

COMMUNICATION

## A New Disintegrant for Pharmaceutical Dosage Forms

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### ABSTRACT

*The current research paper introduces a biodegradable, nontoxic polymer as a new disintegrant for pharmaceutical dosage forms. Gellan gum is a linear anionic polysaccharide approved by the U.S. Food and Drug Administration (FDA) for industrial use as a food additive. Experiments were carried out to evaluate the disintegrant property of gellan gum by taking ibuprofen as a model drug. The study included determination of optimum disintegrant concentration, effect of various binders, and suitable mode of incorporation of the disintegrant. The newly investigated disintegrant was compared with the conventional disintegrants to determine its relative efficiency.*

### INTRODUCTION

The disintegration of tablets in the GI tract is desired to facilitate the dissolution of the drug and its absorption (1). The one basic measurement generally used in evaluating disintegrants in a tablet formulation is the measurement of disintegration time (2). The present work reveals the systematic evaluation of gellan gum, a polysaccharide obtained from *Pseudomonas elodea* consisting of a linear tetrasaccharide repeat structure (3), as a new disintegrant by taking ibuprofen as a model drug (4).

### MATERIALS

Gellan gum (food grade), Kelco International, USA  
Ibuprofen IP, Seksheria Chemicals, India  
Avicel PH 102, FMC Corporation  
Explotab, Edward Mendell  
Ac-Di-Sol, FMC Corporation  
Kollidon CL, BASF, Germany  
Hydroxypropylmethylcellulose (HPMC, 6 cP),  
Courtaulds Chemicals  
Polyvinyl pyrrolidone (PVP K-40), Loba Chemie,  
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Polyvinyl alcohol (PVA, MW: 75,000), Loba Chemie, India

All materials were used as supplied.

## METHODS

Varied concentrations of gellan gum were incorporated intergranularly into the previously prepared ibuprofen granules and compressed into tablets. The disintegration time was noted.

To establish a suitable mode of incorporation of the disintegrant, gellan gum (4% w/w tablet weight) was incorporated intergranularly, intragranularly, and in combined form during the preparation of tablets. The disintegration time and in vitro dissolution rates were noted.

To study the effect of various binders on gellan gum, granules were prepared separately with various binders like starch PVP, PVA, and HPMC. To the dried granules, 4% w/w gellan gum was incorporated intergranularly, and compressed into tablets as above. The disintegration time and in vitro dissolution profiles were recorded. Efficiency of gellan gum was compared with other conventional disintegrants such as dried cornstarch, Explotab, Avicel PH 102, Ac-Di-Sol, and Kollidon CL. Granules were prepared with starch (10% w/w on dry basis) as binder. To these dried granules, the above disintegrants were incorporated intergranularly keeping the same concentration of 4% w/w (tablet weight) and compressed into tablets. The disintegration time and in vitro dissolution rates were determined.

## RESULTS AND DISCUSSION

The tablets ruptured and disintegrated within a few minutes when the concentration of gellan gum incorporated was 4% w/w (tablet weight). The disintegration of tablets might be due to the instantaneous swelling characteristics of gellan gum when it comes into contact with aqueous media, owing to its high hydrophilic nature.

When 4% w/w gellan gum was incorporated intergranularly, the time required to release 90% of the drug was 25 min. This could be attributed to an increase in amount of gellan gum easily available for the hydration when incorporated intergranularly. The other modes of incorporation resulted in increase of disintegration time and decrease in dissolution rate. Therefore intergranular mode of incorporation is the preferred mode of incorporation of gellan gum as the disintegrant in tablet formulations.

Table 1 represents the disintegration and in vitro dissolution profiles of gellan gum in combination with various binders. It has been shown that 4% w/w of gellan gum was required for the effective disintegration, and that 90% of the drug was released within 40 minutes. This clearly indicates the good compatibility of gellan gum with other conventional binders.

The disintegration and in vitro dissolution results of tablets made with gellan gum are tabulated in Table 2. The complete disintegration of the tablets was observed within 4 min with gellan gum concentration of 4% w/w, and 90% of the drug dissolved in 23 min. Ac-Di-Sol and Kollidon CL showed very similar patterns of disintegration and in vitro dissolution rates. With the same

**Table 1**  
*Effect of Various Binders on Gellan Gum*

Binders/ Concentration	Hardness of Tablets (kg/cm <sup>2</sup> )	Gellan Gum Concentration (% w/w)	Disintegration Time (min)	In Vitro Dissolution Time (min)	
				T-50	T-90
Starch (10% w/w)	5-6	4	4	7	25
PVP (2% w/w)	5-6	4	3	8	20
HPMC (5% w/w)	5-6	4	6	12	29
PVA (5% w/w)	5-6	4	7	18	40

**Table 2**  
*Disintegration and In Vitro Dissolution Profiles of Tablets with Various Disintegrants*

Disintegrant	Concentration (% w/w)	Hardness of Tablets (kg/cm <sup>2</sup> )	Disintegration Time (min)	In Vitro Dissolution Time (min)	
				T-50	T-90
Dried starch	4	5-6	> 15	90	220
Avicel PH 102	4	5-6	> 15	65	145
Explotab	4	5-6	7	20	36
Ac-Di-Sol	4	5-6	4	18	29
Gellan gum	4	5-6	4	12	23
Kollidon CL	4	5-6	3	8	20

concentrations of disintegrants, tablets made with Explotab showed 36 min for 90% of the drug release, and those made with dried starch showed 220 min. Avicel PH 102 showed an increase in disintegration time, probably due to insufficient disintegrant concentration. From these results, gellan gum has proved itself as a superior disintegrant and equally competitive with Ac-Di-Sol and Kollidon CL.

### CONCLUSIONS

Tablets prepared with gellan gum as the disintegrant were subjected to disintegration and in vitro dissolution tests. The results obtained were in compliance with the requirements of pharmacopoeias. Experiments showed that gellan gum acts as an excellent disintegrant. It is also compatible with various binders and excipients. The

intergranular mode of incorporation showed the best results. The overall results indicated that gellan gum improves disintegration and dissolution rate of drug, and that it can be very effective at low concentration. Therefore gellan gum is expected to be a new potential disintegrant for pharmaceutical oral solid dosage forms in the near future.

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