Screening of Film Formers for Oral Thin Films, a Novel Pharmaceutical Dosage Form

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ABSTRACT

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Keywords:

Oral thin film, HPMC, MC, Pullulan Oral films have gained popularity in recent years as novel pharmaceutical dosage forms, and are the most Oral dosage forms that avoid the hepatic system and provide a more effective therapeutic response are considered acceptable and accurate. These forms are particularly valued for their ease of use, especially among pediatric and geriatric patients, and are also favored by the pharmaceutical industry. They offer the combined benefits of the stability typically found in solid dosage forms and the practical application of liquids. The aim of the present study was to develop a versatile casting solution suitable for the production of oral thin films to which active pharmaceutical ingredients can be added.

The research aimed to evaluate various film-forming materials for the development of orally dissolving films, with the goal of identifying optimal film formers and an appropriate manufacturing process. Various film forming polymers with different concentrations were used in this study as Hydroxyl Propyl Methyl Cellulose (HPMC), Methyl Cellulose (MC), Pullulan, Carrageenan, Sodium Alginate, Poly Vinyl Alcohol (PVA), Starch and Gelatin.

The solvent casting method with four different techniques was employed to formulate oral thin films. The oral thin films were evaluated for physical characteristics and inspection of its visual properties such as homogeneity, color, transparency, and surface morphology, mechanical properties, disintegration time, physical characteristics such as thickness, uniformity of weight, folding endurance. Among all polymers used, HPMC Pharmacoat 615, HPMC Pharmacoat 606 and Methyl Cellulose showed desired film forming and excellent acceptability with transparent nature showing least disintegration time. HPMC could be the most promising oral film former with the four techniques used in this study. From this study we can conclude that Hydroxy propyl methyl cellulose (HPMC) and Methyl cellulose (MC) can be successful oral film formers for preparing these kinds of oral thin films even without the presence surfactants that increase the speed of disintegration of these films in the mouth.

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1-INTRODUCTION

An oral thin film dosage form is a type of solid dosage that rapidly dissolves or disintegrates in the mouth, forming a solution or suspension without requiring water for administration. In recent years, oral films have become increasingly popular as a pharmaceutical dosage form. They are considered one of the most effective and preferred oral delivery methods, as they bypass the hepatic system and enhance therapeutic response. Their appeal is largely due to their suitability for both pediatric and geriatric patients, as well as their acceptance within the pharmaceutical industry. Oral films offer the stability of a solid dosage form while providing the convenience of liquid administration [1].

In the U.S. Pharmacopeia monograph, oral films are described as single or multi-layer thin sheets, which may or may not contain an active drug, intended for placement in the oral cavity. The European Pharmacopeia further recognizes them as an innovative and novel dosage form. Typically produced through solvent-casting or extrusion, oral films are engineered for either rapid or delayed disintegration and can facilitate gastrointestinal or mucosal absorption. Modifying the base formulation allows for these variations, contributing to the growing interest among pharmaceutical companies in this versatile drug delivery method. Oral drug delivery remains the most favored and non-invasive administration route, with approximately 85% of the top-selling drugs in the U.S. and Europe delivered orally [2].

Many pharmaceutical companies are transitioning their products from traditional tablets to fast-dissolving oral thin films. These films combine the benefits of tablets, such as precise dosing and ease of use, with the advantages of liquid dosage forms, including ease of swallowing and rapid bioavailability. As a novel drug delivery system, oral films are especially valuable in emergency situations where an immediate onset of action is required. They also offer a discrete way for children, the elderly, and others to take medication anytime and anywhere. Additionally, this technology provides an excellent opportunity for developing non-infringing products and extending the patent lifecycle of existing medications [3].

The present study focused on screening different film-forming materials used for the preparation of orally dissolving films in order to optimize and propose suitable film formers with a suitable manufacturing technique. To develop a versatile casting solution suitable for the production of oral thin films to which active pharmaceutical ingredients can be added. To develop and implement effective and efficient manufacturing technology and several methods and techniques for preparing films. Focusing on critical environmental process parameters, we aim to develop a method that ensures the production of the most uniform films in terms of both weight and thickness.

