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VALIDATED SPECTROSCOPIC METHOD FOR ESTIMATION OF IBUPROFEN FROM TABLET FORMULATION

Rupali Kirtawade*, Chhotaram Seervi, Pallavi Salve,Kiran patil. Prof. Anita Kulkarni , Prof. Pandurang Dhabale.

Govt. College of Pharmacy, Karad.

Ibuprofen is a non steroidal anti-inflammatory drug with good analgesic and anti-rheumatic properties. Various methods for analysis of the same are available but are time consuming and expensive. Here we have developed a new, precise and simple UV spectrophotometric method for estimation of ibuprofen from tablet formulation. The drug obeyed the Beer's law and showed good correlation. Absorption maxima of ibuprofen in 0.1 N sodium hydroxide was found to be at 221nm. Beer's law was obeyed in concentration range 5 – 25 mcg/ml. The results of analysis were validated by recovery studies. The recovery was more than 99%. The method was found to be simple, accurate, precise, economical and robust.

KEY WORDS: Accuracy, Ibuprofen**,** Recovery ,UV spectrophotometry.

INTRODUCTION:

Ibuprofen is chemically 2[4-(2-methyl propyl) phenyl] propanoic acid. The structural formula is $C_{13}H_{18}O_2$, and molecular weight is 206. It is non-steroidal anti inflammatory drug (NSAID). It is used for relief of symptoms of arthritis, primary dysmenorrheal, and fever and as an analgesic. Ibuprofen is known to have an anti platelet (blood-thinning effect. Paracetamol is chemically N-(4-hydroxyphenyl) acetamide. It is a centrally and
peripherally acting non-opioid analgesic and antipyretic. Many methods have been described in the literature for the determination of paracetamol with other drugs individually and in combination.[1-11] To overcome these difficulties spectrophotometric analysis serves to be the quickest, promising and reliable method for routine analytical needs. The aim of the present study is to develop a new simple, rapid, reliable and precise UV spectrophotometric method for analysis of ibuprofen from tablet formulation; method is based on measurement of UV absorbance of ibuprofen in 0.1 N sodium hydroxide.

MATERIALS AND METHODS:

Apparatus:

Spectral runs were made on a Shimadzu UV-Visible spectrophotometer, model- 1700 (Japan) was employed with spectral bandwidth of 1 nm and wavelength accuracy of ± 0.3 nm with automatic wavelength corrections with a pair of 10 mm quartz cells. Glasswares used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven.

Reagents and Solution:

All the reagents used in this assay were of analytical grade and the reagent solutions were prepared using preanalysed double distilled water. Ibuprofen pure drug was obtained as a gift sample from BPL Pharmaceuticals (P) Ltd. Mumbai. Tablets of ibuprofen were purchased from local market for analysis 0.1 N sodium hydroxide was used as a solvent for the spectrophotometric estimation.

EXPERIMENTAL:

Determination of λmax:

Weighed an accurate amount 10mg of ibuprofen was dissolved in 20ml 0.1 N sodium hydroxide and diluted up to 100ml by same to obtain a 100mcg/ml concentration of ibuprofen in solution. This solution was subjected to scanning between 200 – 400 nm and absorption maxima at 221nm were determined. The effect of dilution on absorption maxima was studied by diluting the above solution to 25mcg/ml and scanned from 200 – 400nm.

Table No. I: Optical characteristics and Other Parameters

Absorption maxima	221 nm
Beer's law limit	5 – 25 mcg/ml
Coefficient of Correlation	0.99967
Regression equation	Y = 0.03824 X + 0.0736
Slope	0.03824
y intercept	0.0736
Molar absorptivity (lit/mole/cm)	7888.9099
Sandell's sensitivity (mcg/Sq.cm/0.001)	0.026151

Standard Stock Solution:

A stock solution containing 1000mcg/ml of pure drug was prepared by dissolving accurately weighed 100mg of ibuprofen in 20ml 0.1 N sodium hydroxide made up to 100ml mark by same to produce 100ml solution in a volumetric flask

Working standard solution:

10 ml of the stock solution was further diluted to 100ml with 0.1 N sodium hydroxide to obtain a working standard solution containing 100mcg/mL.

Table No. II Result of Analysis of Ibuprofen in Tablet.

Formulation	Label Claim (mg)	% Label Claim found	SD*
Tablet I	200	99.26%	0.3486
RSD*	Standard error	% Recovery	
0.003512	0.201307	99.69%	

* indicates mean of six determinations

Linearity and Calibration:

The aliquots working standard solution was diluted serially with sufficient 0.1 N sodium hydroxide to obtain the concentration range of 5–25mcg/ml. A calibration curve for ibuprofen was obtained by measuring the absorbance at the λmax of 221 nm. Statistical parameters like the slope, intercept, coefficient of correlation, standard deviation, relative standard deviation, and standard error were determined.

