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Difference spectrophotometric estimation and validation of ibuprofen from bulk and tablet dosage form

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ABSTRACT

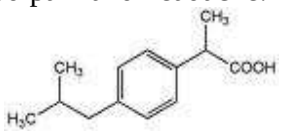
Simple, sensitive and specific spectrophotometeric method were developed and validated for quantification of ibuprofen by difference spectroscopy. Ibuprofen exhibits a substantial difference in absorbance in the two solvents that is in 0.1 N HCL and 0.1 N NaoH at 222 nm. Beer's law was obeyed in the concentration range of 5 to 40 µg /ml for ibuprofen. Results of tablet analysis showed standard deviation in the range of 0.3694 to 1.851 for ibuprofen which indicate repeatability of the method. The results indicated excellent recoveries ranging from 101.13 to 101.23% for ibuprofen with a mean of 101 %. Recoveries obtained do not differ significantly from 100% showed that there was no interference from the common excipients used in the tablet formulation indicating accuracy and reliability of the method.

Key Words: Ibuprofen, Difference Spectroscopy.

INTRODUCTION

The analytical chemistry has challenge in developing various methods for analysis with the help of number of analytical techniques which are available for estimation of the drugs and their combination1. Analytical monitoring of pharmaceutical product or of specific ingredients within the product is necessary to ensure the safety and efficacy throughout the shelf life, including storage, distribution and use2. The selectivity and accuracy of spectrophotometric analysis of samples containing absorbing interferences may be markedly improved by the technique of difference spectrophotometry3. This is simplest and most commonly employed technique for altering the spectral properties of the analyte is the adjustment of pH by means of aqueous solution of acid, alkali, or buffer4. The ultraviolet-visible absorbance spectra of many substances containing ionizable functional group e.g. phenols, aromatic carboxylic acids and amines are dependent on the state of ionization of the functional groups and consequently on the pH of the

solution5. Ibuprofen is a non steroidal anti –inflammatory drug.Ibuprofen is an anti-inflammatory pain killer. It is used to relieve pain and redness in conditions such as osteoarthritis, arthritis, swollen joints, frozen shoulder, bursitis, tendinitis, lower back pain, sprains and strains. It can also be used in the treatment of other painful conditions such as toothache, pain after operations, period pain and headache.



Ibuprofen

MATERIALS AND METHODS

Apparatus

The instrument used for the present study was Jasco UV-Visible double beam Spectrophotometer with 1 cm matched pair quartz cell and spectral bandwidth of 2 nm..

Reagents and materials

Ibuprofen obtained as a gift sample. Distilled water was used throughout the experiment in a tablet dosage form Ibuprofen containing tablet were purchased from local commercial sources.

Standard solution

Selection of Common Solvent

0.1 N HCL and 0.1 N NaoH was selected as a common solvent for developing spectral characteristics of drug. The selection was made after using different acids and bases and their different normality's.

Preparation of Standard Drug Solution

Standard stock solution containing Ibuprofen was prepared by dissolving 10 mg of Ibuprofen separately in 50 ml of 0.1 N HCL and 0.1N NaoH sonicated for 5 min, and then final volume of both solutions was made up to 100 ml with same solvents to get stock solution containing 100 µg/ ml. Ibuprofen in 0.1 N HCL and 0.1 N NaoH in two different 100 ml volumetric flasks.

