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Formulation And Evaluation Of Mouth Dissolving Film Of *Ocimum Tenuiflorum Linn.* And *Glycyrrhiza Glabra Linn.* By Solvent Casting Method

Lamdade Shubhangi, Kolte Shriharsh, Kinake Sharda, Kondewad Pallavi,

Chavan Saiprasad

Dept. of Pharmaceutics, D K Patil Institute Of Pharmacy, Sayal Road, Loha, Nanded.431708

Abstract

This reseach focused on the formulation and evaluation of mouth dissolving film containing extracts of ocimum tenuiflorum and glycyrrhiza glabra. The ocimum tenuiflorum is commonly known as Holy, basil, tulsi or tulasi. The fixed oil of Tulsi have considerable antiulcer action. The glycyrrhiza glabra commonly known as liquorice. Licorice root extract has healing property and it is used to treat mouth ulcer. The different polymers has different drug release effect in the mouth dissolving film. Mouth dissolving fim can treat the different types mouth ulcers like canker sores, leukoplakia. These films are prepared by solvent casting method. These films have several advantages over normal conventional dosage forms. They deliver the drug at target site so dose frequency is reduced, it avoids the hepatic first pass metabolism and due to this the bioavailability is enhanced. These films are evaluated for it's thickness, morphological properties, folding endurance, surface PH, Disintegration time, stability studies.

Keywords:- *Ocimum tenuiflorum*, *Glycyrrhiza glabra*, mouth dissolving film, polymer, solvent casting method.

1. INTRODUCTION

Oral route is regarded as convenient route for administration of dosage form. The mouth dissolving films when administer these rapidly dissolves and disintegrate within a seconds and give its therapeutic action. These mouth dissolving films have various benefits over the normal conventional dosage forms. A mouth ulcer is the loss or erosion of the delicate lining tissue of the mouth (Mucous membrane). Mouth ulcers are small sores that form on gums, lips, tongue, inner chiks or roof of mouth. The mouth ulcer includes the various types like the cancer sores, leukoplakia, oral thrush, gingivostomatitis, oral lichen planus.

1.1 Ocimun tenuiflorum

Ocimum tenuiflorum commonly known as holy basil or tulsi, is a species of basil that is native to the Indian subcontinent and is widely cultivated for it's medicinal properties. The ocimum tenuiflorum are used in various herbal remedies. It is also used for it's anti - inflammatory, antioxidant and antimicrobial properties. The extract of the ocimum tenuiflorum is effective against the mouth ulcer. Holy basil is renowned for it's health benefits and is often used in traditional medicine. Some studies suggest that holy basil may help with respiratory conditions improve heart health, and support mental clarity. Ocimum tenuiflorum beneficial for treating common cold, flu, asthma, stress, diabetes, heart disease, diarrhoea and insomnia. Ocimum tenuiflorum is a versatile plant with significant cultural and medicinal importance.

1.2 Glycyrrhiza glabra:-

Glycyrrhiza glabra commonly known Licorice, is a perennial herbaceous plant that belongs to the family fabaceae. Licorice has been used in traditional medicine for centuries. Some of it's potential benefits including the digestive aid, Anti-inflammatory properties, Respiratory health, Hormonal balance. The glycyrrhiza glabra also beneficial to treat the mouth ulcer. The glycyrrhiza glabra is well known for it's expectorant and demulcent properties. The glycyrrhiza glabra containing glycyrrhizic acid as a therapeutic agent, it has been used in a variety of formulations as it is reported to be anti - inflammatory, anti- ulcer, anti - allergic, antioxidant, anti - tumor, anti - diabetic and hepatoprotective. While licorice has many benefits, it should be consumed in moderation. Excessive intake can lead to the different side effects like high blood pressure, low potassium levels and hormonal imbalances.

2. WHAT IS MOUTH DISSOLVING FILM ?

• It is the film that disintegrates and dissolves rapidly in the saliva within a few seconds.

• There is no need of drinking water or chewing.

• They provide a variety of benefits over conventional dosage form such as tablets and capsules by removing swallowing issues and increases patient compliance.