Historical Overview

Fast dissolving drug delivery systems were first developed by scientists at Wyeth Laboratories in the UK in the late 1970s as an alternative to traditional tablets, capsules, and syrups, specifically for pediatric and geriatric patients who struggle with swallowing conventional solid oral dosage forms. Since oral films were introduced in the 1960s as an advanced therapeutic dosage form, their popularity has steadily grown. Today, oral films are widely available as over-the-counter products, including breath freshening strips, vitamin strips, anti-allergy medications, and other similar products [4].

Oral films initially entered the market primarily as mouth-freshening products containing ingredients like menthol and thymol, with companies like Johnson & Johnson offering them in the United States and Europe, and Boots (Nottingham) in the United Kingdom. Pfizer introduced Listerine Pocket Pak strips in 2001. Recently, pharmaceutical companies have started to explore the benefits of offering prescription drugs in oral film form, recognizing that these films cannot be easily substituted with other dosage forms [4].

The first prescription drug presented as an oral film was Zuphlenz® (Ondansetron), approved by the U.S. Food and Drug Administration in 2010 for the treatment of nausea and vomiting associated with chemotherapy and radiotherapy. In 2012, Applied Pharma Research successfully launched Zolmitriptan oral films for migraine treatment [5, 6]. Since their initial mention in the literature, oral films for various new drug classes have been introduced to the market, gaining acceptance from both patients and healthcare professionals [7, 8]. Table 1 highlights some key milestones in the development of oral films.

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Milestones in oral films Developments	Oral films in patent literature	Oral films as consumable products e.g. Listerine	Other over the counter drugs as oral films e.g. Gas- X(simethicone), Chloraseptic (7- Benzocaine)	First FDA approved prescription only medicine as oral film (Zuphlenx®- Ondansetron)	Insulin oral film patent granted to Pharmedica Ltd	Exservan® (Riluzole) by Aquestive therapeutics presented as oral film
Time lines	1960	2001	2001 - 2005	2010	2018	2019

Table 1: A tabular presentation of notable milestones in oral film delivery systems

Oral Thin Film

An oral fast-dispersing dosage form is a solid dosage form that quickly dissolves or disintegrates in the oral cavity to form a solution or suspension without the need for water, as detailed in Tables 2 and 3.

Table 2: Oral Films Properties

Properties	Oral Thin Films
Area (cm ²)	2-8
Thickness (µm)	20-70
Excipients	Soluble hydrophilic polymer
Dru <mark>g Phase</mark>	Solid solution
App <mark>lication</mark>	Tongue (upper palate)
Dis <mark>solution</mark>	60 sec
Site of Action	Systemic or local

Table 3: The composition of oral thin films

	Composition	Concentration (w/w)	Example		
1	Drug/API	5-30 %	Antiemetic, Antiallergic etc.		
2	Water soluble polymer	40 – 50 %	Carbohydrates, proteins, and cellulose derivatives		
3	Plasticizer	$0 - 20 \ \%$	Glycerol, polyethylene glycol etc.,		
4	Surfactant	Q S	Sodium lauryl sulphate, tween etc.,		
5	Sweeting agents	3-6%	Saccharin, aspartame etc.,		
6	Saliva stimulated agents	2-6%	Citric acid, malic acid, lactic acid		
7	Fillers, color, flavors	Q S	FD and Colour, US FDA approved flavours		

Miscellaneous terms

- \Box Thin-film, Oral thin film
- \Box Oral film Oral soluble film
- □ Wafer,
- \Box Oro dispersible film
- \Box Oral strip
- □ Biodegradable films

Key benefits for pharmaceutical partners

- 1. Easy dosage with fast onset of action.
- 2. Possible avoidance of first-pass effect for improved bioavailability and saving costs for active substance.
- 3. Convenient alternative route for injectable active substances.
- 4. Drug release can be customized via different types of OTF technologies.
- 5. Innovative and appealing form with design options for individual positioning.
- 6. Potential focus on patients with swallowing issues (e.g. Multiple sclerosis, ALS).
- 7. Life cycle management of established products.

