

EFFECT OF AGEING ON THE ELASTIC MODULUS OF SOME TABLET FILM COATINGS

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Adequate mechanical protection of solid dosage forms, especially controlled release preparations, by applied film coatings is important and generally there is a relationship between changes in elastic modulus and film coating defects. The effect of ageing on the Young's modulus of elasticity of some tablet film coatings is examined in this report.

Flat-faced aspirin tablets similar to those used previously (Okhamafe & York 1984) were coated in a 15.1cm Wurster column with the following 10% w/v aqueous formulations: (a) hydroxypropyl methylcellulose (HPMC), (b) HPMC + 20 wt% polyvinyl alcohol (PVA), (c) HPMC + 10 wt% polyethylene glycol (PEG) 400, and also formulations (a), (b) and (c) respectively pigmented with 20 wt% talc or titanium dioxide (TiO_2). Indentation profiles of the film coatings (at 20°C & 37% R.H.) were obtained using a technique and apparatus similar to White & Aulton's (1980) at intervals over the ageing period of 5 months at 37°C & 75% R.H. Young's modulus calculation (Baer et al 1961) was based on the mean of 20 measurements for each test. Coefficients of variation of data (19-30%) were comparable to other reports (e.g. Ridgway et al 1970).

Data (Fig. 1) indicate that with the exception of the plasticized systems (HPMC/PEG 400) the Young's modulus of the other pigmented and unpigmented films decreased on ageing. The moduli of the plasticized films were virtually unchanged. Since a direct relationship generally exists between crystallinity level, molecular order and stiffness, it is thought that the swelling activity of water along with thermal effects under the ageing conditions (37°C & 75% R.H.) could have decreased molecular order in the unplasticized films which have

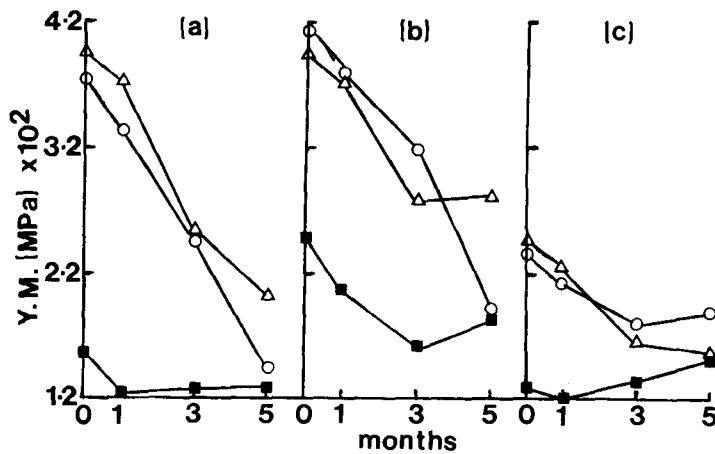


Fig. 1. Effect of ageing at 37°C, 75% R.H. on the Young's modulus of HPMC (O), HPMC/PVA (Δ) and HPMC/PEG 400 (\blacksquare) film coats. NOTE: (a) = unfilled films; (b) = talc-filled films; (c) = titanium dioxide-filled films.

previously been shown to exhibit varying degrees of crystallinity (Okhamafe & York 1985). Similar behaviour was not shown by the non-crystalline plasticized films because plasticization would already have reduced molecular order and modulus to a minimum. An additional consideration is the possible migration of salicylic acid (an aspirin degradation product) from the tablet core into the film coating. Since salicylic acid plasticizes ethyl cellulose (Aulton et al 1983), it could have lowered the elastic modulus of the unplasticized systems while exerting reduced effect on the plasticized films.

Aulton, M.E. et al (1983) Proc. 3rd APGI Int. Conf. on Pharm. Tech., Paris, Vol. III, pp154-162.

Baer, E. et al (1961) Soc. Plastic Eng. J. 17:1203-1205.

Okhamafe, A.O. & York, P. (1984) J. Pharm. Pharmacol. 36 Suppl:1P.

Okhamafe, A.O. & York, P. (1985) Pharm. Res. 2:19-23.

Ridgway, K. et al (1970) J. Pharm. Pharmacol. 22 Suppl:70S-78S.

White, P.J.P. & Aulton, M.E. (1980) J. Phys. E. Sci. Inst. 13:380.