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Colour stability of film coatings: polymer and pigment effects

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The stability of colourants used in pharmaceutical dosage forms is arguably the most important factor used by patients in assessing the quality of the medicines they take. While the amount of colour is usually a very small proportion of the dose form, the human eye is so sensitive to colour differences that even the smallest quantitative changes may be detected by a patient. In this study, the effect of using different pigments and different polymers on the colour stability of film coatings has been determined.

All of the samples used in the study were made to the same basic formula: polymer,62.5%; pigments, 31.25%; plasticiser (PEG400), 6.25%). The pigment component included 22.25% titanium dioxide with the remainder being aluminium lake, as specified below. Each formulation was blended and dispersed at 20% w/w in purified water, prior to casting as a 150µm thick film onto white card. The films were dried at 40°C for 2 hours, then exposed to artificial light (Suntest CPS, Heraeus Instruments) at $765 Wm^{-2}$ for one hour, approximating to 24 hours continuous daylight exposure.

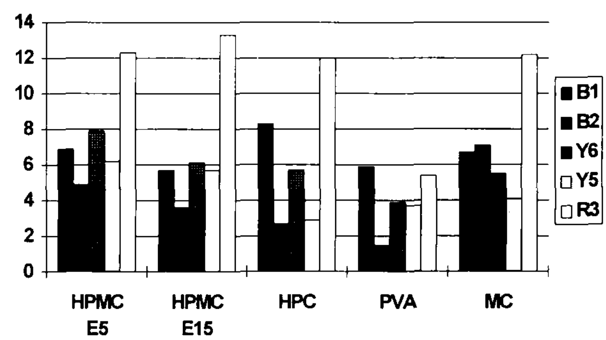
Colour measurement was performed using a Spectraflash 500 spectrophotometer and the results are expressed as ΔE colour units, where $\Delta E= [(\Delta L^*)^2+(\Delta a^*)^2+(\Delta b^*)^2]^{1/2}$. L*,a* and b* deriving from the tristimulus colour measurements. Six different polymers and five different pigments were studied: FD&C Blue 1, FD&C Blue 2, FD&C Yellow 6, FD&C Yellow 5 FD&C Red 3 (all as Aluminium Lake), HPMC 5cps, HPMC 15cps, Hydroxypropylcellulose (HPC), Polyvinyl Alcohol (PVA) and Methylcellulose (MC).

The data, shown in Figure 1, illustrate the complex range of interactions between the polymers and pigments. The figure shows the colour change, ΔE, measured on the same sample before and after exposure to light. ΔE values of less than two are normally considered as insignificant, although even this degree of change may be detectable by eye with some colours. No single polymer is best for all the colours investigated. In general the differences between the polymers were quite small, especially between the cellulosic polymers, but PVA was the best overall, giving the smallest ΔE for three of the pigments and the second smallest ΔE for the others.

Likewise none of the pigments was most stable with all of the polymers. FD&C Blue 2 was the best overall, showing the least colour difference with every polymer except methylcellulose. FD&C Red 3 was least stable with every polymer except PVA, for which the worst was FD&C Blue 1. The same rank order was shown for HPMC E5 and E15, which was expected, since these are the same polymer differing only in molecular weight.

The differences may be explained in terms of the chemical structures of the individual polymers and pigments.

Fig. 1: ΔE values for different polymer/pigment combinations



The conclusions to be drawn from this study are that some pigments do show generally better colour stability than others, but no individual pigment or polymer is best in every case. For optimum colour stability, one must consider the physicochemical interactions between the formulation components.