Key benefits for patients

- 1. Improved compliance due to discreet and convenient application.
- 2. Fast relief from symptoms.
- **3.** Can be taken without extra water.
- **4.** Ideal for when patients are on the go.
- 5. Easier for children, older people and patients requiring complex care.
- 6. Ideal for patients who have difficulty swallowing.

The Advantages of Oral films

- 1. Ease of Use: Particularly beneficial for patients with mental health issues or those who are non-compliant.
- 2. Rapid Action: Ideal for situations requiring quick onset, such as motion sickness, allergic reactions, coughing, or asthma.
- **3.** Versatile Applications: Used in pharmaceuticals, prescription medications, and over-the-counter products for treating various conditions including pain, cough/cold, gastro-oesophageal reflux disease, erectile dysfunction, sleep disorders, and dietary supplements.
- 4. Convenience: No water needed for administration, making them suitable for travel.
- **5.** Enhanced Absorption: Some drugs are absorbed through the mouth, pharynx, and oesophagus, potentially increasing bioavailability as saliva helps the drug reach the stomach.
- **6.** Improved Bioavailability: Offers a larger surface area for drugs that dissolve quickly, which can enhance the absorption of poorly water-soluble drugs.
- 7. Minimal Residue: Leaves little to no residue in the mouth after use.
- 8. Solid Convenience: Provides the benefits of liquid medications in a solid form.
- 9. Compatibility: Can be integrated with existing processing and packaging equipment.

- □ Fast dissolving films,
- □ Buccal soluble film, Buccal film
- \Box Mucoadhesive film
- Transmucosal film
- □ Are some of the in numerous terms that can be found in literature

- **10.** Accurate Dosing: Delivers precise dosing compared to liquid forms.
- 11. Chemical Stability: Generally offers good stability for the drug.
- 12. No Measuring Required: Eliminates the need for measuring, a common issue with liquid forms.
- **13.** Quick Development: Can be developed and launched within 12-16 months, shortening the product development lifecycle.

The Disadvantages of Oral Films

- 1. Uniformity Challenges: Maintaining consistent dose uniformity can be difficult.
- 2. Limited to Small Doses: Only active pharmaceutical ingredients with small doses can be incorporated.
- **3.** API Concentration Limits: Research indicates that the concentration of active pharmaceutical ingredients (APIs) can be enhanced up to 50% w/w; for example, Novartis Consumer Health's Gas-X® thin strip contains 62.5 mg of Simethicone per strip.
- **4.** Costly Packaging: Requires expensive packaging solutions.
- 5. Dose Termination Issues: Due to rapid dissolution, it's challenging to control or terminate the dose once administered.
- 6. Lack of Pharmacopoeia Recognition: Not officially recognized in any pharmacopoeia.

The differences between the oral thin film and oral dispersible tablet are shown in Table 4.

Oral thin film	Oral dispersible tablet		
Film States	Tablet		
More dissolution owing to the larger surface area	Less dissolution owing to the lesser surface area		
It is mor <mark>e durable</mark>	It is less durable		
Patient compliance is high	Patient compliance is low		
It may contain a low dose	It may contain a high dose		
No risk of asphyxiation	There is a fear of asphyxiation		

Table 4: Differences between OTFs and ODTs

Screening of film forming agents for Oral Thin Films pre-formulation

Different types of water soluble polymers with different concentrations were selected in order to choose the suitable polymer and the suitable concentration as shown in Table 5.

