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Comparison of the micro- and macrostructural characteristics of biopolymer cast films

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ABSTRACT

In addition to the chemical composition the molecular architecture has a decisive impact on the formulation of polymeric drug delivery systems. An ideal buccal polymeric film or patch dosage form should be flexible, elastic, soft, yet adequately strong. The microstructural characteristics through the molecular ordering determine the mechanical properties of free films. In the present study sodium alginate–Carbopol cast films containing vitamin B_{12} were formulated. The sodium alginate (SA) concentration was changed from 3 to 6 wt% and the proportion of Carbopol (CP) was varied in the formulations. Texture analysis was carried out for the macrostructural characterization of films based on their mechanical properties and positron annihilation lifetime spectroscopy (PALS) was applied to track the microstructural changes based on the ortho-positronium (o-Ps) lifetime values as a function of their composition. The results indicated that the combination of the evaluation of o-Ps lifetime discrete values with the characteristics of lifetime distribution curves enabled the selection of homogeneous films of required mechanical properties.

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1. Introduction

The use of polymeric films for buccal delivery is preferred over adhesive tablets in terms of flexibility and comfort. An ideal buccal film should be flexible, elastic, soft yet adequately strong to withstand breakage due to stress from mouth activities [1]. The characteristics of polymeric materials depend not only on their chemical composition but also on the structure and morphology developed during processing. The polymers typically exist in one of two amorphous states: glassy and rubbery. In the glassy state there is very limited amount of rotation going around the chain axis. Glassy polymers are usually dense, hard structures with very little internal void space. In rubbery state, more free volume is available thus the polymer chains exhibit a lot more mobility. Diffusion rates are generally higher in rubbery state than in glassy state. The tensile modulus in the glassy state was predominantly related to intermolecular packing, while in the rubbery state crosslink density was the important factor. The large strain properties like tensile strength, elongation-to-break, and puncture strength [2] showed a more complex dependence on chemical structure [3], molecular architecture, intermolecular packing and crosslink density [4].

Various synthetic and biopolymers have been investigated for their application in buccal delivery system including chitosan, poly (acrylic acid), hydro alkyl celluloses, polymethacrylates, sodium alginate, poly-L-(lactide-coglycolide), polycarbophil, and poly(ethylene oxide). From therapeutically point of view the prerequisite of the buccal drug absorption from a polymeric film delivery system is the continuous bioadhesive film formation of good bioadhesivity. One of the selected polymers, the sodium alginate assured the fast dissolving film formation while

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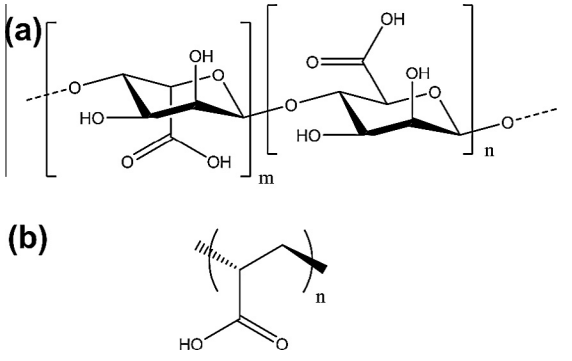

Fig. 1. Chemical structure of (a) SA and (b) CP polymers.

Table 1
Composition and physical characteristics of the samples.

Sample	Amount of excipients (mg/10 g hydrogel)				Water content (wt%)
	SA	CP	Vitamin B_{12}	Water	
A	300	–	2.0	9698	5.7 ± 0.8
B	300	15	2.0	9683	7.4 ± 1.2
C	300	25	2.0	9673	5.3 ± 1.7
D	450	–	2.0	9548	6.0 ± 0.8
E	450	15	2.0	9533	8.1 ± 1.1
F	450	25	2.0	9523	6.4 ± 1.4
G	600	–	2.0	9398	3.6 ± 1.3
H	600	15	2.0	9383	5.6 ± 0.5
I	600	25	2.0	9373	5.6 ± 0.8

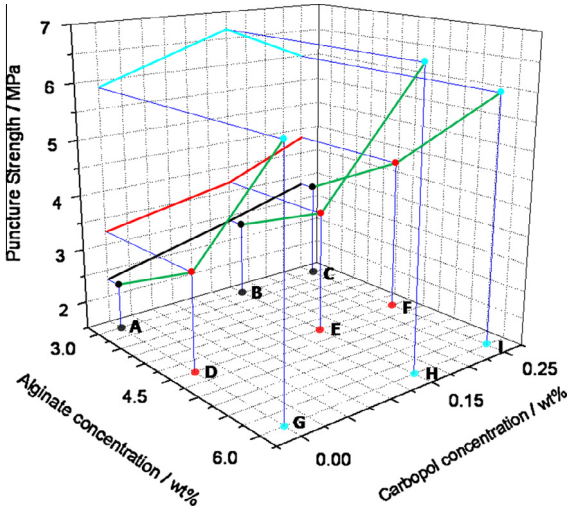

Fig. 2. Puncture strength values of the polymer films.

the presence of Carbopol increased the bioadhesivity but decreased the rate of the drug release from buccal films [5]. The relative bioadhesivity of polymers are summarized by Hunt et al. [6].

PALS is a unique method for the tracking of the microstructural changes of polymeric drug delivery systems. The method is suitable for the determination of the size distribution of free volume holes in polymers. The measurements are based on the interaction of the free volume holes and the so called *ortho*-positronium atom. This 'atom' is a bound state of an electron–positron pair and reacts to the changes of the free volume very sensitively [7,8].

The purpose of the present study was to find a correlation between the micro- and macrostructural properties of cast films based on the free volume and puncture strength changes.

2. Experimental section

2.1. Materials

Alginic acid sodium salt (SA) from brown algae (CAS 9005-38-3) was obtained from Sigma and Carbopol® 71 G NF (acrylic acid cross-linked with polyalkenyl ethers or divinyl glycol, CP) (Fig. 1) was provided by Noveon Inc., Vitamin B_{12} (Ph.Eur.) received from the Gedeon Richter Plc.

2.2. Sample preparation

Samples were prepared by dissolving the necessary amount of solid materials (Table 1) in distilled water under stirring at room temperature for 48 h. 1.6 g of the prepared hydrogels was weighed into 3.5 cm diameter plates then the samples were dried at 22 ± 2 °C temperature and 50 ± 5% relative humidity for 24 h. The thickness of the obtained cast films was 25–40 μm. Freeze-dried samples were also prepared from the same frozen hydrogels with 24 h drying at 6 °C tray heating.

2.3. Texture analysis

Puncture strength (PS) of films was measured with a texture analyzer (TA.XT®plus Texture Analyser, Stable Micro System Ltd., UK) operating with a 5-kg load cell. Three samples were fixed between two perforated special stainless steel plates of 8 mm hole diameter. The cylinder probe of 5 mm diameter was moved perpendicularly with a constant speed of 0.01 mm/s towards the film. During the entire measurement a force–distance curve was recorded and the resulting profiles analyzed using Texture Expert Exceed (Stable Micro System Ltd., UK). The PS was calculated using the equation:

$$\mathrm{PS}\,[\mathrm{N/mm^2}] = F/A,$$

where F is the load required for puncture, A is the cross-sectional area of the of film.

2.4. Scanning electron microscopy

Freeze-dried film samples were fixed on the sample holder using double adhesive tape, and gold coating was applied. Examinations were performed by means of a scanning electron microscope (SEM, Philips XL 30, Amsterdam, The Netherlands) at 15 kV accelerating voltage with a working distance of 10.0 mm. Original magnification 35× with an accuracy of ±2% was used.

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