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Comparative analysis of the physical and chemical properties of new and expired blister pack foils for hard gelatin capsule packaging

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Abstract – **Blister packs are commonly used to package hard gelatin capsules. Shelf life restrictions of the blister pack components can be problematic for low volume users due to the requirement to purchase larger quantities. Here we investigated the physical and chemical properties of blister pack foils to determine if a change in their nature occurred when the expiry date was exceeded.**

INTRODUCTION

Hard gelatin capsules are commonly packaged in blister packs. The unit dose packages retain product integrity and optimise shelf life by protecting the capsule from environmental factors such as moisture [1]. Blister packs are composed of two main components, the forming film and the lidding material. Supplies of these components are generally suited to large-scale production sites such as large pharmaceutical companies and minimum orders are in the range of kilograms. Companies who package small quantities of capsules may find that the packaging material has exceeded the expiry date prior to use, resulting in waste. The aim of this work was to analyse and compare the chemical and physical characteristics of new and expired aluminium foil lidding material using Fourier Transform Infrared (FTIR) and Texture Analysis (TA).

MATERIALS AND METHODS

Texture Analysis: A Texture Analyser (TA-XT2, Stable Micro Systems, Godalming, UK) was used in compression mode with a 10mm delrin probe. 30 mm^2 pieces of Teknilid 1250 blister packing foil (Teknifilms Europe, Belgium) was placed glue side down onto a modified rig and secured in place. The probe was lowered by 8 mm at a force of 1 mm/s and the force required to puncture the foil (F_{max}) and work done (AUC) was recorded. Ten repeats were carried out.

FTIR Analysis: FTIR spectra of the new film (2013) and expired foil (2012) were obtained using an FTIR-4200 spectrometer (JASCO, Tokyo, Japan) equipped with a diamond attenuated total reflectance (ATR) accessory (requires info on ATR). The foil was cut into 2 cm^2 pieces and analysed on the glue side. Spectra were produced over a range of 650 – 4000 cm^{-1}.

Statistical Analysis: The F_{max} and AUC results were statistically evaluated using an Excel 2007. The difference between the two foils was evaluated using a paired T-Test and statistical significance was taken as $P<0.05$.

RESULTS AND DISCUSSION

The F_{max} and AUC results are shown in Figure 1. It can be seen that a small increase in F_{max} was measured for foil 2 but this was not statistically significant. The AUC measurements exhibited a significantly higher AUC measurement for foil 2 suggesting that the expired foil has developed an increase in strength.

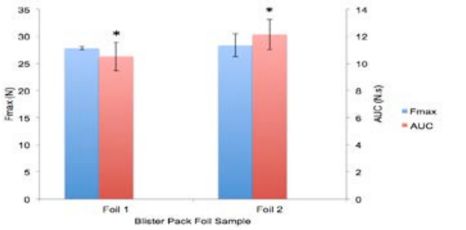

Fig. 1. F_{max} and AUC measurements for new (foil 1) and expired (foil 2) blister pack foils. Values represent the mean ± S.D. (n=10). *denoted statistical significance.

The infrared (IR) spectra for both the new foil (2013) and expired foil (2012) are shown in Figure 2.

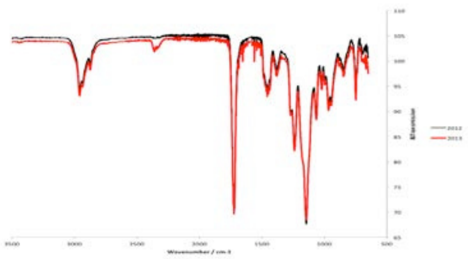

Fig. 2. FTIR spectra for the new foil (2013) and old foil (2012).

IR spectra of the new and expired foils were identical which indicated that the sealing glue on the old foil has not degraded into a degradation product visible by FTIR.

CONCLUSIONS

With the exception of the AUC, the overall results suggested that no significant difference in terms of physical and chemical properties was detected for the new and expired film. This would suggest that the integrity of the blister pack foils has remained even after the expiry date has been exceeded and would be suitable to use. Further work should be carried out to validate these results.

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