



ISSN: 2231-3656
Print: 2231-3648

International Journal of Pharmacy and Industrial Research (IJPIR)

IJPIR | Vol.15 | Issue 1 | Jan - Mar -2025

www.ijpir.com

DOI : <https://doi.org/10.61096/ijpir.v15.iss1.2025.77-86>

Research

Formulation And Evaluation Of Rapid Release Oral Film Of Sucralfate

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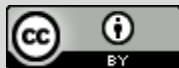
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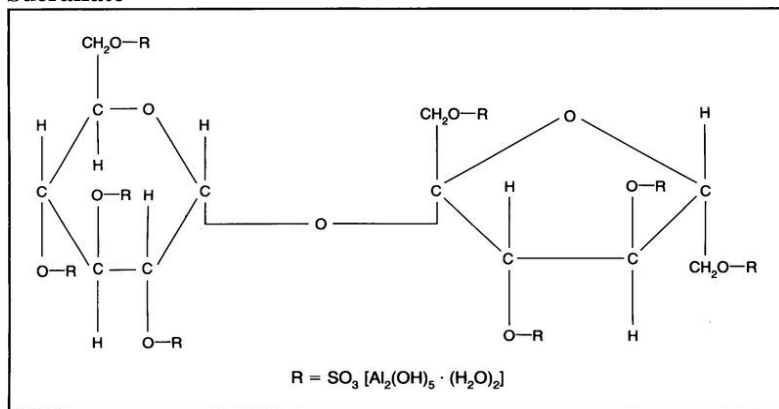
	Abstract
Published on: 21 Mar 2025	<p>The review was designed “Formulation and Evaluation of Fast Dissolving Films of Sucralfate by Solvent Casting Method”. In this research, rapidly dissolving films of sucralfate were developed using low viscosity grades of HPMC as film forming polymers. HPMC is a water soluble synthetic polymer which was used as film former form many years. The films of sucralfate were prepared by solvent casting method using suitable as solvents. The prepared films were evaluated for drug content, weight variation, thickness and in vitro in vivo disintegration time. Sucralfate is moderately bitter drug; taste masking was achieved by use of sweeteners, flavours. Type of flavor significantly affected the taste masking property. The in vitro disintegration time of the optimized formulation was found to be below in the marketed preparation respectively. The prepared films exhibited good integrity and thickness. In vitro dissolution studies were performed as per the FDA dissolution guidelines for about 10 minutes, the optimum formulation released complete drug within 4-6 minutes. FTIR studies were showed no drug polymer interaction.</p>
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INTRODUCTION

The oral route is one of the most preferred routes of drug administration as it is more convenient, cost effective, and ease of administration lead to high level of patient compliance. [1] It is interesting to note that the permeability of buccal mucosa is approximately 4-4,000 times greater than that of the skin, but less than that of the intestine.[2]

Orally fast dissolving film is the kind of drug delivery system which when placed in the oral cavity, disintegrate or dissolve within a few seconds without the intake of water. Oral fast dissolving film is relatively new dosage form in which thin film is prepared using hydrophilic polymers, which rapidly disintegrate or dissolves on tongue or in the mouth cavity. It is an alternative platform for molecules that undergoes high first pass metabolism.[3]

Sucralfate



Description

Sucralfate is white amorphous powder. Hydrated basic aluminium salt of sucrose octasulphate. It is combination of Sucrose Sulphate and Aluminium hydroxide complex [11][12]

Chemical name:

Aluminium hydroxide 1,3,4,6-tetra-O-sulfonato-β-D-fructofuranosyl,2,3,4,6-tetra-O-sulfonato-α-D-glucopyranoside [11][12]

Molecular formula:

$Al_8(OH)_{16}(C_{12}H_{14}O_{35}S_8)[Al(OH)_3]_x(H_2O)_y$ $x=8$ to 10 , m
 $y=22$ to 31 [11][12]

Molecular mass:

1577.823 g/mol [11][12]

Solubility

Insoluble in water [1], ethanol, chloroform, [10]

Soluble in HCL, NaOH [10]

