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Investigation of dermal semisolid in situ film-forming systems containing lidocaine hydrochloride with QbD approach

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Recently, research has been focused on developing dermal local anesthetic treatment to decrease pain before a surgical intervention. This treatment is non-invasive and painless, therefore provides an attractive alternative to injection. Lidocaine hydrochloride (LID-HCl) is a commonly used drug in local anesthesia, but its effective time is short. Film-forming system (FFS) is an innovative drug delivery system, which forms a film after application, dries fast, and has good mechanical properties. These advantages make FFSs a promising choice in local anesthesia.

The aim of my research work was to develop LID-HCl containing semisolid in situ FFSs using the Quality by Design (QbD) approach. The FFSs were developed from the silicone containing blank formulations, which were used in my previous research. They were investigated regarding the effect of LID-HCl on the film-forming properties and the skin permeation of the active ingredients. The QbD approach was used to ensure the quality-based development.

During the research, initial risk assessment identified four high-risk critical quality attributes (CQAs): in vitro drug release, in vitro drug permeation, drying properties and mechanical properties, and three medium-risk CQAs: pH, viscosity, and film appearance. Furthermore, four high-risk critical material attributes (CMAs) were also considered during the formulation: permeation enhancing excipients, drying excipients, film-forming excipients, and emollients. These parameters were investigated during the work.

Results show that LID-HCl has great impact on FFSs. The silicone content can improve the applicability of formulations and has a favorable effect on the permeation rate of LID-HCl.

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