Simultaneous Spectrophotometric Determination of Mefenamic Acid and Paracetamol in Combined Pharmaceutical Dosage Forms

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A simultaneous spectrophotometric procedure for mefenamic acid and paracetamol in two component tablet formulations has been developed. The method is based on two-wavelength method of calculations. The difference in absorbances at 217 nm and 285 nm was used for determination of mefenamic acid and the difference in absorbances at 257 nm and 308.8 nm was used for determination of paracetamol. Beer's law is obeyed by both the drugs within the concentration ranges employed for analysis. The method has been statistically validated and was found to be satisfactory.

MEFENAMIC acid, [(N-(2,3-xylyl) anthranilic acid)], has analgesic and antiinflammatory activity. The drug and its capsules are official in BP.[1] The BP describes titrimetric assay procedure for the bulk drug and capsules. Other reported methods involve spectrophotometric[2,3] polarographic[4] and HPLC technique[5] for the drug in biological fluids. Paracetamol, (4-hydroxy acetanilide), has analgesic and antipyretic activity. It is official in IP,[6] BP[7] and USP[8]. The IP and BP describe titrimetric assay procedures for the bulk drug. The IP, BP and USP describe UV spectrophotometric assay procedures for tablets. The BP describes HPLC procedures for the assay of oral suspension and oral solution whereas the USP describes a colorimetric assay procedure for oral suspension. Other reported methods involve GLC and HPLC techniques in biological fluids.[9]

A combination of mefenamic acid and paracetamol is commercially available. The review of literature revealed that, except HPLC[10], no analytical method is reported for this combination. This paper presents a simple dual wavelength UV spectrophotometric method for simultaneous analysis of mefenamic acid and paracetamol.

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A Shimadzu UV-Visible recording spectrophotometer (Model: UV- 160A) was used for this work. Stock solutions of strength 100 mcg/ml each of mefenamic acid and paracetamol were prepared separately in 0.02 M sodium hydroxide. Mixed standards of mefenamic acid and paracetamol were prepared as per concentrations stated in Table 1. All the six mixed standards were scanned at 217 nm and 285 nm. The values of difference in absorbance (A_{217} - A_{285}) were plotted against the concentration of mefenamic acid to obtain the calibration curve for mefenamic acid. The same six mixed standards were scanned at 257 nm and 308.8 nm. The values of difference in absorbance (A_{257} - $A_{308.8}$) were plotted against the concentration of paracetamol to obtain the calibration curve for paracetamol.

An accurately weighed quantity of the powdered tablets, equivalent to 50 mg of paracetamol for formulation A and 50 mg of mefenamic acid for formulation B was used for analysis. Tablet sample solutions were prepared using the same solvent by dissolution, filtration and appropriate dilutions to obtain sample solutions containing 20 mcg/ml of paracetamol and 10 mcg/ml of mefenamic acid for formulation-A and 9 mcg/ml of paracetamol and 10 mcg/ml of mefenamic acid for formulation-B.

Table - 1: Composition of the Six Mixed Standards

Standard No.	I	II	III	IV	V	VI
Concentration of Mefenamic Acid (mcg/ml)	0	4	8	12	16	20
Concentration of Paracetamol (mcg/ml)	0	25	20	15	10	5

Table - 2: Results of Analysis of Tablet Formulation

Tablet Sample	Label Claim mg/tab		Found* mean % of label claim		Standard deviation		Coeff. of variation		Standard error	
	MA	PM	MA	PM	MA	PM	MA	PM	MA	PM
Formu-lation A	250	500	98.13	97.77	1.57	0.93	1.60	0.96	0.70	0.42
Formu-laton B	500	450	99.00	98.02	1.11	1.44	1.12	1.46	0.49	0.64

* Mean of five estimations.

The absorbance difference at the respective set of two wavelengths selected for estimation of the two drugs was noted and the concentrations of the two drugs in the sample solution were obtained from the calibration curves of mefenamic acid and paracetamol separately. The results obtained from repeated analysis with two different batches of tablets gave impressive statistical parameters (Table 2).

The recovery studies carried out by the addition of different amounts of pure drug(s) to a pre-analysed tablet sample solution gave recoveries in the range of 97.33% to 102.50%.

The two wavelength data processing method employed for this analysis is based on the principle that **"Absorbance difference between two points on the curve of mixture spectra is directly proportional to the concentration of component of interest independent of interfering component"**. The mathematical expression has been described in Instruction manual of Shimadzu- UV 160 A**.

The method is found to be simple and economical as it requires only pure drug samples and sodium hydroxide. Time economy is also quite impressive considering simultaneous analysis. The statistical parameters and the recovery study data clearly indicate the reproducibility and accuracy of the method. Thus the method can be adopted for routine analysis in Quality Control Laboratories.

*** Instruction manual of Shimadzu UV 160A, page 4.8–4.14*

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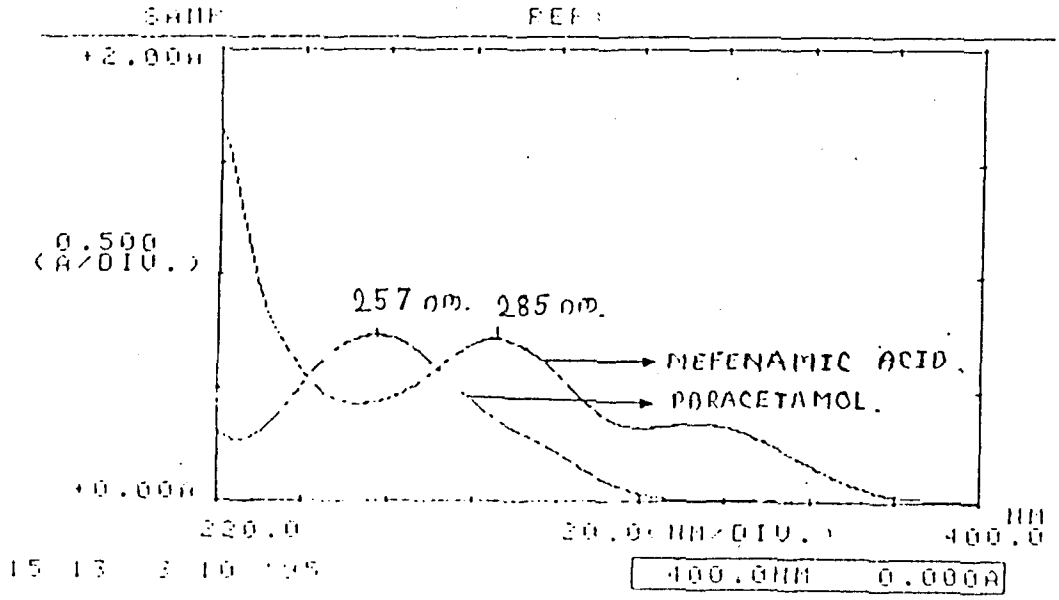

Fig.1: Overlain spectra of mefenamic acid and paracetamol

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