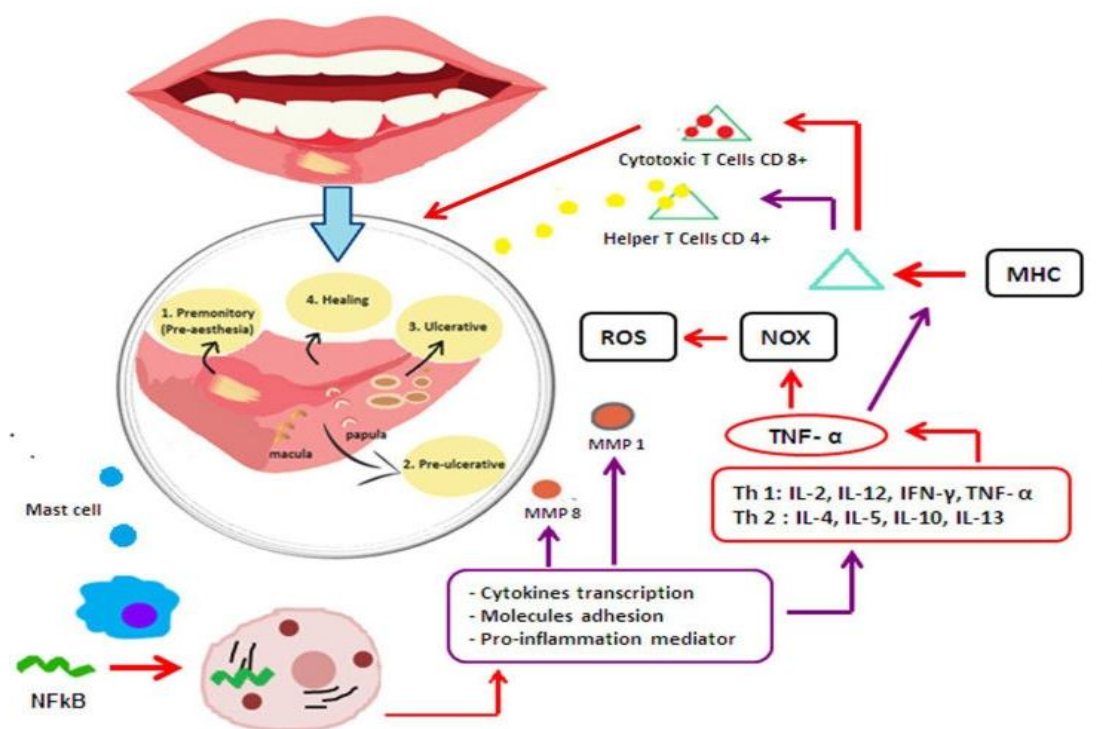
Sucralfate, a complex of aluminium hydroxide with sulfated sucrose, forms a strong gastrointestinal tract (GIT) mucosal barrier with excellent anti-ulcer property. Because sucralfate does not undergo any significant oral absorption, sucralfate resides in the GIT for a considerable length of time. The unabsorbed sucralfate may alter the pharmacokinetics of the oral drugs by impeding its absorption and reducing the oral bioavailability.[4] Sucralfate containing preparation with organic acid having at least one or two carboxylic acid and sucralfate can be used to enhance the adhesion of sucralfate to the mucosal ulcer site even in non acidic condition. This can help in the formulation of a protective layer of sucralfate in case of aphthous stomatitis.

Aphthous stomatitis

Sucralfate is the medicine generally described and commonly used as a therapeutic for gastric acid duodenal ulcer.[10] The principle effect of sucralfate is believed to be forming a highly adhesive gel under an acidic condition to cover the ulcerated surface and in binding with plasma proteins under an acidic condition to cover the ulcerated surface [i.e. a mucous protecting action][10] However for selective binding to the mucosal ulcer site, the formation of gel under the acidic condition caused by gastric acid is essential.[10]

Etiology of aphthous STOMATITIS

- BACTERIAL INFECTION ; a pleomorphic transitional L-form of a haemolytic streptococci, streptococcus sanguis play a significant role
- Immunologic abnormalities
- Iron, vitamin B12, folic acid deficiency
- TRAUMA –due to self –inflicted bites, oral surgical procedures, tooth brushing, dental procedures, needle injections, dental trauma
- ENDOCRINE CONDITION –during premenstrual period and at postovulation period.
- ALLERGIC FACTORS- hay fever, asthma, drug/food allergy [10]



Ulcer

Peptic ulcer disease is a problem of the gastrointestinal tract characterized by mucosal damage secondary to pepsin and gastric acid secretion. It usually occurs in the stomach and proximal duodenum.[11]

A sore that develops on the lining of the oesophagus, stomach or small intestine.

