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GREEN UV SPECTROPHOTOMETRIC METHOD FOR ASSAY OF PROPRANALOL HYDROCHLORIDE TABLETS

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ABSTRACT

Spectrophotometric analysis of majority of water insoluble drugs includes use of organic solvents like methanol, ethanol, chloroform, benzene, dichloromethane, dimethyl formaldehyde, toluene, acetone, hexane for extraction purpose. The primary disadvantage of organic solvents is their high cost and disposal issue along with the toxicity associated with them. Their long term exposure causes serious effects such as neurological disorders, chronic renal failure and liver damage. Therefore there is need for the development of alternative nature friendly methods for solubilization of such drugs. Techniques namely hydrotropy and mixed-solvency are available in the literature for solubilization of such drugs. The present investigation is an attempt to show application of hydrotropic technique using aqueous solutions of Sodium acetate and Sodium citrate for extraction of poorly water soluble drug, Propranolol hydrochloride from its tablet formulation. Recovery studies and statistical data proved the accuracy, reproducibility and precision of the proposed method.

KEYWORDS: Sodium acetate, Sodium citrate, Propranolol hydrochloride (PHL), Specific absorbance method.

1. INTRODUCTION

Spectrophotometric methods of analysis for quantitative estimation of a single component analysis are based on the measurement of absorbance by the solution of the drug which is further related to its concentration as per the Beer Lambert's Law. This necessitates complete extraction of drug with a UV compatible solvent from its dosage form.

Extraction of water soluble drug is not a problem but the extraction of water insoluble drug is a challenge for accurate determination of drug content. In most of the cases, organic solvents are used for solubilization of such drugs. However organic solvents suffer from the disadvantage of high cost, toxicity and pollution. Hence there is need for efficient extraction methods which are eco-friendly and can give similar results without using organic solvents.

The literature survey reveals that the UV-spectrophotometric estimation of poorly water soluble drugs could be conducted successfully by using the approach of hydrotropic solubilization technique.[1-5] Hydrotropy, proposed by Maheshwari is a solubilization technique in which addition of large amount of a second solute results in an increase in the aqueous solubility of another solute.[6-8] The hydrotropic agents are defined as non-micelle-forming substances, either liquids or solids, organic or inorganic, capable of solubilizing water insoluble compounds. The aqueous solubility of many drugs like nalidixic acid, norfloxacin, tinidazole, metronidazole, metformin hydrochloride, etc were found to be enhanced by the incorporation of sodium citrate, sodium salicylate, sodium ascorbate, potassium acetate as hydrotropic solubilizers. The present investigation is an attempt to apply the concept of solid as solvents for quantitative analysis of tablet formulation containing Propranolol hydrochloride (PHL). PHL, {$C_{16}H_{21}NO_2$, HCl} is (RS)-1-[(1-methylethyl) amino]-3-(naphthalen-1-yloxy)propan-2-ol hydrochloride. It is used in arrhythmia, hypertension and angina. It is available in various dosage forms like tablet, capsule, injection and oral solution.

Around 40 different brands of PHL tablet formulations are available in the Indian market. IP 2010 mentions UV spectrophotometric method based on specific absorbance A (1 percent, 1 cm) for assay of PHL tablets.[9] A (1 percent, 1 cm) refers to the absorbance of a 1 percent w/v solution in a 1cm cell and measured at a defined wavelength. The value of A (1 percent, 1 cm) at a particular wavelength in a given solvent is a property of the absorbing substance. The IP method however uses methanol as the solvent. As per the ICH Guidelines Q3C (R7), Guidelines for Residual solvents, methanol comes under Class II solvents.[10] Class II

includes non-genotoxic animal carcinogens or possible causative agents of other irreversible toxicity such as neural toxicity or teratogenicity which are recommended for limited use.[18] Permitted Daily exposure value of methanol is 30 mg per day. It also has various drawbacks such as high cost, toxicity and pollution.

In this research work we have tried to replace methanol with aqueous solutions of sodium acetate and sodium citrate as solvents for extraction of PHL from its formulation prior to its UV spectrophotometric analysis.

