

Short Communication

Comparative *in vitro* dissolution assessment of soluble and plain brands of aspirin tablets marketed in Nigeria

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The *in vitro* dissolution profiles of four commercial brands of aspirin tablets (one soluble brand of aspirin, A1, and three plain brands of aspirin labeled A2-A4) were assessed using the USP XXI dissolution method. Various dissolution parameters such as percent dissolution in 30 min, dissolution rate constant (k), and time for 50% dissolution (DT_{50%}) were obtained. The results indicate that A1 (the soluble aspirin brand) exhibited the highest dissolution profile while brand A3 had the least dissolution profile. The relative ranking in terms of percent dissolution in 30 min and dissolution rate constant (K) are in the order of A1>A4>A2>A3, while the ranking of time for 50% dissolution (DT_{50%}) is in the reverse order of A1<A4<A2<A3. Analysis of variance (ANOVA) performed on the percent dissolved in 30 min showed no significant difference (p > 0.05) among all the brands. They all indicated similar statistical behaviour in terms of their dissolution profiles.

Key words: Aspirin, dissolution profile, Nigeria.

INTRODUCTION

Dissolution test is one of the *in vitro* tests usually employed to assess the quality of oral drug products such as tablets and capsules. The *in vitro* dissolution tests can be used to guide formulation developments, identify critical manufacturing variables, monitor formulation quality from batch to batch, predict *in vivo* performance and serve as a surrogate for bioavailability and bioequivalence (Olaniyi et al., 2001).

Aspirin is one of the most commonly used drugs due to its usefulness as an analgesic, anti-inflammatory, anti-thrombotic and antipyretic agent, and its ready commercial availability (Gordon et al., 1994). It has poor water solubility; hence its dissolution rate is the rate limiting step, thereby affecting its bioavailability. Dissolution rate of aspirin can greatly be affected by its physico-chemical properties, formulation factors and manufacturing procedures as documented by many investigators (Iranloye, 1976; Berges et al., 1977; Lastres et al., 1981; El-sabbagh et al., 1986; El-Din et al., 1989).

In this study, the *in vitro* dissolution profiles of four commercial brands of aspirin tablets (one soluble and three plain) were evaluated. Statistical assessment was further

conducted to establish if there is any significant difference among them.

EXPERIMENTAL

Materials

The following chemicals were used as procured from their manufacturers: aspirin USP fine crystal, salicylic acid USP crystals (BDH laboratory, England). Four commercial brands of aspirin tablets, 300 mg from various manufacturers coded A1-A4, were obtained from a retail pharmacy outlets in Jos, Nigeria. They were well within their expiry dates.

Methods

Aspirin and salicylic acid content assay

The four commercial brands of aspirin tablets were assayed for their initial aspirin content using USPXX1 (1985) residual titration method while their initial content of salicylic acid were determined using USPXX1 (1985) method for determination of non-aspirin salicylate in aspirin products.

Dissolution profile assessment

The dissolution rate of the aspirin tablets were determined using

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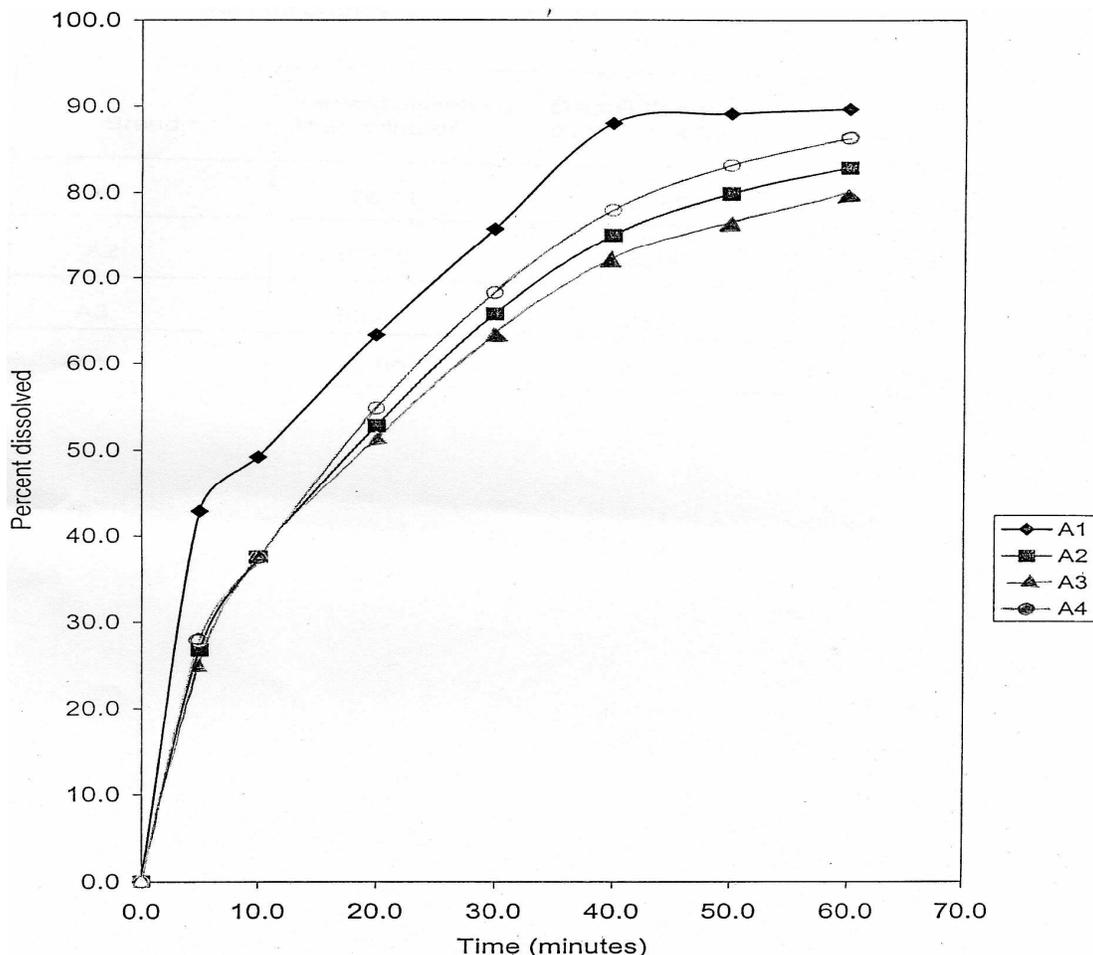