Ulcers occur when stomach acid damages the lining of the digestive tract. Common causes include the bacteria *H. Pylori* and anti-inflammatory pain relievers including aspirin.

Upper abdominal pain is a common symptom.

Treatment usually includes medication to decrease stomach acid production. If it is caused by bacteria, antibiotics may be required [12]

Requires a medical diagnosis

Upper abdominal pain is a common symptom [12]

Pain areas: in the chest or upper abdomen [12]

Pain types: can be burning in the chest or dull [12]

Gastrointestinal: belching, indigestion, nausea, passing excessive amounts of gas, or vomiting [12]

Whole body: fatigue, feeling full sooner than normal, or loss of appetite [12]

Also common: abdominal discomfort [12]

Peptic ulcers

Peptic ulcers are sores or wounds that can develop on:

- the inside lining of your stomach
- the upper portion of your small intestine
- your esophagus

They form when digestive juices damage the walls of your stomach or intestine. These ulcers are quite common. Peptic ulcers are most often caused by inflammation after contracting *Helicobacter pylori* (*H. pylori*) bacteria or through long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs).

There are two types of peptic ulcers:

- gastric ulcers, or ulcers that develop in the stomach lining
- duodenal ulcers, or ulcers that develop in the duodenum (small intestine)
- The most common symptom of this condition is a burning sensation. Other symptoms may include:
- bloating or the feeling of being full
- belching
- heartburn
- nausea
- vomiting

- unexplained weight loss
- chest pain

Treatment depends on the underlying cause of your ulcer. If you have an *H. pylori* infection, your doctor may prescribe antibiotics to kill the harmful bacteria. For the majority of peptic ulcer cases, acid-lowering medication regimens are generally prescribed to help protect the mucosal lining from stomach acid so it has time to heal.

CLASSIFICATION OF ANTI ULCER DRUGS

H₂receptor antagonist

Cimetidine, ranitidine, famotidine

Proton pump inhibitor

Omeprazole, pantoprazole, lansoprazole

Anticholinergics.

Pirenzepine, telzepine. Propanthalin

Prostaglandin analogues;

Misoprostol, enprostil [13]

Anatacids

Systemic; - sodium bicarbonate [13]

Non systemic; - magnesium hydroxide [13]

Ulcer protective

Sucralfate [13]

Ulcer healing drugs; carbenoxolone sodium [13]

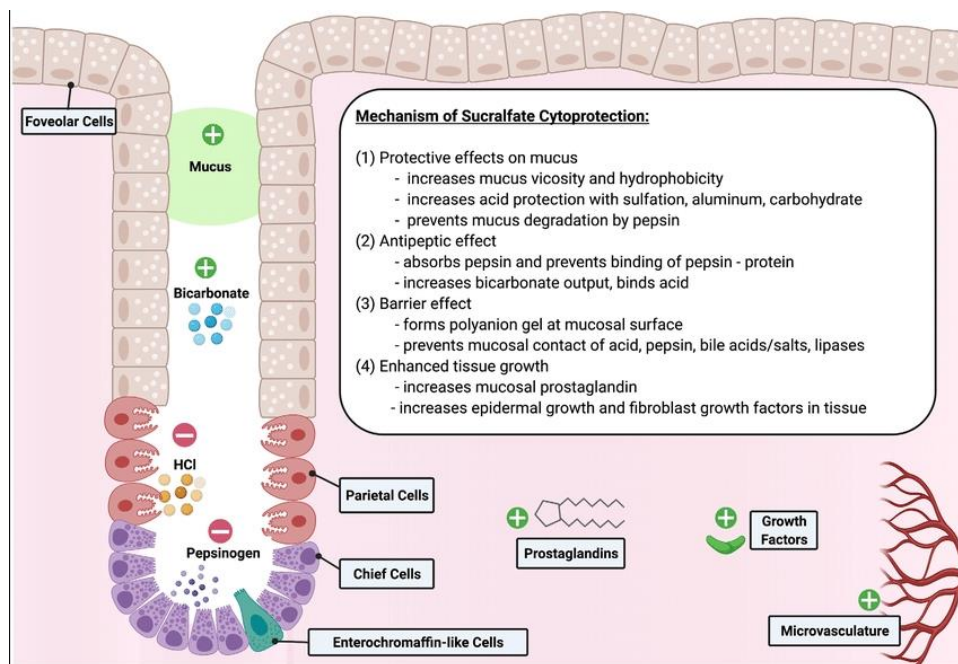
ANTI *H. pylori* drugs;

