RESEARCH PAPER

Formulation and Evaluation of Mouth Dissolving Film of Neem and Portulaca Oleracea Extract

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ABSTRACT

Background

Herbal drugs have been proven to have medicinal properties. ODDS provides a novel approach compared to traditional oral administration in which drug delivery is accomplished through convenient, safe, and patient-friendly means of oral route. MDF is preferred over tablets because of the added advantage of being flexible and easier to use.

Objective

The objective of the present study was therefore to prepare and characterize oral mouth dissolving films of Neem and Portulaca oleracea.

Methods

The films were prepared by the solvent casting technique using Methyl cellulose as polymer, Glycerin as plasticizer and other additives. In-vitro mechanical characterization, disintegration test, and in-vitro dissolution studies were carried out on the prepared films.

Results

Analysis showed that the films of Neem and Portulaca oleracea had good mechanical strength, fast disintegration, and good drug release from the films.

Conclusion

The study successfully formulated and evaluated mouth dissolving films containing Neem and Portulaca oleracea extracts with promising physicochemical properties, suggesting their potential as an effective and patient-friendly herbal drug delivery system.

Keywords: Mouth dissolving film, Neem and Portulaca oleracea, Solvent casting method.

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1. Introduction

Oral administration route is said to be the most widely employed method in systemic drug delivery because of its versatility, ease of administration, high compliance, and non-invasiveness. [1] Increasing patient convenience is expected in each scenario. Considering its cost-effectiveness and ease of administration, oral route continues to be the most preferred method of drug delivery. It improves patient compliance. [2]

Oral film dosage form is a rapidly dissolvable film placed in the mouth or oral mucosa that disintegrates quickly and releases the drug into the body. This film dissolves within seconds. This method prevents any complications associated with ingestion of conventional dosage forms like tablets and capsules thereby proving advantageous for children and aged patients. With the larger surface area of the thin film coming into contact with saliva, it enables quick disintegration and rapid absorption of the drug, thereby providing improved efficacy and patient compliance. [3] Provides fast absorption and quick bioavailability of the drug because of increased blood flow and permeability of the oral mucosa which is 4-1000 times higher than the skin. [4]

Proves useful for any required localized effect such as for treating Toothache, Oral ulcer, Cold sores or Teething. Generally, oral thin films have a shelf life of approximately 2 to 3 years depending upon the active drug; however, they are extremely moisture sensitive. [5]

Advantages

- Easy dosing.
- Taste Masking.
- Stability.
- Patient Compliance.

- Quick Disintegration and Dissolution

Disadvantages

- Requires special packaging.
- Drug loading cannot be done to high concentrations.

Aim and Objective

The aim of the current research study is to prepare a dissolvable oral film. The objectives of this study include isolating the active constituents from Neem and Portulaca oleracea powder, preparation of dissolvable oral film, and determination of antibacterial potential of herbal medicine Neem and Portulaca oleracea.

Experimental Work

Formulation of Fast Dissolving Strips by Solvent Casting Method

In the process of solvent casting, the water soluble polymers are initially dissolved in water while stirring for around 1,000 rpm. In some cases, the temperature can be raised to 60°C to dissolve. The next step is dissolving of other additives like coloring agents, flavors and sweeteners. All these are then mixed together under the same stirring speed.

Then the active pharmaceutical ingredient (API) which was initially dissolved in an appropriate solvent is introduced. Any trapped air in the mixture is then eliminated with the help of vacuum. Finally the solution is poured and left to dry. After drying, strips are cut into required sizes. [6]

2. Literature Review

This 2013 review article from IJPRAS covers Fast Dissolving Films as a new drug delivery method. These thin films evolved from breath strips and are solid dosage forms that dissolve in the mouth within 1 minute without water. They're used for vitamins, personal care, and drugs needing rapid action. Made with polymers, plasticizers, flavors, and sweeteners, the paper reviews their formulation, evaluation methods, and future potential. [7] This overview highlights Fast Dissolving Films as a new drug delivery system gaining popularity for better safety, efficacy, and patient compliance. Placed on the tongue, the film dissolves instantly in saliva and releases the drug, which can absorb through the mouth, throat, or esophagus. Key benefits include higher bioavailability, no choking risk, good mouth feel, and ease for people who struggle to swallow tablets. The article reviews advances in formulation, preparation, evaluation, and marketed products of these oral films.