Determination of Sampling Wavelength for Simultaneous Analysis

By appropriate dilution of two standard drug solutions with 0.1 N HCL and 0.1 N NaoH solutions containing 10 µg /ml of ibuprofen were scanned separately in the range of 200-400 nm to determine the wavelength of maximum absorption for the drug. The difference spectrophotometric method developed for analysis of ibuprofen and one wavelength was selected for estimation of Ibuprofen from the overlain spectra as shown as **Fig. No.2** and **Fig. No.3**

Selection of Method and Wavelengths

Difference spectrophotometric method is used for determination of Ibuprofen. The wavelength was selected for estimation of ibuprofen from the overlain spectra as shown in **Fig.4.** Ibuprofen was estimated by recording the absorbance difference in 0.1N HCL and 0.1 N NaoH at 222 nm and results are shown in **Table no.1**

Fig(1) Linearity of ibuprofen

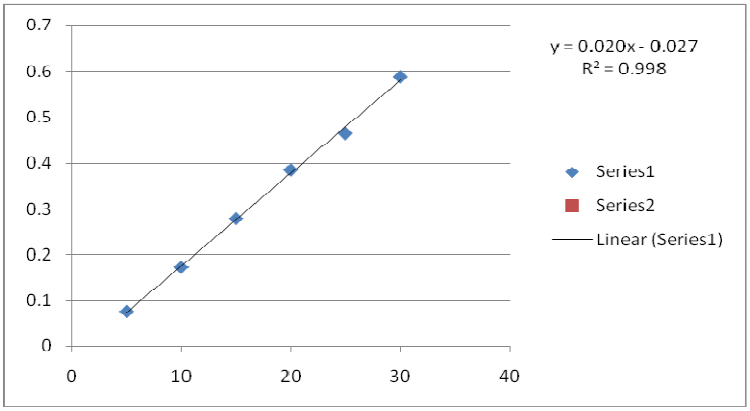


Fig.2 Spectra of ibuprofen in 0.1N HCL

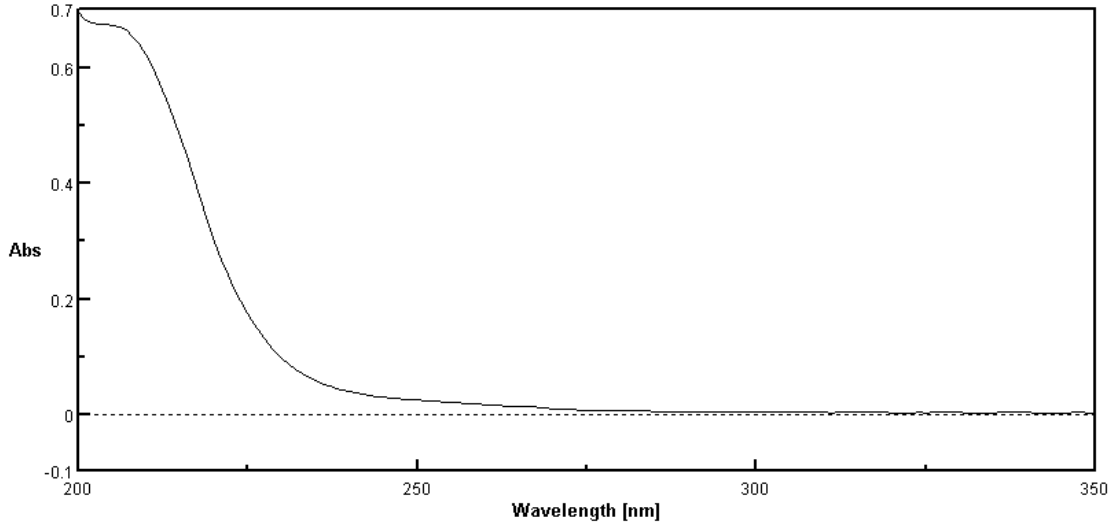