Amoxicillin, clarithromycin, metronidazole, tinidazole, tetracycline [13]

Mechanism of action of sucralfate

Sucralfate is a locally acting substance that in an acidic environment (pH < 4) reacts with hydrochloric acid in the stomach to form a cross-linking, viscous, paste-like material capable of acting as an acid buffer for as long as 6 to 8 hours after a single dose.^[7] It also attaches to proteins on the surface of ulcers, such as albumin and fibrinogen, to form stable insoluble complexes. These complexes serve as protective barriers at the ulcer surface, preventing further damage from acid, pepsin, and bile.^[7] In addition, sucralfate prevents back diffusion of hydrogen ions, and absorbs both pepsin and bile acids.

It has been thought that sucralfate also stimulates the production of prostaglandin E₂, epidermal growth factors (EGF), bFGF, and gastric mucus.^{[8][9]}



- **Sucralfate Indications:** Sucralfate is a unique anti-ulcer drug. It is a basic aluminum salt of sucrose octasulfate. Treatment of duodenal ulcer: Sucralfate is FDA approved for the treatment of duodenal ulcers up to 8 weeks. Sucralfate forms a protective coat and protects the gastric mucosa from pepsin, pectic acid,

and bile salts. It binds to positively charged proteins in exudates, forming a thick viscous substance locally.[14]

- Sucralfate Sucralfate has also been used to treat various other conditions that are non-FDA approved as outlined below a) Dyspepsia. b) Treatment of epithelial wounds. c) Treatment of chemotherapy-induced mucositis. d) Treatment of radiation proctitis. e) Prevention of ulceration of diversion colitis. f) Stress ulcer prophylaxis in ventilated patients. g) Behcet Disease.[14]
- Sucralfate Mechanism of Action The principal action of sucralfate is unknown. The following actions of sucralfate have been the object of study in vitro, but the in vivo actions remain unknown. Antipeptic effects - It prevents hydrolysis by preventing the formation of the enzyme-substrate complex. It adsorbs to pepsin and decreases its concentration. Site-protective effects - By forming a polyanion gel, it acts as a physical barrier between luminal contents and mucosa [14]
- Sucralfate Effects on mucus- Increases mucous hydrophobicity, viscosity, sulfation, and the aluminum and carbohydrate content, which leads to improved mucosal protection from acid. It also increases the production of mucus by increasing prostaglandin production. Sucralfate prevents the breakdown of mucus by pepsin a, reducing ulcer genesis 4. Effect on bicarbonate output - It increases prostaglandin dependent and independent production of bicarbonate by stomach and duodenum. 5. Effects on tissue growth, regeneration, and repair- It binds epidermal growth factor and tissue growth factor to tissues and facilitates repair [14]
- Sucralfate Adverse Effects Sucralfate acts locally with negligible absorption making it relatively safe. The most common side effect is constipation seen in 1-10% of patients Sucralfate has several drug interactions and can decrease the serum concentrations of digoxin, levothyroxine, furosemide, quinolones, oral phosphate supplements, warfarin, antiretrovirals like raltegravir, bisphosphonates amongst other [14]

Pharmacokinetics of sucralfate

- Onset: 1–2 hr. (initial onset for peptic ulcer disease (PUD))
- Absorption: <5% Orally
- Duration: Up to 6 hours due to high affinity for defective mucosa (PUD)
- Bioavailability: 5%, sucralfate is considered non-systemic, sucrose octasulfate: 5%, aluminum: 0.005%
- Metabolism: Not metabolized, excreted unchanged in urine
- Excretion: Primarily in feces as unchanged drug^{[5][6]}

