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The Chemical Resistance of Capsule Shells Based on Vegetable Analogs of Pharmaceutical Gelatin

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Abstract

This article investigates the chemical resistance of films and capsules based on vegetable analogs of pharmaceutical gelatin and estimates the chemical resistance of films and capsules per hour for the final destruction of structures in aggressive environments. It has been established that the greatest dissolution rate of films and capsules based on vegetable analogs of pharmaceutical gelatin is in concentrated hydrochloric acid, which to some extent reproduces the acidic environment of the stomach. The chemical resistance of films and capsules based on vegetable analogs of pharmaceutical gelatin is also associated with the ability of the filler to be wetted by the aggressive environment. It has been established that the best wetting of films and capsules occurs also with concentrated hydrochloric acid. The impact of hydrochloric acid leads to the loosening of the polymer, to a decrease in its density, and consequently to rapid degradation and dissolution. It is proved that the air cavities and microcracks facilitate migration of the fluid into the film or capsule, which reduces the intermolecular interactions and reduces the strength characteristics of the material.

Keywords

Capsule shells; Gelatin; Chemical resistance of capsules

Introduction

Market analysis of encapsulated drugs and biologically active additives (BAA) suggests close attention of capsule-manufacturing companies to seek alternatives to traditionally used gelatin [1,2]. This trend is based on the laws of development of the global consumer market: economic viability due to cheaper raw materials, consumer demand for encapsulated drugs and dietary supplements with new and different characteristics that meet a wide range of consumers, including those who do not use animal products for religious and/or behavioral (vegetarians) motives. All these factors lead to the relevance of technological development for the production of capsules based on non-traditional raw materials, including hydrocolloids of vegetable origin that can act as part of the composition [3,4].

Analysis of the world literature shows that to alternatively obtain gelatin capsules, various neutral and acid plant polysaccharides can be used: modified and unmodified starches, various gums, carrageenans, pectins, cellulose derivatives – hydroxypropylmethylcellulose and carboxymethylcellulose [5,6]. It should be noted that the Russian Federation has both sufficient crop area and production base for the majority of the items. In addition, the crisis in the livestock sector, coupled with the spread of infectious diseases (swine flu, spongiform encephalitis in cattle) among productive animals, and non-availability of by-products which are used as raw materials for producing gelatin contribute to the relevance of research on the composition of vegetable polysaccharides which are alternative in the manufacture of gelatin capsules.

The chemical resistance of polymer films depends on the stability of the operating properties of the films under the influence of the media. The latter can initiate in the films sorption medium components, desorption of the polymeric material additives (stabilizers, plasticizers, dyes, etc.), swelling (i.e., an increase in volume of the film due to the absorption of the medium) until dissolution, a change in the physical structure (crystallinity, microporosity, etc.) and chemical degradation of the polymer. These processes may occur simultaneously in any combination. Hence, to estimate the chemical resistance of polymer films, it is advisable to apply several methods [7,8].

Also, the chemical resistance of polymer materials depends on the nature, structure and chemical composition, and can be quantified by kinetic, diffusion, sorption, mechanical, and other parameters. However, such data is scarce, and therefore qualitative assessment of durability of materials is used. Typically, a three-point scale is used to change the strength and deformation properties of materials under the influence of the environment [9,10].

Materials and Methods

The following materials were used:

– Corn starch (Danisco, Denmark);

– Glycerin (99.0%, AppliChem, Germany);

– Gelatin (AppliChem, Germany);

– Kappa-carrageenan (Danisco, Denmark);

– Iota-carrageenan (Danisco, Denmark);

– Gelamil 308 (Danisco, Denmark);

– Starch amylase (Danisco, Denmark).

The capsule shells investigated were divided into three groups depending on the composition.

The samples of shells from vegetable analogs of pharmaceutical gelatin (in an amount of 10 pieces) were divided according to visual characteristics into three groups and numbered.

Samples from each group were examined [11].

