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Formulation and Evaluation of Oral Thin Film

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Abstract: *The aim of this study was to develop a fast-releasing oral polymeric thin film, prepared by solvent casting method, with good mechanical properties, instant disintegration and dissolution. Phenylephrine hydrochloride, a sympathomimetics drug belonging to BCS class I was used for oral thin film preparation. The formulations from the preliminary trial were analyzed which was applied to optimize the type of polymers (Sodium alginate, HPMC & cross povidone), concentration of polymers, plasticizer (Glycerol, Propylene Glycol,), surfactant (Sodium lauryl sulfate) and sweetener (sorbitol). The resultant films were evaluated for thickness, folding endurance, drug content, Surface pH, in vitro disintegration time, in vitro dissolution studies. The in vitro release study revealed that B4 formulation showed maximum release in 240 sec. For B4 Formulation In-vitro disintegration time was found to be 30sec, Thickness was 0.24mm, Folding endurance 78 and Swelling Index was 14.64. The B4 formulation was found to be stable as there was no drastic change in the Physico-chemical properties of the films. Thus, conclusion can be made that stable oral disintegrating film of Phenylephrine Hydrochloride has been developed. B4 formulation showed highest cumulative percentage drug release of 98.75% obtained during In vitro drug release studies after 240 sec. Based upon the in vitro dissolution data the B4 formulation was concluded as optimized formulation.*

Keywords: Phenylephrine hydrochloride, sodium alginate, oral polymeric thin film, solvent casting technique, HPMC, In vitro drug release studies.

I. INTRODUCTION

Oral Film Introduction:

Oral films are newer technologies in the production of oral disintegrating dosage forms. They are thin, elegant films composed of edible, water-soluble polymers in different sizes and shapes such as rectangles, squares, and discs. The stripes may be flexible or brittle, opaque, or transparent. They are intended to dissolve quickly on the tongue without the need for water. Fast dissolving films (FDFs) have a wide specific surface area for disintegration. The films minimize the risk/fear of choking, are easy to handle and administer, and provide easy-to-manufacture packaging, overcoming the short fails of oral fast disintegrating Film. The low drug loading capacity and limited taste masking possibilities of these dosage forms are significant drawbacks. A fast-disintegrating film is a thin film with a thickness of 1-10 mm and an area of 1-20 cm2 of any geometry. Drugs should be incorporated up to a single dosage of around 30 mg. The quick dissolving of saliva is due to a special matrix composed of water-soluble polymers; it has a low tack for ease of handling and application. However, when wetting the wet tack and muco adhesiveness properties of system are designed to secure the film to the application site. The flexibility and strength of the films were chosen to facilitate the production process as well as processes such as rewinding, die cutting, and packaging. A fast-dissolving film is put on the patient's tongue, which is mucosal tissue that is immediately wetted by saliva. The film hydrates quickly and adheres to the application site. It then quickly disintegrates and dissolves, releasing the drug for oral mucosal absorption or gastric absorption on swallowing.

Phenylephrine Hydrochloride

Phenylephrine Hydrochloride is a Sympathomimetic agents used as Nasal decongestant symptoms of Allergy and the common cold. These symptoms include rash, itching, watery eyes, itchy Eyes/nose/throat, cough, runny nose, and sneezing. It is also used to prevent and treat nausea, Vomiting and dizziness caused by motion sickness.

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Advantages: [2,3]

- The large surface area promotes fast disintegration and dissolution in the mouth cavity.
- It is flexible and less fragile, it is easier to transport, store, and handle by the consumer.
- Ease of administration of mentally ill, disabled, and uncooperative patients.
- Accuracy in dosage administration.
- Excellent mouthfeel.
- Provides water-free treatment.
- Increased bioavailability, better absorption, and faster action.

