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# Exploration of Film Forming Properties of Film Formers Used in The Formulation of Rapid Dissolving Films

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**Abstract:** In the recent years, many of the pharmaceutical groups are focusing their research on rapid dissolving technology. Amongst the rapid drug releasing products, Oral film technology is gaining much attention. The main advantage of this technology is the administration to pediatric and geriatric patient population where the difficulty of swallowing larger oral dosage forms is eliminated. The aim behind this study was to explore the film forming properties of various film formers used in oral film technology. Different grads of methocel, polyox and natural gums were used as film formers. Films were prepared by solvent casting method. Films composed of Pullulan in combination with Xanthan gum showed excellent film forming capacity along with tensile strength 5.56 N/mm$^2$, disintegration time 22 sec and dissolution time 42 sec.

**Keywords:** Rapid dissolving film, Solvent casting method, Film formers.

## Introduction

Rapid dissolving dosage form (RDDFs) has become increasingly important because of their unique properties. They quickly disintegrate and dissolve, and can be administered without water, making them particularly suitable for pediatrics and geriatric patients[1-2]. Rapid dissolving films (RDFs), have gained popularity not only in breath strips but also in personal care, food and drug delivery markets[3]. Pharmaceutical companies and consumers alike have embraced RDFs as a practical and accepted alternative to traditional OTC medicines, such as liquids, tablets and capsules, because of the various benefits of the films. RDFs offer fast, accurate dosing in a safe, efficacious format that is convenient and portable, without requiring the use of water or a spoon. A variety of polymers are available for preparation of RDFs. The polymers can be used alone or in combination to obtain the desired films properties. The films obtained should be tough enough so that there won't be any damage while handling or during transportation[4]. The robustness of the strip depends on the type of polymer and the amount in the formulation[5]. On the other hand, RDFS dosage form should have the property to disintegrate in seconds when placed in mouth and deliver the drug to the oral cavity instantaneously. As the film forming polymer (which forms the platform for the RDFs) and plasticizer are the most essential and major component of the RDFs, at least 40-50 % w/w of polymer and upto 20% (total weight of polymer) of plasticizer should generally be present based on the total weight of dry RDFs [6]. Plasticizer is one of the vital ingredients of the RDFs formulation. It helps to improve the flexibility of the strip and reduces the brittleness of the strip. Plasticizer significantly improves the film properties by reducing the glass transition temperature of the polymer. In present study various film forming polymers were used and evaluated for various film

forming properties like, film forming capacity, appearance, mechanical properties, disintegration time and dissolution time.

## Materials and Methods

Pullulan gum was provided as gift sample by Gengwal Chemicals, Mumbai. Carrageenan gum, locust bean gum was purchased from Himedia, Mumbai. Hydroxyl propyl methyl cellulose (Methocel) K3, E3, E5, and E15, Ethyl Cellulose (Polyox) N10, N80 and N750 were provided as gift sample by Colorcone Asia Pvt Ltd. Goa. Propylene glycol (PG) and polyethylene Glycol 400 (PEG400) were purchased from Sigma chemicals.

**Preparation of films**

Required quantity of film formers were soaked in half the quantity of water for 8 hours to get uniform dispersion, in remaining quantity of water Plasticizers was mixed. Both solutions are mixed together for 1 hours using magnetic stirrer to obtain homogenous solution then solution is kept a side for 3 hours to escape air bubbles. Solution was then casted into petridishes having area of 64 $cm^2$ and 1.3 cm wall height. Petridishes were kept in hot air oven for 8 hours at 50˚ C. After drying films were removed with the help of sharp blade and kept in desicator for 24 hrs before cutting into small piece having area of 6 $cm^2$. Films with air bubbles, cuts or imperfections were excluded from study. Selected films were subjected for different evaluation parameters.

## Evaluation of rapid dissolving films:

**Film forming capacity**

It is ability of film formers to form desired films. It is categorized according to strip forming capacity such as very poor, poor, average, good, very good, excellent[1].

**Appearance of films**

Appearances of films were evaluated by visual observation such as transparent or opaque[8-9].

**Disintegration and Dissolution time**

The require size of film (3×2 $cm^2$) was placed in a stainless steel basket containing 900 ml of pH 6.4 buffer solution. Time taken by film to break and dissolve was measured as *in-vitro* disintegration time and *in-vitro* dissolution time. All studies were performed in triplicate for each batch[10].

## Results and Discussion

Determination of film forming capacity, appearance, disintegration time and dissolution time of all the formulations were shown in table I. Methocel K3, Polyox N10 and Polyox N80 these polymers found to have very poor film forming capacity with poor tensile strength, where as Methocel E15 and Pullulan gum were amounts the very good film forming capacity and tensile strength. Disintegration time and dissolution time of methocel E15 and pullulan gum was found to be 35 sec, 70 sec and 28 sec, 52 sec respectively. Appearances of all the films were opaque except methocel films. Films with Pullulan and Xanthan Gum were showed excellent film forming capacity and better tensile strength (5.56 $N/mm^2$) with disintegration time (22 sec) and dissolution time (42 sec). Optimized oral rapid dissolving films should have good film forming capacity, better appearance, lowest disintegration and dissolution time. The pullulan based film formulation was showed excellent film formulation capacity, lowest disintegration (22 sec.) and dissolution time (42 sec) time. So that pullulan is best film forming polymer among the all polymers.

**Table 1: Films of different polymers and their evaluations**

| Polymers used | Film forming capacity | Appearance | Tensile strengths $N/mm^2$ | % Elongation | Disintegration Time(sec) | Dissolution Time (sec) |
|---|---|---|---|---|---|---|
| Methocel K3 | Very poor | Transparent | 1.31 | 1.67 | 39 | 62 |
| Methocel E3 | Poor | Transparent | 1.46 | 1.36 | 43 | 63 |
| Methocel E5 | Good | Transparent | 3.72 | 4.38 | 35 | 70 |
| Methocel K15 | Very good | Transparent | 6.32 | 8.56 | 52 | 78 |
| Polyox N10 | Very poor | Opaque | 1.05 | 1.37 | 27 | 39 |
| Polyox N80 | Very poor | Opaque | 1.26 | 1.92 | 29 | 43 |
| Polyox N750 | Poor | Opaque | 1.43 | 1.78 | 34 | 50 |
| Pullulan gum | Very good | Opaque | 3.34 | 5.87 | 28 | 52 |
| Carrageenan gum | Very poor | Opaque | 0.73 | 1.45 | 32 | 67 |
| Xanthan gum | Very poor | Opaque | 0.65 | 2.62 | 45 | 60 |
| Pullulan + Xanthan gum | Excellent | Opaque | 5.56 | 10.76 | 22 | 42 |

## Conclusion

Various film former were used and evaluated as mention in table 1, films prepared with pullulan and xanthan gum were having good visual appearance, excellent film forming capacity, good mechanical strength (5.56 N/mm$^2$) least disintegration (22 sec) and dissolution time (42). So it can be concluded that pullulan is the best film forming agent among all film forming polymers.

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