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Development and Validation of UV-Spectrophotometric Method for Estimation of Ibuprofen in Bulk and Marketed Tablets

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ABSTRACT

The aim of present investigation was to develop a simple UV-visible spectrophotometric method for the determination of Ibuprofen (IBF) in its pure form and marketed formulations and to validate the developed method. Ibuprofen was estimated at UV maxima of 222.8 nm in pH 7.2 phosphate buffer using UV-Visible double beam spectrophotometer. Following the guidelines of International Conference on Harmonization (ICH), the analytical parameters like linearity, precision, and accuracy were studied. The obtained results of analysis were validated statistically and by performing recovery studies to confirm the accuracy of the proposed method. In the developed method, linearity over the concentration range of 2-20 µg/ml of IBF was observed and was found in agreement of Beer's law. The linear regression was found to be 0.999. The precision (intra-day & inter-day) of method was found within limits (RSD < 2%). The sensitivity of the method was assessed by determining limit of detection and limit of quantification. It could be concluded from the results obtained that the method for estimation of IBF in pure form and in marketed tablets is simple, rapid, accurate, precise and economical and can be used, successfully, in the quality control of pharmaceutical formulations and routine laboratory analysis.

Keywords: Ibuprofen, UV Spectrophotometer, Inflammation, Validation.

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INTRODUCTION

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAIDs). The chemical name of ibuprofen is 2-(4-isobutylphenyl) propanoic acid. It is prescribed to manage the conditions of mild to moderate pain and also in inflammation conditions which include dys-menorrhoea, headache including migraine, postoperative pain, dental pain, musculoskeletal and joint disorders. It contains chiral carbon atom on the propionic acid side-chain, so it exists as two enantiomers named as S- and R enantionmers. Its pharmacological activity is due to the S-enantiomer. Like acetylsalicylic acid (aspirin), another NSAID, and acetaminophen, ibuprofen works by inhibiting the activity of a class of enzymes called cyclooxygenases (COX). Ibuprofen is characterized by its better tolerability compared with other NSAIDs.[1,2,3]

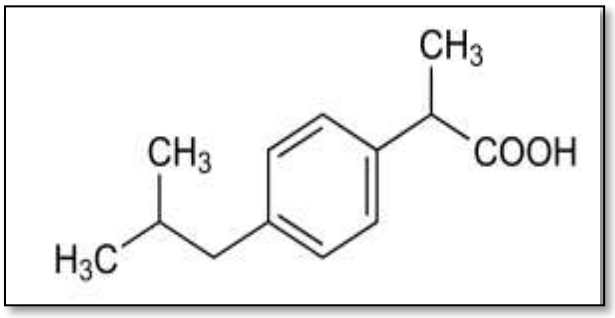

Figure 1: Structure of Ibuprofen

MATERIALS AND METHOD

Materials

Standard sample of Ibuprofen was a kind gift from IOL Chemicals And Pharmaceuticals Ltd., Punjab (India). The marketed Ibuprofen tablets (Brufen) containing 400 mg of Ibuprofen and manufactured by Abbott India Ltd., Goa, India were used for the analysis. All other chemicals used in study were of analytical grade.

Instrumentation

A double beam Systronics UV-Visible Spectrophotometer, model UV-2201 (India) with a spectral bandwidth of 1nm, wavelength accuracy of ±0.5nm and a pair of 1cm quartz cells were used to measure absorbance of the resulting solutions.

Preparation of standard stock solution (1000µg/ml)

Accurately weighed quantity of 100 mg IBF was transferred into 100 ml volumetric flask and dissolved and diluted up to the mark with pH 7.2 phosphate buffer. The solution is sonicated on bath sonicator to get a clear solution having the strength of 1000 µg/ml[4-7].

Preparation of sample stock solution (100µg/ml)

Two tablets of IBF (label claims 400 mg IBF per tablet) were crushed and a weight of the powder equivalent to 100 mg of IBF was transferred to a 100 ml volumetric flask containing pH 7.2 phosphate buffer and the mixture was sonicated for 1 minute and made up the volume with pH 7.2 phosphate buffer (stock solution). The solution was filtered.

VALIDATION OF UV SPECTROPHOTOMETRIC METHOD

Linearity and range

To determine the linearity, five independent levels of calibration curve were analyzed in the range of 2-20 µg/ml. Absorbance of each solution was recorded at 222.8 against pH 7.2 phosphate buffer. The calibration curve was plotted and correlation co-efficient and regression line equation for IBF were determined[8-12].

Precision and Accuracy

Determination of intra-day precision is done by analyzing IBF (2-20µg/ml) at three different time points of the same day and the determination of the inter-day precision was determined by analyzing IBF (2-20µg/ml) at three different time points on different days[8-12].