Disadvantages:

- Film packing requires the use of specialized equipment.
- Difficult to pack.
- A high dose cannot be incorporated in an oral film.
- Oral films that are moisture sensitive

Properties:

- Thin elegant film
- Available in various size and shapes
- Unobtrusive
- Excellent mucoadhesion
- Fast disintegration and dissolution
- Rapid drug release
- Bypasses first pass effect

Types of Oral Thin Film

Oral thin films (OTFs) are a type of dosage form that has gained popularity due to their convenience, ease of administration, and rapid onset of action. They are typically made from water-soluble polymers that dissolve in the mouth, releasing the medication for absorption. Here are the main types of oral thin films:

- Fast-Dissolving Oral Films (FDOFs): These films dissolve rapidly in saliva, usually within seconds to a minute, without the need for water. They are designed to disintegrate quickly upon contact with saliva, making them suitable for patients who have difficulty swallowing tablets or capsules, such as pediatric and geriatric populations. FDOFs are often used for medications that require rapid onset of action.
- Oral Dissolving Strips (ODS): Similar to FDOFs, ODS also dissolve rapidly in the mouth but may have a slightly longer disintegration time. They are typically thin, flexible films that adhere to the oral mucosa and deliver the drug for absorption. ODS can be used for a wide range of drugs, including antiemetics, analgesics, and anti-allergic medications.
- Mucoadhesive Oral Films: These films are designed to adhere to the oral mucosa for an extended period, allowing for controlled drug release and absorption. They contain mucoadhesive polymers that help them stick to the mucosal surface, increasing drug residence time and bioavailability. Mucoadhesive films are commonly used for local drug delivery to treat conditions like oral ulcers, gingivitis, and mucositis.
- Buccal Films: Buccal films are placed against the buccal mucosa (inner cheek) for drug delivery. They can bypass the gastrointestinal tract and liver metabolism, leading to enhanced bioavailability and reduced first-pass metabolism. Buccal films are used for drugs that undergo extensive hepatic metabolism or have poor oral bioavailability.
- Sublingual Films: These films are placed under the tongue (sublingual region) for drug absorption through the highly vascularized sublingual mucosa. They offer rapid absorption in systemic circulation, bypassing the gastrointestinal tract and liver first-pass effect. Sublingual films are commonly used for drugs like

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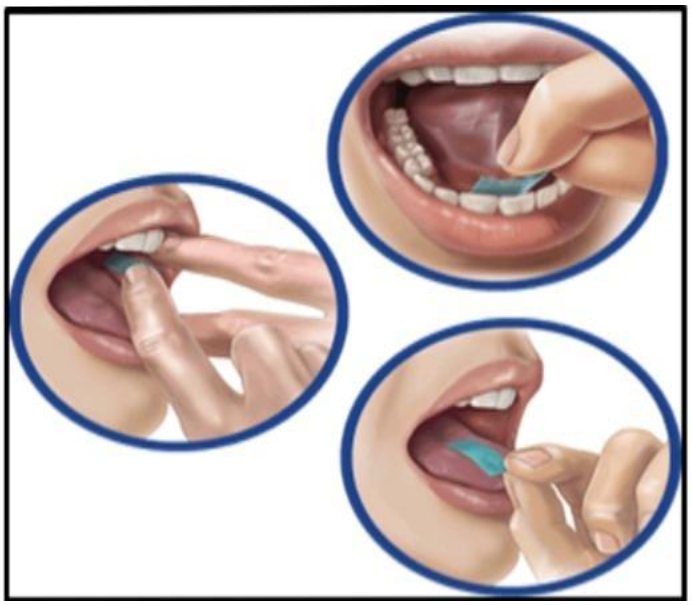
nitroglycerin for angina relief and some medications for opioid dependency Each type of oral thin film has its advantages and is specific patient needs and drug characteristics.



