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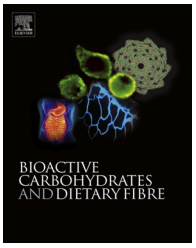

Surface properties of semi-synthetic enteric coating films: Opportunities to develop bio-based enteric coating films for colon-targeted delivery

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ABSTRACT

This study investigated the surface properties of the semi-synthetic enteric coatings materials for colon-targeted bioactive delivery. The enteric coating materials were prepared by combining nanoscale resistant starch, pectin, and carboxymethylcellulose. The surface properties of the coating materials were characterized by atomic force microscopy for barrier properties, physical stability, and the viscoelastic properties: the surface of the coatings was characterized in terms of root-mean square roughness (RMS), peak- to-valley height (R_z), surface skewness (R_{sk}), and surface kurtosis (R_{ku}). The coating with pure nanoscale resistant starch was used as a control, which showed poor surface properties compared to the other films. However, the enteric coating films with nanoscale resistant starch: pectin 90:10 and nanoscale resistant starch: carboxymethylcellulose 10:90, showed very good barrier properties, visoelasticity, and physical stability. Therefore, the results of study suggest that the nanoscale resistant starch, pectin, and carboxymetylcellulose could be used to produce novel enteric coatings with good surface properties towards targeted delivery of bioactive compounds to the colon.

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1. Introduction

Enteric coating materials for targeted bioactive compounds delivery should be effective, efficient, and safe (Parveen, Misra, & Sahoo, 2012). The enteric coatings should also be stable during their passage through the gastro intestinal (GI) tract. In addition, the enteric coatings that are biocompatible will have greater appeal in human applications (Parveen et al., 2012; Dimantov, Greenberg, Kesselman, & Shimoni, 2004). Thus, the design and selection coating materials is critical for targeted deliveries of pharmaceutical and nutrients.

Development of coatings for colon-targeted delivery has progressed rapidly in the recent years; use of nanoparticles has become popular in the development of enteric coatings for targeted delivery. Most of the coating materials that are currently used, are derived from natural, semi-synthetic or synthetic sources (Nazzaro, Orlando, Fratianni, & Coppola, 2012; Dimantov et al., 2004). However, lately, a combination

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of resistant starch (RS), a fraction of starch that resists the digestion in the small intestine (Gibson & Roberfroid, 1995), with pectin and cellulose (ethylcellulose and carboxynethylcellulose) has shown potential value towards colon-targeted delivery (Dimantov et al., 2004; Liu, Fishman, Kost, & Hicks, 2003; Macleod, Fell, & Collett, 1997). The efficiency of these coatings can be further increased by reducing the particle size of one or more compounds, which are combined to form enteric coatings; the reduced particle sizes of the components can retain the bioactive compounds until they reach the colon (Dimantov, Kesselman, & Shimoni, 2004; Sivapragasam, Thavarajah, Ohm, & Thavarajah, 2014 and Sivapragasam, Thavarajah, Ohm, Khaitsa, & Thavarajah, 2014). Therefore, a potential approach to design efficient coating materials for colon- targeted delivery.

The overall goal of this study was to develop coatings with pectin and carboxymethylcellulose with nanoscale RS to determine their barrier properties, viscoelasticity, and diffusivity properties; semi-synthetic enteric coatings were produced with different combinations of RS nanoparticles, pectin, and carboxymethyl cellulose. The RS was isolated from soybean meal (SBM) (Sivapragasam, Thavarajah, Ohm, Khaitsa, & Thavarajah, 2014), soybean meal is a by-product of soybean oil processing, and used to produce nanoscale RS. Surface properties of the coatings were characterized by atomic force microscopy (AFM).

2. Materials and methods

2.1. Materials

Soybean meal was obtained from Northern Crops Institute (NCI), Fargo, North Dakota. Pectin, carboxymethylcellulose, and enzymes were purchased from Sigma Aldrich Co (St. Louis, MO). Glass slabs (3″ × 6″) were purchased from a local glass ware supplier at Fargo, North Dakota.

2.2. Coating materials

Resistant starch from soybean meal was isolated from a previously reported procedure (Sivapragasam et al., 2014b). Soybean meal was defatted using Soxhlet extraction. Defatted sample were mixed with 150.0 ml extraction buffer (50 mM ethylenediaminetetraacetic acid (EDTA), 50 mM sodium acetate, and 50 mM sodium oxalate at pH 5.2). The mixture was stirred for 60 minutes at 70 °C using a magnetic stirrer plate (VWR International LLC, West Chester, PA). This was followed by centrifugation for 15 minutes at 5000 rpm in a Beckman J2-HS (Beckman Coulter Inc., Brea, CA).The supernatant was mixed with ethanol to a final alcohol concentration of 70%. The sample was centrifuged again under the same conditions and the resulting precipitate was collected and dissolved in 50 mM sodium hydroxide with heating to 70 °C. Non-soluble particles were removed by filtration through Whatman filter paper number 4 (Whatman International Ltd., Maidstone, UK) and pectin was precipitated from clear solution by addition of solid barium chloride. The sample was then centrifuged for 10 min at 6000 rpm and the supernatant was mixed with ethanol to a final alcohol concentration of 70%. The sample was again centrifuged, with the precipitate air dried. The resulted sample was subjected to enzymatic assay to isolate resistant starch.

Table 2.1 – Composition of the enteric coatings.

Resistant starch (%)	Pectin (%)	Resistant starch (%)	Carboxymethylcellulose (%)
100	0	100	0
90	10	90	10
80	20	80	20
70	30	70	30
60	40	60	40
50	50	50	50
40	60	40	60
30	70	30	70
20	80	20	80
10	90	10	90
0	100	0	100

The soybean meal resistant starch was used to prepare nanoparticles by mechanical agitations. The resistant starch solution was prepared with ethanol at 1:5 (w/v). The solution was subjected to mechanical agitation by sonicating (40 kHz) using an ultra sonicator (Branson Inc., Chicago, IL) at 40 °C for 5 h.

The resistant starch nanoparticles were dissolved in 50 mM NaOH (3% w/v); the pectin and carboxymethylcellulose were individually dissolved in Millipore water (3% w/v). Different combinations of the enteric coatings were prepared as shown in Table 2.1.

2.3. Surface characterization

The thickness of the coatings casted on the glass slabs were 75 μm. The surface characterization was studied by AFM (Veeco technologies 3100, Santa Clara, CA) in a tapping mode. Scans were performed in air. The cantilever resonance frequency was 47–76 kHz with a force constant of 12.64 N m^{-1}. Sampling resolution were 512 × 512 points. Three different representative spots were selected and the measurements were averaged across the representative spots. The root mean square roughness (RMS) was directly obtained from the image. The peak-to-valley height (R_z), surface skewness (R_{sk}), and surface kurtosis (R_{ku}) were calculated using the following formulas (Stawikowska & Livingston, 2013):

$$Rz = Z\max - Z\min$$

$$R_{sk} = \frac{1}{nRq3}\sum_{i=1}^{n} Zi3$$

$$R_{ku} = \frac{1}{nRq4}\sum_{i=1}^{n} Zi4$$

3. Results and discussion

3.1. Surface roughness analysis

Surface roughness can be studied by root- mean square roughness (R_q) and peak-to-valley height (R_z). Figs. 3.1 and 3.2 show the changes in the R_q and R_z with different combinations of pectin and carboxymethylcellusose with resistant starch (RS); both R_q and R_z showed similar patterns. As shown in Fig. 3.1,

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