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Effects of lecithin on the mechanical properties of hydroxypropylmethylcellulose free films

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The effects of the biocompatible surfactant lecithin (a pigment-stabilizing agent) on the mechanical properties of free hydroxypropylmethylcellulose films were evaluated. The film thickness and the characteristics of the deformation curve were not altered relevantly by the incorporation of lecithin. The deformation force decreased markedly when the lecithin content of the film exceeded 5%.

The use of film-forming polymers in aqueous solutions to produce coated solid dosage forms is very popular (Cole et al. 1995). Numerous water-soluble and insoluble additives (plasticizers, pigments, dyes etc.) are applied to change the properties of such films and to increase the processibility of coating liquids (Routsalainen et al. 2003; Satturwar et al. 2003). Insoluble pigments (e.g. iron oxide, titanium dioxide, etc.) are employed to ensure an appropriate appearance of the coated product. Such additives can modify the properties of the resulting film (Nimkulrat et al. 2004; Plumb et al. 2002) and their homogeneous distribution is therefore indispensable. The main problem that can arise during formulation of a coating fluid is sedimentation of the pigments, which can give rise to an uneven coating layer and/or difficulties in the coating process. Various additives (viscosity-increasing agents or surface-active wetting components) are applied to eliminate this problem for orally or topically used suspensions (Aulton 2002). These materials are restricted to pigment suspensions prepared for coating dispersions because of the possibility of changes in the properties of the films. The effects of wetting tensides (e.g. polysorbate or nonoxynol) on the stability of films, for instance, are very well known. The thermal and mechanical properties of the films are changed appreciably by the presence of these components (Bajdik et al. 2003, Bajdik and Pintye-Hódi 2006).

Table: Properties of free films

Sample	Lecithin content (%)	Thickness (μm)	Deformation force (N)
S0	0	118 ± 18	77.66 ± 7.93
S1	5	129 ± 7	76.77 ± 6.34
S2	10	133 ± 11	39.18 ± 5.56
S3	15	138 ± 17	8.79 ± 2.19
S4	20	158 ± 9	7.61 ± 1.54
S5	25	166 ± 12	7.47 ± 1.49

The use of biocomponents (e.g. chitosan, alginates and lecithin) as additives is currently becoming more widespread. These materials are biocompatible and biodegradable, with an expanding field of application (Sonvico et al. 2006; Cui et al. 2006). Lecithin is a well-known surfactant phospholipid which can be used in the pharmaceutical and food industries (Rowe et al. 2003). It is able to bind to certain oligosaccharide moieties. Thanks to these interactions and the alterations in the glycosylation pattern of cells in response to malignant transformations, lecithin-mediated targeting is an encouraging approach to site-specific antitumour therapy (Plattner et al. 2008). It forms an emulsion in water. It is mainly applied as an emulsifying agent, viscosity enhancer, dissolution modifier or wetting agent, since it provides the rapid and complete wetting of powders into aqueous systems (Szuhaj 1983). It is also used to produce nanosuspensions (Schubert and Müller-Goymann 2005), a form that can be useful in aqueous coating liquids containing water-insoluble particles. As an example, the conventional methods of formulating suspensions containing titanium dioxide often result in insufficient liquid. An inappropriate particle size can lead to imperfect refractive properties. There have been a few attempts to formulate nanosuspensions from titanium dioxide in order to increase the sun-screen effect of dermal preparations (Villalobos-Hernández and Müller-Goymann 2006). However, lecithin has not been used in a method to produce a light-protective coating. Before formulation, it is very important to know how lecithin influences the properties of the final film.

In the present study, the conventional protective coating agent hydroxypropyl-methylcellulose (HPMC) was used as film-former. Films containing different proportions of lecithin were prepared. The process of film deformation was evaluated with an apparatus developed in our institute. The deformation force was measured at the deformation point of free polymer films, and the effects of the lecithin content were studied.

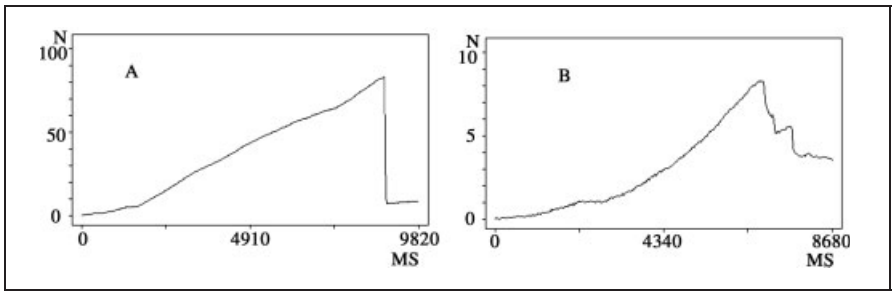

Fig.:
Deformation curves of films (A – film without lecithin (S0); B – film with lecithin (S5))

The results revealed that the thickness of the free films tended to increase with increasing concentration of lecithin. The characteristics of the deformation curve did not change relevantly on the application of lecithin; they demonstrated strongly elastic behaviour (Fig.). Each curve can be divided into three parts: a short elastic period with low slope, a short horizontal visco-elastic segment, and a long elastic segment, continuing up to the deformation point.

The change in the value of the deformation force was very significant (Table). A higher force was necessary to break a film of the same thickness prepared from the same liquid, but without lecithin. At 5–15% lecithin content, the deformation force decreased considerably, with the further change of the deformation process at $> 15\%$ lecithin.

It may be concluded that the application of lecithin in an aqueous coating liquid containing HPMC is restricted. The increase in the thickness of the film can be explained by the change of the structure of the film. The binding between the macromolecules is disturbed, the mechanical strength thereby becoming weaker. Lecithin can serve as a pigment-stabilizing component, but its content must not exceed 5%. Otherwise, independently of the other insoluble particles, the mechanical strength of the free film is insufficient.

Experimental

HPMC (Pharmacoat 606, Shin-Etsu Chemical Co., Ltd., Tokyo, Japan) was used as film-forming component, and deoiled lecithin (The Solae Company, Solae Europe, Geneva, Switzerland) as surface-active agent. Liquids were prepared with 10% solid content. The lecithin content in the film was 0, 5, 10, 15, 20 or 25%. Two ml of each liquid were poured onto a circular even teflon surface with a diameter of 3.3 cm. This liquid was then dried at $25 \pm 2\ ^{\circ}C$ and $50 \pm 5\%$ RH.

The strength tester and the software employed were developed in our institute. This device contains a special specimen holder and a hemispherical stamp, and is connected to a computer via an interface; thus, not only the ultimate deformation force can be measured, but the process (force-time and force-displacement curves) can be followed. The round specimen is located horizontally and the stamp moves vertically. Film thickness was measured at the middle of the specimen with a screw micrometer (Mitutoyo, Japan). Ten parallel tests were performed.

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