Limit of Detection (LOD) and Limit of Quantitation (LOQ) [13]

The set of five calibrations which were used to determine the linearity, were used in the estimation of LOD and LOQ.

$$LOD = 3.3*\sigma/S$$

and $$LOQ = 10*\sigma/S$$

Where, σ = the standard deviation of y-intercepts of regression lines

S = the slope of the calibration curve

Analysis of marketed formulation (Ibuprofen) by UV spectrophotometric method

Single tablet was taken and crushed in the mortar and pestle and the calculations were done to get equivalent 100 mg of IBF in the sample. That amount was dissolved in 100 ml volumetric flask with pH 7.2 phosphate buffer. The solution was sonicated in bath sonicator to get the clear solution of 1000 µg/ml, which was stock solution. From this stock solution 10 ml of solution was taken and transferred to 100 ml volumetric flask and diluted with pH 7.2 phosphate buffer to get 100 µg/ml solution. From this solution, dilutions were prepared in the range 2-20µg and were analyzed at 222.8 nm

RESULTS AND DISCUSSION

Linearity

Table 1: Calibration data of ibuprofen pure drug by simple UV spectroscopy

Sr. No.	Concentration (µg/ml)	Absorbance
1	2	0.112
2	4	0.211
3	6	0.333
4	8	0.435
5	10	0.548
6	12	0.648
7	14	0.747
8	16	0.856
9	18	0.950
10	20	1.047

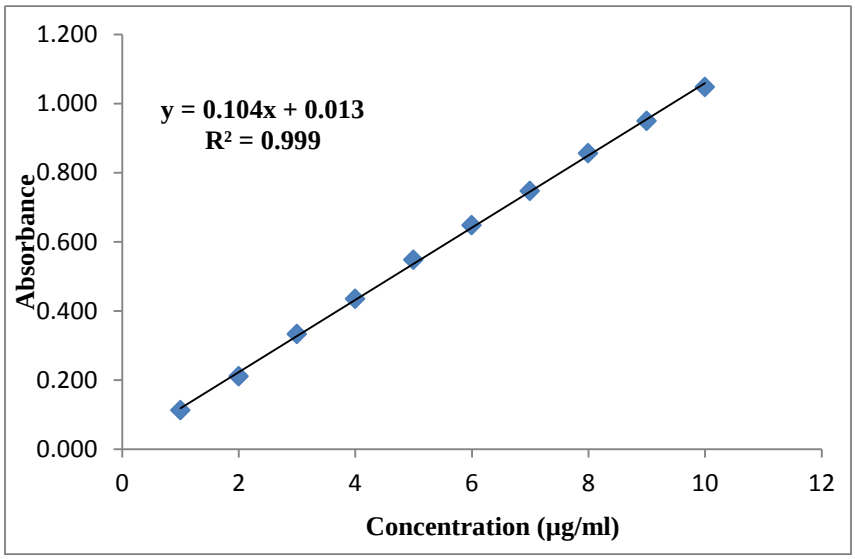

Figure 2: Calibration curve of standard IBF by simple UV spectrophotometer

Accuracy

Accuracy of the method was checked by carrying out the recovery studies at three different levels- 50%, 100%, and 150%. The mean % recovery for IBF was found to be 100.11%. The results obtained are shown in table 2.

Table 2: Results of recovery studies

Recovery Level	Initial Concentration (µg/ml)	Concentration of standard drug added (µg/ml)	% Recovery (n=3)
50%	10	5	100.86
100%	10	10	100.20
150%	10	15	99.29
Mean			100.11

Precision

Intra-day precision

%RSD was found to be in the range of 0.121-1.007

Table 3: Results of Intra-day precision

Concentration (µg/ml)	Absorbance mean	%RSD
6	0.319	1.007
10	0.404	0.286
14	0.476	0.121

Inter-day precision

%RSD was found to be in the range of 1.002-1.582

Table 4: Results of Inter-day precision

Concentration (µg/ml)	Absorbance mean	% RSD
6	0.316	1.292
10	0.403	1.002
14	0.475	0.947

The results indicated acceptable accuracy and precision of the proposed methods for the analysis of the drug.

LOD and LOQ

The results obtained for LOD and LOQ are shown in table 5.

Table 5: LOD and LOQ of IBF

Concentration (µg/ml)	Absorbance	Standard deviation	LOD	LOQ
2	0.112	0.031	0.993	3.008
4	0.211	0.036	1.139	3.452
6	0.333	0.061	1.951	5.911
8	0.435	0.056	1.786	5.412
10	0.548	0.050	1.601	4.852
12	0.648	0.049	1.557	4.717
14	0.747	0.052	1.638	4.964
16	0.856	0.075	2.378	7.207
18	0.950	0.090	2.870	8.696
20	1.047	0.092	2.905	8.804

The summary of all the validation parameters is presented in table 6.

Table 6: Summary of Validation parameters

Validation Parameters	Result
Absorption maxima (nm)	222.8
Linearity range (µg/ml)	2-20
Standard Regression Equation	y = 0.104x + 0.013
Slope (m)	0.104

Y – intercept (c)	0.013
Correlation Co-efficient (R^2)	0.999
% Recovery	100.11
Precision (%RSD)	
Intra-day (n=3)	0.471
Inter-day (n=3)	1.080
LOQ (µg/ml)	5.702
LOD (µg/ml)	1.886

CONCLUSION

The proposed spectrophotometric method was found to be simple, sensitive, accurate, precise, reproducible and economical which can be used for the routine simultaneous estimation of IBF in bulk form as well as marketed formulations.

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