

How to Maximize Shelf Life of Topical Formulations

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Topical formulations as drug delivery systems are becoming increasingly popular. The ease with which creams, lotions, and ointments are applied makes them popular among consumers and pharmaceutical companies. One important feature to the marketability of a product,

especially topical medicines, is its shelf life. The shelf life, or period of time before the expiration date, is determined by the stability of the delivery system containing the drug. If the topical formulation is unstable over time, it may change in consistency, discolor, grow microbes, develop unpleasant odors, or have crystal growth, all of which are very important to avoid. To create an effective and long-lasting topical formulation, the initial suspension that contains the actual drug must be stable.

An indication of the stability of suspensions can be determined by zeta potential analysis. By knowing the zeta potential of formulations, the number of candidate formulations for a pharmaceutical product decreases which helps minimize the time and cost of testing a potentially unstable suspensions. Zeta potential measures the charge repulsions or attractions among particles which in turn affects the stability of a suspension. A high zeta potential value signifies a more stable suspension where particles are evenly distributed and tend to remain suspended. A lower value signifies an unstable suspension where particles tend to clump and aggregate. Zeta potential is commonly used to predict the stability of suspensions.

A couple of different factors can influence the zeta potential of a substance. A suspension's zeta potential relies on the nature of the active pharmaceutical ingredient (API) and excipients, but it can be modified. Topical formulations contain active ingredients that are usually dispersed throughout a base formulation containing necessary excipients. A variety of considerations go into choosing a base formulation such as: the physicochemical properties of the drug, the shelf life, the environment of where the drug is being applied, etc. Emulsions are often used as a base for lotions, creams, or ointments,

and are accompanied by emulsifiers or surfactants. Emulsions are unstable by nature since they are usually composed of two immiscible liquids that separate into layers over time. To increase the zeta potential of a topical formulation, emulsifiers are usually added. These surfactants will help keep particles apart and avoid clumping, creating a more stable dispersion. Choosing an appropriate emulsifier is also an important step in the formulation process. Some emulsifiers may inhibit the drug from being delivered effectively, so separate studies must be conducted to test the effect of emulsifiers on drug delivery.

Certain conditions can also facilitate a high zeta potential value. More acidic conditions can raise zeta potential because of the presence of numerous hydrogen ions creating a charged system. Optimizing the pH of a suspension can help raise the zeta potential to optimize shelf life.

Topical formulations are easy to use, but present challenges to properly formulate. A variety of factors such as whether the drug will reach its targeted area or whether the suspension will remain stable must be considered when making a topical pharmaceutical product. The shelf life is a very important characteristic of any pharmaceutical product. In topical formulations or other suspension based drug delivery systems, zeta potential plays an important role in determining the stability and effectiveness of a drug over time, and thus should be measured carefully.