Marketed formulation of sucralfate and their uses

1. Sucralfate oral suspension: - mucositis, ulcer protection, acidity, stomach ulcer, heart burn
2. Sucralfate gel: - stomach ulcer, bowel ulcer, inflammation of ulcer.
3. Sucralfate cream: -shield the several wounds from external irritant
 1. Regeneration of damage
4. Sucralfate tablet: - prevention of duodenal ulcer

Dose of the all type of formulation suspension

adults –one gram [g] [10 ml]

Four times in a day taken on an empty stomach for 4 to 8 weeks

Children-40 to 80 mg [15]

Tablet

Adult – one gram [g] four times a day taken on an empty stomach for 4 to 8 Weeks

Children- 40 to 80 mg [15]

Major disadvantages of conventional dosage form

1. stability

Most of the current marketed preparation in the market are either in a gel form or in a liquid form so the stability of the dosage form is always an issue.[10]

2. compatibility

Applying gel over an ulcerated area is always problematic and is not very compatible with patients perspective.[10]

3. Erosion

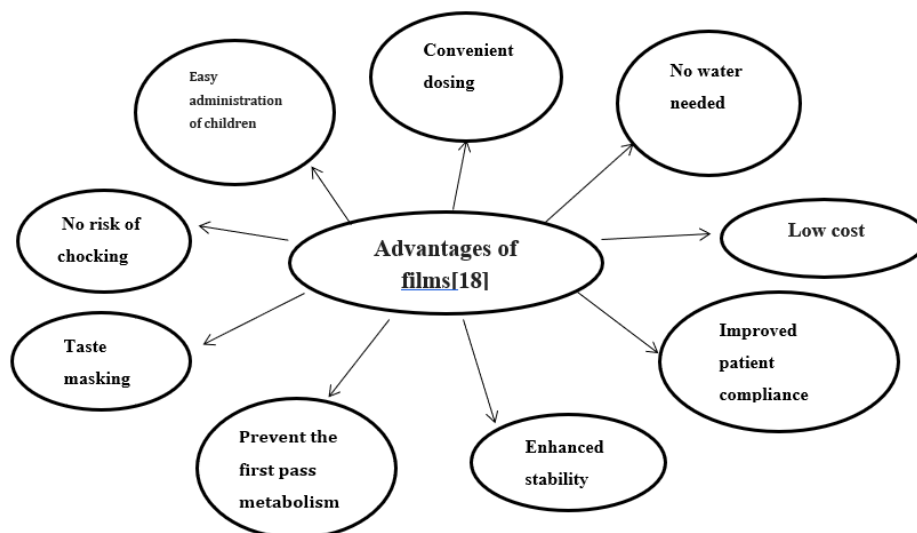
Gel and liquids get eroded from the oral mucosa over a short period of time leading to unprotected ulcerated area.[10]

4. oral problems

Most of the mouth wash preparations contains alcohol, which may cause problem like taste, disturbance staining, drymouth, and halitosis.[10]

- More likely to cause irritation. Tablets are more likely to irritate the gastrointestinal tract.[17]
- Slower acting. Once in the body, tablets are absorbed more slowly than capsules. [17]
- Uneven disintegration. [17]
- Less palatable.[17]

Advantages of films



Drug interaction

Some products that may interact with this drug include: antacids that contain aluminum, certain antibiotics (for example, quinolones such as, ciprofloxacin, norfloxacin, levofloxacin, tetracyclines, digoxin, ketoconazole, Levo ketoconazole, penicillamine phenytoin, quinidine, thyroid medications (such levothyroxine, liothyronine). [16]

Advers drug reaction

- Constipation occurs in 2percentags of patients due to the aluminium salt
- Small amount of aluminium is absorbed.
- Sucralfate should not be used for prolonged periods in patients with renal insufficiency.
- Sucralfate may bind to other medications, impairing their absorptoion.[20]

Pharmacodynamics

- Negatively charged sucrose sulphate binds to positively charged ptoteins in the base of ulcers or erosions.
- A physical barrier is formed.
- Barrier restricts futher caustic damage and stimulates mucosal prostaglandin and bica
- rbonate secretion.[19]

Formulation of Film[21]

One or more of the following processes can be used combinly to manufacture the mouth dissolving films.

