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Development and Validation of Analytical Method for Simultaneous Estimation of Paracetamol and Ibuprofen Using UV-Visible Spectroscopy

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ABSTRACT

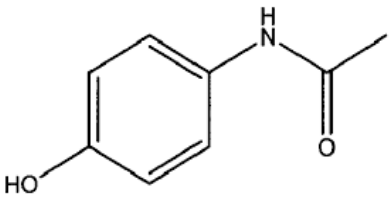
A simple, specific, accurate and precise UV spectrophotometric method has been developed for the simultaneous estimation of paracetamol and ibuprofen in pharmaceutical dosage form. The absorption maxima of the paracetamol and ibuprofen were found to be 240 nm and 220 nm respectively using 0.1N NaOH as a solvent. This method obeys Beer's law in the employed concentration range of 2-80 µg/ml and 2-50 µg/ml of paracetamol and ibuprofen respectively. Different analytical performance parameters such as linearity, precision, accuracy, limit of detection (LOD), limit of quantitation (LOQ) were determined according to ICH guidelines. The developed method was free from interferences due to excipients present in formulation and it can be used for routine quality control analysis.

INTRODUCTION

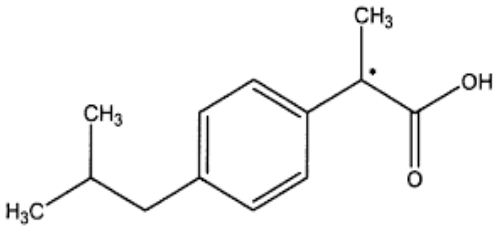
Chemically, paracetamol is [N-(4-hydroxyphenyl)acetamide]. It is an analgesic, antipyretic agent. It is effective in treating mild to moderate pain such as headache, neuralgia and pain of musculoskeletal origin. The most recent methods for determination of paracetamol included chromatographic, electrochemical and spectrophotometric techniques.

The 2-aryl propionic acid derivative, Ibuprofen, [RS-2-(4-isobutyl-phenyl)propionic acid] is one of the most potent orally active antipyretic, analgesic and nonsteroidal anti-inflammatory drug (NSAID) used extensively in the treatment of acute and chronic pain, osteoarthritis, rheumatoid arthritis and related conditions. Ibuprofen is characterized by a better tolerability compared with other NSAIDs. The techniques most recent used for determination of ibuprofen included chromatographic, electrochemical and spectrophotometric methods.[1,2]

Method validation is an important issue in pharmaceutical analysis. It confirms that the analytical procedure employed for the analysis is suitable and reliable for its intended use. In present study, all validation parameters for quantitative analysis of paracetamol and ibuprofen in tablets were tested and data were evaluated according to their acceptance criteria. The review of literature revealed that the combined dosage form has been estimated by spectrophotometric methods using methanol as a solvent. However, there is a need to develop simple, accurate, precise and economic UV spectrophotometric analytical method for simultaneous analysis of paracetamol and ibuprofen. Methanol is an expensive solvent and also being volatile in nature, it might cause errors in the analytical results. In the present work, an attempt has been made to use simple 0.1N NaOH as a solvent to make the method economical and more accurate over the reported methods.[3,4]



Paracetamol



Ibuprofen

PROCEDURE:

Selection of solvent and wavelength

Solubility of ibuprofen and paracetamol was checked in different solvents. 0.1N NaOH has been selected as a common solvent for developing spectral characteristics. The absorbance of paracetamol and ibuprofen was found maximum at 240 nm and 220 nm wavelength respectively.

Preparation of standard stock solution and study of Beer-Lambert's law

The standard stock solutions of paracetamol and ibuprofen, each of 250 µg/ml were prepared by dissolving 0.025 gm of each drug in 100 ml of 0.1N NaOH. Aliquots of working stock solutions of paracetamol and ibuprofen were diluted with 0.1N NaOH solution to get concentration in range of 2-80 µg/ml for both the individual drug. The absorbances of resulting solutions were measured at their respective wavelength.[5,6]

Simultaneous Equation Method

If a sample contains two absorbing drugs, each of which absorbs at the λmax of the other, it may be possible to determine both drugs simultaneously using multicomponent analysis UV Spectrophotometric 'Simultaneous Equation Method.'

Two wavelengths selected for the development of the simultaneous equations are 220 nm and 240nm. The absorptivity values determined for ibuprofen are 0.0081 (ax1), 0.032 (ax2) and for paracetamol are 0.0203 (ay1), 0.00284 (ay2) at 220 nm and 240 nm respectively. These values are means of six estimations. The absorbances and absorptivity at these wavelengths were substituted in equation 1 and 2 to obtain the concentration of both drugs.

$$Cx = \frac{A2ay1 - A1ay2}{ax2ay1 - ax1ay2}$$

$$Cy = \frac{A1ax2 - A2ax1}{ax2ay1 - ax1ay2}$$

Where Cx and Cy are concentration of ibuprofen and paracetamol respectively in µg/ml. A1 and A2 are the absorbances of the mixture at 220 nm and 240nm respectively.[7]

VALIDATON[8,9]

Accuracy:

The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found.

To ascertain the accuracy of the proposed method, recovery studies were carried at three different levels (80%, 100% and 120%). Percent recovery for paracetamol and ibuprofen at 220 nm and 240 nm was found in the range of 96.3-99.4%.

