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Research Article

FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILM OF SITAGLIPTIN PHOSPHATE BY SOLVENT CASTING METHOD

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ABSTRACT

The primary objective of this study was to develop sitagliptin phosphate oral films that dissolve quickly in order to treat diabetic mellitus. The solvent casting method was employed to make the sitagliptin phosphate films that dissolve quickly. Film forming polymers HPMC E 15 and HPMC E 50 cps were utilised, along with plasticisers PEG and propylene glycol. We tested the films for stability, in-vitro disintegration time, in-vitro dissolving test, drug content, thickness, folding endurance, percentage elongation, tensile strength, and scanning electron microscopy. The outcomes met or exceeded expectations. Formulation 3 had the quickest disintegration time at 20 seconds and the fastest drug release time at 3 minutes out of all the formulations. From the data shown above, it can be inferred that Sitagliptin phosphate fast-dissolving oral films have the potential to increase absorption by bypassing the first-pass effect and producing quick action.

INTRODUCTION

An oral fast-dispersing dosage form is defined as a solid dosage form that dissolves or disintegrates rapidly in the mouth, creating a solution or suspension without the requirement to administer water[1]. Any age group, but notably the elderly, can experience dysphagia, or difficulty swallowing, and this includes those who have trouble with more traditional forms of medication administration, such as pills and capsules[2]. There are numerous medical illnesses linked to dysphagia, such as stroke, Parkinson's, AIDS, thyroidectomy, thyroid treatment for the head and neck, and other neurological problems like cerebral palsy. Surface, form, and flavour were the next most popular complaints, after tablet siz[3]. Elderly and young patients, along with those on the go who might not have access to water, were more likely to have difficulty swallowing tablets[4].

Patients with dysphasia may find it easier to accept and take their medication as prescribed when it dissolves quickly. Likewise, from a business perspective, FDDS implementation will aid in medication life cycle management, particularly in cases when the drug is patent protected [5-7].

Dysphasia, sometimes known as trouble swallowing, affects people of all ages. Research found that 35% of the general population, 30% to 40% of the elderly, and 18% to 20% of all residents in long-term care facilities experience dysphasia. Many people have issues with swallowing tablets because of their size, surface, shape, and flavour [8,9]. It is important to have dose forms that are easy to swallow for patients of all ages, especially those who are travelling and may not always have access to water. These findings highlight the critical need for a dosage form such as FDDS, which allows tablets to dissolve in the mouth without the need to chew or drink extra water, hence improving patient compliance [10,11].

Poor patient compliance with current administration regimens, a small market size for drug firms and drug uses, and high costs of illness management all contribute to the ongoing need for noninvasive delivery systems. A rise in accessible fast-food options is attributable, in part, to pharmaceutical marketing [12-14].

Products that dissolve or disintegrate. Pharmaceutical companies often create new and enhanced dosage forms of an existing therapeutic molecule when its patent life is almost up[15]. A dosage

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form provides a more convenient dosing regimen for the patient population and allows the producer to extend the market exclusivity [16,17]. This is where many of the currently available sustained release formulations resemble quick dissolving/disintegrating formulations. Increased revenue and access to treatment for underprivileged populations can result from a fast-solving/disintegrating dosage form's prolongation of market exclusivity[18].

A more recent innovation in the production of oral disintegrating dose forms is the oral film. The films are made of edible, water-soluble polymers and come in a variety of sizes and forms, including squares, rectangles, and discs[19,20]. The stripes could be opaque or see-through, pliable or fragile. They dissolve quickly on the tongue and don't require water for dissolving. A high specific surface area for disintegration characterizes fast dissolving films (FDFs)[21]. In contrast to oral rapid disintegrating pills, these films eliminate the risk of choking, are straightforward to administer, and keep to a basic, standard packaging style that is easy to make. These dosage forms have few alternatives for disguising flavour and a low drug loading capacity, which is a big drawback[22-24].

