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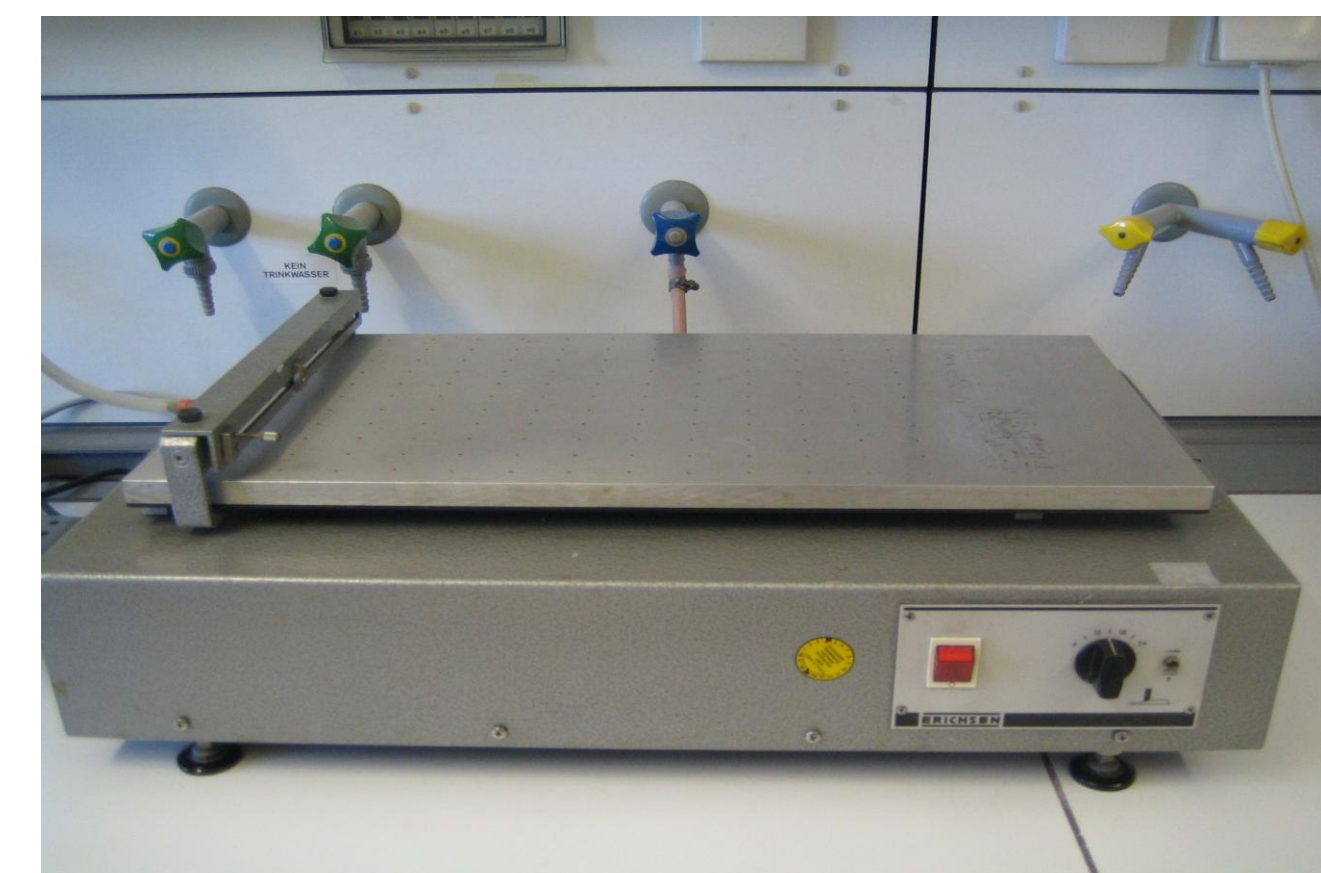
Introduction

The rotary die process for the manufacture of soft capsules (SC) was originally developed for gel forming shell polymers such as gelatin. Defined thickness of gelatin ribbons is provided by a defined gel mass viscosity. Fast setting and microstructure formation allows elastic gelatin films to be removed from the casting drums [1-2]. It was the purpose of the present study to evaluate a film forming, non gelling polymer (Kollicoat Protect[®] / BASF SE) for (1) its ability to form homogeneous films of well-defined thickness, and (2) the time necessary to remove elastic free films from two different casting devices.

