ISSN 2394-7446
INTERNATIONAL JOURNAL OF APPLIED PHARMACEUTICAL SCIENCES

NEW SPECTROPHOTOMETRIC METHODS FOR THE DETERMINATION OF PARACETAMOL IN PURE FORM AND PHARMACEUTICAL FORMULATIONS

Siva lokesh.B, Uma maheswari.T, Anusha.B, Ramya.B, Sri Sai Rohini.T, Sudheerbabu.I*
Sir C.R.R College Of Pharmaceutical Sciences, Eluru, West Godavari District, Andhra Pradesh, India.

ABSTRACT

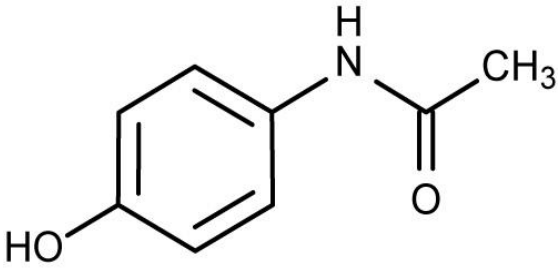
Two simple spectroscopic methods (A&B) have been described for the assay of Paracetamol in bulk and in pharmaceutical formulations. In method **A** Paracetamol is condensed with Folin-ciocalteu phenol reagent (FC reagent) to form a purple coloured product having an absorption maximum (λ_{max}) of 780nm. In method **B** Paracetamol is condensed with para-dimethyl amino benzaldehyde (PDAB) to form an yellow coloured schiff's base having an absorption maximum(λ_{max}) at 450nm. These methods have been statistically evaluated and are found to be prescise and accurate.

Key words:- Paracetamol, UV,Colourimetry.

.

INTRODUCTION

Paracetamol (N-4hydroxy acetamide) is widely used as anti-pyretic, anti-inflammatory, and analgesic. A survey of literature revealed that there are less number of work done on visible spectrophotometry. Therefore the need for a fast, low cost and selective method is obvious, especially for the routine quality control analysis of pharmaceutical formulations containing Paracetamol.



Chemical structure of paracetamol

This paper describes two visible spectrophotometric methods for the determination of Paracetamol by making use of reported procedures. Method A is based on formation of colour due to the reaction between Paracetamol and FC Reagent. Method B is based on formation of colour due to the reaction between Paracetamol and P-di methylaminobenzaldehyde.

EXPERIMENTAL

Instrument:

A systronics UV-VIS double beam spectrophotometer (model: 116) with 1cm matched quartz cells was used for all spectral measurements.

Reagents:

All the chemicals used were of analytical grade and all the solutions were prepared with double distilled water. FC reagent (1 ml FC reagent in 4 ml water), 10%sodium carbonate in method A.PDAB (1%w/v) in 5% v/v sulphuric acid was used in method B.P-dimethylaminobenzaldehyde (1% w/v) in 5% v/v sulphuric acid was used in method B.

Standard drug solution:

100mg of paracetamol was dissolved in 100ml of water to get 1mg/ml paracetamol solution. From that 1ml solution was dissolved in 100ml water to get 1µg/ml paracetamol solution was used in MethodA.

150mg of Paracetamol was dissolved in 10ml methyl alcohol and dilute to 200ml with 0.1N Hcl (0.75mg Paracetamol per ml) was used in MethodB.

Sample solutions:

Tablets of two brands (Brand A & Brand B) were used for the purpose of analysis. 20 tablets were powdered and powder equivalent to 100mg, 150mg of Paracetamol was weighed

and the solution was prepared under standard solution preparation and filtered if insoluble portion present.

Assay procedure:

Method A:

Into a series of 20ml graduated test tubes 1-5ml (1µg/ml) solution of Paracetamol was transferred into test tube, to that 2.5ml of FC reagent was added and then 10% sodium carbonate was added. Keep aside for 10 minutes and then make up the volume to 20 ml with water and the absorbance was measured at 780nm against reagent blank. The amount of drug in the sample was calculated from the calibration curve (Figure 1).

Method B:

Into a series of 50ml volumetric flasks 1-5ml (0.75mg/ml) solution of Paracetamol was transferred and 5ml of 1N hydrochloric acid was added. It was then heated on a water bath for 30 minutes, cooled and 10ml of p-dimethyl amino benzaldehyde reagent was added and kept aside for 10 minutes. It was made up to 50ml with water and the absorbance was measured at 450nm against reagent blank. The amount of drug in the sample was calculated from the calibration curve (Figure 2).

