Analytical Investigation of the Excipient Polysorbate 80

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Proteins are increasingly used as active substances in medicine. Because their stability and physiological action largely depends on their environment, a well-tolerated, stable formulation is required to maintain the activity of the protein. One common issue related to proteins in solution is their tendency to form aggregates, which is usually prevented by the addition of non-ionic surfactants to the formulation. However, the current knowledge on the prevention of aggregation by excipients tends to be inconsistent [1, 2], and some of these substances may promote rather than prevent protein aggregation, especially if other stress factors such as light or shaking are involved. Polysorbate 80, which is commonly used as excipient in a variety of formulations as well as other polysorbates were selected for a detailed analytical investigation. Characterization of Polysorbate 80 by various physical and chemical methods, such as polarimetry, cloud point, refractive index and viscosity determination, differential scanning calorimetry, chromatographic and spectroscopic methods, revealed that the substances from different suppliers considerably varied in composition and stability. Furthermore, we also found divergences in the composition of different batches from the same supplier. This heterogeneity most likely has an effect on the stability of the protein in a formulation. Our results will give an insight into the influences of excipients in protein solutions and may provide guidelines for the future development of formulations.

References

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