Experimental methods

Casting devices:

Two casting devices were used for film preparation: (A) an Erichsen film forming device with a moveable wiper and a stationary horizontal plate; (B) a small-scale casting drum developed inhouse with a stationary wiper and a crescent-shaped, heatable and moveable drum.



Erichsen film forming device (A)

Preparation of Kollicoat Protect[®] model films:

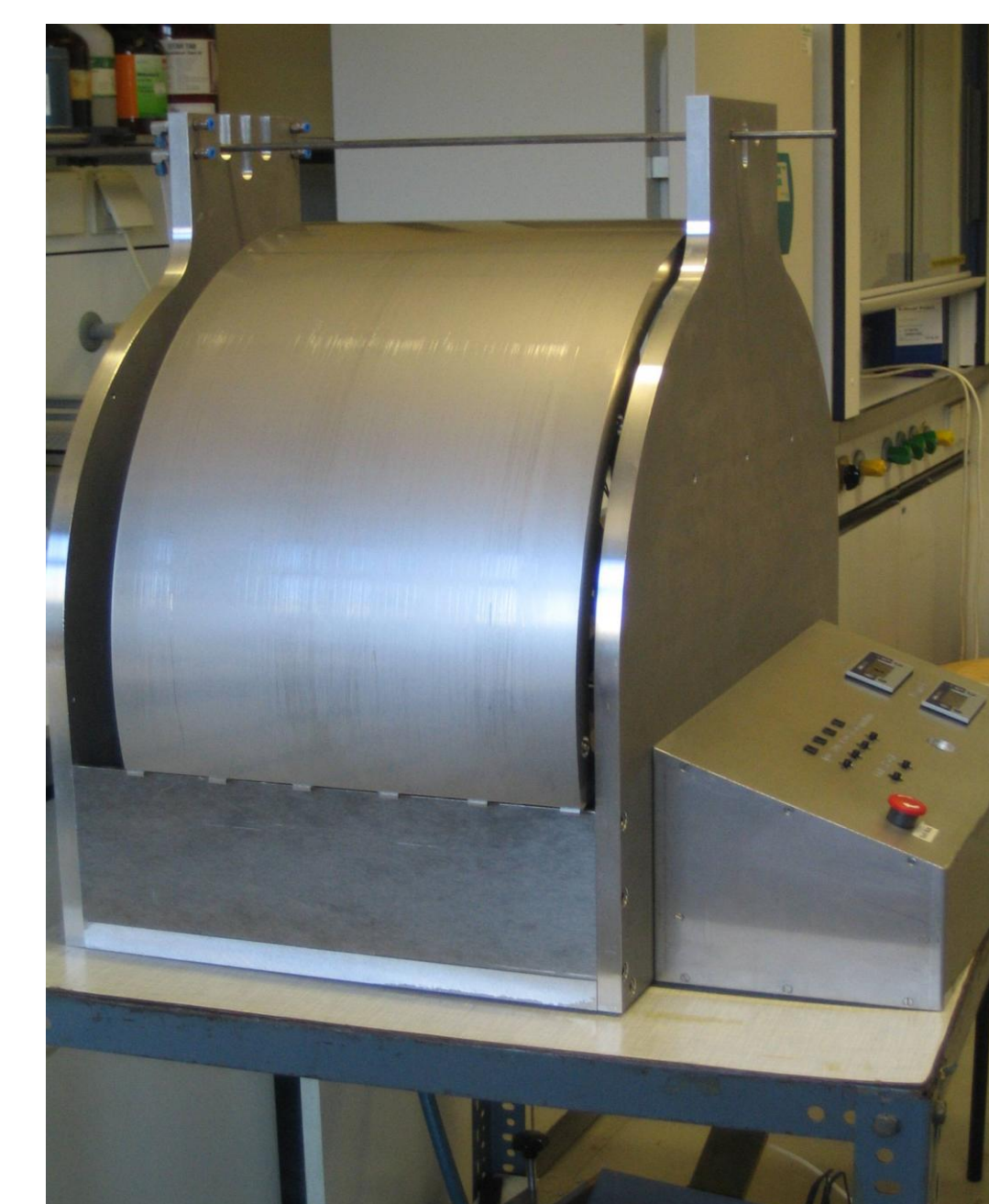
Polymer films were prepared using two different concentrations of Kollicoat Protect[®] (40 % and 45 % w/w) and 20 % w/w of glycerol, relative to the polymer mass. Films were cast with a constant gap width of 800 µm, at two different velocities (800 and 1200 mm/min) and three different drum temperatures of the casting device (B) (30, 35, 40 °C). The removal time was defined as the specific time when free elastic films were completely detachable from the surface of the casting devices. After storage at 25 °C in a drying chamber for 24 h, film thickness was determined with a micrometer screw.