Fig. 3 Spectra of ibuprofen in 0.1N NaOH

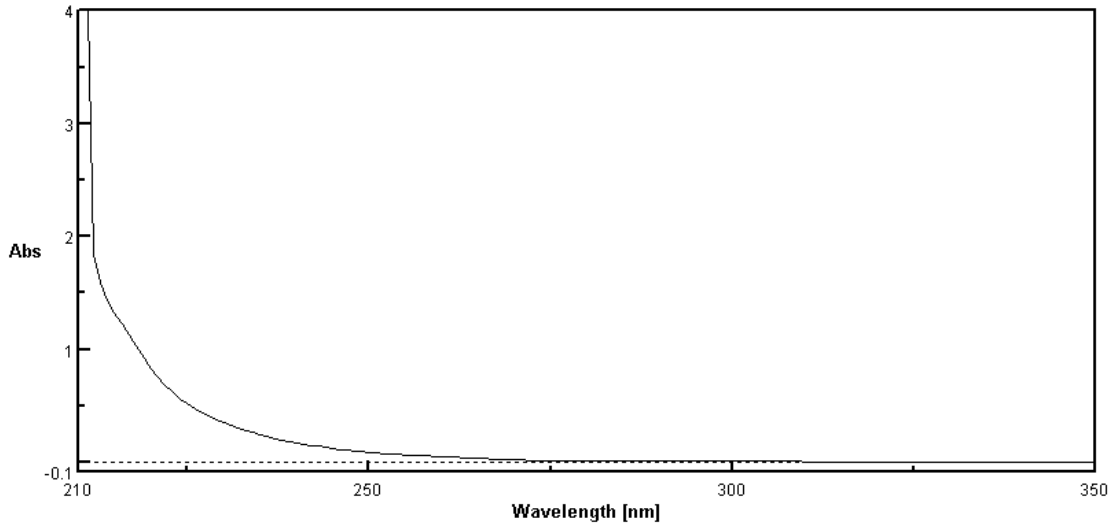
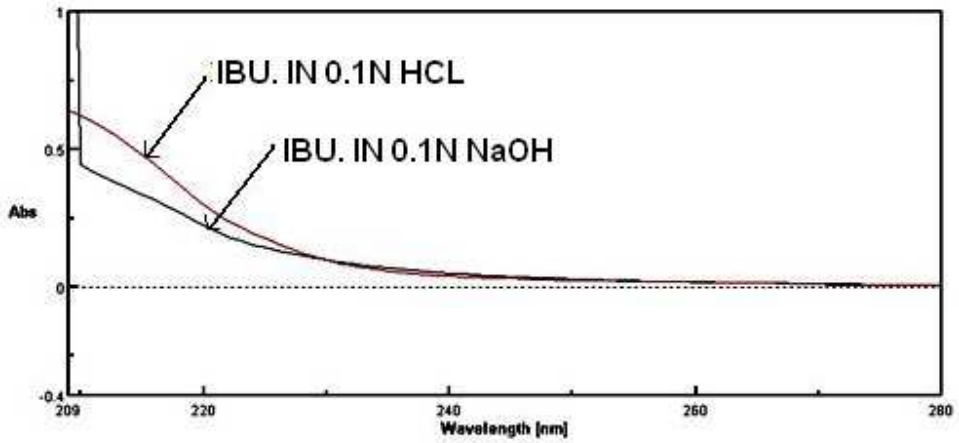


Fig. 4: Overlain spectra of Ibuprofen in 0.1 N HCl and 0.1 NaOH



IBU-Ibuprofen

Procedure for Plotting Calibration Curve

From standard stock solution of drug six working standard solutions prepared and scanned in the wavelength range of 200-400 nm. The appropriate aliquots of drug were pipette out from standard stock solution of the drug in 0.1 N HCL and 0.1 N NaoH into series of 10 ml volumetric flask. The volume was made up to mark to get solution of concentration 5-40µg/ml ibuprofen in both 0.1 N HCL and 0.1 N NaoH separately. Calibration curve was constructed at wavelengths 222 nm by recording absorbance difference between two solvents against concentration of drug. Ibuprofen obeyed Beer's law in the concentration range of 5- 40 µg ml/ml. By using quantitative modes of instrument slope, intercept and correlation coefficient values for calibration curve was obtained.

