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# " A REVIEW ON NOVEL DRUG DELIVERY SYSTEM ORAL STRIPS TECHNOLOGY"

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## Abstract

Many research groups have recently directed their attention toward this technology. Oral Strip Technology (OST), one of the several approaches being investigated for fast medication release devices, is becoming increasingly popular. One benefit of OST is that it can be administered to both pediatric and elderly patient populations. when the challenge of swallowing more substantial oral dosage forms is removed. The applications of this technology include fast release products, local action, and buccoadhesive systems that are kept in place for a longer amount of time oral cavity to provide medication in a regulated manner. OST provides a different platform for molecules undergoing for peptide administration and first pass metabolism.

**Keywords-** Wefars , ODF , NDDS , Dysphasia , Fragile , Buccoadhesive

## Introduction

ODF is a dosage from that employs hydrophilic polymer which allows the dosage form to quickly hydrate by saliva and / or adhere to mucosa, dissolve and releases medication for oral-mucosal absorption when placed on the tongue or oral cavity. The alternative to traditional oral dosage forms such capsules, syrups, pills, etc. is oral strips. The transdermal technique was used to create the oral strips. When making oral strips that quickly dissolve and deliver the medication into the bloodstream through the or mucosa, hydrophilic polymers are crucial.The medicine is directly absorbed into the systemic circulation as a result of the or mucosa's thin membrane, providing rapid bioavailability and a quicker commencement of action. Classification of oral strips- Oral fast dissolving strips- a.Flash delivery, Mucoadhesive sustained release wafers, Mucoadhesive melt-away wafers, Buccal slow-release strips, Transdermal strips.

**Table 1 : Types of films and their properties**

| **Property/SubType** | **Flash ReleaseFilm** | **Mucoadhesive Melt Away Film** | **Mucoadhesive Sustained ReleaseFilm** |
|---|---|---|---|
| Area (cm2) | 2-8 | 2-7 | 2-4 |
| Thickness (μm) | 20-70 | 50-500 | 50-250 |
| Structure of Film | Single layer | Single or multilayer system | Multilayer system |
| Excipients | Soluble, highly hydrophilic polymers | Soluble, highly hydrophilic polymers | Low/non-soluble polymers |
| Drug phase | Solid solution | Solid solution or suspended drug particle | Suspension and/or Solid solution |
| Application | Tongue (upper palate) | Gingival or buccal | Gingival,(other region inthe oral cavity) |
| Dissolution | Maximum 60 seconds | Disintegration in a few minutes, forming gel | Maximum 8-10 hours |
| Site of action | Systemic or local | Systemic or local | Systemic or local |

**Advantages:**

1) It provides the fastest onset of therapeutic action because drug directly goes intothe systemic circulation
2) It provides the ease of administration of pediatrics and geriatrics patients who face theproblem of dysphasia
3) Increased Bioavailability, due to absorption via oro-mucosa which hasbetter permeability properties
4) No water is required; therefore, it useful for those patients who are traveling
5) Due to the availability of a larger surface area, it leads to the rapid dissolution of the drug
6) Oral stripes are more flexible, easily handled storage and transportation
7) They are available in various size and shapes

**Disadvantage:**

1) The disadvantage of OS is that high dose cannot be incorporated into the strip. The doseshould be between 1-30 mg
2) There remain a number of technical limitations with use of film strips; the thicknesswhile casting the film Glass Petri plates cannot be used for casting
3) The other technical challenge with these dosage forms is achieving dose uniformity
4) Packaging of films requires special equipment‘s and it is difficult to pack
5) Drugs that irritate the oral mucosa and which are unstable at mucosal pH cannot beadministrated
6) Oral strips require a special type of packaging because they are fragile and protect fromwater

**Formulation consideration:**

1. Active pharmaceutical ingredient
2. Film forming polymers
3. Plasticizer
4. Sweetening agent
5. Saliva stimulating agent
6. Flavoring agent
7. Coloring agent