[8] This 2014 review discusses Oral Strip Technology (OST) as a growing focus in oral drug delivery. OST is especially useful for kids and elderly patients because it eliminates the need to swallow tablets and requires no water. It works for local action, rapid release, or controlled buccal delivery, and can bypass first-pass metabolism. Ideal strips are stable, portable, easy to handle, and taste good. OST is cheaper and simpler to make than ODTs. A drawback of buccal delivery is low drug flux, but penetration enhancers can improve it. The paper covers materials, preparation, uses, and future prospects of OST. [9] This study looked at using low dextrose equivalent maltodextrins (MDX) to make oral fast-dissolving films. Glycerin at 16–20% w/w worked best as a plasticizer for flexibility. The films were made by solvent casting or hot-melt extrusion, with sorbitan monooleate or microcrystalline cellulose added. MCC reduced ductility and affected disintegration time: <10s for casting, 1 min for extrusion. When loaded with the poorly soluble drug piroxicam, the films held up to 25 mg per 6 cm² and kept good flexibility. Series C films showed much better drug dissolution regardless of drug load.[10] This study developed fast dissolving films of TC for local delivery in

the mouth. Researchers tested different polymers, modifiers, and polyhydric alcohols to optimize the films. Poloxamer 407 and HPBCD were used to boost TC solubility, with poloxamer 407 films showing better in vitro dissolution and antimicrobial activity than HPBCD films. The films were made with HPMC, xanthan gum, and xylitol. Adding eugenol improved taste and mouth feel in human volunteers without slowing dissolution time. [11] This study aimed to develop a sublingual fast-dissolving film of salbutamol sulphate for treating acute asthma attacks. The film was made by solvent evaporation using polyvinyl alcohol as polymer, glycerol as plasticizer, and mannitol as filler. A 3^3 factorial design optimized the formula. Results showed that polymer, plasticizer, and filler levels had complex effects on mechanical strength and drug release. The best batch used medium levels of polyvinyl alcohol and glycerol with high mannitol. The final film was clear, smooth, and had similar dissolution in water, simulated saliva pH 6.8, and gastric fluid pH 1.2.[12] This 2012 study focused on making a fast dissolving oral film of dicyclomine for buccal delivery. Buccal delivery is a safe, easy route that uses the rich blood supply in the mouth for better drug absorption. The films were made by solvent casting with HPMC, PVA, Eudragit RL-100, and other excipients. They were tested for mechanical strength, swelling, disintegration, dissolution, and drug release. Formulation X1 gave the best result with 93.88% drug release in vitro following first-order kinetics. Release occurred through Fickian diffusion, showing the film improves bioavailability over regular tablets. [13] This 2009 review discusses Mouth Dissolving Films (MDF) as a fast drug delivery system that improves patient compliance. MDFs dissolve quickly in the mouth, making them ideal for children, elderly, and anyone with swallowing issues. Because the drug absorbs through the oral mucosa, it works faster and bypasses first pass metabolism, so lower doses can be used. The paper reviews polymers and plasticizers used in

MDFs, how they affect the film's properties, formulation methods, and common manufacturing problems. [14]This 2018 review looks at Oral Fast Dissolving Films (OFDF) as a way to improve patient acceptance of drugs. OFDFs dissolve rapidly in the mouth without water or chewing, making them a convenient intraoral delivery system. Many drug types can be made into these films, including neuroleptics, cardiovascular drugs, analgesics, antihistamines, antiasthmatics, and drugs for erectile dysfunction. The buccal mucosa absorbs drugs quickly into the bloodstream. The paper covers preparation methods, polymer selection. [15] Oral dissolving films are flexible, self-administered films that stick to the mouth lining and dissolve in seconds. They improve drug bioavailability by bypassing first-pass metabolism and offer better patient compliance. Made mainly by solvent casting with hydrophilic polymers, they're cost effective and suitable for both local and systemic drug delivery. [16] Fast dissolving films are stamp-like oral films that dissolve in seconds without water. They're ideal for kids and elderly patients, improve bioavailability by bypassing first-pass metabolism, and offer a cost effective, patient-friendly drug delivery option. [17] Ropinirole tablets have low bioavailability and are hard for Parkinson's patients to take due to tremors and frequent dosing. This study developed sublingual/buccal fast-dissolving films of ropinirole that are non-toxic, stable for 28 days, and disintegrate quickly. The films improved bioavailability by avoiding first-pass metabolism and reached circulation within 15 min, making drug delivery easier for PD patients.[18] This study made fast-dissolving films (FDFs) using natural polysaccharides like pullulan without heating, pH control, or extra additives. Drug type and concentration affected film formation, while film thickness was controlled by polysaccharide concentration. The films swelled, released the drug, and disintegrated in dissolution medium. Dexamethasone released completely in 15 min, though slower than pilocarpine or lidocaine. Overall, polysaccharide-based FDFs are promising oral dosage forms that dissolve quickly in the mouth. [19] This review highlights Oral Fast Disintegrating Films (OFDFs) with phytochemicals as a patient friendly alternative to tablets. The films dissolve rapidly in the mouth and use herbal actives like flavonoids and polyphenols. They show anti-inflammatory, antiviral, antioxidant, and other effects, and can be used for conditions like dementia and Alzheimer's. [20]

3 . Materials and Method

Extraction of drugs:

1) Neem: Through maceration 10g neem powder +100 ml chloroform, shaking for 7 days and then filtering.