Accuracy:

To determine the accuracy of the proposed method, recovery studies were carried out by adding different amounts of bulk samples of Paracetamol within the linearity range were taken and added to the preanalyzed formulation. From that percentage recovery, values are calculated.

Precision:

The precision of the proposed method was ascertained by actual determination of six replicate samples of fixed concentrations of the drug within the Beer's range and finding out the absorbance by the proposed method. From this absorbance mean, standard deviation and %RSD was calculated.

RESULTS AND DISCUSSION

The optimum conditions for each method were established by varying one parameter at a time and keeping the other fixed and observing the effect produced on the absorbance of the coloured species and incorporated in the procedures. The optical characteristics and figures of merit are given in Table 1, together with the regression equations (obtained by linear least square treatment) for the calibration plots. The precision and accuracy were found out by analysing six replicate samples containing known amount of drug and the results were summarised in Table 1.

Commercial formulations (Tablets) containing Paracetamol successfully analysed by the proposed methods. The values obtained by the proposed and reference (UV method) for formulations were compared statistically by the T and F tests and found not to differ significantly. As an additional check of accuracy, recovery experiments were performed by adding a fixed amount of the drug to the pre analysed formulations. These results are summarised in Table 2. The ingredients usually present in the formulation of Paracetamol did not interfere with the proposed analytical methods.

Chemistry of coloured species:

The method A is based on the formation of purple colour is a condensation product of Paracetamol and FC reagent. Method B is a condensation product (Schiff's base) from Paracetamol and P-dimethylamino benzaldehyde which produces a characteristic yellow colour.

The proposed methods are found to be simple, sensitive and accurate and can be used for determination of Paracetamol in their pharmaceutical dosage forms in a routine manner.

ACKNOWLEDGEMENTS

The authors are grateful to SIR C.R.R COLLEGE OF PHARMACEUTICAL SCIENCES, ELURU for their co-operation.

REFERENCES

1. Qualitative analysis of drugs in pharmaceutical formulations-by P.D.SETHI.
2. Analytical chemistry- by GARG D. CHRISTIAN.
3. Instrumental methods of chemical analysis - by GURDEEP R. CHATWAL and SHAM K. ANAND.
4. Instrumental analysis - by SKOOG. HOLLER. CROUCH.
5. Introduction to instrumental analysis- by ROBERT D. BRAUN..
6. Instrumental method of analysis- by WILLARD, MERRITT, DEAN, SETTLE.
7. Pharmaceutical analysis- by DR. S. RAVI SANKAR.
8. 3. DAVIDSON AG (2002) Ultraviolet-visible absorption spectrophotometry. In BECKETT AH, STENLAKE JB, (4thedn), Practical Pharmaceutical chemistry.
9. BERTOLINI A, FERRARI A, OTTANIA, GUERZONI S, TACCHI R, et al. (2006) Paracetamol: new vistas of an old drug. CNS Drug Reviews 12: 250-275.
10. Spectrophotometric Estimation of Paracetamol in Bulk and Pharmaceutical Formulations. Int J Res Pharm Biomed Sci. 2011;8:149–52.
11. Development of a UV-spectrophotometric method for the simultaneous determination of aspirin and paracetamol in tablets. Sci Res Essays. 2011;6:417–21

