Chapter 1

Introduction

1.1 Background

Creams are semi-solid dosage formulations typically intended for topical application, known to be capable of delivering active ingredients to the underlying skin or tissue layer effectively. It is an emulsion-based system composed of an oil and water phase, in which the ratio between the two determines whether the cream is Oil-in-Water (O/W) or Water-in-Oil (W/O) (Khare et al., 2021). Creams are widely preferred compared to other dosage forms as they are convenient, easy to apply, and non-intrusive in nature, becoming an effective method of delivering medication molecules with lower concentrations than traditional methods (Nunse et al., 2022; Sonawane et al., 2021). However, in order for the cream to be able to function as intended, the formulation is expected to have favorable physicochemical and sensory attributes (Ali et al., 2022). Properties such as organoleptics, pH, viscosity, and stability would greatly contribute to the effectiveness and longevity of the product, as well as the satisfaction of the user during application (Nunse et al., 2022). As such, it is important to place much consideration during formulation development to ensure that the cream products maintain appropriate quality attributes while delivering their intended therapeutic benefits effectively.

The selection of ingredients and multiple processing variables can significantly influence product characteristics. The parameters include the concentrations of emulsifiers and stiffening agents, the composition of the oil phase, and the oil-to-water ratio, all of which can affect the overall performance and comfort in use of the final product. Emulsifiers, such as the stearic acid-triethanolamine (TEA) system, play a great role in the overall viscosity and stability of the cream (Chow et al., 2024; Safta et al., 2023). Traditionally, optimization of such formulations would often be time-consuming and inefficient. Therefore, systematic statistical design methods, as applied within

the Quality by Design (QbD) concept, provide a more structured way to evaluate formulation variables simultaneously. Among these approaches, factorial design is particularly useful as it allows the investigation of both the individual and interaction effects of multiple factors while identifying optimal formulation conditions with fewer experimental trials (Pavčnik et al., 2025).

The aim of this study is to create a stable cream delivery system in which the stearic acid-TEA ratio is optimized via the application of factorial design. The different creams produced are evaluated for their physicochemical properties via technical and sensorial methods in determining an optimal product within the different variations.

1.2 Objective

- To develop and evaluate anti-acne topical cream formulations using varying stearic acid-TEA ratios using factorial design.
- To determine the effect of the variations applied to the physicochemical properties of the cream in order to identify the optimal cream formulation.

1.3 Hypothesis

- The cream formulations with different stearic acid-TEA ratios can be successfully developed and evaluated.
- The different ratios of the two ingredients will significantly affect the physicochemical properties of the formulation variations.
- The different ratios of the two ingredients will significantly affect the stability of the formulation variations.
- Comparison between the different cream variants based on their respective evaluation results will lead to the identification of optimal cream(s).