2) Portulaca oleracea (Purslane): By maceration process,10g of Portulaca oleracea powder+50 ml of 96% ethanol, shaking for 3 days and then filtering.

Strip Preparation

The fast dissolving strip is prepared through the solvent casting technique.The preparation technique is such that the formulation is made up of the active component incorporated at various concentrations together with other ingredients.

Ingredients for Strip formulations along with their quantity and role

Sr.no	Ingredients	Quantity	Role
1	Methyl cellulose	2gm	Film forming agent
2	Glycerin	1ml	Plasticizer
3	citric acid	0.25gm	Saliva stimulant
4	Peppermint oil	2 drops	Taste masking
5	Water	Q.S.	Solvent
6	Neem	2ml	API
7	Portulaca Oleaceae	2ml	API
8	Liquorice	2gm	Sweetening agent

Table 1: Composition of formulation of Strip

Characterization of Drug – Phytochemical testing of Neem

Sr.no	Test	Inference
1	Alkaloid (Dragen doffs test)	Positive test
2	Saponin's (Foam test)	Positive test
3	Terpenoid (Salkowski)test)	Positive test

Table 2: Phytochemical test for Neem

Phytochemical testing of Portulaca Oleracea

Sr.no	Test	Inference
1	Alkaloid (Dragen Dorff's test)	Positive test
2	Saponin's (Foam test)	Positive test
3	Terpenoid (Salkowski test)	Positive test
4	Flavonoid (Shinoda test)	Positive test

5	Phenolic Compound (Ferric Chloride test)	Positive test
6	Tannin (Ferric Chloride test)	Positive test

Table 3: Phytochemical test for Portulaca Oleracea

Antimicrobial Property

The antimicrobial property of the extract was determined by the use of Agar Well Diffusion method.

Evaluation Test

1) Morphological Test:

The morphological properties of the films were tested through visual inspections based on their uniformity, colour, transparency and surface texture. All formulations were kept in air-tight boxes at room temperature (25 ± 3°C). [21]

2) Thickness Test:

I measured the thickness of the films using a micrometer screw gauge at three points. Then I calculated the average of these readings. This test is important because it helps ensure the films have a thickness. If the thickness is not uniform it can affect how much of the drug is, in the film.[22]

3) Dryness Test / Tack Tests:

The drying of film falls into around eight categories including set to touch, dust free, surface dry (tack free), dry to touch, dry hard, dry-through (dry to handle), dry-to re-coat and dry print free.

These tests are generally conducted in relation to paint films and

therefore not elaborated here. Tack is the degree to which the film will adhere to other substrates, such as a piece of paper. [23]

4) Weight Variation Test:

Film strips measuring 3 × 2 cm² in size were prepared by cutting the cast film from three different sites. They were separately weighed, and variation in their weights was noted. [24]

5) Disintegration Time:

The time it takes for something to break apart is really important. This is because oral dissolving films need to release the drug. There are no rules, for this test. People think the films should break apart in under a minute. Usually oral dissolving films break apart in 5 to 30 seconds. This is what we want to see with disintegration of dissolving films. Disintegration time of dissolving films is something we care about. [25]

6) pH Value:

pH value was determined by placing the single oral film into 2 ml of distilled water and then measuring the pH value of the solution with pH paper. Variations in pH values occurred due to varying polymers and active pharmaceutical ingredient (API).

4. Results

1) Phytochemical Analysis: The following table shows the result of the qualitative analysis performed using the

extracts of neem and purslane (Portulaca oleracea)

- Qualitative determination of bioactive compounds present in Neem

Sr.no	Name of tests	Observation	Inference
1	Alkaloids: Dragendroff test	Orange or reddish brown color	Positive test
2	Mayers test	Cream or white ppt	Positive test
3	Saponin :Foam test	Foam formation	Positive test
4	Emulsion test	Formation of emulsion	Positive test
5	Terpenoids test	Reddish brown color	Positive test

Table 4: Observation table of Neem constituents

- Qualitative determination of bioactive compounds present in portulaca oleracea

Sr.no	Name of test	Observation	Inference
1	Alkaloids: Dragendroff test	Orange or reddish brown color	Positive test

2	Flavonoids Shinoda test	Yellow color disappear with acid	Positive test
3	Phenolic compound	Blue or green color	Positive test
4	Tannins	Blue black color	Positive test
5	Saponin :Foam test	Foam formation	Positive test
6	Terpenoids test	Reddish brown color	Positive test

Table 5: Observation table of Portulaca Oleracea constituents

2) Antimicrobial study: Antimicrobial susceptibility test was done against lactobacillus using neem and portulaca oleracea extract.

