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Tracking of Physicochemical Properties in Free Films Containing an API

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Coated dosage forms in which the active pharmaceutical ingredient (API) is incorporated in the film layer in order to achieve rapid release have become very common in recent years. Our present aim was to develop a matrix pellet containing an API in the coated layer. The presence of insoluble particles in the coating liquid is a critical parameter in the preparation of films as such particles can modify the properties of the film formed [1, 2]. The film surface is required to be smooth, resistant against mechanical effects, heat and light. The excipients and APIs incorporated in a film layer influence the structure of the film significantly.

In this work, films were prepared on a teflon surface. The coating liquid was prepared as reported previously [3]. Eudragit[®] L 30 D-55 dispersion was used as polymer, and Diclofenac sodium as API. The samples contained 0, 1 and 5% of the API. Measurements were made on the mechanical properties, surface properties and glass transitions of the free films, and on the free volume holes in the films.

The mechanical strength and the degree of deformation of the films were determined by the recording of deformation curves. Contact angles were measured to evaluate the surface free energy, solid surface free energy, liquid surface tension and polarity. Glass transition temperatures were detected by means of DSC. Positron annihilation spectroscopy was applied to study the free volume and track interactions between the polymer and the active ingredient. The size distributions of free volume holes were calculated from positron lifetime data for films of different compositions. The long-term stability of films was also studied.

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