- I. Solvent evaporation
- II. Semisolid casting
- III. Hot melt extrusion
- IV. Solid dispersion extrusion
- V. Rolling

Formulation Consideration

- Active pharmaceutical ingredient
- Film forming polymers
- Plasticizer
- Sweetening agent
- Saliva stimulating agent
- Flavoring agent
- Coloring agent

Active pharmaceutical ingredient**API is the drug compound which is converted into film**

Sucralfate, a basic aluminum salt of sucrose octasulfate, was developed to counteract the activities of both acid and pepsin. It differs chemically from other sulfated anionic inhibitors of pepsin in being a base and a derivative of pure disaccharide sucrose. The development of sucralfate was guided by the observations that sulfated disaccharides do not exhibit the anticoagulant activity of sulfated polysaccharides, and that the inhibition of peptic activity and the protection against experimental ulceration depend only on the degree of sulfation. Sucralfate has been found to protect pylorusligated animals from peptic ulceration more effectively than a mixture of sucrose octasulfate and aluminum hydroxide.

Polymers

A polymer a substance or material consisting of very large molecules called macromolecules, which are composed of many repeating subunits called monomers. Due to their broad spectrum of properties, both synthetic and natural polymers play essential and ubiquitous roles in everyday life. Polymers range from familiar synthetic plastics such as polystyrene to natural biopolymers such as DNA and proteins that are fundamental to biological structure and function.[22]

Polymers examples [22]

1. HPMC – Hydroxypropyl methyl cellulose
2. CS- Croscarmellose sodium
3. CMC-carboxy methyl cellulose
4. CP-crospovidone
5. PEG- Poly ethylene glycol

Plasticizers

Plasticizers are used in the film forming systems to impart flexibility to the film and improve the tensile strength of the film formed. The plasticizer used should be compatible with the polymers used and should have low skin permeability.

Commonly used plasticizers are

glycerine,
polyethylene glycol,
sorbitol,
dibutyl phthalate,
propylene glycol,
triethyl citrate etc. [23]

SWEETENING AGENT [24]

Sweetening agents are the substances which are added to a drug formulation to mask its bitter taste.

Sugar is the most widely used natural sweetening agent.

Sugar having lots of disadvantages like dental caries, high blood sugar, calories etc.

Among the various substitutes available over sugar.

There are 2 types of substitutes which are used as sweetener

1. Natural sweeteners: -Stevioside

Glycyrrhizin
Thaumatococcus
Monellin's
Sucralose
Sorbitol

2. artificial sweeteners: -Aspartame,

Saccharin,
cyclamate
alitame etc

Colouring Agents [25]

Colouring agents are known as substances used to regulate the colour of a given pharmaceutical formulation and can be classified as water-soluble dyes and lake pigments. Colouring agents are added to food to enhance its sensory characteristic, replace color lost during processing, and influence the consumer perceptions of the food's flavor and quality. Example: Quinoline Yellow, and Sunset Yellow FCF

Flavouring agent [26]

Flavoring agents are additive substances that give a tablet an additional taste or flavor. In particular, they help in masking unpleasant tastes (e.g., bitter or pungent taste) of drugs/excipients and instead improve the quality of their taste. Flavoring agents include aromatic oils (e.g., caraway, clove, lemon, spearmint, rose, and peppermint) ginger; raspberry; maltol; syrups (e.g., citric acid, sarsaparilla, and cherry); glycerin; cocoa; licorice; vanillin; and ethyl vanillin. It is worth noting that sweetening agents (e.g., sucrose and sorbitol) are also often used as flavoring agents[26]

Solvent evaporation method**PROCEDURE**

The film was prepared using the solvent casting method. The polymer solution was prepared by dissolving the required quantity of polymers in 10ml water in a container. To that polymeric solution in the container, added the plasticizer, super disintegrants and sweetening agents. In another container, accurately weighed quantity of sucralfate was taken and dissolved in ethanol. The prepared drug solution was transferred to the container having polymeric solution slowly with continuous stirring. The mixed solution was slowly poured to cast on the petri dish and allowed to dry for 120–180 minutes at $55^{\circ}\text{C} \pm 2^{\circ}\text{C}$. The formed films were carefully removed from the petri dish and cut into the size of $2 \times 2 \text{ cm}^2$. The dried and sized films were packed individually into an aluminium pouch and sealed.