RATIONAL BEHIND DRUG SELECTION :-

1. For mouth dissolving film the dose of drug should be less
2. For mouth dissolving film the bioavailability of the dose is also more
3. For mouth dissolving film the onset of action is also fast

IDEAL PROPERTIES OF MOUTH DISSOLVING FILM :-

1. It should easily dissolve and disintegrate
2. Have a pleasing taste
3. It should have ability to permeate through oral mucosal layer
4. It should be stable in water and saliva
5. Be less sensitive to environmental conditions like temperature and humidity
6. It should not require water and other liquid to swallow

Advantages: -

1. No need of water to take oral film
2. Best for pediatric and geriatric
3. Convenient to administer during travelling without need of water
4. Quick onset of action and enhance efficacy
5. Excellent mouth feel property produced by use of flavors and sweeteners
6. Available in various sizes and shapes
7. Fast disintegration and dissolution
8. Taste masking
9. Enhanced stability
10. Small size for improved patient compliance
11. To avoid first pass metabolism
12. Easy to handling and transportation

Disadvantages: –

1. High dose cannot be incorporated into film
2. Some films are moisturous and temperature sensitive
3. It is hygroscopic in nature so must kept in dry places
4. Eating and drinking must be restricted
5. Packing of film requires special equipment and it is difficult to pack

3. WHAT IS MOUTH ULCER?

- Mouth ulcer is the loss or erosion of the delicate lining tissue of the mouth (mucous membrane).
- Mouth ulcers are small sores that form on your gums, lips, tongue, inner chicks or roof of your mouth.
- The most common cause is injury, such as accidentally biting the inside of your cheek.
- In most cases, mouth ulcers are harmless and resolve by themselves in 10 to 14 days without the need for treatment.
- Aphthous ulcers are recurring ulcers with no known cause that affect around 20 per cent of the population.

Fig.1: Mouth Ulcer

Types of mouth ulcer :-

a.Canker sores:- Canker sores, also known as aphthous ulcers or mouth ulcers, are small, painful lesions that develop on the soft tissues inside the mouth, tongue, or lips. They are common, affecting up to 20% of the population.

Causes and Triggers:

1. Unknown (most cases)
2. Stress
3. Hormonal changes
4. Nutritional deficiencies (e.g., vitamin B12, iron, folic acid)

Symptoms:

1. Pain or tenderness
2. Small, round, or oval-shaped ulcers
3. White or yellowish center

Fig.2: Canker sores

B. Leukoplakia:- Leukoplakia is a condition characterized by the formation of white patches or lesions on the mucous membranes of the mouth, tongue, or lips.

Fig.3: leukoplakia

Causes and Risk Factors:

1. Tobacco use (smoking, chewing)
2. Betel nut or paan consumption
3. Alcohol consumption
4. Human papillomavirus (HPV) infection
5. Chronic irritation (e.g., ill-fitting dentures)
6. Nutritional deficiencies (e.g., vitamin A, B12)
7. Genetic predisposition
8. HIV/AIDS or immunosuppressant

Symptoms:

1. White or greyish patches on mucous membranes
2. Lesions may be flat, raised, or verrucous
3. Asymptomatic, but may cause discomfort or pain
4. May bleed or ulcerate

c. Oral thrush:- Oral thrush, also known as oropharyngeal candidiasis, is a fungal infection caused by Candida albicans. It affects the mouth, tongue, and throat.

Symptoms:

1. White patches or lesions on the tongue, inner cheeks, gums, and tonsils
2. Redness and inflammation around the affected areas
3. Soreness or pain
4. Difficulty swallowing
5. Dry, cracked mouth corners
6. Loss of taste
7. Bad breath (halitosis)

Fig.4: Oral thrush

Causes and Risk Factors:

1. Weakened immune system (e.g., HIV/AIDS, cancer

treatment)

2. Antibiotic use

3. Steroid use

4. Diabetes

5. Poor oral hygiene

6. Dentures or oral appliances

7. Vitamin deficiencies (e.g., vitamin B12)

8. Hormonal changes (e.g., pregnancy, menstruation)

9. Smoking

d. Oral lichen planus:-

Oral lichen planus (OLP) is a chronic inflammatory condition affecting the mucous membranes inside the mouth.

Symptoms:

1. White, lacy patches or lesions

2. Red, inflamed, or ulcerative areas

3. Pain or discomfort

4. Burning sensation

5. Difficulty swallowing (in severe cases)

6. Dry mouth

7. Bad taste

Fig.5: Oral lichen planus

Causes and Risk Factors:

1. Autoimmune response
2. Genetic predisposition
3. Stress
4. Hormonal changes
5. Vitamin deficiencies (e.g., vitamin B12)
6. Medications (e.g., NSAIDs, beta-blockers) 7. Allergic reactions
8. Infections (e.g., Candida)
9. Dental materials (e.g., amalgam)

e. Gingivostomatitis:- Gingivostomatitis is an inflammatory condition affecting the gums (gingiva) and mucous membranes in the mouth.