Determination of dynamic viscosity:

Viscosity measurements of polymer mass were carried out with a Haake Viscotester 550 (constant shear rate of 10/s for 30 s) at 90°C.

Determination of water content:

After 1 h and 24 h storage in a drying chamber at 25 °C, water content of films was determined by Karl-Fischer Titration.



Small-scale casting drum (B)

Acknowledgment

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Results

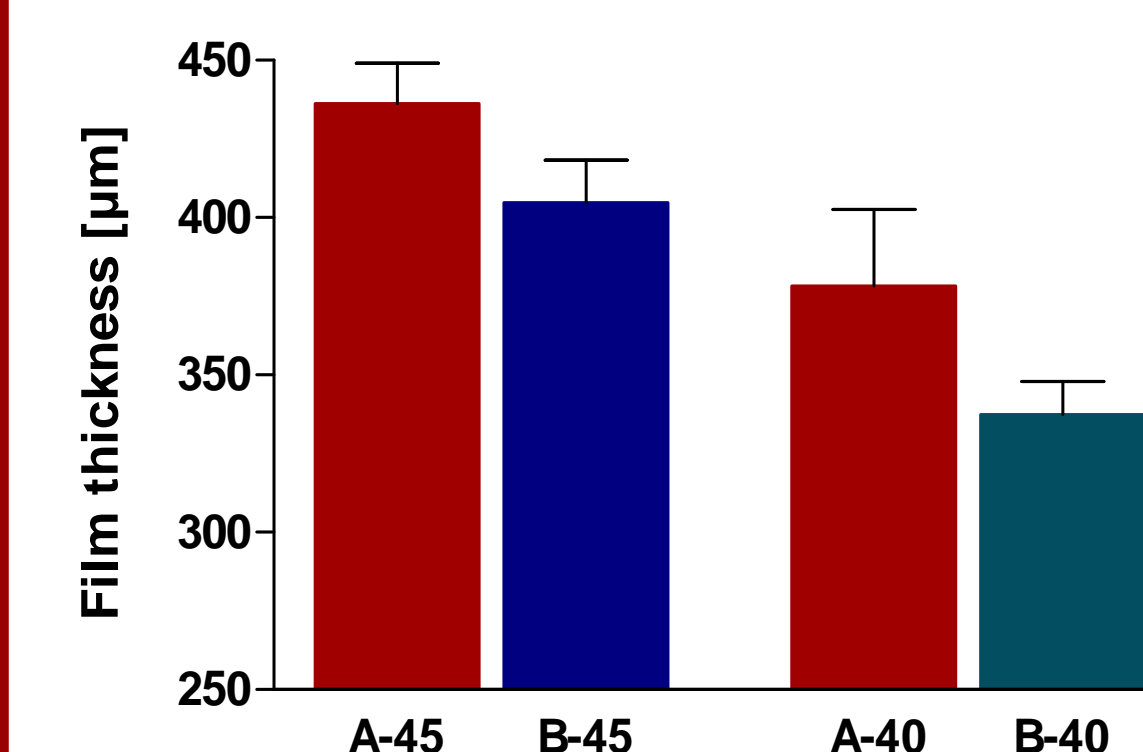


Fig. 1 : Effect of polymer conc. (45 and 40 % w/w) and film forming device on film thickness [µm] at constant velocity of 800 mm/min.

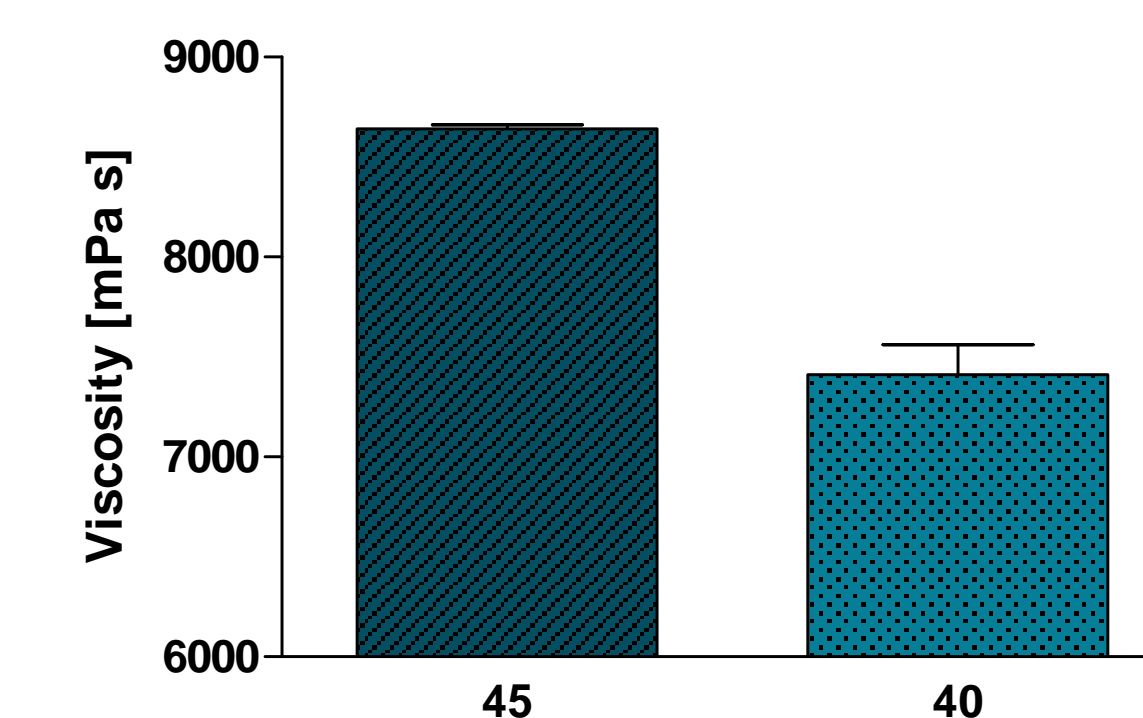


Fig. 2 : Effect of polymer conc. (45 and 40 % w/w) on viscosity of molten mass at T= 90 °C

