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Short Paper

Reclosure Efficiency of Plastic Container Used for Multidose Packaging of Moisture Sensitive Aspirin Tablets

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Abstract

This study was conducted to determine the suitability of packaging aspirin tablets in one thousand tablet packs that require reclosure after dispensing each dose. The reclosure efficiency of the push-fit type closure of a plastic container in preventing moisture entry was determined and compared to a control container. Aspirin tablets used in this study were shown to be susceptible to moisture degradation leading to significant losses of potency ($p < 0.05$). Loose placement of closure on container allowed significant gain of moisture into the container ($p < 0.05$) and this could lead to significant loss of potency of aspirin tablets. However, if the closure is properly pushed down to fit, the moisture gain is not significant ($p > 0.05$). It can, therefore, be concluded that the proper use of push-fit closures on containers for packaging aspirin tablets provides effective protection and the use of more expensive single unit strip packaging, for example, is therefore not necessary.

Keywords: Moisture sensitive aspirin tablets, plastic container, reclosure efficiency.

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Introduction

Aspirin is capable of absorbing moisture leading to hydrolytic reactions, and it has been predicted that over the pH range of 1 – 12, six simultaneous reactions occur to give salicylic and acetic acids[1] and these could be injurious to the gastrointestinal tract. This study was conducted to find out if the protective wrapping of single-unit strip packaging[2] may be necessary for aspirin tablets, as against the multi-dose packing such as packs of one thousand tablets, commonly used by manufacturers. The ability of containers to protect their contents from external conditions is a function of the effectiveness of the closure applied[3].

In this study, the loss of potency of aspirin tablets in the presence of moisture was determined. Thereafter the reclosure efficiency of a sample container used for packaging aspirin tablets was tested at different temperature and humidity conditions against a control container. The sample container has a push-fit type renewable closure[2], in which was placed anhydrous hygroscopic calcium carbonate which would absorb moisture from the atmosphere if the closure is not effective. The extent of weight gain gives the effectiveness of the closure[1].

Methods

Test of aspirin sensitivity to moisture

The initial potency of the aspirin tablets (C_o) representing 100% potency was determined using the assay method described below. For the test, 100 tablets were placed in an unclosed container which was then placed in a moisture saturated oven chamber at 38°C. Saturation of the oven chamber was achieved by placing a beaker of boiling water in the oven and allowing it to stabilize to the required temperature. The potencies of aspirin tablets were determined at intervals over a period of 24 days as percentages of C_o. A control pack was set up in which 100 tablets were packaged in a cellophane bag in a tightly reclosed container, which was then placed in a dry oven at 38° C.

Determination of reclosure efficiency of container

About 50 g of accurately weighed calcium carbonate, $CaCO_3$ (May and Baker, Germany) powder was placed in the container which was either tightly reclosed (TR) or loosely reclosed (LR), i.e., the push-fit closure was either pushed down to lock or not pushed down. The container with its content was weighed to give the initial weight (W_o) and subsequently stored in a moisture saturated oven chamber at 25 or 38° C. Thus four storage conditions were studied: tightly or loosely reclosed at 25°C (TR 25° C and LR 25° C) and tightly or loosely reclosed at 38° C (TR 38°C and LR 38° C). At time intervals, each container was reweighed (W_t), and the difference in weight ($W_t – W_o$) is the weight gained by the hygroscopic $CaCO_3$ powder due to moisture entry.

A control container was similarly prepared, but was sealed to prevent moisture entry by dipping the entire tightly reclosed container into a melted wax before the initial determination of W_o. Analysis of variance (ANOVA) was used to determine any statistical differences between the test and control containers.