Symptoms:

1. Redness and swelling of gums and mucous membranes

2. Pain or tenderness
3. Bleeding gums
4. Ulcers or sores on gums, tongue, or lips
5. Bad breath (halitosis)
6. Difficulty swallowing
7. Fever (in AHGS)

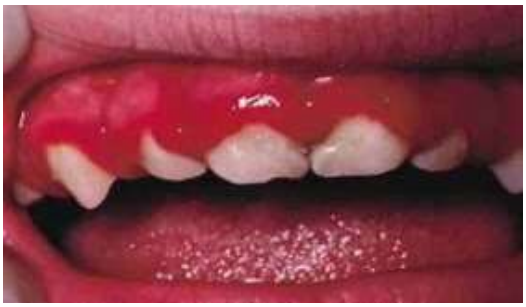


Fig.6: Gingivostomatitis

Causes and Risk Factors:

1. HSV infection (AHGS)
2. Poor oral hygiene
3. Dental plaque and tartar buildup
4. Gum recession
5. Hormonal changes (e.g., pregnancy, menstruation)
6. Nutritional deficiencies (e.g., vitamin C, B12)
7. Medications (e.g., corticosteroids, chemotherapy)
8. Stress

f. Oral cancer :- Oral cancer, also known as mouth cancer, is a type of cancer that affects the mouth, tongue, lips, gums, or throat.

Risk Factors:-

1. Tobacco use (smoking, chewing)
2. Alcohol consumption
3. Human papillomavirus (HPV) infection
4. Betel nut or paan consumption
5. Family history
6. Age (over 40)
7. Poor oral hygiene
8. Irritation (e.g., dentures, sharp teeth)
9. Nutrition deficiencies (e.g., vitamin A, C)
10. Exposure to radiation

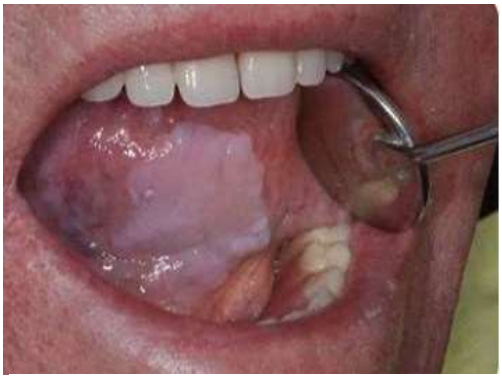


Fig.7: Oral cancer

Symptoms:-

1. Persistent mouth sores or ulcers
2. White or red patches on mucous membranes

3. Unexplained bleeding or pain
4. Difficulty swallowing or speaking
5. Swelling or lumps in the mouth or neck
6. Loose teeth or changes in bite
7. Numbness or tingling in the mouth or tongue

4. Plant profile :-

A)Tulsi

***Fig.17: Ocimum tenuiflorum* (TULSI)**

Synonym:- Holy Basil ,Tulsi, Tulas, sacred basil

Biological source: -Tulsi consist of fresh and dried leaves of plant *Ocimum tenuiflorum L.*

Family: - Lamiaceae

Scientific classification :-

Kingdom:- Plantae

Division:- Magnoliophyta

Class:- Magnoliopsida

Order:- Lamiales

Family:- Lamiaceae

Genus:- Ocimum

Spices:- tenuiflorum

Chemical constituents: -

The Tulsi plant contains numerous active compounds and the major compounds are linalol, eugenol, methylchavicol, methylcinnamat, linolen, ocimene, pinene, cineol, anethol, estragol, thymol, citral, and camphor.

Medicinal Properties :-

1. Antimicrobial
2. Anti-inflammatory
3. Antioxidant
4. Adaptogenic
5. Immunomodulatory

Common Uses:- Mouth ulcer , cold , headache, stomach issues, heart disease

Traditional Uses: - Ayurvedic medicine **,** Unani medicine **,** Homeopathic medicine **,** Folk medicine

B)Liquorice

***Fig.18: Glycyrrhiza glabra* (LIQUORICE)**

Synonym:- Glycyrrhiza , Liquorice root , Glycyrrhizae radix , Mulhatti (hindi), Mulhethi , Jethi Madh ,Yashtimadhu

Biological source: - Liquorice is the dried, peeled or unpeeled roots, rhizome and stolon of *glycyrrhiza glabra Linn.*

Family: - Fabaceae

Scientific classification :-

Kingdom:-Plantae

Division:- Angiospermae

Class:- Dicotyledoneae

Subclass:- Magnoliidae

Order:-Rosales

Family:- Fabaceae

Genus:- Glycyrrhiza

Species:- glabra Linn.

Chemical constituents: - Liquorice root contains triterpenoids, polyphenols, and polysaccharides.

