Research

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# Disintegration Properties and Drug Release Profiles of Sodium Alginate Films Modified with Additives

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## 1. Abstract

Film dosage forms (FDs) represent a promising approach for localized drug delivery due to their rapid disintegration and ease of administration. In this study, FDs were prepared using sodium alginate (Alg-Na) combined with different additives. The disintegration behavior of the films was evaluated by determining the quantity of Alg-Na released from the films in a limited aqueous environment. Caffeine and dexamethasone were selected as model drugs to examine drug release characteristics.

The results showed that incorporation of ascorbic acid into the film matrix significantly accelerated the disintegration of the alginate films. However, this effect was not observed when sodium ascorbate was used instead. The rate of caffeine release remained largely unaffected by the disintegration behavior of the films. In contrast, the release of dexamethasone increased when the disintegration rate of the films was enhanced. These findings indicate that modification of alginate-based films with suitable additives can influence film disintegration and control the release profile of poorly water-soluble drugs.

## 2. Introduction

Film dosage forms (FDs) are thin polymeric films containing active pharmaceutical ingredients. They are designed to rapidly swell and disintegrate when exposed to biological fluids such as saliva. As the film hydrates and breaks down, the incorporated drug is released from the polymer matrix. Due to this mechanism, FDs have become attractive systems for delivering drugs directly to specific sites within the oral cavity.

These dosage forms offer several advantages, particularly for patients who experience difficulty swallowing conventional tablets or capsules. The thin films are easy to administer, require no water, and can dissolve quickly in the mouth.

Water-soluble polysaccharides are commonly used in the preparation of such films because they can form thin layers upon solvent evaporation. Sodium alginate (Alg-Na), a natural polysaccharide derived from brown seaweed, is especially attractive due to its biocompatibility, safety, and excellent film-forming properties. Alginate-based films can be easily produced using the solvent casting method without the need for organic solvents or high temperatures.

Previous studies have demonstrated that alginate films can be useful in treating localized oral conditions such as stomatitis and oral mucositis. One of the most important characteristics influencing the performance of FDs is their disintegration rate. However, accurately measuring film erosion and disintegration can be technically challenging.

Earlier research introduced a simple colorimetric method capable of determining the amount of sodium alginate present in aqueous solutions. This technique allows the monitoring of alginate dissolution and has been applied to evaluate disintegration behavior of alginate-based films.

In the present study, film dosage forms were prepared using sodium alginate solutions containing various additives. Sodium glucuronate, glucuronic acid, ascorbic acid, and sodium ascorbate were incorporated into the film matrix. The disintegration profiles of the prepared films were analyzed by measuring the amount of alginate dissolved in the test medium. Additionally, the relationship between film disintegration behavior and the drug release rate was investigated using caffeine and dexamethasone as model compounds.

## 3. Experimental

### 3.1. Materials

Three different sodium alginate grades were used as film-forming polymers: Alg-A (300 cps), Alg-B (500 cps), and Alg-C (150M). These materials were obtained from Nacalai Tesque Inc. (Kyoto, Japan) and Kibun Food Chemifa Co. (Tokyo, Japan).

Hydroxylamine, caffeine, and dexamethasone were purchased from Wako Pure Chemical Industries (Osaka, Japan). Caffeine (CAF) and dexamethasone (DM) were selected as model drugs representing water-soluble and poorly soluble compounds, respectively.

1-Cyclohexyl-3-(2-morpholinoethyl) carbodiimide metho-p-toluenesulfonate (CMEC) was obtained from Aldrich Chemical Company (Milwaukee, USA). All additional reagents were of analytical grade and used without further purification.

### 3.2. Preparation of Alginic Acid (ALG)

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Alginic acid (ALG) was prepared through an acid precipitation method. Initially, a 1% (w/w) sodium alginate solution was prepared. A 2 M hydrochloric acid solution was slowly added to the alginate solution under continuous stirring while the mixture was maintained in an ice bath to prevent overheating.

As the pH of the solution decreased below 3, a coacervate precipitate formed. The resulting precipitate was separated by centrifugation at 1900 × g for 5 minutes. The collected material was washed once with deionized water and then rinsed three times with ethanol to remove impurities. The purified material was subsequently dried to obtain solid alginic acid.

The dried product appeared as a white block, which was ground into a fine powder using a mortar and pestle. The powder was then sieved through a 75 µm mesh to obtain uniformly sized particles suitable for further experimentation.

### 3.3. Preparation of Film Dosage Forms

Film dosage forms were prepared using the solvent casting method. Sodium alginate and the selected additive were dispersed in deionized water to create a film-forming solution. The mixture was thoroughly homogenized by sonication to ensure uniform dispersion of all components.

Approximately 3 g of the prepared solution was poured into plastic petri dishes with a diameter of 54 mm. The dishes were then placed in an incubator at 37 °C for 24 hours to allow solvent evaporation and film formation. After drying, the circular films were carefully removed and stored in a desiccator until further analysis.

Drug-loaded films containing caffeine or dexamethasone were prepared using the same procedure by dissolving the model drug in the alginate solution before casting.

### 3.4. Solubility Study of Model Drugs

The solubility of the model drugs in the presence of additives was examined using a shaking method. The drug and additive were introduced into the test medium and the suspension was maintained at 37 °C with continuous shaking for 24 hours to reach equilibrium.

After incubation, the suspension was collected using a preheated plastic syringe and filtered through a syringe-driven membrane filter with a pore size of 0.45 µm. The filtrate was then diluted with physiological saline before analysis.

Drug concentrations were quantified using high-performance liquid chromatography (HPLC), allowing accurate determination of the solubility behavior of the model compounds.

## 4. Conclusion

Fast-dissolving film dosage forms are particularly useful for delivering drugs in environments where only limited amounts of biological fluid are available, such as saliva. In this study, sodium alginate-based films containing different additives were successfully prepared and evaluated.

The results demonstrated that the addition of certain additives significantly influenced the disintegration behavior of the films. Accelerated film erosion enhanced the dissolution rate of dexamethasone, a poorly water-soluble drug. However, the release of the highly soluble drug caffeine was not affected by changes in film disintegration.

These findings suggest that alginate-based film dosage forms can provide flexible drug delivery systems. By modifying the film composition with suitable additives, it is possible to regulate both disintegration characteristics and drug release profiles. Such films may offer a convenient and effective dosage form for patients, particularly in oral drug delivery applications.

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