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UV spectrophotometric estimation of dexibuprofen in bulk drug and its pharmaceutical formulation.

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ABSTRACT

A simple, precise and rapid UV spectrophotometric method has been developed for the estimation of dexibuprofen in bulk drug and its pharmaceutical formulation. Dexibuprofen showed linearity in the concentration range of 2.5 – 20 µg/ml with coefficient of correlation as 0.9998. The assay result showed that the label claim was around 100 % with a standard deviation of about 0.2598. The recovery close to 100 % and the standard deviation of about 0.2768 shows the precision of the method. Hence, the proposed method can be used for the routine analysis of dexibuprofen from its formulation.

Keywords: UV Spectroscopy, Dexibuprofen, Estimation, Validation

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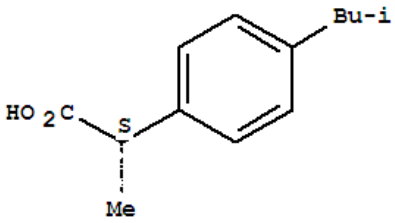
INTRODUCTION

Dexibuprofen is a non-steroidal anti-inflammatory drug. It is the 'd' isomer of ibuprofen [1,2]. Chemically it is 2S-2[4-(2-methyl propyl) phenyl] propanoic acid. The exact mechanism of action of dexibuprofen is unknown. Its anti-inflammatory effects are believed to be due to inhibition of both COX-1 and COX-2 which leads to the inhibition of prostaglandin synthesis. Antipyretic effects may be due to the action on the hypothalamus, resulting in an increased peripheral blood flow, vasodilation, and subsequent heat dissipation.



The literature survey showed that an HPLC method with UV detection was developed for the determination of dexibuprofen from plasma [3] using the internal standard carbamazepine. However, there was no method developed for the estimation of the drug in its formulation. Therefore, an attempt has been made to develop a simple spectrophotometric method for the estimation of dexibuprofen from its formulation and to validate the same according to ICH guidelines.

MATERIALS AND METHOD

Chemicals and reagents

Dexibuprofen was procured as a gift sample from Noven Life sciences (P) LTD, Hyderabad. All the chemicals used are of analytical grade. The experiments were carried out using Perkin Elmer UV-Visible double beam spectrophotometer (lambda 25) with 1cm matched quartz cells.

Preparation of standard stock solution

About 25 mg of pure drug sample was accurately weighed and dissolved in little quantity of methanol and sonicated for 10 minutes. The volume was made up to 25 ml with more methanol. This was taken as the stock solution. From the stock solution, suitable dilutions were made in distilled water to get the concentration ranging from 2.5 to 20 µg/ml.

Beer's law plot

All the solutions were scanned in the UV region between 200-300 nm using distilled water as the blank. The $\lambda_{max,}$ was found to be 222 nm. The spectrum was given in figure-1. The

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absorbance of each of the solution at 222 nm was recorded (Table-1). A calibration curve was prepared by plotting absorbance versus concentration of dexibuprofen as shown in figure -2.

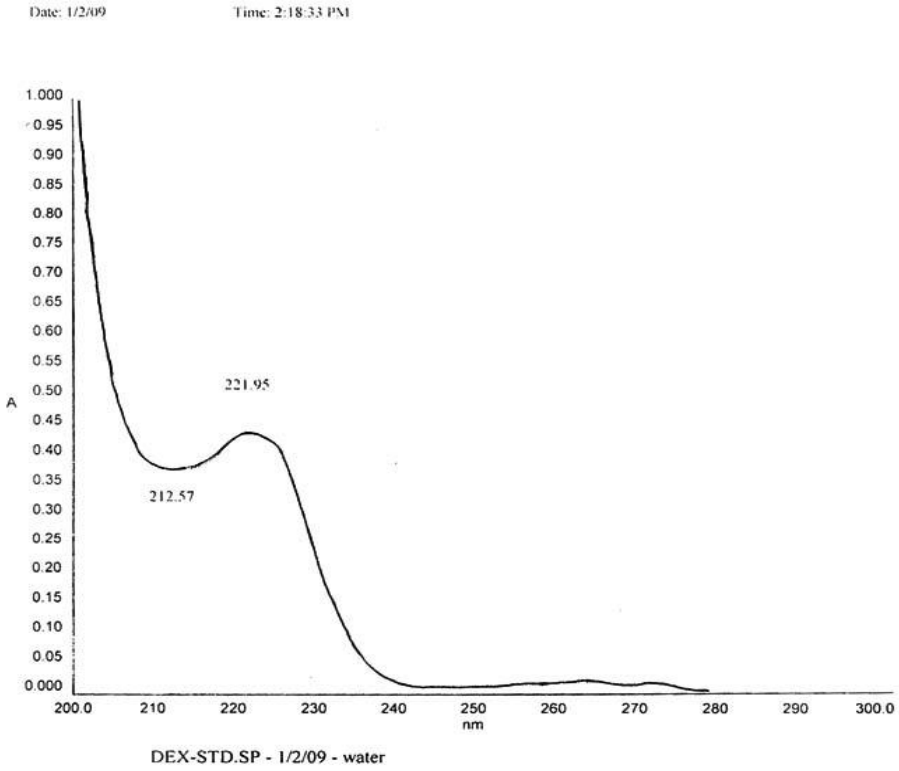

Figure 1: Absorption maximum of dexibuprofen standard

Table 1: Data for the calibration curve

Drug concentration in µg/ml	Absorbance at 222 nm
2.5	0.1140
5	0.2275
7.5	0.3380
10	0.4412
12.5	0.5470
15	0.6484
17.5	0.7538
20	0.8453