1.Glycyrrhizin/ glycyrrhizic acid (major glycoside)

2.Glycyrrhitic acid (aglycone)

3.Glucoronic acid

4.Liquiritoside, iso-liquiritoside, liquiritin, isoliquiritin (Flavonoid/5.Chalcone glycosides)

5.Sugars-Glucose, mannitol

6.Resin, Volatile oil, Starch

Medicinal Properties: -

1. Anti-inflammatory
2. Antimicrobial
3. Antioxidant
4. Expectorant

Traditional Uses:- Traditional Chinese Medicine**,** Ayurvedic medicine**,** Unani medicine**,** European folk medicine

Common Uses :- Expectorant, Demulcent, Mouth ulcer, Anti asthmatic

5. Drug and excipients profile: -

Table No.1:- Drug and excipients with their role

Sr.no	INGREDIENTS	ROLE
1.	Ocimum tenuiflorum extract	antiulcer
2.	Glycyrrihiza glabra extract	antiulcer
3.	HPMC E5	Film forming agent
4.	HPMC E15	Film forming agent
5.	Sodium alginate	Natural polymer
6.	Propylene glycol	plasticizer
7.	Honey	Sweetning agent
8.	Water	vehicle

INGREDIENTS:-

a.Ocimum tenuiflorum extract (Tulsi) :-

Ocimum tenuiflorum extract, derived from the leaves and stems of the holy basil plant, is known for its numerous health benefits and applications in herbal medicine and wellness products. Ocimum tenuiflorum extract, derived from the leaves and stems of the holy basil plant, is known for its numerous health benefits and applications in herbal medicine and wellness products. Ocimum tenuiflorum extract is known for its adaptogenic properties, helping to reduce stress and anxiety levels. The extract has been shown to reduce inflammation and may benefit conditions such as arthritis. It exhibits antimicrobial activity against various pathogens, including bacteria and fungi, making it useful in treating infections. The extract may enhance immune function and improve overall health. Ocimum tenuiflorum extract is a valuable herbal product with a wide range of health benefits, making it popular in both traditional and modern wellness practices.

Phytochemicals:
1.Volatile compounds
- Eugenol

- Linalool
- Beta-caryophyllene
- Geraniol

2. Phenolic Compounds
- Ursolic acid
- Rosmarinic acid
- Caffeic acid
- Ferulic acid

3. Flavonoids
- Quercetin

4. Alkaloids
5. Glycosides
6. Other Compounds
- Saponins
- Tannins
- Minerals

Fig.8: Ocimum tenuiflorum extract

b. Glycyrrhiza glabra extract (liquorice):- Liquorice extracts have been used in herbalism and traditional medicine. A substance prepared from dried roots of the plant Glycyrrhiza glabra. It is used as a flavoring in medicines, drinks, and sweets, and it is being studied in the treatment of cancer. Licorice root extract contains several compounds that reduce inflammation, kill certain bacteria and viruses, act like estrogen and other hormones, and may cause cancer cells to die. It is a type of antioxidant. The United States Food and Drug Administration regards that foods containing liquorice and its derivatives (including glycyrrhizin) are generally recognized as safe for use as a food ingredient, if not consumed excessively. Glycyrrhiza glabra (Licorice) extract has been traditionally used to treat mouth ulcers due to its:

Phytochemicals:

1. Glycyrrhizin

2. Flavonoids (e.g., liquiritin, isoliquiritin)

3. Phenolic acids (e.g., ferulic acid)

4. Terpenoids (e.g., beta-sitosterol)

Fig.9: Glycyrrhiza glabra extract

c. HPMC E5 :- Hydroxypropyl methylcellulose (HPMC), HPMC is white or milky white, odorless and tasteless, fibrous powder or granules, the loss on drying does not exceed 10%, can be dissolved in cold water but not in hot water, slowly in hot water Swells, peptides, forms a viscous colloidal solution, cools to a solution, and accordingly becomes a gel when heated. It is usually used in pharmaceutical excipients and can be used as thickener, dispersant, emulsifier and film-forming agent. Hydroxypropyl methylcellulose (HPMC) 2910 E5, also known as Hypromellose, is a semi-synthetic cellulose ether and viscoelastic polymer. It is derived from cellulose, a natural substance

found in cotton and wood, and is widely used across various industries due to its unique properties. Hydroxypropyl methyl cellulose is a thickener for aqueous and non-aqueous systems, clear films with grease resistance, binders, lubricants, steric stabilizer and water retention aid. Dissolves in water, undergoes reversible gelation upon heating, non-ionic, does not complex with ionic species and is surface active and enzyme resistant. Solutions are pseudoplastic. This product is a multifunctional pharmaceutical excipient, which can be used as thickener, dispersant, emulsifier, film forming agent, etc. As film coating and adhesive in oral solid preparations, it can significantly improve the stability and dissolution of drugs, and enhance the waterproof of tablets. It can also be used as a suspension aid in suspension, as a matrix material in ophthalmic preparations, as a skeleton material in hydrophilic gel skeleton sustained release tablets and intragastric floating tablets. HPMC E5 (Hydroxypropyl Methylcellulose E5) is a film-forming agent commonly used in pharmaceutical and cosmetic applications.