	Polymer	Concentrations W/V
1	Hydroxyl Propyl Methyl Cellulose (HPMC)	2.5%, 5%, 7.5%, 10%
1	(Pharmacoat 615)	
2	Hydroxyl Propyl Methyl Cellulose (HPMC) (Pharmacoat	7.5% and 10 %
2	606)	
3	Metolose 60SH	5 %
4	Starch	10 %
5	Sodium Carboxy methyl cellulose (CMC)	2.5 %, 3 % and 5%
6	Methyl Cellulose	2%,5%
7	Pullulan	5%, 7.5%, 10%
8	Carrageenan	1%, 2%, 3%, 5%
9	Sodium Alginate	2%, 2.5 %, 3%
10	Gelatine	2.5%, 5%, 7.5%, 10%
11	Polyvinyl alcohol	7,5 %, 10 %

2- SOLVENT CASTING METHOD

The Fast dissolving films were prepared by solvent casting technique. Various polymers were used as a film forming as shown in (**Table 5**). The oral thin films were prepared by dissolving film forming polymer each one according to the concentrations (w/v) in distilled water, then solution was continuously stirred till a homogeneous solution has been achieved, and finally casted by the aid of a syringe on to

- 1. A petri dish (9 mls) (Figure 1)
- 2. Suitable platform of glass and then spread the polymer solution along the glass with the aid of the film applicator with maintaining a specific thickness of 0.05 micrometre (9 mls) (Figure 2)
- 3. Ice moulds (2 mls in each) (Figure 3)
- 4. Cups (1.5 mls in each) (Figure 3)

Figure 1 The solvent casting method with four different techniques was employed to formulate oral thin films as shown in table 3.



Figure 2: Film applicator



Figure 3: Ice molds (A) and Cups (B)



A

3- RESULTS AND DISCUSSION

Each polymer and film former was precisely measured and dissolved in 100 ml of purified water to create a uniform, clear, viscous solution. These solutions were subsequently mixed and stirred to achieve a homogeneous viscous consistency.

B

The oral thin films were evaluated for physical characteristics and inspection of its visual properties such as homogeneity, colour, transparency, and surface morphology, mechanical properties, disintegration time, physical characteristics such as thickness, uniformity of weight, folding endurance.

The results in **Tables 6, 7, 8 and 9** showed that preparing films using film applicator is the best technique among the four techniques used in this study, especially when HPMC **606 and 615** were used as film formers, and to a lesser extent with **metolose 60 SH, methyl cellulose and PVA.**

HPMC oral films prepared using the film applicator is easy to peal; there is no noticeable difference in weights and thickness, showed the least disintegration time.

On the contrary, the use of petri dish, ice moulds and cups showed that there was a difference in weights and thicknesses and a noticeable increase in the time of disintegration.

In cases of **CMC**, **Sodium Alginate**, **Carrageenan**, **Pullulan** and **Gelatine**, pealing was very difficult in case of the film applicator (**Table 6**) and it was not easy in petri dish (**Table 7**), ice moulds (**Table 8**) and cups (**Table 9**).

	Film	Peal	D T	Thickness	Weight
			second		_
HPMC 606 10%	Very good	Easy	23	40 - 50	518 – 523 mg
HPMC 615 10 %	Very good	Easy	27	40 - 60	523 – 584 mg
Metolose 60SH	Good	Easy	50	30-30	729 – 739 mg
Methyl Cellulose	Good	Easy	37	30 - 40	946 mg
PVA	Good	Not easy	35	40	541 – 590 mg
CMC 5%	Bad film	Not easy	15	30 - 40	NA
Sod Alginate 3 %	No film	NA	NA	NA	NA
Carrageenan	No film	NA	NA	NA	NA
Pullulan	No film	NA	NA	NA	NA
Gelatine	No film	NA	NA	NA	NA

	Film	Peal	DT	Thickness	Weight
		_	second		
HPMC 606	Good film	Easy		40 - 50	518 – 523 mg
HPMC 615	Good film	Easy	$\geq 2 \min$	70 - 100	967 mg
Metolose 60SH 5%	Good	Easy		30 - 30	729 – 739 mg
Methyl Cellulose	Good	Easy		30 - 40	946 mg
Methyl Cellulose	Good	Easy			
PVA	Good	Easy	NA	100 - 110	541 – 590 mg
CMC 5%	Bad film	Not easy	NA	NA	NA
Sod Alginate 3%	Broken film	Not easy	NA	20 - 30	217 mg
Carrageenan	Broken film	Not easy	NA	40 - 50	294 mg
Pullulan	No film	Not easy	NA	120 - 130	NA
Gelatine	Broken film	Not easy	NA	110 - 130	1.143 g

