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Simultaneous Spectrophotometric Determination of Amoxycillin Trihydrate and Metronidazole in Dental Films

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Accepted 8 November 2003
Revised 28 August 2003
Received 3 April 2002

A simple, accurate and reproducible method for simultaneous estimation of amoxycillin and metronidazole in combined dosage form has been developed. The method involves analysis by multicomponent mode. Amoxycillin and metronidazole have absorption maxima at 272 nm and 320 nm, respectively, in alkaline borate buffer (pH 8.1). The results of analysis were validated statistically.

Amoxycillin is an amino-penicillin with spectrum of activity similar to that of ampicillin[1]. Metronidazole is the prototype nitroimidazole introduced in 1959 and has broad-spectrum bactericidal activity against protozoa and many anaerobic bacteria[2]. The combination of amoxycillin and metronidazole has been successfully used in the treatment of advanced periodontitis; especially with *A. actinomycetemcomitans* associated infections[3]. The rationale for the use of this combination is that metronidazole is very active against anaerobic microorganisms and is known to act synergistically with penicillin. Furthermore both drugs are bactericidal, which may be essential for the elimination of subgingivally occurring microorganisms. The combination of both the drugs covers a wide range of microflora, which is important for the successful treatment.

The IP suggests a titrimetric method with potentiometric determination of end point for amoxycillin and metronidazole[4,5]. No spectrophotometric method is available for simultaneous estimation of these drugs in pharmaceutical formulations. However an HPLC method for simultaneous quantification of amoxycillin and metronidazole in plasma has been reported[6]. This paper presents a simple, accurate, economical and reproducible method for the simultaneous analysis of amoxycillin and metronidazole in dental film formulation.

A Shimadzu UV spectrophotometer 1601 model with spectral bandwidth of 2 nm and wavelength accuracy of ±0.5 nm was used. Ten mm matched quartz cells were employed for this work. Alkaline borate buffer of pH 8.1 (ABB) was used for the preparation of solutions. The buffer was prepared by placing 50 ml of 0.2 M boric acid and 50 ml of 0.2 M potassium chloride solution in a 200 ml volumetric flask, pH was adjusted to 8.1 with 0.2 M sodium hydroxide and water was added to make up the volume. Standard stock solutions of amoxycillin trihydrate and metronidazole of 400 µg/ml and 100 µg/ml, respectively, were prepared in ABB. Film samples containing 5 mg each of amoxycillin and metronidazole were placed in 10 ml acetone to dissolve the polymer polylactide-co- glycolide (PLGA). After the polymer had dissolved, volume was made up to 100 ml with ABB. Aliquots of solution were diluted to get a final concentration

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TABLE 1: ANALYSIS OF DENTAL FILM

Film sample	Label claim (mg/film)		% Obtained of labeled claim (n=6)		Coefficient of variation (%)	
	Amox.	Met.	Amox.	Met.	Amox.	Met.
Batch 1	5	5	99.3	100.6	1.895	1.735
Batch 2	5	5	100.6	102.0	1.975	1.845

Two batches of films were analysed for amoxycillin and metronidazole. All the experiments were repeated six times (n=6). Amox stands for amoxycillin trihydrate and Met for metronidazole.

of 10 μg/ml each of amoxycillin and metronidazole.

Solutions containing 10 μg/ml each of amoxycillin and metronidazole were prepared and were scanned in the spectrum mode from 400 nm to 200 nm and the overlain spectra of the drugs were recorded. From the spectra it was observed that wavelength which could be utilized for the simultaneous analysis of amoxycillin and metronidazole using the multicomponent mode was 272 nm and 320 nm respectively. Four mixed standards of pure drug with different compositions were prepared using amoxycillin in concentration Range of 40, 80, 120, 160 μg/ml and metronidazole 4, 8, 16, 120 μg/ml, respectively. The sampling wavelengths (272 nm and 320 nm) and the concentration of two components in each of the mixed standards were fed into the multicomponent mode of the instrument. These mixed standards were scanned between 400 to 200 nm (fig. 1). The concentration of each component in sample solutions was determined using spectral data of mixed standards by the instrument. In order to ascertain the reproducibility of the proposed method, recovery studies were carried out on admixtures containing known amount of drug.

The results of analysis were validated statistically. The values of % standard deviation varied from 1.74 to 1.98. The % coefficient of variation varied between 1.74 and 1.98, which were significantly low. The recovery studies carried out gave recovery between 98 and 101% over the concentration range studied. The method is rapid and easy because it does not require manual calculations. However the method is specific for the instrument having multicomponent mode. It is concluded that the proposed method can be successfully employed for routine simultaneous estimation of amoxycillin and metronidazole in dental films or other formulations.

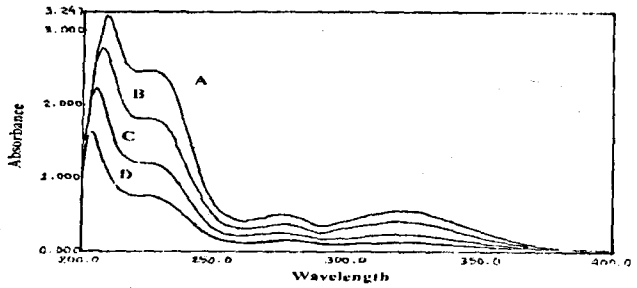

Fig. 1: Overlain spectra of four mixed standards in the wavelength range of 400 to 200 nm.

A stands for amoxycillin:metronidazole::160:20, B represents amoxycillin:metronidazole::120:16, C denotes amoxycillin:metronidazole::80:8 and D is amoxycillin: metronidazole::40:4.

ACKNOWLEDGEMENTS

The authors are thankful to Lark Laboratories (India), Limited New Delhi, for providing the gift samples of amoxycillin trihydrate and metronidazole.

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