Properties:

1. High viscosity
2. High molecular weight
3. Good film-forming properties
4. Water solubility
5. Non-toxic and non-irritating

Fig.10: HPMC E5

d. HPMC E15 :- Hydroxypropyl methylcellulose (HPMC) 2910 E15, USP42 is a semisynthetic, viscoelastic polymer, it is a cellulose ether. Hydroxypropyl methyl cellulose (HPMC) can be dissolved into some organic solvents and also in water-organic solvent mixed solvents. it does not have a gelation property when heated. HPMC is a is non-toxic to humans the raw material from cotton and wood. Hydroxypropyl methylcellulose (HPMC) E15 is used as a film coating or adhesive agent in oral solid preparation significantly increase the stability, dissolution rate as well as enhance the water-retention properties of a tablet. HPMC can be also used as a suspending agent in the suspension, a matrix material for ophthalmic agent, a skeleton material for hydrophilic gel skeleton sustained-release and gastric floating tablets. HPMC E15 (Hydroxypropyl Methylcellulose E15) is a film-forming agent with higher viscosity and molecular weight compared to HPMC E5.

Properties:

1. Higher viscosity (15,000-30,000 mPa.s)
2. Higher molecular weight (100,000-200,000 Da)
3. Improved film strength and flexibility
4. Enhanced barrier properties

Fig.11: HPMC E15

5. Water solubility

e. Sodium alginate :- Sodium alginate is a naturally occurring polysaccharide extracted from brown seaweed. It's widely used in the food industry as a thickening, gelling, and stabilizing agent. Sodium alginate is particularly known for its ability to form gels in the presence of calcium ions, making it useful in applications like spherification in molecular gastronomy. In addition to food applications, sodium alginate is also used in pharmaceuticals, cosmetics, and various industrial processes due to its biocompatibility and versatility. It can also serve as a dietary fiber supplement. sodium alginate of high molar mass has been processed with glycerol as a nonvolatile plasticizer and water as a de-structuring agent. The obtained materials have been characterized and compared to similar plasticized polysaccharide systems based on starch and chitosan. Sodium alginate is a naturally derived polymer extracted from brown seaweed. It's widely used in various industries due to its unique properties.

Properties:

1. Thickening agent
2. Emulsifier
3. Stabilizer
4. Film-forming agent
5. Biodegradable
6. Non-toxic
7. pH-sensitive

Fig.12: Sodium alginate

f. Propylene glycol:- Propylene glycol is used as a plasticizer in various applications due to its ability to enhance the flexibility, workability, and durability of plastics. As a plasticizer, it reduces the glass transition temperature of polymers, allowing them to become more pliable.

Key Points: Functionality: It helps to lower viscosity and improve processing characteristics in polymer formulations.

Compatibility: Propylene glycol is compatible with many polymers, including polyvinyl chloride (PVC) and various thermoplastics.

Applications: It's used in coatings, adhesives, and sealants, as well as in some consumer products like toys and food packaging.

Safety: Considered safe for use in many applications, propylene glycol is non-toxic, making it suitable for products that may come into contact with food or skin.

Properties:

1. Low volatile
2. High boiling point (188.2°C)

3. Low toxicity
4. Good solvent properties
5. Compatible with many polymer

Fig.13: Propylene glycol

g. Honey :- Honey is a sweet, thick fluid produced by honey bees and derived from the nectar of flowers. Honey contains mostly sugar, as well as a mix of amino acids, vitamins, minerals, iron, zinc and antioxidants. In addition to its use as a natural sweetener, honey is used as an anti-inflammatory, antioxidant and antibacterial agent. Honey is approximately 40% fructose, 30% glucose and 17% water, with the remainder being other sugars, carbohydrates and a small amount of vitamins and minerals.A potential health benefit of honey is its role in cough suppression. Infants under one year old should not be given honey due to its risk of containing the bacteria that causes infant botulism. Scientifically speaking, honey is a type of carbohydrate, mainly consisting of the monosaccharides fructose and glucose.

