The Stability of the Free Eudragit NE Films Stored under Different Conditions

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Film coatings are very popular in the pharmaceutical technology, and are applied during the formulation of solid dosage forms. This is a widespread method for protection, retardation and identification. Eudragit NE 30 D aqueous dispersion is a commonly used coating material, which contains methacrylate copolymers as film-forming agent and nonoxynol 100 as an endogenous emulsifier with a melting point of 58-59 °C. The dissolution of the active ingredient from Eudragit NE-coated samples during storage is known to undergo change. The crystallization of the emulsifier agent can play an important role in this [1].

This polymer is not soluble in the gastrointestinal tract, but is permeable for different active agents. Various parameters can influence the permeability of this film, e.g. via the tensile properties of the film. Change in the film thickness can cause the stretching of the film on a solid surface. Alterations in this physical parameter of the film were measured and the effects of three different storage conditions (40±2 °C/75±5% RH, 25±2 °C/60±5% RH and ambient (25±3 °C)/ RH < 35%) and storage times (1, 2 and 4 weeks) were evaluated.

In this study, free films were prepared from Eudragit NE 30 D without any additives. The dispersion was sprayed onto a rotating telfon surface. The crystallization of nonoxynol was followed via the changes in the DSC curve of the free film. A screw micrometer was used for the determination of thickness.

The thickness of the free films changed during storage. The alteration in thickness for the films stored at 40 °C/75% RH was significantly differed from the other two cases. A slight reduction can be detected for films stored at 40 °C and a significant increase in film thickness was for films stored at 25 °C. Lengthening of the storage time increased the relative change in film thickness for both films stored at 25 °C.

It can be seen from the DSC curve of the every film that there is an endothermic peak around the melting point of nonoxynol. This peak therefore can be explained by the presence of nonoxynol crystals in the film. The both films stored at 25 °C gave similar curves, containing an endothermic peak. The films stored at 40 °C/75% RH yielded curves with different shapes. There are two peaks at about this temperature. It point to different changes in the structure. The time of storing did not influence the peak temperature significantly, but the lengthening of the storage time continuous increased the peaks under every condition. It refers also to the increase of the crystallised part of the emulsifier within the samples. A higher extent of change in the crystallinity of nonoxynol can be seen in the films stored at 25 °C, especially at lower RH.

A relationship was found between the film thickness and the crystallization of nonoxynol. It was established that the different storage conditions influence these changes. The temperature and the air humidity are important in this phenomenon. Lengthening of the storage time increased the difference in film thickness and crystallisation of emulsifier.

Reference

1. A. Y. Lin, N. A. Muhammad, D. Pope, L. L. Augsburger, AAPS PharmSci, 3 (2), (2002) article 14.