2. EXPERIMENTAL

2.1 MATERIALS AND METHODS

Commercial tablets of PHL of three different brands namely Ciplar (10mg), Inderal (10mg), and BetaCap (20mg) were procured from the local market. All other reagents like Methanol, Sodium citrate, Sodium acetate were of AR grade procured from Research-lab fine chem industries.

A Shimadzu-1700 UV visible spectrophotometer with 1 cm matched silica cells was used for spectrophotometric analysis.

2.2 Preparation of solutions of Sodium acetate and Sodium citrate

41.01 gm and 8.203 gm of Sodium acetate were weighed and dissolved in distilled water to make individual 1000 ml of solutions having strength of 0.5M and 0.1M respectively.

129.03gm and 25.80 gm of Sodium citrate were dissolved in distilled water to make individual 1000 ml solution having strength of 0.5M and 0.1M respectively. All the solutions were scanned in the UV-visible range from 200 nm-800 nm.

2.3 Assay procedure for PHL tablets

20 tablets of each of the selected three brands were separately weighed and powdered. For each brand of tablet, a quantity of the powder equivalent to 20 mg of PHL was weighed and shaken with 20 ml of water for 10 minutes. To the flask 50 ml of 0.1M solution of Sodium acetate was added and the mixture was shaken further for 10 minutes using magnetic stirrer. Volume was made up to the mark using 0.1M solution of Sodium acetate. The resulting solution was filtered and 10 ml of the filtrate was diluted to 50 ml with 0.1 M Sodium acetate solution. The absorbance of the resulting solution was measured at the maximum at about 290 nm using 0.1 M Sodium acetate as blank. The content of $C_{16}H_{21}NO_2$, HCl was

determined taking 206 as the specific absorbance at 290 nm. The assay procedure was repeated using 0.5 M solution of Sodium acetate and 0.5M and 0.1M solution of Sodium citrate.

3. RESULTS AND DISCUSSION

In order to replace methanol from the IP procedure mentioned for UV Spectrophotometric assay of PHL tablet, a concept of hydrotropy was used. Two commonly available reagents namely sodium acetate and sodium citrate were employed as the hydrotropic agents in different strengths of 0.1N and 0.5 N. For these solutions to be used in UV spectrophotometric analysis of PHL, it was necessary to check that all four solutions namely 0.1 N and 0.5 N solutions of sodium acetate and sodium Citrate are transparent in the UV region of electromagnetic radiations and especially at 290 nm, which is the wavelength maximum of PHL.

The UV spectral scans of 0.5 M solutions of sodium acetate and sodium citrate are shown in figure number 1. The scans indicated that all the solutions proposed to be used as extracting solvents are transparent above 240 nm and won't interfere in the absorbance measurement of PHL at 290nm.