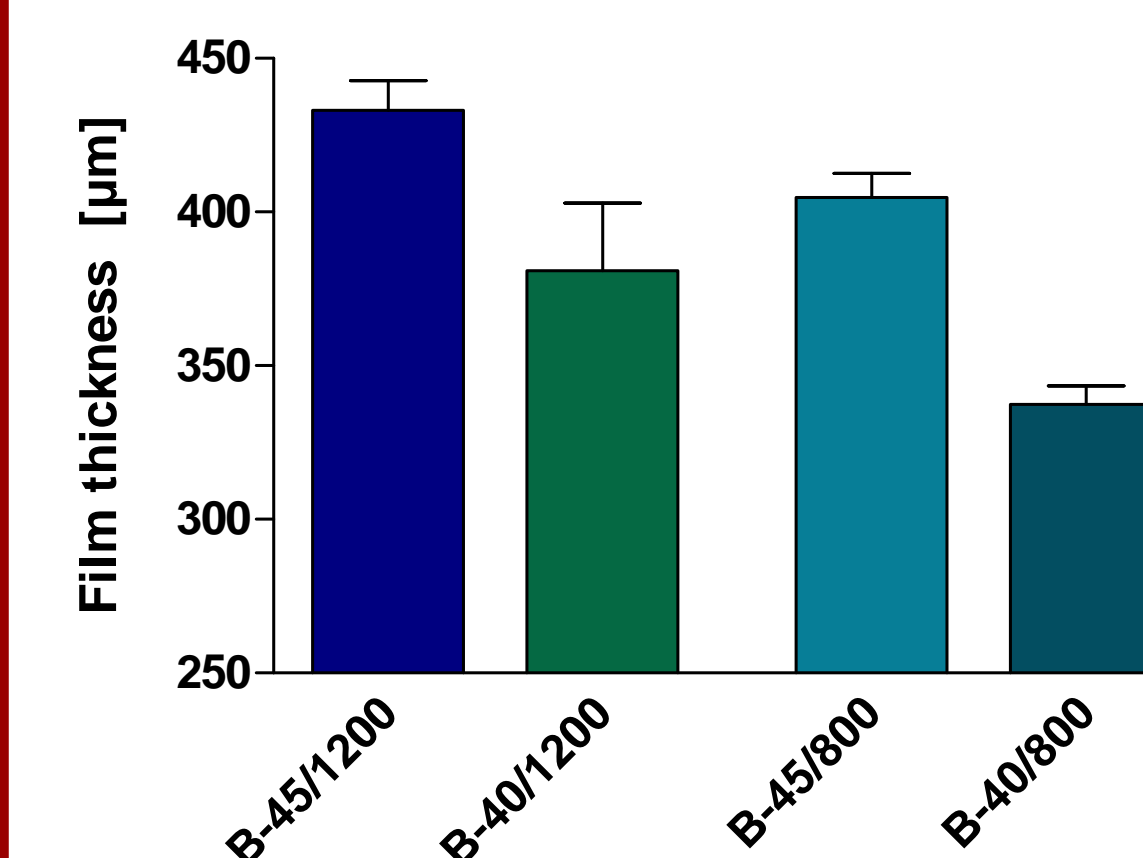


Fig. 3 : Effect of polymer conc. (45 and 40 % w/w) and velocity (800 and 1200 mm/min) on film thickness (device B).