Fast Dissolving Drug Delivery System

Rapid drug delivery is a new form of delivery, also known as rapid-dissolving/disintegrating films, for oral administration of drugs, which emerged in the late 1970s as an alternative to tablets, capsules, syrups. Other formulations for children and adults with dysphagia. The dosage form combines with the quality of capsule and liquid forms. FDDS is easy to administer and administer to elderly, children, mentally ill, nauseated, and uncooperative patients. The dispensing machine has a dosage form that dissolves quickly in the mouth for a few minutes, for example without drinking water. This delivery consists of a thin mouthpiece that is placed over the patient's tongue or other oral tissues and immediately moistened with saliva. The film moistens rapidly at the application site. It dissolves and disintegrates quickly, releasing the drug for absorption through the oral mucosa. The rapid development of oral films has become widely accepted by patients and caregivers due to their ease of distribution, portability, and accuracy. The strength of the film depends on the type and amount of polymer; The breaking time of orally dissolving films varies between 5-20 minutes. According to the Pharmacopoeia. They also have a rapid onset of action within seconds, because oral absorption of the drug occurs directly from the site of application into the body without first going through metabolism to produce the desired effect.

Oral Cavity Anatomy

The structure and anatomy of oral cavity is studied for understanding the environment provided for delivering drugs. The oral mucosa allows direct access of drug to the systemic circulation and avoids first pass metabolism. The epithelium of the oral cavity is quite similar to that of the skin, with slight differences with regard to keratinization, protective and lubricant mucous which is spread across its surface. The permeability of oral mucosa is 4–1000 times greater than that of the skin. The oral cavity is divided into two regions: outer being the oral vestibule bounded by the lips and cheeks; the hard and soft palates, the floor of the mouth and tonsils. Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The oral mucosa is constructed of an outermost layer of stratified squamous epithelium. Below this is a basement membrane, then a lamina propria, and finally the submucosa as the innermost layer. The epithelium is comparable to stratified squamous epithelia found throughout the body in that it has a mitotically active basal cell layer that advances through a number of

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differentiating intermediate layers to the superficial layers, where cells are shed from the epithelium's surface. The buccal mucosa epithelium has 40-50 cell layers, whereas the sublingual epithelium has less. The epithelial cells increase in size and become flattened as they travel from the basal layers to the superficial layers. The surface epithelium of all covering and lining tissues in the body is supported by fibrous connective tissue.

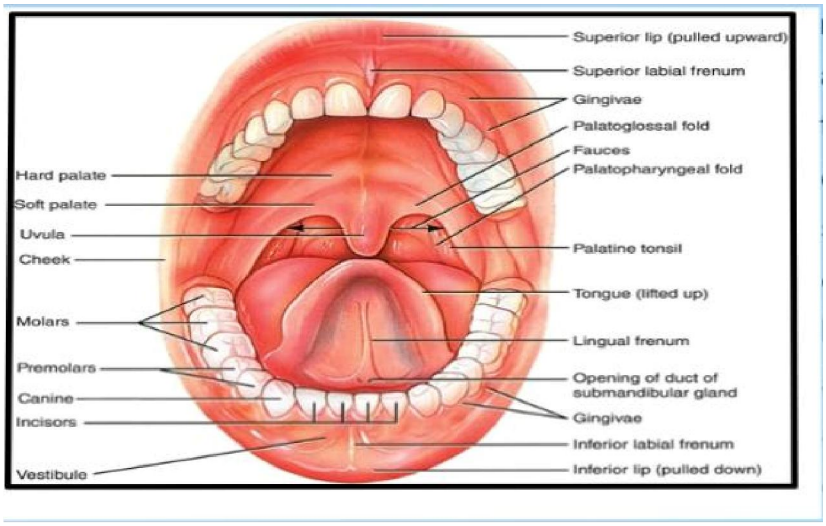
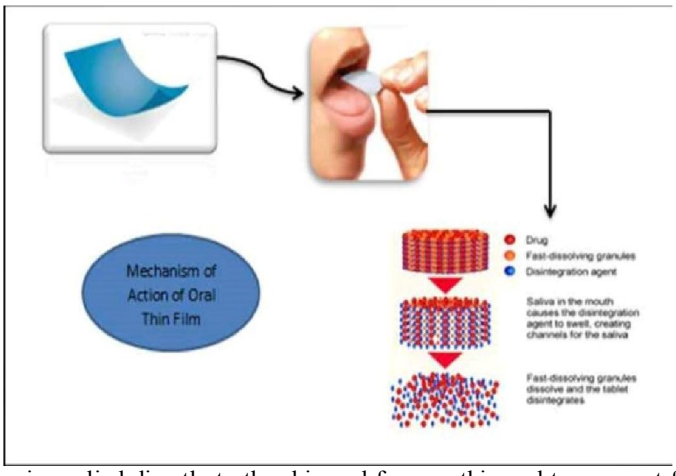