A fast-disintegrating film can have any shape and a thickness of 1–10 mm and an area of 1–20 cm^2. Medications can be mixed up to a maximum of 15mg in a single dose. A unique matrix composed of water-soluble polymers allows for rapid dissolving in saliva; this matrix often has little tack, making it easier to work with and apply. Nevertheless, the film remains securely in place at the application site when wet thanks to the system's wet tack and muco adhesiveness qualities. The production process and related operations, including as rewinding, die cutting, and packing, rely on the strength and flexibility of the films used[25].

The current research aims to develop and assess a solvent-casting method for a fast-solving oral film containing sitagliptin phosphate.

MATERIALS AND METHODS

Pre-formulation studies

One definition of pre-formulation is the process of characterizing a drug substance's physical and biological qualities. It plays a significant role in the process of developing new drugs. In the subsequent stages of medication development, the data gathered during this period is crucial for decision-making. Formulations can only be rationally developed with a large diversity of data. An essential part of developing a product before its formulation is analysing the drug's characteristics and the effects of the excipients' features on their compatibility[26].

Solubility: One gramme of solid is considered soluble in 1,000,000 parts per million of solvent, the unit of solubility measurement. We tested the powder's solubility at 20°C in a variety of solvents, including water, ethanol, and others[27].

Heavy metal content: By comparing the sample solution with a standard solution containing 10 ppm of lead for 2gm of material, the part of lead per million parts of powder was analysed[28].

Melting point: In order to determine the melting point, the capillary tube method was employed[28].

Compatibility Studies: The drug's compatibility with polymers was examined by an FTIR investigation. With the help of a Fourier Transform Infrared Spectrophotometer and the KBr dispersion method, the infrared spectrum of sitagliptin phosphate was measured. Dried potassium bromide was used to conduct the baseline correlation. Afterwards, an FTIR spectrophotometer was used to run the spectra of a dried mixture of the drug and potassium bromide, and subsequently, the drug in conjunction with other polymers. The location and relative strength of the absorption maximums in the reference spectrum match those in the spectrum acquired with the chemical under investigation[28].

Formulation development of Sitagliptinphosphate oral film

Table 1: Formulation trials

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Sitagliptin phosphate (g)	0.625	0.625	0.625	0.625	0.625	0.625	0.625	0.625	0.625
HPMC E15 (g)	1.0	1.25	1.5	-	-	-	1.25	-	1.25
HPMC E50 (g)	-	-	-	1.0	1.25	1.5	-	1.25	1.25
PEG 400 (g)	1.5	1.25	1.0	-	-	-	-	1.25	-
Propylene glycol (ml)	-	-	-	1.5	1.25	1.0	1.25	-	-
Citric acid (g)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
Sodium saccharin (g)	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125
Flavour (g)	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
Distilled water (ml)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs

Fig 1: Fast Dissolving Film

Procedure: Distilled water was used to dissolve the plasticisers and water-soluble polymers. To get rid of any trapped air bubbles, the solution is agitated for two hours using the magnetic stirrer and then set aside. In the meantime, dissolve the excipients and drug in equal parts of water and stir thoroughly for 30 minutes. After stirring, combine the two solutions. The last step is to create a film by casting the solution onto an appropriate petriplate. For one hour, the plates were heated in a hot air oven set at 60°C. Mildly separating the dry film from the glass plate allowed for precise cutting to size[29].

Dose calculations

Length of glass plate=10cm. Width of glass plate=10cm.

Area of the plate =100 cm^2; No. of 4 cm^2 films present whole plate =100/4 =25 films.

Each films contains 25mg of drug; 25 films contain 625 mg drug (25×25).

Labelled claim= 25mg

Standard Graph of Sitagliptin Phosphate

In 100ml of water, 50mg of sitagliptin phosphate was dissolved to create a stock solution. We took 10ml of this stock solution and used water to dilute it to 100ml. A calibration curve was created by diluting the stock solution appropriately and utilising concentrations ranging from 20µg/ml to 100µg/ml. Absorbance was assessed at a wavelength of 267nm[29].

Evaluation of oral film [30-35]

Thickness: The film thickness was measured using a micrometre screw gauge. The film's homogeneity is ensured by taking thickness readings at five separate points. It is recommended that the film thickness is less than 5%.

Weight variation: We averaged the weights of ten films that were chosen at random. To find the standard deviation, we compared the weight of each film to the average weight.