Figure 1: calibration curve of the Method A

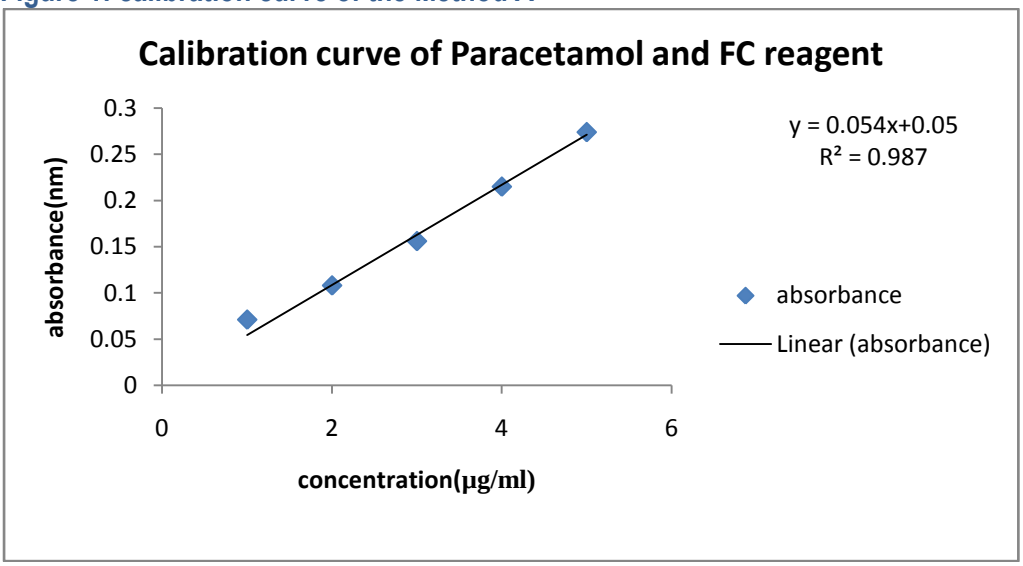


Figure 2: calibration curve of the Method B

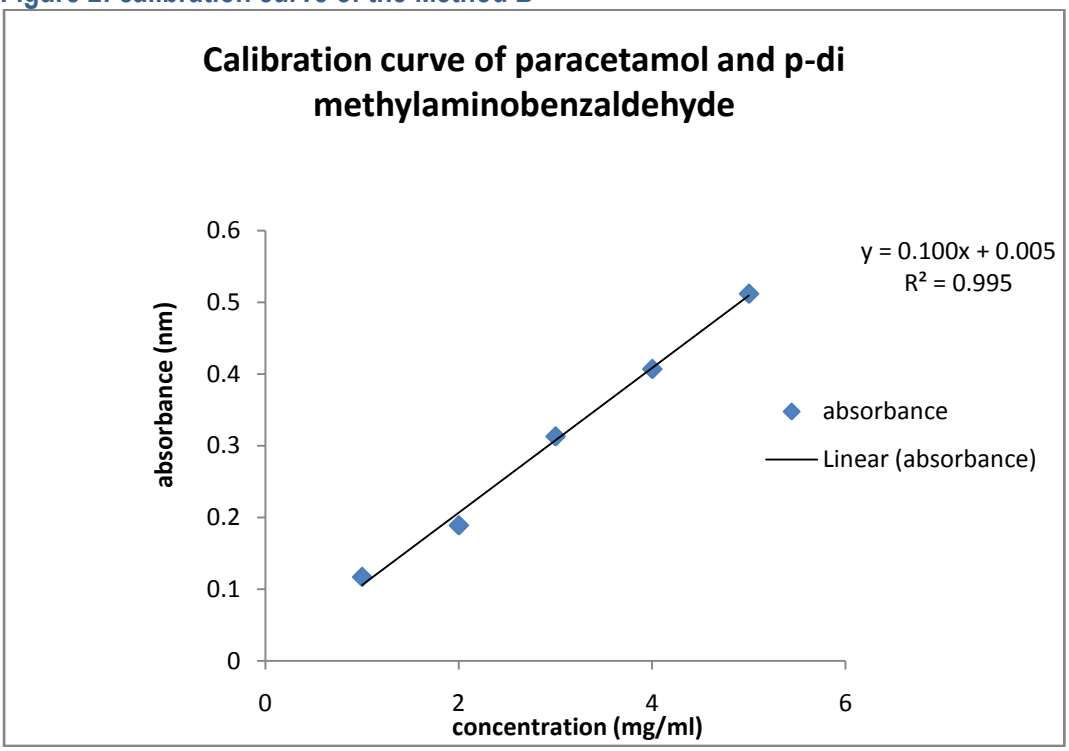


TABLE 1 optical parameters

Optical character	Methods	
	A	B
λmax(nm)	780	450
Beer's law limits	1-5 (µg /ml)	0.75-3.75(mg/ml)
Molar absorptivity(litre/mole.cm)	5.734 x 10^3	3.408×10^3
Sandell's sensitivity(mg/cm²/0.01abs.unit)	0.0659	0.0650
Regression equation (Y)		
Slope(b)	0.054	0.100
Intercept (a)	0.05	0.005
%RSD	0.52	0.81
% Range of error(0.05 level)	±0.78	±0.44

Y=a+bX where X is the concentration of Paracetamol in mg/ml and Y is the absorbance at respective λmax.

For six replicate samples.

TABLE 2 Recovery studies

Pharmaceutical formulation	Labelled amount (mg/tablet)	Amount Found (mg)		% Recovery	
		Method A	Method B	Method A	Method B
Paracetamol (Brand A)	500mg	458.8	457.5	92.9%	91.5%
Paracetamol (Brand B)	500mg	471.5	467.5	95.5%	93.5%