Fig.15: Honey

h. Water :- Water is the preferred vehicle, but only works with soluble drugs with an agreeable taste. Water serves as an important vehicle in various formulations, particularly in pharmaceuticals, cosmetics, and food products. Water dissolves active ingredients, ensuring their availability and effectiveness. This is crucial for drug delivery systems and formulations. It can help maintain the stability of certain compounds, preventing degradation that might occur in dry formulations. Water influences the texture and viscosity of products, contributing to the desired sensory attributes in creams, gels, and beverages. In some formulations, water acts as a reactant in chemical processes, enabling the formation of desired compounds. Water is generally safe and non-toxic, making it an ideal vehicle for formulations intended for human use. It is inexpensive and widely available, making it a practical choice for large-scale production. water is a versatile and essential component in many formulations, enhancing solubility, stability, and user experience.Water is a commonly used vehicle in various formulations, particularly in pharmaceuticals, cosmetics, and food products.

Fig.16: Water

Instrument :-

1.Electronic weighing balance
2.Magnetic stirrer
3.Hot air oven

Equipment :-

1.Petri dish
2.Conical flask
3.Aluminium foil
4.Stirrer
5.Beaker

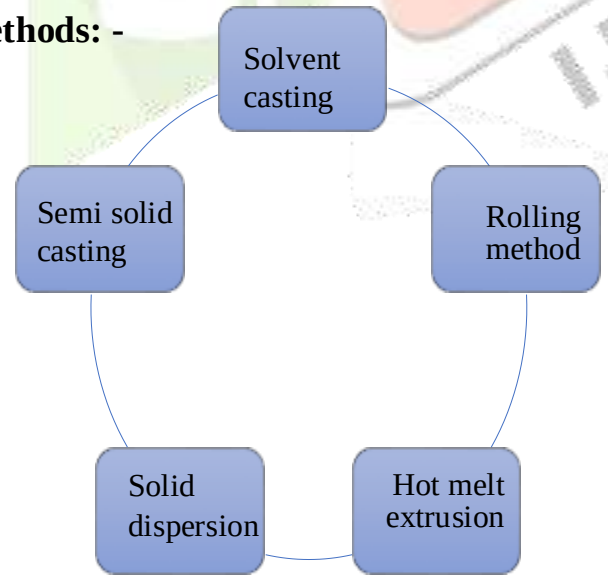
5. Marketed examples of mouth dissolving film:-

1.Snore relief throat strips

2.Mint oral film

3.Quick dissolve strips

6. Manufacturing methods: -



a. Hot melt extrusion: -

Hot melt extrusion (HME) is the process of applying heat and pressure to melt a polymer and force it though an orifice in a continuous process. HME is a common processing technique for polymers that dates back to the 1930s. Today, over half of all plastic products are produced via HME. With a long history in plastics and food processing, HME is a well-known and established manufacturing technique with growing popularity in the pharmaceutical industry. Pharmaceutical formulations for HME include combinations of API, polymers, and mostly plasticizers or other excipients. Here's how HME works. The polymer is melted in a twin-screw extruder, and all ingredients are mixed and kneaded; thus, intense compounding takes place. The die, which is placed at the end of the twin-screw extruder, defines the shape of the extrudate. The melt is squeezed through the die hole. Downstream equipment, such as a conveyor, pelletizer, or take-off system and cutters, provides further continuous processing. Using HME granules, tablets with a modified drug release profile can be produced as well as transdermal, transmucosal or subcutaneous drug delivery systems.

b. Solid dispersion technique :-

The solid dispersion technique is a method used to improve the solubility and bioavailability of poorly water-soluble drugs. In the content of mouth dissolving films, it involves dispersing the drug in a polymer matrix to create a uniform solid dispersion. This technique can enhance the dissolution rate and oral bioavailability of the drug, making it suitable for mouth dissolving films. The term solid dispersion refers to the dispersion of one or more active ingredients in a hydrophilic inert carrier matrix at molecular level. It is prepared by the melt (fusion) method and solvent evaporation technique. However, the process is individualized depending on the interaction between drug and carrier. Principles:

1. Solubilization: The drug is dispersed in a polymer matrix, which can be a hydrophilic or hydrophobic polymer, depending on the drug's properties.
2. Particle size reduction: The drug particles are reduced in size to increase their surface area, facilitating faster dissolution.
3. Homogeneous distribution: The drug is evenly distributed throughout the polymer matrix to ensure consistent drug release.

c. Semi solid casting :-

Semi-solid casting is a method used to produce mouth-dissolving films, also known as orodispersible films or fast-dissolving films. These films are designed to dissolve quickly in the mouth, releasing the active pharmaceutical ingredient (API) or other desired substances. Here's an overview of the semi-solid casting method for producing mouth-dissolving films:

Principle: The semi-solid casting method involves casting a semi-solid mixture of the API, polymers, and other excipients onto a surface, where it is allowed to set and form a thin film.