Table 7: Petri dish

Table 8: Ice Mould

	Film	Peal	D T second	Thickness	Weight
HPMC 606 10%	Good film	Easy	100	120 - 150	198 – 220 mg
HPMC 615 10%	Good film	Easy	57	100 - 150	157 – 172 mg
Metolose 60SH	NA	NA	NA	NA	NA
Methyl Cellulose	Good film	Easy	43	30 - 40	44 – 66 mg
PVA	Good film	Easy	50	60 - 90	120 – 130 mg
CMC 5 %	Good film	Not easy	40	60 - 90	105 – 129 mg
Sod Alginate 3%	Broken film	Not easy	61	20 - 40	64 – 66 mg
Carrageenan	Bad film	Not easy	$\geq 2 \min$	40 - 60	75 – 87 mg
Pullulan	Not good	Not easy	50	110 - 140	242 – 271 mg
Gelatine	Bad film	Not easy	≥ 5 min	110 - 120	182 – 185 mg

Table 9: Cup

	<mark>Film</mark>	Peal	D T second	Thickness	Weight
HPMC 606 10%	Good film	Easy	NA	NA	NA
HPMC 615 10 %	Good film	Easy	68	120 - 150	153 – 170 mg
Metolose 60SH	Good film	Not easy	$\geq 2 \min$	70 - 80	131 – 137 mg
Methyl Cellulose	Bad film	Easy	40	30 - 40	52 – 70 mg
PVA	Not good	Not easy	50	70 - 90	101 – 103 mg
CMC 5 %	Good film	Not easy	40	30 - 50	100 – 106 mg
Sod Alginate 3%	Not good	Not easy	55	40 - 50	50 – 66 mg
Carrageenan	Bad film	Not easy	NA	NA	NA
Pullulan	Not good	Not easy	55	70 - 90	159 – 168 mg
Gelatine	Bad film	Not easy	120	90-100	143–169 mg

Among all polymers used, **HPMC** Pharmacoat 615 (**Figure 4**), **HPMC** Pharmacoat 606 and Methyl Cellulose (**Figure 5**) showed desired film forming and excellent acceptability with transparent nature showing least disintegration time. **HPMC** could be the most promising oral film former with the four techniques used in this study.

Metolose 60SH (Figure 6), did not show the same good properties as that shown with HPMC

A film could be formed with **Polyvinyl Alcohol (PVA) (Figure 7)** when film applicator was used, with disintegration time more than 5 minutes.

This study showed the possibility of obtaining good films with equal or homogeneous doses using ice moulds and cups, especially with HPMC grad 615 & grad 606, Pullulan (Figure 11), Gelatine (Figure 12) and Carboxy methyl cellulose CMC (Figure 8).

Sodium Alginate (Figure 9), showed difficulties and longer time to be prepared, so it is not a promising film former specially when used alone.

In case of Carrageenan (Figure 10), good films can be formed with the ice and cup moulds, and with petri dish.

Pullulan (Figure 11) did not show the desired film forming when the film applicator was used, while good films were achieved when ice and cup moulds used. The films needed longer time to be disintegrated.

Gelatine (Figure 12) films were hard and sometimes were sticky with disintegration time more than 5 minutes.

The film applicator technique gave films with homogeneity in thickness and weights especially when **HPMC grad 606 & 615** used while we failed to obtain films in this way with the other polymers.

We got good films, when we applied the classic casing solvent technique in petri dish, the method most used in oral thin films studies, the best films were obtained when HPMC grads 615, HPMC grad 605 and Methyl cellulose.

So it was concluded that **HPMC 606 & HPMC 615** are the first film forming agents of choice to obtain oral films with good specifications in terms of homogeneity in weights and thicknesses with a suitable in vitro disintegration time using the four techniques applied in this study.

In addition to that, the preparation of the **HPMC** casting solvent is easy, not complicated and not consuming a long time.