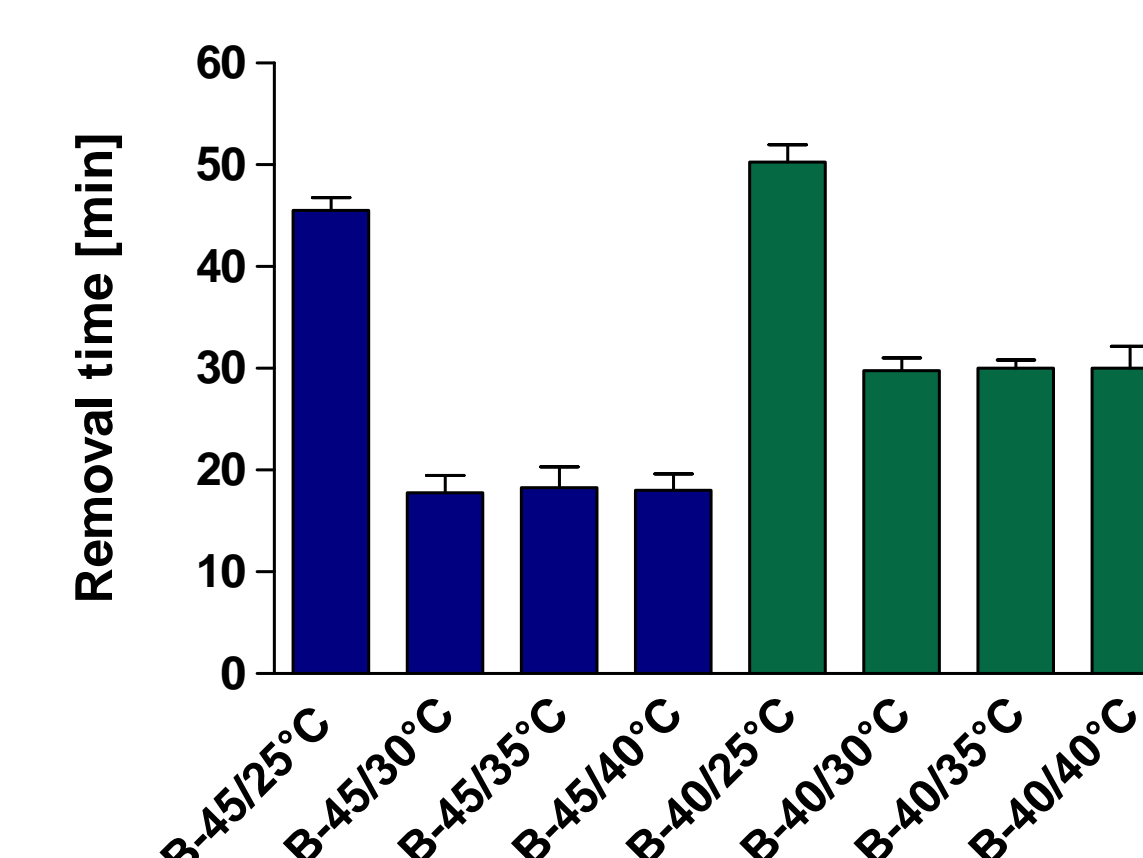


Fig. 4 : Effect of polymer conc. (45 and 40 % w/w), drum temperature on removal time (device B) at constant velocity of 1200 mm/min.

Discussion

- Film thickness was affected by the film forming device. For Kollicoat Protect[®] formulations with the same viscosity, thinner films were obtained with casting drum (B) compared to device (A) (Fig. 1).
- Viscosity effects were more pronounced at device (B), indicating the impact of the slope (Figs. 2 and 3).
- An increase of drum temperature reduced the removal time of the film from the drum. This can be explained by an increased drying rate, which obviously controls the mechanical performance of the films (Fig. 4).

Conclusion

The study revealed that the small-scale casting drum (device B) simulating the conditions at the rotary die machine is a useful tool to screen non-gelatin film forming polymers for their SC applicability. Kollicoat Protect[®] allowed homogenous SC films of appropriate thickness to be formed. Since the mechanical properties of Kollicoat Protect[®] films are controlled by their water content, the time to remove elastic free films is still relatively long and needs to be optimized by formulation strategies for transfer to SC manufacturing.

References

- [1] G. Reich, Formulation and physical properties of soft capsules, Chap. 11 in: Pharmaceutical Capsules, 2 nd edition, eds. F. Podczek and B.E. Jones (2004).
- [2] S. Pohl, G.Reich, Evaluation of a novel small-scale casting drum for soft gelatin capsule shell formulation screening, AAPS Annual Meeting 2009, # M 1245, L.A./USA (2009)