Analysis of Marketed Tablet Formulation:

Accurately weighed the 20 tablets of Brufen200 (Abbott India Ltd,Mumbai) and powdered. The powder equivalent to 100mg of ibuprofen was transferred to 100ml volumetric flask and 20ml 0.1 N sodium hydroxide is added to dissolve the ibuprofen in it and made the volume to mark with same. This mixture was sonicated for 15 minutes and filtered through Whatmann filter paper No. 41. Aliquots (1ml, 2ml, 3ml, 4ml, 5ml) of the sample were removed and diluted to 10 ml with 0.1 N sodium hydroxide diluted with same to obtain strengths as 10mcg/ml, 20mcg/ml, 30mcg/ml, 40mcg/ml and 50mcg/ml and determined the respective absorbance at 221nm against the 0.1 N sodium hydroxide diluted with same as blank. Two different formulations of different manufacturers were used for study.

Recovery studies:

Recovery studies were performed to judge the accuracy of the method. 1ml of standard formulation (100mcg/ml) was taken in three 10ml volumetric flask and to it 80%, 100% and 120% (i.e. 0.8ml, 1.0ml, 1.2ml) of working standard solution (100mcg/ml) added respectively and made the volume up to the mark. The respective absorbance at 221nm was recorded against the blank. The amount of added concentration was determined from the obtained absorbance values and percent recovery was determined for each formulation.

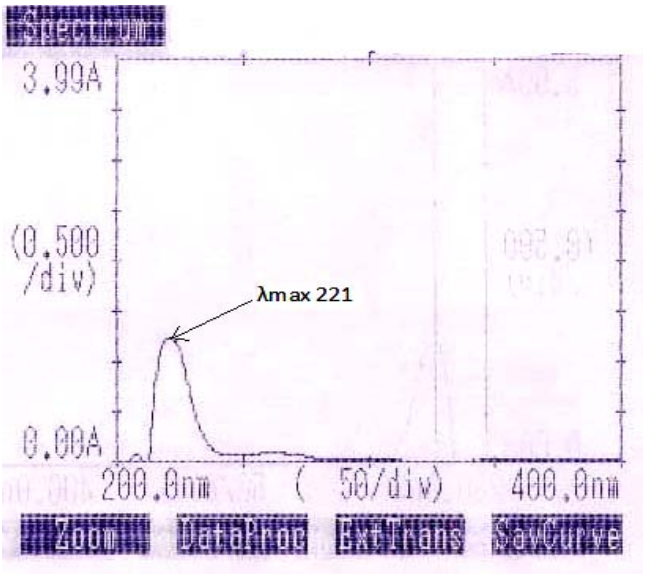
Robustness:

The evaluation of robustness was performed for system suitability to ensure the validity of analytical procedure. This was done by varying the instrument, analyst, and time of study. The analysis was performed on Shimadzu UV-Visible spectrophotometer, model- 1700 (Japan) and UV-Visible Spectrophotometer model -1800 (Japan). Interday and intraday analysis was performed by changing the analyst.

RESULTS:

The UV scan of standard solution between 200 – 400 nm showed the absorption maxima at 221nm,

Fig. 1: UV Scan of Ibuprofen in 0.1 N Sodium Hydroxide.



shown in fig. 1. The Beer's law was verified from the calibration curve by plotting a graph of concentration vs. absorbance. The plot is shown in fig. 2. Regression analysis showed very good correlation. The calibration plot revealed zero intercept which is clear by the regression analysis equation Y = mX + C. (Where Y is absorbance, m is the slope and X is the concentration of ibuprofen in mcg/ml) as obtained by the least square method. The results thus obtained are depicted in Table No. I. The results of analysis for assay and recovery studies for two different formulations were studied and are shown in Table No. II. No significant variations were observed on interday and intraday analysis. Also no significant variations were observed on changing the instrument make and model.

DISCUSSION:

The spectrum of ibuprofen in 0.1 N Sodium Hydroxide showed the absorption maxima at 221 nm. No effect of dilution was observed on the maxima, which confirmed the maxima at 221nm. The statistical analysis of data obtained for the calibration curve of ibuprofen in pure solution indicated a high level of precision for the proposed method, as evidenced by low value of coefficient of variation. The coefficient of correlation was highly significant. The linearity range was observed between 5 – 25 mcg/ml. The plot clearly showed a straight line passing through origin (Y = 0.03824 X + 0.0736). The estimated method was validated by low values of % RSD and standard error, indicating accuracy and precision of the methods. Excellent recovery studies further proves the accuracy of the method. Robustness of the method was studied by varying the instrument, time of study and analyst. Reproducibility of the results confirmed the robustness of the method.

CONCLUSIONS:

From the results and discussion the method described in this paper for the determination of ibuprofen from tablet formulation is simple, accurate, sensitive reproducible and economical. The proposed method utilizes inexpensive solvents. The proposed method could be applied for routine analysis in quality control laboratories.

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