Folding endurance: One way to test a film's folding endurance is to quickly fold it in the same spot until it breaks. The folding endurance value is the maximum number of times a film can be folded in the same spot without breaking. The film had a topical folding endurance of 100 to 150 minutes.

Percentage elongation: It was calculated by

$$\text{Percentage elongation} = \frac{\text{Increase in length of strip} \times 100}{\text{Initial length of strip}}$$

Tensile strength: The ultimate tension that causes a strip specimen to rupture is known as its tensile strength. Its value is determined using the formula

$$\text{Tensile strength} = \frac{\text{Load at failure} \times 100}{\text{Strip thickness} \times \text{strip width}}$$

***In-vitro* disintegration:** The duration in seconds it takes for a film to dissolve when exposed to acids like saliva or water is called its disintegrating time.

Cell culture technique: The oral film was dissolved entirely after 2ml of distilled water was applied to a petri dish, and the time was then measured.

***In-vitro* dissolution:** The working conditions included 900ml of 0.1 N HCL as the media, a temperature of 37 +0.5°C, and a rotational speed of 100 rpm for the basket. The basket was filled with a 4cm^2 (2×2 cm) film sample that had been sliced. Every two minutes, 5ml of the sample was removed and replaced with 5ml of fresh 0.1N HCL. After withdrawal, the samples were filtered and examined with a 267nm UV spectrophotometer[36].

Drug content: In order to conduct this test, a 4cm^2 portion of film was dissolved in 50ml of 0.1N HCL while stirring. Using Whatmann filter paper, this solution was filtered. The filtrate was then diluted to 100ml in a volumetric flask using the same buffer. We used a UV spectrometer to examine this blend[37].

Assay: A 4cm section of thin film was dissolved in 50ml of pH 6.8 phosphate buffer while stirring in order to conduct this test. Using Whatmann filter paper, this solution was filtered. The filtrate was then diluted to 100ml in a volumetric flask using the same buffer. A UV spectrophotometer was used to examine this solution[38].

Stability studies: The stability experiments were conducted in accordance with ICH guidelines to evaluate the stability of the medication formulation. An aluminium container laminated with polyethylene was used to seal the optimised F3 mixture. After three months, the samples were stored at 40°C with a relative humidity of 75%. When the research period came to a close, researchers checked the formulation for any changes in colour, shape, drug content, or release characteristics[39].

SEM analysis: The scanning electron microscopy (SEM) was used at a specific magnification to examine the oral strip's morphology. Comparing the top and bottom of the movie is what the study is all about. The spread of APIs can also be better ascertained with its assistance[40].

RESULTS AND DISCUSSION

Pre-formulation studies

Solubility: One gramme of solid is considered soluble in 1,000,000 parts per million of solvent, the unit of solubility measurement. We tested the powder's solubility at 20°C in a variety of solvents, including water, ethanol, and others.

Heavy metal content: By comparing the sample solution with a standard solution containing 10 ppm of lead for 2gm of material, the part of lead per million parts of powder was analysed.

Melting point: In order to determine the melting point, the capillary tube method was employed.

Table 2: API characterization - Sitagliptin phosphate

S.No	Test	Specification	Result
1	Description	White powder	White powder
2	Solubility	Soluble in water	Complies
3	Taste	Bitter	Complies
4	Odor	Odourless	Complies
5	Heavy metals (ppm)	Should not be more than 20 ppm	Less
6	Melting point	Range: 205-207°C	206

Calibration curve of sitagliptin phosphate: To make a stock solution, 50mg of Sitagliptin phosphate were dissolved in 100ml of water. We took 10ml of this stock solution and used water to dilute it to 100ml. Different concentrations (20µg/ml-100µg/ml) were used to generate the calibration curve by appropriately diluting the stock solution. At 267nm, the absorbance was recorded. Table 3 shows the absorbance at 267nm at different concentrations. The Sitagliptin phosphate standard curve is displayed in figure 2.