Fig 2: Anatomy of oral cavity

When the structure of the skin and oral mucosa is compared to the gastrointestinal tract, a major difference in epithelial organization appears, which reflecting the different functions of these regions. The lining of the stomach, small and large intestines are made up of a simple epithelium with only a single layer of cells, which allows for easy absorption across the tissue.

MECHANISM OF FILM FORMATION: [11]



The film-forming system is applied directly to the skin and forms a thin and transparent film in place after the solvent evaporates. After application of the formulation to the skin, the composition of the film-forming system underwent significant changes due to the loss of volatile components of the carrier, which led to the formation of a comfortable residual film on the skin. During this process, the drug concentration increases, reaching the saturation level and potentially oversaturation of the skin. Supersaturation improves the flow of the drug through the skin by ensuring that the thermodynamic effect of the formulation does not affect the skin barrier, thus reducing side effects or irritation. The concept of supersaturation can be explained by a modification of Fick's law of diffusion. Fick's law of diffusion is given by

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Eq.:

Where

J = rate of drug permeation per unit area of skin per unit time (flux)

D = diffusion coefficient of drug Cv= concentration of drug

H = thickness of barrier to diffusion

From this equation, it is clear that the rate of drug permeation across the skin is proportional to the concentration of the drug. However, this is true when the entire drug is dissolved in the vehicle. Equation describes the modified form of Fick's law of diffusion:

$J = \alpha D/\gamma h$

Where a = Thermodynamic activity of drug within formulation

Γ= Thermodynamic activity of drug within membrane

According to this equation, the flux of the drug is directly proportional to the thermodynamic activity of the system, which is related to saturation. However, increasing the super saturation increases thermodynamic instability.

II. MATERIAL & METHODS

Material: -The pharmaceuticals including Phenylephrine Hydrochloride was purchased from AG Traders, Pune (India). Citric acid, Hydroxy propyl methyl cellulose, sodium alginate, polyethylene glycol, glycerin, were also obtained from AG Traders, Pune.

Methodology: -

Fig. Phenylephrine hydrochloride

Drug pre-formulation study:

Angle of repose (θ): Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. The frictional force in a loose powder or granules can be measured by angle of repose. It is an indicative of the flow properties of the powder. To measure angle of repose, powder materials are allowed to flow from the funnel which is fixed with the stand at definite height. The radius and height of heap of powder formed is measured. Apart from flow property, Frictional force between powder and granules can be measured with the help of it.

$\theta = tan$ -1 h /r

Where, θ – is the angle of repose, h- is height of pile, r- is radius of the base

Bulk Density: The bulk density was obtained by dividing the mass of a powder by the bulk volume in cm3. The sample of about 50 cm3 of powder, previously been passed through a standard sieve no. 20, was carefully introduced into a 100ml graduated cylinder. It was calculated by using equation below

Db = M/Vp

Where, Db = bulk density, M = weight of samples in grams, Vp = final volumes of granules in cm3

3.Tapped density: The tapped density was obtained by dividing the mass of a powder by the tapped volume in cm3. The sample of about 50 cm3 of powder previously been passed through a standard

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Sieve. The cylinder was dropped at 2-second intervals onto a hard wood surface 100 times from a Height of 1 inch. The tapped density of each formulation was then obtained by dividing the weight of

Sample in grams by the final tapped volume in cm3 of the sample contained in the cylinder.
It was calculated by using equation given below:

$$Dt=M/VP$$

1.Carr's Index Hausner ratio: An indirect method of measuring powder flow from bulk densities was developed by Carr. The percentage compressibility of a powder was a direct measure of the potential powder arch or bridge strength and stability. Carr's index of each formulation was calculated according to equation given below:

$$\%Compressibility = D1 – D2/D2 \times 100$$

Where, D2 = Poured bulk or bulk density
D1= Tapped or Consolidated bulk density.

$$\%Compressibility = D1 – D2/D2 \times 1$$

1.Hausner ratio was calculated by the following equation.

$$Hausner\ ratio = Dt / Db$$

Where Dt = Tapped Density. Db = Bulk Density.