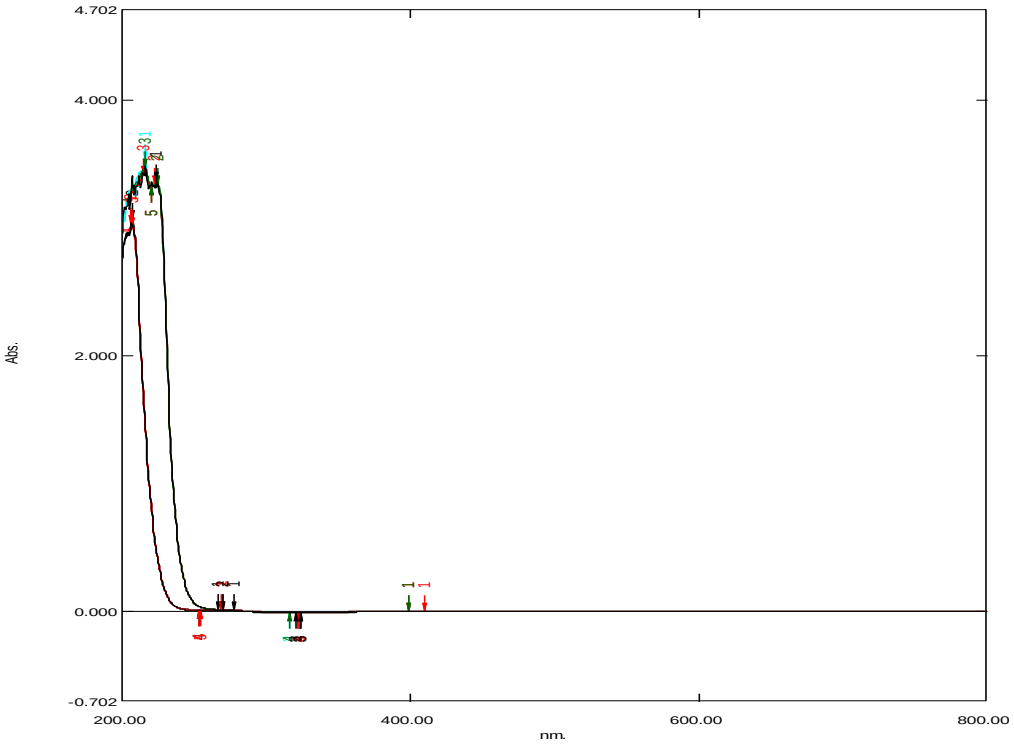

Figure number 1: Overlain Spectra of 0.5M solutions of Sodium acetate and Sodium Citrate.

Table 1: Analysis data of PHL tablet formulation using Sodium acetate solution with statistical evaluation.

Tablet Formulation	Label Claim (mg/tablet)	Percent drug estimated using Sodium acetate solution (mean ±SD)		Percent coefficient of variation using Sodium acetate solution	
		0.1M solution	0.5 M solution	0.1 M solution	0.5 M solution
Ciplar	10	102.3±0.992	99.8±0.239	97.9±0.981	93.75±1.007
Beta Cap	10	97.9±1.127	93.75±1.069	105±0.984	103.7±0.937
Inderal	10	105±1.009	103.7±0.997	102.3±1.009	99.8±0.994

Table 2: Analysis data of PHL tablet formulation using Sodium citrate solution with statistical evaluation.

Tablet Formulation	Label Claim (mg/tablet)	Percent drug estimated using Sodium citrate solution (mean ±SD)		Percent coefficient of variation using Sodium citrate solution	
		0.1 M solution	0.5 M solution	0.1 M solution	0.5 M solution
Ciplar	10	96.11±1.221	93.44±1.007	97.11±1.067	98.91±0.989
Beta Cap	10	93.75±0.997	98.65±1.018	94.32±1.228	98.98±0.997
Inderal	10	105.00±0.891	102.40±1.089	99.27±1.337	99.51±1.053

Table 3: Results of recovery studies for PHL tablet formulation using Sodium acetate solution with statistical evaluation (n=3).

Tablet Formulation	Drug in pre-analyzed tablet powder (mg)	Amount of standard drug added (mg)	% Recovery estimated using Sodium acetate solution (mean ±SD)		Percent coefficient of variation	
			0.1 M solution	0.5M solution	0.1M solution	0.5 M solution
Ciplar	10	2	97.81±1.005	96.15±1.046	97.11±1.067	98.91±0.989
Beta Cap	10	2	99.70±1.221	98.99±1.027	94.32±1.228	98.98±0.997
Inderal	10	2	99.65±1.007	98.07±1.038	99.27±1.337	99.51±1.053

Table 4: Results of recovery studies for Propranolol Hydrochloride tablet formulation using Sodium citrate solution with statistical evaluation (n=3).

Tablet Formulation	Drug in pre-analyzed tablet powder (mg)	Amount of standard drug added (mg)	% Recovery estimated using Sodium citrate solution (mean ±SD)		Percent coefficient of variation	
			0.1 M solution	0.5 M solution	0.1 M solution	0.5 M solution
Ciplar	10	2	98.81±1.135	98.97±1.025	98.91±1.031	99.51±1.053
Beta Cap	10	2	99.50±1.019	98.30±1.031	99.80±1.009	99.70±1.127
Inderal	10	2	97.68±1.117	99.28±1.219	98.62±1.071	98.52±1.352

The UV Spectrophotometric assay method mentioned in the research work is new, simple and environment friendly. This method has advantage over the conventional method which uses methanol for extraction of drug from the tablets. Apart from this, if this method is validated, it may prove boon to analysts as it will reduce the cost of analysis. This would definitely serve as a new approach in green chemistry being related with reduction in use of organic solvents.

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