Fig 1: Antimicrobial Test

3) Formulation of Strip: The strip was formulated with extract from neem and purslane (Portulaca oleracea) with all other constituents of above mentioned table. Different parameters were checked in the formulated strip

***Physical observation:** Observations about appearance, color, odor, pH and antimicrobial.

Sr.no	Test	Observation
1	Appearance	Non-sticky surface
2	Color	Slightly brownish
3	Oduor	Pleasant
4	pH	6.5-7.5
5	Antimicrobial	Show antimicrobial activity

Table 6: Morphological Test

4) Evaluation test table:

Sr.no	Test	Observation	Inference
1	Morphological test	Smooth, uniform surface, Slightly brownish color	Acceptable appearance, No cracks, no bubbles
2	Thickness	Uniform Thickness	Uniform thickness within acceptable range
3	Dryness test	Non-sticky on touch, no adhesion to fingers	Proper drying, good integrity
4	Weight variation test	Nearly uniform weight	Uniform weight variation within acceptable range
5	Disintegration time	35-45 sec.in stimulated saliva	Rapid disintegration (within 60sec.)
6	pH value	6.5-7.0	Neutral, non-irritating to oral mucosa
7	Antimicrobial activity	Zone of inhibition:12 mm	Good antimicrobial activity due to Neem and Purslane (portuluca oleracea)

Table 7: Evaluation test

5. Discussion

The current research work has successfully managed to formulate and evaluate a Mouth Dissolving Film (MDF), comprising herbal extracts from Neem (Azadirachta indica) and Portulaca oleracea (Purslane). This research clearly shows how important it is nowadays to use innovative drug delivery methods, especially those that pertain to oral thin films. Such films serve as a good substitute for traditional formulations like tablets and capsules. Oral thin films are highly beneficial for children, elderly people, and those suffering from swallowing problems.

The development was done through the solvent casting method, where methyl cellulose acted as the film forming polymer, glycerol as the plasticizer, and other suitable additives were used to ensure the masking of taste and stability of the formulation. The ability to form uniform and pliable films that are not sticky means that the proper materials were chosen for the development of an efficient oral thin film. The addition of the herbal extract to the film was successfully done without affecting the properties of the film.

It was found by phytochemical investigation that there are valuable bioactive constituents like alkaloids, saponins, terpenoids, flavonoids, phenolics,

and tannins present in Neem extract and Portulaca oleracea. These compounds have been known to have good medicinal properties, especially antimicrobial properties. In antimicrobial analysis, performed through agar well diffusion method, it has been observed that there is a considerable amount of zone of inhibition by the films.

The results obtained regarding the parameters of the films fabricated were quite satisfactory. The films had good appearance, smooth texture, and desirable physical properties such as desirable thickness, balanced distribution of weight, and non-adhesiveness. Also, it was found that the pH value of the films was 6.5–7.5, which is neutral and implies that the films are not irritating to the mucous membrane of the mouth and can therefore be administered via the buccal route. In addition, it was found that the disintegration time of the films was 35–45 seconds, which is the best for fast dissolving films.

The quick dissolution and release of drugs from the developed films is due to the high surface area and permeability nature of the oral mucosa, thus enabling quick entry of drugs into the blood stream. This makes their use more convenient since they offer better availability and quicker action than other conventional forms of oral preparations. The presence of a pleasant odor and taste- masking property also adds to their acceptability.

As such, it is clear from the findings of the present research that mouth dissolving films with Neem and Portulaca oleracea extract will make excellent choices for an herbal drug delivery system owing to the effectiveness and safety offered by this method of drug delivery in terms of both local and systemic delivery systems.

Conclusion

In summary, fast dissolving oral films are considered an innovative and effective drug delivery system that possesses many benefits, such as a quick onset of effect, improved bioavailability, easy administration, and increased patient compliance. It can be concluded that the development and evaluation of Neem and Portulaca oleracea MDFs in this research can be a foundation for future research to develop and market these novel products.

Conflict of Interest

Regarding the publication of this research work, the authors declare that they have no conflicts of interest.

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