Table 3: Standard graph of Sitagliptin phosphate

S. No	Concentration µg/ml	Absorbance (267 nm)
1	20	0.228
2	40	0.436
3	60	0.641
4	80	0.864
5	100	0.998

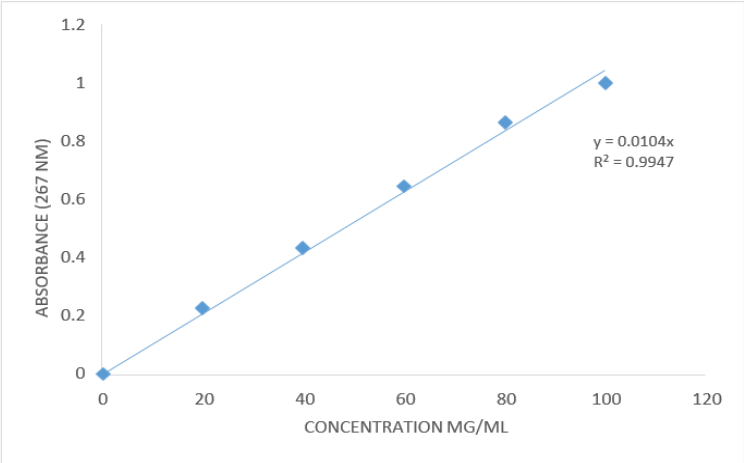

Fig 2: Standard graph of sitagliptin phosphate

FT-IR Studies: The drug's compatibility with polymers was examined by an FTIR investigation. With the help of a Fourier transform infrared spectrophotometer and the KBr dispersion method, the infrared spectrum of sitagliptin phosphate was measured. Dried potassium bromide was used to conduct the baseline correlation. Afterwards, an FTIR spectrophotometer was used to run the spectra of a dried mixture of the drug and potassium bromide, and

subsequently, the drug in conjunction with other polymers. The location and relative strength of the absorption maximums in the reference spectrum match those in the spectrum acquired with the chemical under investigation.

