TECH TIP 11

How to Maximize Shelf Life of Topical Formulations

Jack G. Saad

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 suspension that contains the drug. If the topical formulation is unstable over time, it may change in consistency, change color, grow microbes, smell, or have crystal growth, all of which is very important to avoid. To create an effective and long-lasting topical formulation, the initial suspension that contains the actual drug must be stable.

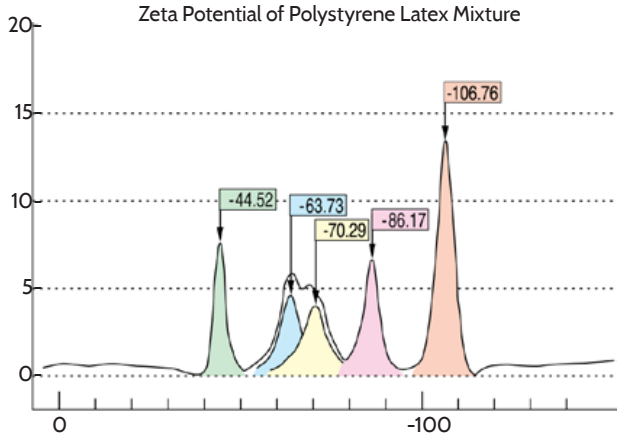
The stability of suspensions can be determined through zeta potential. By knowing the zeta potential of formulations, the number of candidate formulations for a pharmaceutical product decreases which helps minimize the time and cost of testing an unstable suspension. Zeta potential measures the charge 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. A lower value signifies an unstable suspension where particles tend to clump and aggregate. Zeta potential is commonly used to improve the stability of suspensions.

A couple of different factors can influence the zeta potential of a substance. A suspension's zeta potential relies mainly on the nature of the active pharmaceutical ingredient (API), but it can be modified. Topical formulations contain active ingredients that are usually dispersed throughout a base and necessary excipients. A variety of considerations go into choosing a base such as: the nature 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 with emulsifiers, or surfactants. Emulsions are unstable by nature since they are usually composed of two immiscible liquids that settle into layers over time. To raise the zeta potential of a topical formulation that contains emulsions, emulsifiers are usually added. These surfactants will help keep particles apart and avoid clumping, creating a more stable dispersion. Choosing the emulsifiers is a separate process. Some emulsifiers may inhibit the drug from being delivered, 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. Changing the pH of a suspension can help raise or lower the zeta potential to optimize shelf life.

Topical formulations are easy to use, but not so easy to make. A variety of factors like 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, the zeta potentials of suspensions play an important role in determining the stability and effectiveness of a drug over time, and thus should be measured carefully.



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