

Title: Effect of drug loading on release liner removal from drug-in-adhesive transdermal films

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Abstract:

I. Background: Release liner removal from adhesive films is a newly introduced Pharmacopoeial test. Release liner should detach easily and completely from the adhesive. II. Aims: To examine whether and how drug loading in adhesive films affects removal (peel) of the release liner from the adhesive film; and to correlate peel forces with film viscoelastic properties. III. Methods: Acrylic (DURO-TAK 87-4287) films at ibuprofen concentrations of 0%, 5%, 15% & 25% (w/w) were prepared in triplicate. Viscoelastic measurements of the bulk adhesive were performed at 32°C using a Bohlin Gemini rheometer with a 20mm stainless steel parallel plate and 1mm gap size. The peel force to detach the release liner (Scotchpak 9742) from the adhesive film was measured at a constant rate of 300mm/min at an angle of 90°; using a Zwick Z010 material tester. Microscopic examination of the films was undertaken using an Olympus BH2 polarised microscope with an Olympus 10x lens fitted with a camera (AxioCam MRc-Zeiss, UK) and AxioVision v4.4 image analyser software. IV. Results: Films containing 5% w/w ibuprofen were unsaturated, whereas films at 15% and 25% w/w ibuprofen concentrations contained undissolved drug. Peel force to remove the release liner was lowest for the unmedicated films and highest for the 5% w/w ibuprofen films. Viscoelastic measurements showed softening of the adhesive at 5% w/w compared to the unmedicated film, followed by gradual film strengthening at the saturated concentrations. V. Summary / Conclusions: Addition of drug in the adhesive at unsaturated concentrations (5% w/w) caused film softening and subsequent increase in the force required to remove the release liner.