Assay of aspirin tablets

The back titration method described by Olaniyi and Ogungbamila[4] was adopted as follows. A few tablets were crushed into powder, out of which 1.5 g was accurately weighed and placed in a conical flask. 50 ml of 0.5% w/v sodium hydroxide, NaOH (BDH, Poole, England) solution was added and heated for 10 min and then cooled. The excess alkali was then titrated with 0.5 M hydrochloric acid, HCl (Fisons plc, Loughborough, England) using phenol red indicator (laboratory grade). A blank determination was also carried out by titrating 0.5 M HCl against 50 ml of the 0.5% w/v NaOH solution without aspirin. The

difference between the blank and the test readings represented the amount of alkali required by the aspirin which was converted to equivalent aspirin content. The equivalent aspirin contents at the various time intervals were calculated as percentages of the potency of the original tablets.

Results and Discussion

Susceptibility of aspirin tablets to moisture

It is usually useful to test the sensitivity of unpackaged product to moisture. It then becomes possible to determine rapidly whether the product is susceptible to moisture, and also whether the final container needs to provide a high degree of protection[4]. The ANOVA result in the table indicates that there is significant difference in potency losses between the control and test as shown in Figure 1. This confirms that the aspirin tablets are sensitive to moisture and need protection, which must be afforded by the container and closure if the patient is to receive the correct product in a safe and efficacious form.

Table: Aspirin tablets moisture sensitivity and container reclosure efficiency

Parameter	F-ratio	p-values
Moisture sensitivity	5.773	NS
Reclosure efficiency		
• TR 25° C	3.73	NS
• LR 25° C	5.55	< 0.05
• TR 38° C	4.57	NS
• LR 38° C	8.05	< 0.05

NS, not significant; TR, tightly reclosed; LR, loosely reclosed

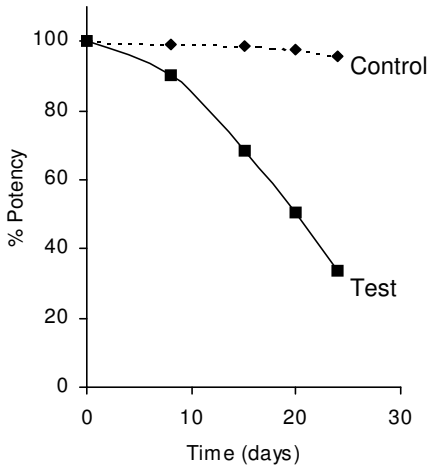

Figure 1: Aspirin susceptibility to moisture

The reclosure efficiency of container

Figure 2 shows the moisture gain profile of both the control and test containers. The ANOVA results show that the moisture gain is not significant when the containers are properly reclosed. However if the closure fit loosely on the container without pushing it down to lock, the moisture gain becomes significant. Such significant moisture gain can result in significant potency loss. It therefore becomes evident that if the aspirin tablets are to retain their potency and safety throughout the use of the pack, the closure must be securely pushed down after each dispensing operation. The practice of prepacking the tablets in cellophane bags before putting in the container may further ensure the protection of the tablets. It may, therefore, be suggested that packing aspirin

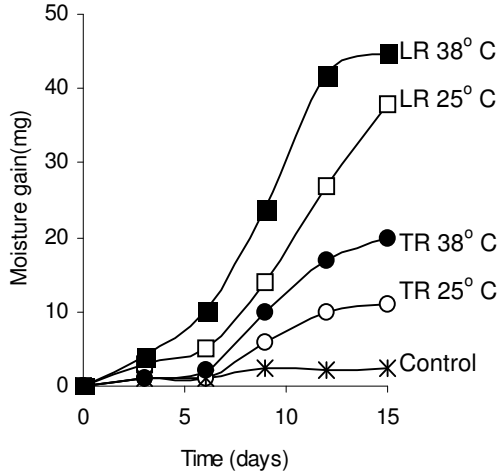

Figure 2: Reclosure effeciency of aspirin container under different conditions

tablets in more expensive unit strip packaging is not necessary.

Conclusion

Aspirin tablets are significantly susceptible to moisture and their package needs to offer effective protection. The push fit type closure offers good protection if properly pushed down to fit. There may, therefore, be no particular necessity to package aspirin tablets in single unit strip packaging.

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