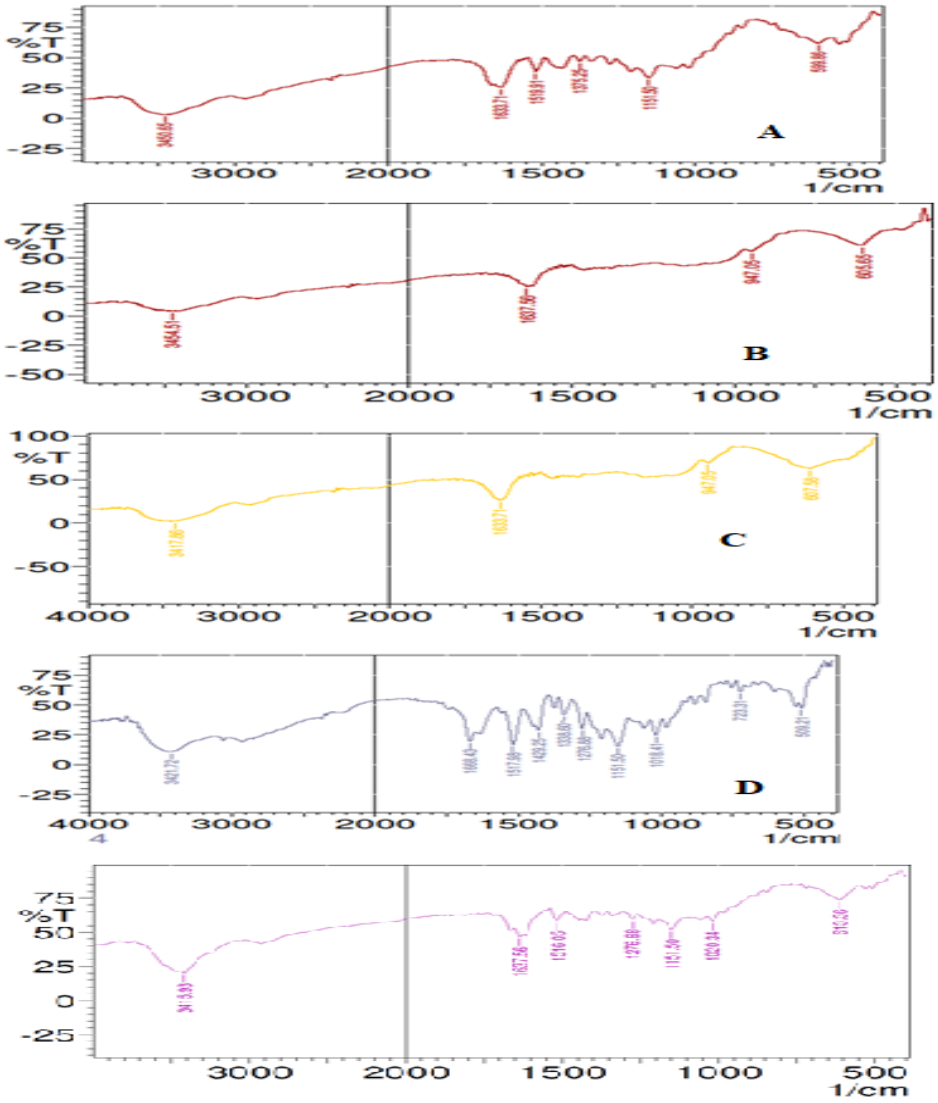

Fig 3: FTIR spectra of A. Sitagliptin phosphate, B. HPMC E15, C. HPMC E50, D. Sitagliptin Phosphate + HPMC E15 and Sitagliptin Phosphate + HPMC E50

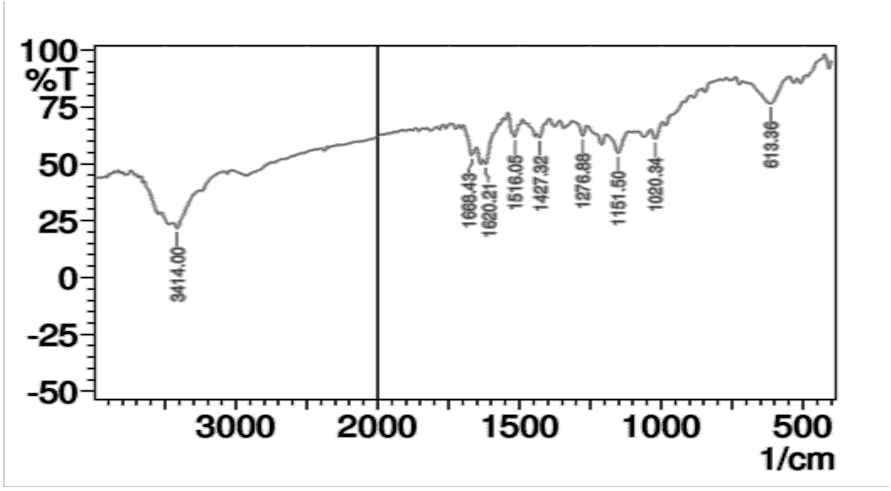

Fig 4: IR Spectra of sitagliptin Phosphate + HPMC E15 + HPMC E 50

Evaluation Parameters

Thickness: The film thickness was measured using a micrometre screw gauge. The film's homogeneity is ensured by taking thickness readings at five separate points. Make sure the film is thinner than 5%. Table 4 show the film thicknesses of all the formulations that dissolve quickly.

Folding endurance: One way to test a film's folding endurance is to quickly fold it in the same spot until it breaks. The folding endurance value is the maximum number of times a film can be folded in the same spot without breaking. The film had a topical folding endurance of 100 to 150 seconds. All formulas' folding endurance as shown in table 4 for fast-solving films.

Tensile strength: The ultimate tension that causes a strip specimen to rupture is known as its tensile strength. Its value is determined using the formula.

$$\text{Tensile strength} = \frac{\text{Load at failure} \times 100}{\text{Strip thickness} \times \text{strip width}}$$

Table 4 show the tensile strengths of all formulations of fast-solving films.

Percentage elongation: It was calculated by

$$\text{Percentage elongation} = \frac{\text{Increase in length of strip} \times 100}{\text{Initial length of strip}}$$

Table 4 show the % elongation of fast-solving films for all formulations.

***In-vitro* disintegration Petri dish method:** After adding 2ml of distilled water to the petri dish, we added one film on top of the water and timed how long it took for the film to dissolve entirely. Table 4 show the in-vitro disintegration times of all formulations of fast-solving films.