Process:

1. Formulation: The API, polymers (e.g., hydroxypropyl methylcellulose, HPMC), and other excipients (e.g., plasticizers, sweeteners, flavorings) are mixed together to create a uniform semi-solid mixture.

2. Heating: The mixture is heated to a temperature range of 50°C to 80°C to create a semi-solid state.
3. Casting: The semi-solid mixture is cast onto a surface, such as a stainless steel belt, a silicone mat, or a release liner.
4. Spreading: The mixture is spread evenly to a uniform thickness using a blade or a spreading device.
5. Setting: The cast film is allowed to set and solidify at room temperature or under controlled temperature and humidity conditions.
6. Drying: The film is dried to remove any residual solvent or moisture. 7. Cutting: The dried film is cut into desired sizes and shapes.
The semi-solid casting method is widely used in the pharmaceutical industry for producing mouth-dissolving films, and ongoing research and innovations aim to improve the process and expand its applications.

d. Rolling method :-
Rolling method for creating mouth dissolving films involves mixing the drug solution and film-forming polymer solution thoroughly, then subjecting the resultant solution or suspension to rollers. This process requires specific rheological considerations to ensure the proper consistency of the solution or suspension. The film is then dried on the rollers and cut into the desired shapes and sizes. In this method, both water-soluble and insoluble ingredients are combined to form a uniform solution. The solution is then rolled out to the desired thickness, allowing for even drying and film formation. The rolling method is often compared to the solvent casting method, which involves dissolving the ingredients in a solvent and then evaporating the solvent to form the film. In general, the process of using two rollers involves rolls extending over a set distance. The material is fed between these rolls. While the rolls rotate, frictional and compressive forces compel the rolling stock to enter the roll gap, resulting in a reduction in its thickness.

e. Solvent casting method :-
The solvent casting method is a popular technique for producing mouth dissolving films, also known as orodispersible films or fast dissolving films.
Principle:
The solvent casting method involves dissolving a polymer and other ingredients in a suitable solvent, followed by casting the solution onto a surface, where the solvent evaporates, leaving a thin film.
Process :-
1.Polymer solution was prepared by using polymers (HPMC, Sodium alginate) with continuous stirring by using magnetic stirrer
2.After that the solution kept for 3-6 hrs to expel the air bubbles within the solution

3.In separate beaker herbal drugs, plasticizer and other excipients dissolved in distilled water
4.The drug plasticizer and all excipient solutions were added and mixed after that polymer has been fully hydrated with water and final volume make up (10ml) with water
5.The resultant solution was poured into petri dish with defined surface area then left to dry using an oven .The film was carefully taken into petri dish and trimmed to the desired size.

7. Evaluation parameters:-1.Morphological properties

Visual observations were made of the morphological characteristics, such as the homogeneous nature of the films, color, transparency, and surface texture. All the formulations were stored at room temperature 25±30 ℃ in air-tight containers**.**

2. Weight variation

Films can be weighed on an analytical balance to determine the average weight for each film. It is helpful in ensuring that a film includes the appropriate amount of excipients and medication.

3. Folding Endurance

The folding endurance of the film was evaluated by folding a tiny strip of film (2x2cm2) repeatedly until it broke. The number of times that the film could be folded at the same place without breaking gives the value of folding endurance.

4.Surface pH

The film kept in a Petri dish was moistened with 5 ml of distilled water and kept for a few minutes. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min 19s.

5. Disintegration time

In vitro disintegration time was determined visually in a glass beaker. 25 ml distilled water maintained at 37℃ is taken in the beaker and the OFDF strip was added. The time taken for the film to disintegrate is noted.

6. Stability studies

The accelerated stability was checked by keeping the film at room temperature up to 30 days. Samples were evaluated for assay and drug release.

8. RESULT AND DISCUSSION :-

A.Collection of sample :-

Sample is collected from the local areas from Loha , dist – Nanded.

B. Authentication letter :-

The sample was authentified by Dr.Marahthe, HOD (botany dept.) of NES Science College, Nanded.

C. Extraction of sample :-

Extraction of tulsi leaves and liquorice powder is done in D K Patil institute of pharmacy, Loha, Nanded by maceration process.