Figure 1. Percent of actual amount of aspirin dissolved as a function of time for the four different brands.

USPXX1 (1985) method which employs a rotating basket (Erweka, GmbH, Germany) at 50 rpm in 500 ml of 0.05 M acetate buffer of pH 4.5 ± 0.05 at a temperature of $37 \pm 0.05^\circ\text{C}$.

Samples were withdrawn and filtered at various intervals of 5, 10, 20, 30, 40, 50 and 60 min and analysed spectrophotometrically at 265 nm using UV spectrophotometer (UV-160A Shimadzu Corporation, Japan). The amount dissolved at the time intervals were determined using the Beer's plot and the profiles were obtained for all the brands. The plot of percent of aspirin dissolved as a function of time for all the brands is shown in Figure 1.

Various dissolution parameters such as percents dissolved in 30 min, dissolution rate constant (k) and time for 50% dissolution ($DT_{50\%}$) were obtained for all the brands using standard methods (Lopez et al., 1986; Sharge and Vu, 1993). These parameters are presented in Table 1.

RESULTS AND DISCUSSION

The result of the drug content assay is as follows: A1 118.63%, A2 105.84%, A3 98.84% and A4 103.03%. Since the USPXX1 (1985) limit of the labeled amount of aspirin is between 95 and 105%, only A3 and A4 brands met the official specification. The result of salicylic acid

content in all the brands was less than 0.1% which is far below the 0.3% of USPXX1 (1985) limit of salicylic acid content for aspirin tablet. The salicylic acid content in all the brands is negligible and cannot in any way affect the results obtained for all the brands. The low level of salicylic acid in all the brands may be due to the fact that, they all have long expiry date and not much degradation from aspirin to salicylic acid has occurred at the time the experiment was conducted.

Table 1 shows that none of the brands met the USPXX1 dissolution requirement of not less than 80% (Q) of the labeled amounts of aspirin that should have dissolved in 30 min. A1 exhibited the highest dissolution rate while the other three brands (A2-A4) has similar dissolution rates ($p < 0.05$). The overall relative ranking of all the brands in terms of the percent dissolved in 30 min and dissolution rate constant (k) followed the order of $A1 > A4 > A2 > A3$ while the ranking of time for 50% dissolution ($DT_{50\%}$) follows the reverse order (i.e $A1 < A4 < A2 < A3$). A1 is a soluble brand of aspirin containing calcium carbonate which can provide a reactive medium by changing the pH of the environment adjacent to the

Table 1. Dissolution parameters obtained from the dissolution tests of various brands of aspirin.

Brand	Percent dissolved at 30 min	Dissolution rate constant, k (hr ⁻¹)	Time for 50% dissolution, DT _{50%} (min)
A1	75.71	0.0588	11.79
A2	65.75	0.0398	17.41
A3	63.47	0.0374	18.53
A4	68.90	0.0427	16.23

drug to alkaline, thus making acidic drug like aspirin form a water soluble salt, thereby enhancing its rapid dissolution. This possibly accounted for its highest dissolution rate and shortest time for dissolution compared with the other three plain brands. The observation was similar to the reports of Berges et al. (1977) and Nayak et al. (1977).

Brands A2, A3 and A4 are all plain aspirin tablets; various factors such as the particle size and shape of the aspirin content, of type and/or amount of excipients, method of formulation and compression force employed may influence their dissolution rates (Lastres et al., 1981; Smith and Stewart, 1981; El Din et al., 1989; Akanni, 1993; Olaniyi et al., 2001). The analysis of variance (ANOVA) performed on the dissolution parameters (percent dissolved in 30 min) showed no significant difference ($p > 0.05$) among all the brands, they all indicated similar statistical behaviour in their dissolution profiles.

Conclusion

It was established that A1, a soluble brand of aspirin tablet had the highest dissolution rate compared with three other plain brands of aspirin. However, no significant statistical difference was observed among the dissolution profiles of all the brands.

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