered, residues were washed twice and volumes of solutions were made to 100 ml with isopropyl alcohol. 10 ml aliquots of these solutions were diluted to 20 ml using isopropyl alcohol and titrated potentiometrically with 0.1 M solution of potassium hydroxide in potentiometrically using a pair of platinum and saturated calomel electrodes. Standardization of titrant was done by potentiometric titration using 0.1 M benzoic acid in isopropyl alcohol. End points were determined by plotting the graphs and then amount of drugs present in titrated weights of tablet powder was calculated. On the basis of average weight of tablet, amount of active components (drugs) present in single tablet was calculated. Then after, same tablets were analyzed by method given in pharmacopoeias for the purpose of comparison of results.

RESULTS AND DISCUSSION

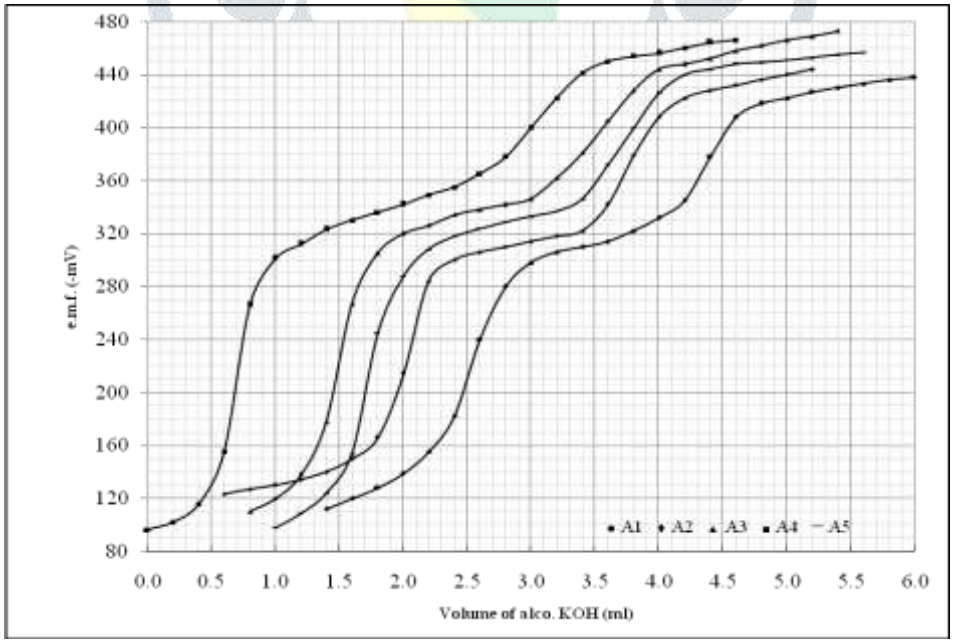
Ten tablets of drugs paracetamol and aceclofenac of same batch were weighed accurately and powdered. Amount of powder equivalent to 325 mg of paracetamol and 100 mg of aceclofenac was accurately weighed, extracted with isopropyl alcohol and the volume was made to 100 ml. 10 ml aliquot of this solution was diluted to 20 ml with isopropyl alcohol and titrated with potassium hydroxide in isopropyl alcohol using potentiometer. Titrant was standardized using standard benzoic acid in isopropyl alcohol by potentiometric titration. Weight of paracetamol and aceclofenac drugs present in titrated amount of tablets was calculated. Same tablets were analyzed by IP method and results for five tablets of different brands are tabulated. It was observed that, present non-aqueous potentiometric titration method gives fairly accurate and comparable results to those obtained by IP method (**Table-1**). Present method is simple, precise and free

from indicator error or interferences. Acidic drugs get hydrolyzed in presence of aqueous alkali, but this is avoided in non-aqueous medium. As per the procedure given in US Pharmacopoeia, alcoholic solution of acidic drugs is to be titrated with aqueous alkali and such a titration must be done quickly so as to minimize hydrolysis. Present method has not such type of limitations. Most common additives present in the tablets are calcium carbonate, sugars, gum etc., these are insoluble in isopropyl alcohol and do not affect the results. Solvent isopropyl alcohol can be used as a good differentiating solvent. Here, potentiometric breaks obtained are very much pronounced and prominent with minimum error using solvent isopropyl alcohol (**Graph-1**). Near end point, solvent isopropyl alcohol permitted a large change in solvated proton concentration. Isopropyl alcohol can be purified and made anhydrous very easily. Its dielectric constant is smaller. Present method is simple than other methods where components are first separated and then determined by the techniques spectrophotometry, chromatography or other.

Table-1 : Estimation of paracetamol-aceclofenac combination pharmaceuticals

Sample	Weight Claim by Label (mg)		Weight Found by IP method (mg)		Weight Found by present method (mg)	
	Paracetamol	Aceclofenac	Paracetamol	Aceclofenac	Paracetamol	Aceclofenac
PA-1	325	100	323.82	99.32	324.78	99.87
PA-2	325	100	324.06	99.81	324.61	99.94
PA-3	325	100	323.78	99.68	324.55	99.77
PA-4	325	100	323.96	99.72	324.47	99.88
PA-5	325	100	324.27	99.81	324.89	100.02

Graph-1 : Estimation of paracetamol-aceclofenac combination pharmaceuticals



CONCLUSION

Non-aqueous potentiometric estimation of drugs paracetamol and aceclofenac in double component pharmaceuticals is most simple and precise method. It can be carried out without using any type of sophisticated instruments in all common laboratories. A pair of platinum and calomel electrodes gave stable

potentials and attained quickly. Solvent isopropyl alcohol was found to be excellent for titration of drugs in non-aqueous condition and gave very good results. Potassium hydroxide in isopropyl alcohol was found to be better basic titrant to the alkoxide solvents that are susceptible to atmospheric moisture and carbondioxide.

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