2. Solubility Test: -A little amount of drug is mixed in different solvents distilled water, acetone, ethanol and its solubility are found out.

Method of Film formulation: -
Mouth dissolving films can be prepared
Solvent casting method
Semisolid casting method
Hot-melt extrusion
Solid dispersion extrusion
Rolling method

Solvent Casting Method:
In this method firstly water-soluble ingredients are mixed in water to form a viscous solution. Remaining ingredients are dissolved in a smaller amount of solution. Both the solutions are combined by using a high shear Process. Vacuum is used to remove the air entrapped. The solution formed is then poured into a glass mold and allowed the solution to dry in the oven at 45-50˚C. Then cut into pieces of desired size and shape.

Semisolid casting method:
If film formulations contain some acid-insoluble polymers, then this system is acceptable. In this method initially prepared water-soluble polymeric solution. Then this solution was added to the solution containing acid-insoluble polymer (Examples: cellulose acetate phthalate, cellulose acetate butyrate, etc.). The plasticizer is added in applicable quantity in order that a gel mask is created. It is then cast into the films or ribbons by exploitation heat management drums. The ratio of the acid-insoluble polymer and film forming polymer keep as 1:4

Hot melt extrusion:
Hot metal extrusion technique is commonly used to put together granules, sustained release drugs, transdermal and transmucosal drug deliveries. In this technique first of all the drug is blended with carriers in solid shape. Then dried granular material is add into the extruder. The screw pace needs to be set at 15 rpm so that you can manner the granules in the barrel of the extruder for about 3–4 min.

Solid dispersion extrusion:
This method is also used to improve the solubility of the poorly water-soluble drug. The term solid dispersion is used for the dispersion of one or additional active ingredients in a very inert carrier in a solid-state within the presence of

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amorphous hydrophilic polymers. The drug is dissolved in an appropriate liquid solvent and obtained resultant mixture is further added to the previously dissolved polymeric solution available below 70°C while not removing the liquid solvent to get the solid dispersion. Finally, the obtained solid dispersions are formed into films by using dyes.

Rolling method:
In this method, suspension or solution containing API is prepared. Then this solution is completely mixed with the solution of film-forming polymer. The prepared solution was placed on a carrier and allowed to move onto it. Certain rheological properties of the solution should take into consideration. Films are dried on the rollers and cut into desired shapes and size.
Solvent Casting method:

Ingredients that are water soluble are dissolved in water.
Drug and other ingredients are dissolved in a suitable solvent to form a clear viscous solution.
Both solutions are mixed.
Degass under vaccume
The resulting solution casted as a film.

Procedure: -
Weigh all ingredients accurately.
Phenylephrine Hydrochloride oral thin film formulated by the solvent casting evaporation technique.
HPMC, sodium alginate, povidone cross taken as polymer (The strength of the film depends on the type of polymer and the amount in the formulation.)
Glycerin was taken as a plasticizer (it increases the film flexibility while decreasing its brittleness), Citric acid taken as saliva stimulating agent (promoting the disintegration of fast dissolving oral films by stimulating saliva in the oral cavity)
Sodium lauryl sulphate taken as surfactant (surfactant enhance the solubility of poorly soluble drug); Sorbitol taken as sweetening agent.
Hydrophilic polymers like HPMC, Sodium Alginate, Cross povidone was weighed and dissolve in 10ml hot distilled water and plasticizer (glycerin) was add in that and stirred for 30 min – 1st solution
Drug and other ingredients like surfactant, saliva stimulant, sweetener, flavoring agent was dissolved 3-4 ml distilled water to form – 2nd solution
Second solution were dissolved in first solution and kept for 2hrs to remove air bubble and the resultant homogenous solution was poured into a clean Petridish.
Then the film was dried at room temperature for 24 hrs.
The dried film were drapped in a butter paper and cut into 2*2 cm2 area, covered with an aluminum foil and kept in a desiccator.
Selected films were subjected to different evaluation parameters:

1) Thickness of film
2) Folding endurance
3) Swelling index
4) Weight variation

EVALUATION PARAMETER:
Pre – Formulation study
The track of the proposed study's product development would be illuminated by the preformulation parameters, which include the solubility of the API (Phenylephrine HCL), powders, physical appearance, solubility of the powder, angle of repose, compressibility index, tapped and bulk density of the API

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1) Solubility study:
The solubility test procedure is based on attempting to dissolve chemicals in water and alcohol. The Phenylephrine hydrochloride is dissolved in water and aqueous Solution are acidic.
2) Fourier transform infrared (FTIR) spectroscopy
Compatibility studies of the drug and the polymers were carried out using an FTIR spectrometer. Part of the sample is mixed thoroughly with 3 parts of dried potassium bromide and it was compressed into thin pellets. The pellets are then scanned under the region from 4000 cm-1 to 400 cm-1.

Post – Formulation study:
1. Weigh variation of Films:
On an analytical balance, mouths dissolving oral films were weight and the average weight for each film was calculated. It is desirable for films to have a nearly constant weight. It is helpful for ensuring that a film has the appropriate amount of excipients and API.

2.Visual inspection:
The Color, homogeneity, and transparency of a prepared orally Disintegrated film can be evaluated visually.

3.Thickness Test:
The thickness of the film was measured at five different places using micrometer screw gauge, and an average of three values was calculated. This is essential to ensure uniformity in the thickness of the film, which is directly related to the accuracy of the dose in the film.
Folding Endurance:
Folding endurance is measured by manually folding the same place film repeatedly until it breaks. The folding endurance value is the number of ties the film can be folded without breaking.
PH test:
The test film was placed in a Petri dish and moistened with 0.5 ml of distilled water for 30 sec. After putting the electrode of the pH meter into contact with the surface of the formulation and allowing for 1 minute of equilibration, the PH was measured. For each formulation, an average of three determinations was performed.
Disintegration test:
The disintegration apparatus mentioned in official pharmacopeias is used to determine a film's disintegration time. The disintegration time of film is normally a function of its composition, as it varies with formulation and generally ranges from 5 to 30 sec. The USP disintegration apparatus is commonly used for this test. There are no official guidelines for determining the disintegration time of orally fast disintegrating films.
There are two methods of determining film disintegration time:
* The slide frame method – Pouring a drop of distilled water onto the film clamped into slide frames placed on a petri dish. The time it takes for the film to dissolve is noted.
* Petri dish method – A film is placed in a petri dish with 2 mL of distilled water. The time it takes for the film to dissolve completely is referred to as the disintegration time.
Dissolution test:
Dissolution testing can be carried out using either a standard basket or paddle apparatus described in any of the pharmacopeias. The dissolution medium will be chosen based on the sink conditions and the highest dose of the API. Many times, the dissolution test can be difficult due to the tendency of the strip to float onto the dissolution medium when the paddle apparatus is employed.

III. RESULTS AND DISCUSSION

Pre – Formulation Study
1. Solubility: - The drug was found to be freely soluble in water, and sparingly soluble in organic solvent. But soluble in ethanol.