Fig.19: Extraction of Tulsi and Liquorice by maceration process

Fig.20: Filtration of extract

Fig.21: Extract of Tulsi and Liquorice

D. Formulation Table :-

Table no.3: Formulation table

Sr.no	INGREDIENTS	F1	F2	F3	F4	F5
1	Ocimum tenuiflorum extract (mg)	10	10	10	10	10
2	Glycyrrhiza glabra extract (mg)	10	10	10	10	10
3	HPMC E5	20	40	-	-	-
4	HPMC E15	-	-	20	-	-
5	Sodium alginate (mg)	-	-	-	20	40
6	Propylene glycol (ml)	2	2	2	2	2
7	Honey (ml)	2	2	2	2	2
8	Water (ml)	10	10	10	10	10

Fig.22: Polymer solution

Fig.23: Drug and excipients solution

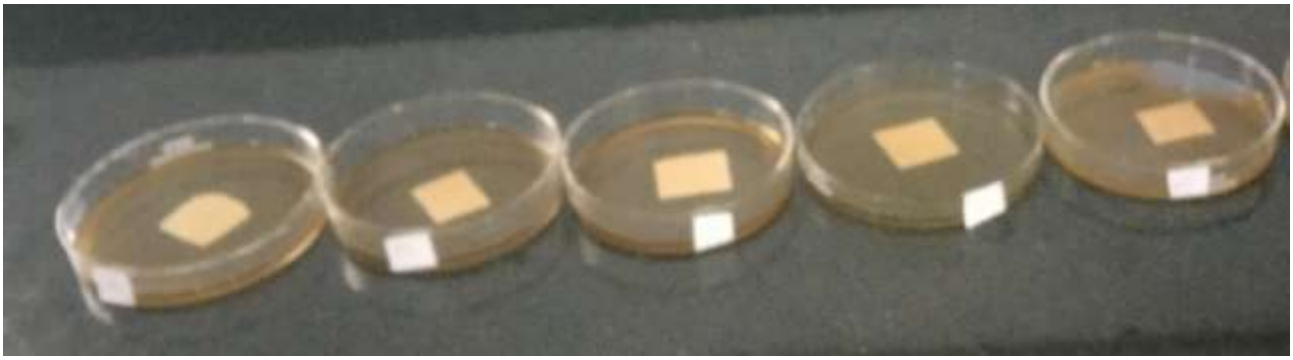
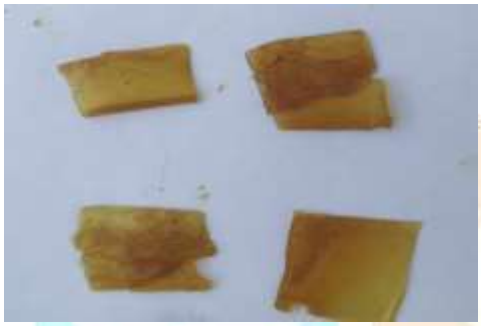


Fig.24: Formulation batches



F1

F2

F3

F4

F5

E. Evaluation :-

Table no. 4: Evaluation table

Sr.no	Test	F1	F2	F3	F4	F5
1	Morphological properties					
a.	Colour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
b.	Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
c.	Surface texture	Smooth	Smooth	Smooth	Smooth	Smooth
2	Weight variation	Fail	Fail	Pass	Pass	Fail
3	Folding endurance	4	3	5		3
4	Surface ph	8	7.5	7.1	6.9	6.5
5	Disintegration time	0.43	0.5	0.37	0.35	0.45
6	Stability studies	Stable	Stable	Stable	Stable	Unstable

Summary :-

Mouth dissolving Films when, administered it rapidly dissolves and disintegrate into saliva within a seconds. Herbal drugs are used in mouth dissolving film it more beneficial for use. These mouth dissolving film have several advantages over conventional dosage form, such as not require to swallow, enhance bioavailability. The mouth dissolving containing the extract of the ocimum tenuiflorum and glycyrrhiza glabra which are used to treat mouth ulcer. The combined effect of both are most beneficial to treat the mouth ulcer. These mouth dissolving Films are prepared by solvent casting method, by using the different polymers like HPMC E5 HPEC E15, sodium alginate. These films evaluated by film thickness, folding endurance, disintegration time, surface pH. These films are continent to use, economic, more beneficial and do not show side effects.

Conclusion:-

The main objective of the present study is to formulation and evaluation of mouth dissolving film of ocimum tenuiflorum and glycyrrhiza glabra to treat the mouth ulcer. The extract of ocimum tenuiflorum and glycyrrhiza glabra was collected by using the maceration process of extraction. These extract containing the fixed oil, saponins, tannins and flavonoids. The formulation batches are prepared by using the different polymers like the HPMC E5, HPMC E15, sodium alginate. Then by using polymers and plasticizer films are formulated and evaluate. All these films are good in appearance and having smooth texture. But the thickness and stability of the F3 batch is good. Based on these study results it can conclude that ocimum tenuiflorum and glycyrrhiza glabra can effectively formulated and evaluate.

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