Methods of preparation Following methods can be used for the preparation of fast dissolving oral films:

1. Solvent casting method
2. Semisolid casting method
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method

Solvent casting method

In solvent casting method excipients are dissolved in water, then water soluble polymers and in last drug is added and stirred to form homogeneous solution. Finally solution is casted in to the Petri plate and dried [27]. Semisolid casting This method is preferably adopted when acid insoluble polymers are to be used in the preparation of the films. In Semisolid casting method gel mass is casted in to the films or ribbons using heat controlled drums. Gel mass is obtained by adding solution of film forming to a solution of acid insoluble polymer in ammonium or sodium hydroxide. Acid-insoluble polymers used to prepare films include: cellulose acetate phthalate, cellulose acetate butyrate. Acid insoluble polymer and film forming polymer should be used in the ratio of 1:4 [28]

Advantages

- Better film clarity and thickness uniformity than extrusion method.
- Fine gloss on film and lack of die lines.
- Films with more flexible and better physical properties are produced by this method.

Disadvantages

- Polymers to be used should be soluble in volatile solvents
- Formation of a stable solution with considerable minimum solid content and viscosity is required, which is difficult to attain.
- Homogenous film preparation with proper drug release from casting support must be attained.

Hot melt extrusion

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then dried granular material is introduced into the extruder. The screw speed should set at 15 rpm in order to process the granules inside the barrel of the extruder for approximately 3–4 min. The processing temperatures should be 800°C (zone 1), 1150°C (zone 2), 1000°C (zone 3) and 650°C (zone 4). The extrudate ($T = 650^{\circ}\text{C}$) then pressed into a cylindrical calendar in order to obtain a film. There are certain benefits of hot melt extrusion[29].

- Fewer operation units
- Better content uniformity
- An anhydrous process

Advantages

1. Less processing steps.
2. No need of solvent or water
3. Less energy is required compared to high shear methods.
4. Uniform dispersion of fine particles due to intense mixing and agitation.

5. No importance of drug compressibility properties

Disadvantages

1. Number of polymers is limited
2. Polymer flow properties are essential to processing.
3. Drug/polymer stability problem as it is a thermal process

Solid dispersion extrusion

In this method immiscible components are extruded with drug and then solid dispersions are prepared. Finally the solid dispersions are shaped into films by means of dies [30]

Precautions while preparing solid dispersions

The selected solvent or dissolved drug may not be miscible with the melt of polyethylene glycol and polymeric form of drug precipitated in the solid dispersions may get affected by the liquid solvent used.

Advantages

- Low shear method.
- Uniform dispersion of fine particles.
- Less processing steps.

Rolling Method

In rolling method a solution or suspension of drug with film forming polymer is prepared and subjected to the roller. The solution or suspension should have specific rheological consideration. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cutted into desired shapes and sizes. [31]

CONCLUSION

The study focuses on the formulation and evaluation of rapid release oral films of Sucralfate using the solvent casting method. Hydroxypropyl Methylcellulose (HPMC) was used as the film-forming polymer due to its water solubility and biocompatibility. The films exhibited good integrity, uniform thickness, and rapid disintegration within 4-6 minutes, making them a promising alternative to conventional dosage forms. Key evaluations such as drug content, weight variation, thickness, and dissolution time confirmed that the optimized formulation ensured complete drug release within 10 minutes. The study highlights the advantages of oral films, including enhanced patient compliance, rapid onset of action, and improved bioavailability. Furthermore, FTIR analysis showed no drug-polymer interaction, confirming the stability and efficacy of the formulation. The research suggests that rapid release oral films could be a more efficient and patient-friendly alternative for delivering sucralfate in the treatment of peptic ulcers and other gastrointestinal disorders.

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