Analysis of Tablet Formulation

Marketed tablet formulations containing 5 mg of ibuprofen were analyzed by this method. From the triturate of 20 tablets, an amount equivalent to 10 mg of ibuprofen was weighed and transferred to 100 ml volumetric flask. The contents of the flask were dissolved in the 50 ml of the 0.1 N HCL and 0.1 N NaoH separately with the aid of ultrasonication for 10 min. The solution was filtered through Whatmann filter paper no. 41 and then final volume of the solution was made up to 100 ml with same solvents to get a stock solution containing 100 µg/ml of ibuprofen in 0.1 N HCL and 0.1 N NaoH. After appropriate dilutions, the absorbances were measured and the concentration of each analyte was determined with the equations obtained from calibration curve.

Recovery Studies

Accuracy and sensitivity of analysis was determined by performing recovery studies by spiking different concentrations of pure drug in the reanalyzed tablet sample. Results of recovery studies indicated that the method is rapid, accurate and reproducible. The recovery obtained after replicate determinations (n=6) is shown in **Table No.4.**

Method Validation

The proposed method was validated for the following parameter accuracy, precision, repeatability, robustness, linearity, range, sensitivity, limit of detection and quantitation and results are shown in **Table No. 5**

Absorbance values for, calibration curve of Ibuprofen at 222 nm

Table No(1)Result of data characteristics of ibuprofen

Parameters	Values of Ibuprofen
Working λ nm	222
Beer's Law Limit(µg/ml)	5-40
Absorbtivity Value (Mean)	0.018
Correlation coefficient	0.998
Intercept	0.027
Slope	0.020

Table No (2)Result Of Sample Analysis

Sr.no	Conc. (µg/ml)	Absorbance	% conc. Estimated	S.D	S.E	C.V
1	**5**	**0.0754**	**101.13**	**±1.851**	**0.0366**	**0.0487**
2	**10**	**0.172**				
3	**15**	**0.278**				
4	**20**	**0.384**				
5	**25**	**0.464**				
6	**30**	**0.587**				

Result of validation parameters

Analyte	Parameters	Interday	Intraday	Different Analyst
Ibuprofen	**Percentage Recoverd (mean)**	**100.77**	**101.68**	**101.23**
	S.D	**±0.9890**	**±0.3495**	**±0.3694**
	C.V	**0.05841**	**0.04501**	**0.154**

RESULT AND DISCUSSION

Ibuprofen exhibits a substantial difference in absorbance in the two solvents that is in 0.1 N HCL and 0.1 N NaoH at 222 nm so determination of ibuprofen by difference spectroscopic method was thus attempted. Beer's law was obeyed in the concentration range of 5 to 40 µg ml/1 for ibuprofen. Interday and intraday studies showed high degree of repeatability of an analytical method under normal operating conditions. Results of tablet analysis showed standard deviation in the range of 0.3694 to 1.851 for ibuprofen which indicate repeatability of the method. The accuracy of the method was determined by investigating the recovery of the drugs using spiked concentrations of the standard drug. The results indicated excellent recoveries ranging from 101.13 to 101.23 % for ibuprofen with a mean of 101%. Recoveries obtained do not differ significantly from 100% showed that there was no interference from the common excipients used in the tablet formulation indicating accuracy and reliability of the method. Precision for tablet analysis was determined by analysis of tablets containing ibuprofen.

CONCLUSION

The accuracy of the method was determined by estimating the recovery of Ibuprofen. Accuracy of analysis was determined by performing recovery studies by spiking different concentration of

pure drug in the preanalyzed tablet samples. Results of recovery studies indicated that the method of precise, accurate and reproducible. The proposed method for different spectrophotometric estimation of Ibuprofen was found to be simple, accurate and reproducible for routine estimation of Ibuprofen in tablet formulation. The recoveries obtained from table no.5 for each drug do not differ significantly from 100 % and there were no interferences from common excipients used in the formulation indicating accuracy and reliability of the method.

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