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We analyzed the composition and properties of the structure of stabilizers for products based on vegetable analogs of pharmaceutical gelatin (CMC Akutsel 3265, 4500-6000 CMC, 6000-9000 CMC, pectin ARA 105, locust bean gum, sodium alginate NO4-600, sodium pyrophosphate SAPP 28, 2785 Akutsel CMC, sodium pyrophosphate SAPP 40, xanthan gum). Bulk density, viscosity, proportion of the insoluble residue content of microvoids, specific volume, specific surface area and characteristic diameter were selected as examined characteristics.

Acid and alkaline solutions were prepared in accordance with the regulations.

Results and Discussion

Results of the study of the chemical resistance of the capsule shells from vegetable analogs of pharmaceutical gelatin are presented in Table 1.

The table data shows that dissolution of the best specimens of capsule shell from vegetable analogs of pharmaceutical gelatin occurs in a solution of concentrated hydrochloric acid, due to an extremely aggressive environment.

Resistance of polymers to different chemical reagents and solvents varies widely, not only from polymer to polymer, but in some cases, within different grades of the same polymer. Generalizations regarding the chemical resistance of a polymer should be done with great caution, because very often there are exceptions. However, certain structural and chemical properties of the polymer can be used to approximate evaluation of resistance to various chemicals.

The chemical resistance of capsule shells based on vegetable analogs of pharmaceutical gelatin is also associated with the ability of the filler to be wetted in an aggressive environment. As can be seen from Table 1, the best wetting of the capsule shell occurs with concentrated hydrochloric acid.

The impact of hydrochloric acid leads to the loosening of the polymer, to a decrease in its density and consequently to rapid degradation and dissolution.

Reducing the density of the structure due to the presence of defects, particularly in the surface layer, at the interface between the polymer – solvent. Microcracks and air cavities facilitate migration of the liquid medium in a shell and reduce the intermolecular interactions and the strength characteristics of the material.

The impact of moisture and water on capsule shells based on vegetable analogs of pharmaceutical gelatin was studied. For this purpose, varying temperature determines the degree of change in mass of structured products with different mass fraction of fat and moisture. We assessed the overall dynamics of the content of the various forms of communication moisture (free water, osmotic moisture, moisture micropores multilayer moisture adsorption, moisture adsorption monomolecular) depending on the type and weight of the component casing.

Further studies are devoted to the study of forms of communication moisture in the capsule shell, depending on the mass fraction of protein. We analyzed the dynamics of change of content of various forms of moisture (free water, osmotic moisture, moisture micropores multilayer moisture adsorption, moisture adsorption monomolecular) depending on the mass fraction of various proteins. Further experiments are related to the study of activity of water in the capsule shell from vegetable analogs of pharmaceutical gelatin depending on the type and the mass fraction of protein. The activity of water, humidity and hygroscopic equilibrium moisture content were determined.

Conclusion

Thus, it was found that the best dissolution of the capsule shell samples from vegetable analogs of pharmaceutical gelatin takes place in the solution of concentrated hydrochloric acid, which is due to its extremely aggressive environment, the best wetting materials in hydrochloric acid and the presence of micro voids and cracks in structure of the films and capsules. Also, under the influence of acid, the density of polymers decreases and structures are destroyed very quickly.

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Solvent	Sample	No. 1	No. 2	No. 3	Capsule with Vaseline oil	Capsule with vitamin E
The dissolution time of the sample	H_2SO_4, Concentrated	*	*	*	*	*
	H_2SO_4, 0.1 M	–	–	–	18 h (turbidity)	4 h
	HCl, Concentrated	52 min	52 min	40 min	40 min	40 min
	HCl, 0.1 M	–	–	–	4 h (precipitate)	4 h
	NaOH, 2 M	55 min	52 min	40 min	40 min	55 min
	NaOH, 0.1 M	18 h	18 h (precipitate)	18 h (precipitate)	4 h (turbidity)	130 min
	Lactic acid	–	18 h (precipitate)	18 h (precipitate)	18 h (precipitate)	18 h
	Ethyl acetate	–	–	–	–	–
	Ethanol	–	–	–	–	–

*: Sample darkened, but did not dissolve
–: Did not dissolve within 18 h.

Table 1: Study of the chemical stability of samples of capsule shells from vegetable analogs of pharmaceutical gelatin

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