Table 4: Evaluation parameters

Formulations	Thickness (mm)	Folding endurance	Tensile strength (g/cm²)	% elongation	*In-vitro* disintegration time (sec)
F1	0.58	9	48.41	8	25
F2	0.55	10	51.18	9	28
F3	0.59	13	62.04	11	20
F4	0.51	9	54.25	9	31
F5	0.53	11	53.68	10	35
F6	0.52	11	52.33	8	27
F7	0.55	12	56.45	7	36
F8	0.57	1.0	57.62	9	32
F9	0.53	9	48.63	10	35

Weight variation: We averaged the weights of ten films that were chosen at random. Each film was weighed and then compared to the average weight to find the standard deviation. For each formulation, the weight variation of the fast-solving film is shown in figure 5.

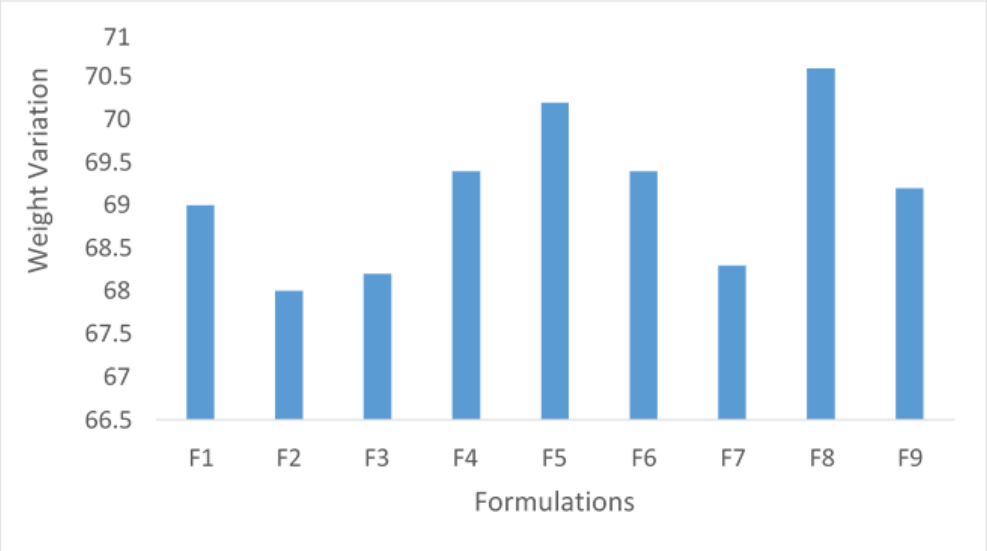

Fig 5: Bar chart of weight variation

Drug Content and Assay

Drug content: In order to conduct this test, a 4cm² portion of film was dissolved in 50ml of 0.1N HCL while stirring. Using Whatmann filter paper, this solution was filtered. The filtrate was then diluted to 100ml in a volumetric flask using the same buffer. Using a UV spectrometer, we examined this composition. All of the formulations' drug content results are displayed in figure 6 shows the numbers graphically.

Assay: A 4cm section of thin film was dissolved in 50ml of pH 6.8 phosphate buffer while stirring in order to conduct this test. Using Whatmann filter paper, this solution was filtered. The filtrate was then diluted to 100ml in a volumetric flask using the same buffer. A UV spectrophotometer was used to examine this solution. All of the formulations' assay results are graphically represented in figure 6.