Figure 4: HPMC 615 10% w/v





Figure 6: Metlose 60 SH 5% w/v



Figure 7: Poly vinyl alchohol (PVA) 10% w/v



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Figure 8: Carboxy Methyl Cellulose (CMC) 5% w/ v

Figure 9: Sodium Alginate 3 % w/v



Figure 10: Carrageenan 5% w/v



Figure 11: Pullulan 10 % w/v



Figure 12: Gelatine 10 % w/v



4- CONCLUSION

From this study it was concluded that **Hydroxy propyl methyl cellulose** (**HPMC**) and **Methyl cellulose** (**MC**) can be successful oral film formers for preparing these kinds of oral thin films even without the presence surfactants that increase the speed of disintegration of these films in the mouth.

Moreover, the results show that preparing films using film applicator is the best technique among the four techniques used in this study.

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فحص المواد المصنعة لتحضير الشرائط الفموية, الشكل الصيدلاني الجديد

الخلاصة:

تُعرف الشرائط الفموية بانها اشكال صيدلانية صلبة تذوب أو تتفكك بسرعة في تجويف الفم، مما يجعلها محلول أو معلق يمتص من قبل اغشية الفم دون الحاجة إلى تناول الماء. وقد اكتسبت الشرائط الفموية شعبية في السنوات الأخيرة كأشكال صيدلانية جديدة، وهي أكثر أشكال الجرعات الفموية قبولا ودقة والتي تتجاوز تاثير انزيمات الكبد وتظهر استجابة علاجية أكبر, بسبب قبول المريض لها (خاصة الأطفال وكبار السن), حيث تجمع بين الثبات الأكبر لشكل الجرعة الصلبة بالاضافة الى مواصفات السائل الجيدة.

تهدف هذه الدراسة الى تطوير محلول صب متعدد الاستخدامات ومناسب لإنتاج أغشية الفم الرقيقة والتي من الممكن إضافة المكونات الصيدلانية الفعالة إليها. ركزت الدراسة على فحص بوليمرات مختلفة من الممكن استخدامها في تحضير الرقائق السريعة الذوبان في الفم من أجل التوصل الى البولمر الاكثر ملائمة لتحضير هذه الشرائط من ناحية قبول المريض مع التوصل الى التقنية المثلى لتحضير هذه الشرائط.

تم استخدام 11 بوليمر في هذه الدراسة وهي الهيدروكسي بروبيل مثيل سليلوز HPMC، الهيدروكسي بروبيل مثيل سليلوز OM6 HPMC، ميتولوز Metolose، كاربوكسي مثيل سليلوز CMC، مثيل سليلوز MC، النشا Starch، الجيلاتين، بولي فنيل الكحول PVA، الجينات الصوديوم Sodium Alginate، البولولان Pullulan، الكار

تم اذابة هذه البوليمرات بالماء وبتراكيز مختلفة واستخدم طريق الصب في قوالب وبأربع تقنيات مختلفة لتكوين الشرائط الفموية. وتم تقييم الشرائط الفموية من حيث الخصائص الفيزيائية وفحص خصائصها البصرية مثل تجانس السمك واللون والشفافية وشكل السطح، والخواص الميكانيكية، وزمن التفكك، والخصائص الفيزيائية مثل السُمك، وتوحيد ال<mark>وزن، وتحمل الطي.</mark>

اظهرت النتائج بان الشرائط المحضرة من كل من الهيدروكسي بروبيل مثيل سليلوز بنوعيه 606 و 615 والمثيل سليلوز كانت احسن انواع الشرائط من ناحية الشكل والشفافية وتمتلك صفات ميكانيكية و فيزيائية مقبولة. كذلك تم الحصول على احسن نوع من الشرائط باستخدام اداة فرش محلول الصب للحصول على شرائط متجانسة السمك.

نستنتج من هذه الدراسة بانه يمكن تحضير شرائط فموية ناجحة وذات مواصفات ميكانيكية وفيزيائية جيدة باستخدام كل من الهيدروكسي بروبيل مثيل سليلوز بنوعيه 606 و 615 والمثيل سليلوز.