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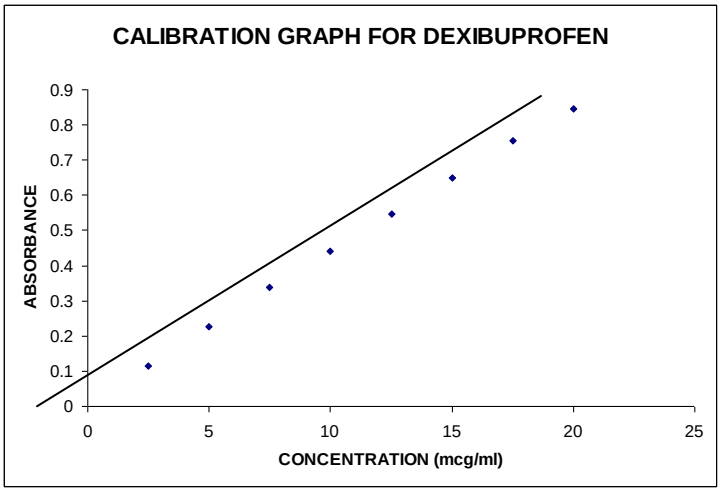

Figure 2: Calibration graph for dexibuprofen standard

Estimation of dexibuprofen from its formulation

The average weight of 20 tablets was determined and the tablets were powdered. The powdered tablet equivalent to 25 mg of dexibuprofen was weighed and dissolved in methanol. The solution was sonicated for 15 minutes. The volume was made up to 25 ml with methanol. This is taken as stock solution and filtered. The filtrate was suitably diluted within the linearity range (5, 7.5, 10 µg/ml) using distilled water. The absorbances of the resulting solutions were measured at 222 nm. The amount of dexibuprofen present in the average weight of each tablet was calculated (Table-2).

Table 2: Assay results for dexibuprofen tablet

Label claim (mg)	Amount found (mg)	% label claim	SD	RSD	SE
200	201.12	100.56	0.2598	0.00257	0.1502
200	202.92	101.46			
200	202.01	101.01			

Validation [4,5]

As per the ICH guidelines, the method was validated with respect to linearity, accuracy, precision and repeatability.

Accuracy

To study the accuracy of the method, recovery studies were carried out by adding the standard drug to the pre-analyzed sample at three different concentration levels taking in to consideration the percentage purity of the drug sample (Table-3).

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Table 3: Results of recovery studies:

Amount of drug in sample (mg)	Amount of standard added (mg)	Amount recovered (mg)	% recovery	SD	RSD	SE
200	160	158.71	99.19	0.1758	0.00177	0.1016
200	200	199.15	99.58			
200	240	237.54	98.98			

Precision

The reproducibility of the proposed method were determined by performing the tablet assay at different time intervals on the same day(intra-day assay precision) and on three different days(inter-day assay precision).The results of intra-day and inter-day precisions were expressed in %RSD. (Table- 4)

Table 4: Optical Characteristics of dexibuprofen

Parameters	Observations
Absorption maxima (nm)	222
Linearity Range (µg/ml)	2.5 to 20
Molar absorptive (l/mol/cm)	9.1×10^3
Standard Regression Equation	Y = 0.042 X + 0.0126
Sandell's sensitivity(µg/cm^2/0.001AU)	2.26×10^{-2}
Correlation Coefficient (R^2)	0.9998
Precision (% RSD) Intraday Interday Repeatability	 0.27 0.46 0.77

Linearity

The linearity of the analytical procedure is its ability to obtain the best results, which is directly proportional to the concentration of analyte in the sample.

RESULTS AND DISCUSSION

Spectral analysis shows the maximum absorbance of dexibuprofen in methanol at 222 nm. The linearity was found to lie in the concentration range of 2.5 to 20 µg/ml. The molar absorptivity was found to be 9.1×10^3 l/mol/cm. Assay was found to be in good agreement with the label claim. To confirm with ICH guidelines, the accuracy was assessed by standard addition method and the percent recovery was found to be in the range of 98 to 99. It indicates that there is no interference of excipients present in the tablet formulation. The RSD levels were found to be very low in terms of repeatability, intraday and interday variability. Therefore, the proposed spectrophotometric method can be successfully employed for the estimation of dexibuprofen in routine analysis.

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REFERENCES

[1] CIMS, July- Oct 2008; 216.
[2] Martindale, The Complete Drug Reference, 2005 edited by Sean C Sweetman, 34th edition: pp 46.
[3] Mandal U, Das A, Agarwal S, Chatraborty U, Nandi, Chattaraj TK. Arzneimittelforschung 2008; 58(7):342-347.
[4] ICH, Q2 (R1), Harmonized tripartite guideline, Validation of analytical procedures: text and methodology International Conference on Harmonization ICH, Geneva, Nov 2005.
[5] Taverniers I, Loose MD, Bockstaele EV. Trends in Analytical Chemistry 2004; 23: 480-490.