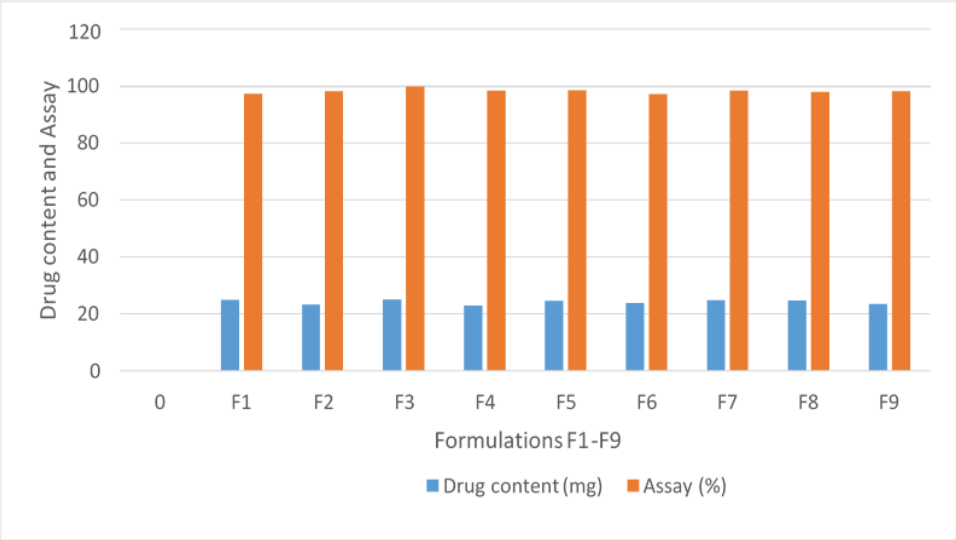

Fig 6: Bar chart of drug content and assay

In-Vitro Dissolution

***In-vitro* dissolution:** The working conditions included 900ml of 0.1 N HCL as the media, a temperature of 37 +0.5°C, and a rotational speed of 100 rpm for the basket. The basket was filled with a 4cm² (2×2 cm) film sample that had been sliced. Every two minutes, 5ml of the sample was removed and replaced with 5ml of fresh 0.1 N HCL. The extracted samples underwent filtration before being examined with a UV spectrophotometer operating at a 267nm wavelength. Results showed in fig 7.

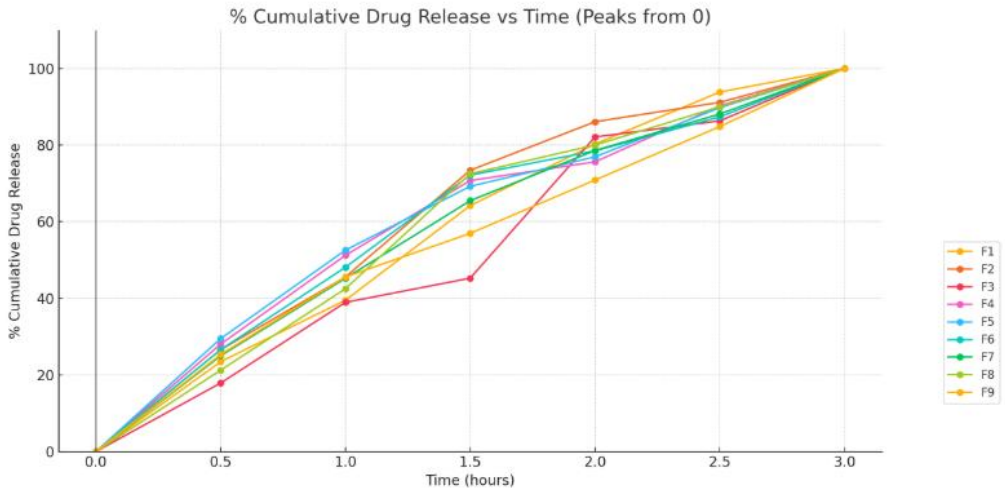

Fig 7: % CDR of F1-F9

Stability Studies (F3)

The stability experiments were conducted in accordance with ICH guidelines to evaluate the stability of the medication formulation. An aluminium container laminated with polyethylene was used to seal the optimised F3 mixture. After three months, the samples were stored at 40°C with a relative humidity of 75%. When the research period came to a close, researchers checked the formulation for any changes in colour, shape, drug content, or release characteristics.

Table 5: Stability studies [Condition (40°C/75%RH)]

Parameters	Initial	1 month	3 months
Thickness (mm)	0.59	0.59	0.59
Folding endurance	13	13	12
Tensile strength (gm/cm^2)	54.25	54.25	53.01
in-vitro disintegration time (sec)	20	20	22
in-vitro dissolution (%)	99.26	99.26	99.06

Test frequency: Initial and 3 months

- Initial stability data indicates that all physical and chemical parameters are satisfactory.
- Photo stability experiments have confirmed that the medicinal product is not affected by light.