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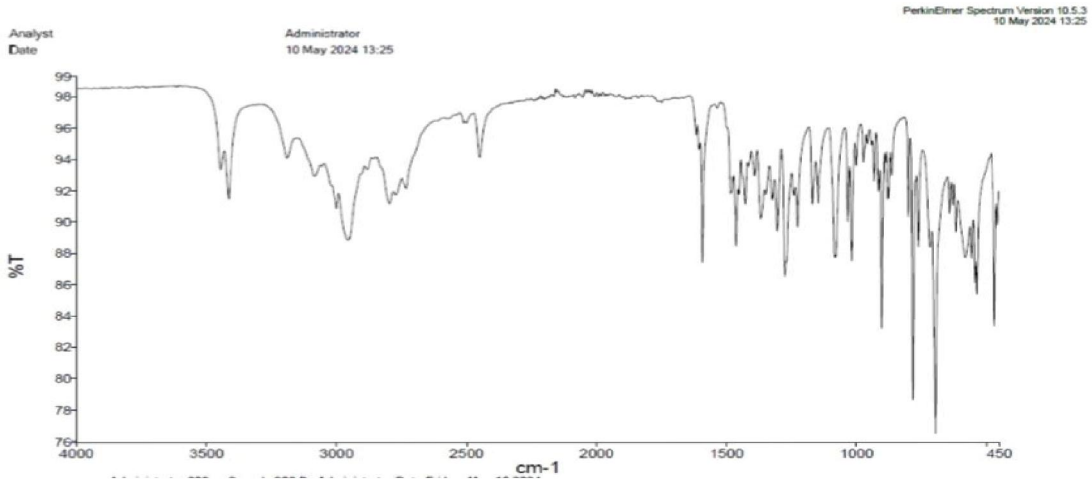
2. Flow properties of Phenylephrine HCL: - We perform the all-flow properties like angle of repose, bulk density, tapped density, Hauser's ratio, and Carr's index. Then we get good flow property of Phenylephrine HCL drug.

Drug- Excipient Compatibility Studies:

Compatibility studies were performed using IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studied. The peaks obtained in the spectra of each formulation correlates with the peaks of drug spectrum. This indicates that the drug was compatible with the formulation components.



Evaluation parameter-

Physical appearance and surface texture:

These parameters were checked simply with visual inspection of films and by feel or touch. The observation reveals that the films are having smooth surface and they are elegant in appearance.

Thickness:

Thickness of the film was measured using a screw gauge with a least count of 0.01 mm at different spots of the film. The thickness was measured at three different spots of the film and the average was taken by using the following formula

Least count = pitch/Total number of divisions of the circular scale

= 1 mm/100

= 0.01 mm

Weight Variation of oral films: The weight of the films was determined using digital balance and the average weight of all films.

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Drug content uniformity of oral films:

Phenylephrine hydrochloride oral films prepared with various polymers were subjected to the valuation for uniform dispersion of drug throughout the patch. In each case films were used and the average drug content was calculated

Folding endurance of oral films:

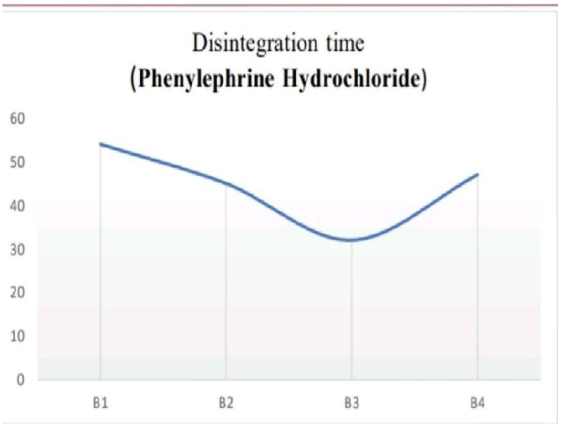
The folding endurance gives the idea of flexible nature of films. The folding endurance was measured manually, films were folded repeatedly till it broke, and it was considered as the end point. The folding endurance was found optimum and the films exhibited good physical and mechanical properties and the average folding endurance of all films

Swelling index:

The swelling index in the oral films ranged from 14.28 to 15.28 %

In- vitro disintegration test:

Formulation containing surfactant show better disintegration time F4 batch show better disintegration compare to F3.



