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Investigation of semi-solid in situ film-forming systems with QbD approach

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The development of dermal preparations is a great challenge to provide good penetration through the skin because of the barrier function of stratum corneum. Film forming systems (FFSs) are new alternative drug delivery systems which can increase the impact of dermal preparations.

The aim of my research work was to develop dermally applicable semi-solid in situ FFSs containing silicones, which form a film on the skin, with appropriate mechanical properties. Silicones were used in the systems because of their “silky-touch” and protective effects to improve the quality of FFSs. FFSs were developed and investigated using the Quality by Design (QbD) approach. During the initial risk assessment, critical attributes were distinguished and measured. These critical quality attributes (CQAs) were skin adhesion, film flexibility and burst strength, film appearance, film integrity and the drying time of the semi-solid system. Critical material parameters (CMAs), namely the type of silicones, film forming excipients, drying excipients, and viscosity enhancing excipients were also found.

The results showed that the silicone content had a great effect on the FFSs. They had an influence on the mechanical properties of the films, and on the drying time. The investigation of the drying mechanism showed promising results because of the silicon content.

References:

1. Nikolett K. et al. *Pharmaceutics* 11(12), 660 (2019)

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