SEM Analysis

The scanning electron microscopy (SEM) was used at a specific magnification to examine the oral strip's morphology. Comparing the top and bottom of the movie is what the study is all about. The spread of APIs can also be better ascertained with its assistance fig 7.

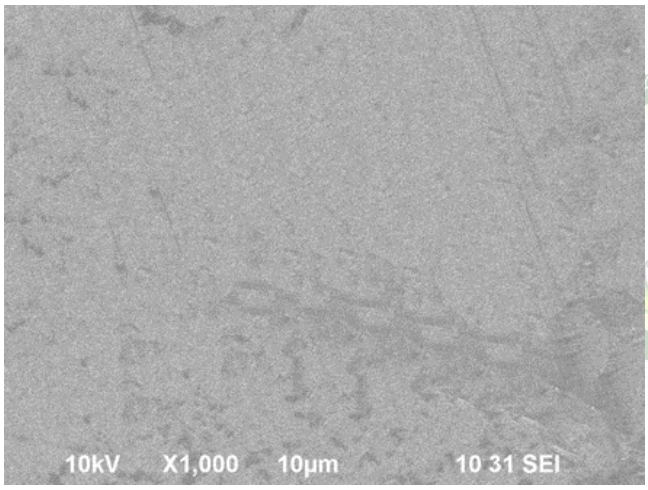

Fig 7: SEM images

DISCUSSION

Oral films containing Sitagliptin phosphate were the focus of the current study. For the purpose of managing diabetes mellitus effectively.

Flavour, citric acid, sodium saccharin, PEG 400, and HPMC E15 cps were used in F1–F3. There was no haze or obstruction in the films. The thickness is consistent as well. Also, it's quite adaptable. The films exhibited excellent mechanical characteristics. The assay result confirmed that the medication was put correctly into the film.

Sodium saccharin, citric acid, propylene glycol, HPMC E50, and flavour were used in F4-F6. Good looks are on display in the flick. Its thickness is also uneven. There was an issue with the film's pliability. Researchers determined the percentage of medication release to be.

The ingredients that went into making F7 were flavour, citric acid, sodium saccharin, propylene glycol, and HPMC E15. The film had a decent appearance, but it was thick and took a long time to dissolve.

Flavour, citric acid, sodium saccharin, PEG 400, and HPMC E50 were the ingredients that went into making F8. F9 was created using HPMC E15 and E50 in a plasticizer-free formulation. The formulated films exhibited a higher degree of fragility. F3 had the best mechanical qualities and the quickest disintegration time (only 20 seconds) of all the formulations. We were pleased with all of the film's specifications. Additionally, the dissolution profile was determined to be both desirable and repeatable.

There is higher porosity in F3, according to the morphological research (SEM). This allowed for the quick commencement of action by achieving fast drug release. The duration of the stability studies ranged from one month to three months. The in-vitro disintegration, tensile strength, thickness, and drug release were not affected in any meaningful way. The maximal release from the tested film (F3) samples occurred within three minutes, suggesting a fast drug release profile that means the medicine takes effect sooner. Because of this, oral films have many benefits over other types of dosage forms.

SUMMARY AND CONCLUSION

A mouth-dissolving film containing Sitagliptin phosphate and other basic elements such as polymers, plasticisers, sweetener, saliva stimulating agent, and flavour was the main goal of this work. The solvent casting procedure was used to prepare the films. HPMC E50 cps, which failed to increase the film's thickness. Flexible HPMC E15 has been shown. Propylene glycol, a plasticiser, failed to give the film the properties of being both flexible and folding durability. Folding endurance, tensile strength, and % elongation were all positively impacted by PEG 400. The improved formula (F3) demonstrated desirable mechanical qualities, a pleasant tongue feel, and rapid drug release in addition to folding durability. In comparison to the commercial formulation, which took an hour to disintegrate, the F3 only required 20 seconds, and 99% of the medication was released within three minutes. Consequently, the medicine was able to be rapidly released for an

instantaneous start of action, which is an improvement over the traditional tablet dosing form.

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