In vitro dissolution studies:

Formulation containing Sodium lauryl sulphate showed maximum drug release within 120 sec the release was found to be 98.8%. The release of F4 is less than F3 this can be attributed due to less concentration of surfactant. F2 shows less percentage release than F4. F5 shows still lesser due to less surfactant concentration. The formulation without surfactant shows the following order of release .The other formulation released almost appropriately same amount of drug. The least percentage drug release was found to be F7

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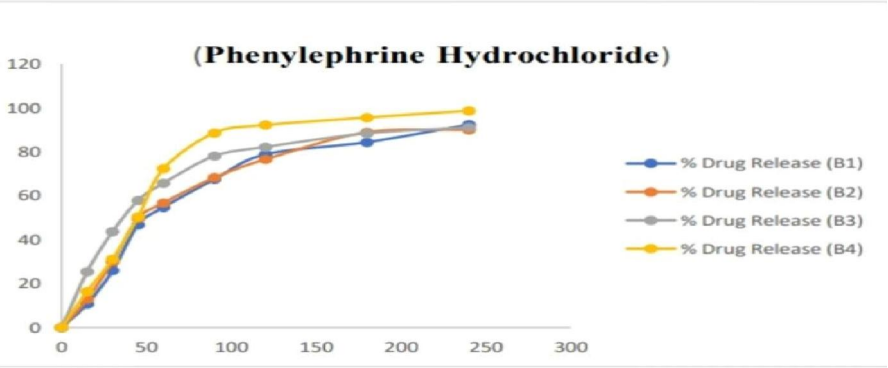
Sr. No	Time (sec)	F1%	F2%	F3%	F4%
1.	0	0	0	0	0
2.	15	10.81	12.98	25.42	16.43
3.	30	25.92	30.12	43.67	31.15
4.	45	46.78	49.67	57.87	50.42
5.	60	54.78	56.76	65.78	72.35
6.	90	67.54	68.25	78.12	88.67
7.	120	78.87	76.59	82.23	92.22
8.	180	84.43	88.98	88.45	95.67
9.	240	92.4	90.14	91.12	98.75

Table 3: - In vitro dissolution studies



➤ Evaluation test for oral thin film

Parameter	F1	F2	F3	F4
Average Weight(mg)	42.12	44.78	43.24	47.88
Thickness (mm)	0.26	0.28	0.25	0.24
Swelling index	14.43	13.42	15.22	14.64
Folding endurance	72	77	74	78
Drug content (%)	88.55	90.14	91.82	93.54
Disintegration time	35	46	39	28

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IV. CONCLUSION

This study concluded that release rate regulating polymers can be used to successfully manufacture oral films containing Phenylephrine Hydrochloride. Thus, these oral film formulations of Phenylephrine Hydrochloride exhibit good permeability. It may be inferred from the current study that there is no interaction or incompatibility between Phenylephrine hydrochloride and excipients, according to FTIR investigations. The physical appearance, surface texture, weight uniformity, thickness uniformity, folding durability, surface pH, percentage swelling index, percentage moisture uptake, drug content uniformity, and in-vitro drug release of oral films that are formulated are all satisfactory. The homogeneity within the batches was demonstrated by the low standard deviation values for the following parameters: average weight, thickness, surface pH, percentage swelling index, percentage moisture uptake, in vitro drug release, and drug content. The F4 formulation satisfies the prerequisite. The good rapid dissolving oral film formulation criteria is met by the F4 formulation. In the in vitro dissolving tests, formulation F4 released 98.7% of the drug in 240 seconds and over 90% of the drug in 120 seconds. The sodium alginate polymer has the lowest viscosity of any polymer—that is, 25-30 poise—when compared to other polymers, meaning that low viscosity signifies greater solubility. It was discovered that the F4 formulation had an in-vitro disintegration time of 30 seconds, a thickness of 0.24 mm, a folding endurance of 78, and a swelling index of 14.64. Consequently, it may be said that oral films containing Phenylephrine hydrochloride may have a quicker acting formula and a higher drug bioavailability. It is necessary to carry out additional clinical research to verify the safety and effectiveness of the created formulation.

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