Linearity:

The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

The linearity of method was established by analyzing different concentrations of ibuprofen and paracetamol at 220 nm and 240 nm. Ibuprofen in the concentration range 2-50 µg/ml obeyed Beer's Law at 220 nm and 240 nm. Linearity equation is $y = 0.023x + 0.064$ with r^2-0.993. Paracetamol in the concentration range 2-80 µg/ml obeyed Beer's Law at 220 nm and 240 nm. Linearity equation is $y = 0.031x + 0.004$ with r^2-0.995.

Precision:

The precision of an analytical procedure expresses the closeness of agreement (degree of scattering) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

Intermediate precision studies were carried out by analyzing three concentration in hexaplicate in one day.

Intermediate Precision (Interday and Intraday precision)

The interday and intraday precision was determined by assay of the sample solution on the same day and on different days at different time intervals respectively.

Linearity

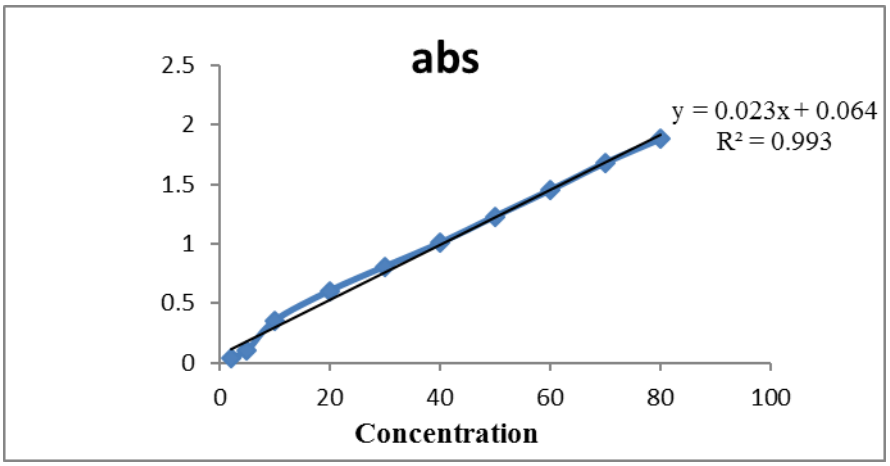


Figure 1: Linearity graph of Paracetamol

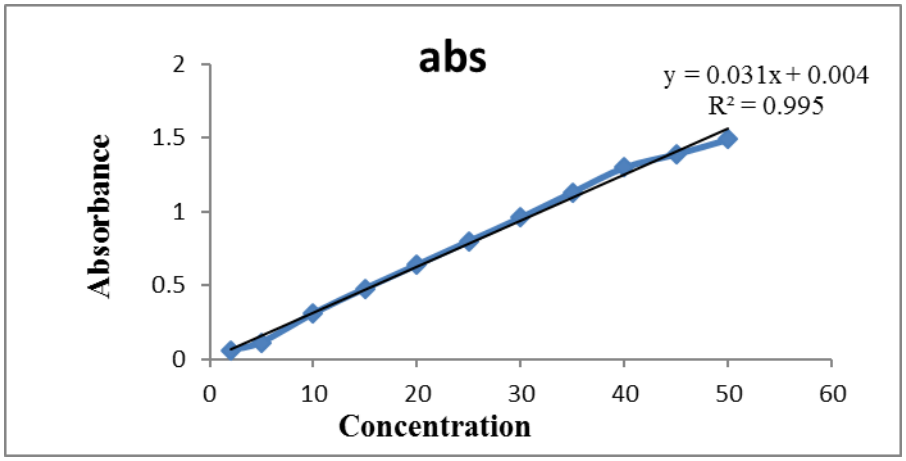


Figure 2: Linearity graph of Ibuprofen

Table No.1 Linearity

Parameter	**Paracetamol**	**Ibuprofen**
Linear Range	10-60 µg/ml	2-50 µg/ml
Correlation coefficient	0.022	0.031
Slope	0.989	0.994
Intercept	0.083	0.004

Accuracy

Table No. 2 Recovery study Data of Paracetamol and Ibuprofen

Levels	% Recovery	
	Paracetamol	Ibuprofen
80%	96.3	98.3
100%	97.5	99.4
120%	96.9	98.1

Precision

Table No.3 Precision studies

Drug	Intraday precision % RSD	Interday precision % RSD
Paracetamol	0.29	0.69
Ibuprofen	0.89	o.61

$$*\%\ \text{RSD} = \frac{\text{S.D}}{\text{Mean}} \times 100$$

Detection Limit and Quantitation Limit

$$\text{LOD} = \frac{3.3\times\sigma}{S} \quad \text{LOQ} = \frac{10\times\sigma}{S}$$

Where,

σ = Standard deviation

S=slope

Table No.4 Detection & Quantitation Limit

Drug	Paracetamol	Ibuprofen
LOD	0.6097	0.1985
LOQ	1.8478	0.6015

RESULTS AND DISCUSSION

A simple, economic, precise, accurate method for UV spectrophotometric method for paracetamol and ibuprofen using simultaneous equation was successfully achieved. The linearity range and regression coefficient for ibuprofen and paracetamol was found to be 2-50 µg/ml, 0.995 and 2-80 µg/ml, 0.993. The results of recovery for ibuprofen and paracetamol was found to be 98.1 % and 96.9 %.

CONCLUSION

The proposed spectrophotometric method is simple, rapid, accurate, precise, and economic and validated in terms of linearity, accuracy, precision, specificity and reproducibility. This method can be successfully used for simultaneous estimation of ibuprofen and paracetamol in pure and tablet dosage form. The described method give accurate and precise results for determination of ibuprofen and paracetamol mixture in marketed formulation.

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