**Active pharmaceutical ingredient**

A typical film composition has 1-25% weight/weight of the medication. Fast-dissolving films can deliver a variety of APIs. The ideal compounds have little doses. Candidates for inclusion inthe OFDFs.The dry film weight of up to 10% w/w was integrated in the movies that dissolve in less than 60seconds. It is having a micronized API is usually beneficial as it will enhance the film's texture, as well as for improved disintegration, consistency across all OFDFs. Several APIs that have thepossibility. Technology candidates for the OFDF have a bad taste. This makes the formulation taste unpleasant, particularly for preparations for children. Therefore, prior to implementing the API. The flavor needs to be concealed in the OFDF. Various methods can be used to improvethe palatability of the formulation.

**Criteria for selection of drug candidate:**

1. The drug should have a pleasant taste.
2. A higher dose of the drug is not required. The dose should be minimum 40mg.
3. Stability and solubility of the drug should be good in the water as well as saliva.
4. It should have the ability to pass the oral mucosal tissues
5. Drugs having smaller and moderately molecular weights are selected as candidates.
6. Drugs which partially unionized at oral cavity pH should be selected.

**Film-forming polymer-**

Since all thin film oral dose forms rely on their disintegration in the oral cavity's saliva for their principal usage, cavity, the final film employed must inevitably soluble in water. Making a thin film formulation in order to Excipients are or polymer must be water-soluble. High water solubility, low molecular weight capability for making films. The used polymer should be non- leachable impurities, non-irritating, and non-toxic. It should have good spreading and wetting properties. The polymer must show enough peel, shear, and the tensile capacities. The polymer needs to be easily accessible. and shouldn't be too pricey.

The oral films are proposed to utilize the polymers in the several research teams and writers haveintroduce different materials.

The polymers can be employed singly or in combination to increase the hydrophobicity, flexibility, mouth feel, and solubility of fast dissolving films.

The stiffness of the strip is determined by the type of polymer used. as well as the amount of polymer in the mix. Polyvinyl because pyrrolidone films are fragile in nature, Copovidone is combined with polyvinyl pyrrolidone to create Flexible rapid dissolving films are created. Microcrystalline cellulose combined with Malt dextrin has been utilized to create rapid dissolving products. Piroxicam films produced using the hot melt extrusion process. Microcrystalline cellulose is employed in this situation to render. The film is not sticky and is smooth. Cellulose microcrystalline was also utilized to shorten the disintegration period and improve drug dissolution from films.

Water soluble polymer that may be used include natural gums such as those derived from guar, xanthan, Arabic, or tragacanth, other available polymers are, polyethylene oxide, acrylic based polymer and several types of sodium carboxymethyl cellulose (CMC), several types of hydroxypropyl methyl cellulose (HPMC), a synthetic copolymer of polyethylene glycol- polyvinyl alcohol (Koll coat IR) and sodium alginate

**Polymers that use for OST:**

**1.Hydroxy propyl methyl cellulose (Hypromellose)**

**Synonym :** HPMC, Methocel, Metolose,Benecel

**Description**-It is a odorless, tasteless and white or creamy white fibrous or granular powder

**Molecular weight**-10,000–1,500,000

**Solubility**-Soluble in cold water, forming a viscous colloidal solution,Insoluble in Chloroform, ethanol.

**Film forming-**It has a film forming ability

**Viscosity-** A wide range of viscosity grades are commerciallyAvailable. Viscosity of various grades ranges

From 3 mPa s–100,000 mPa s

**Capacity-**2–20%w/w concentrations

**Melting point-**Browns at 190–200 °C. glass transition temperature is170–180 °C

**2.Hydroxy propyl cellulose**

**Synonym :** Hydroxyl propyl ether, hydrolase, Klucel, Nisso HPC.
**Description**- It is a white to slightly yellow colored, odorless and tasteless powder. It is stable material
**Molecular weight**-50,000–1,250,000
**Solubility**- It is freely soluble in water below 38 °C forming a smooth, clear.

**Film forming-** It has a good film forming

**Capacity-** property and5%w/w solution is generally used for film

**Viscosity-** A wide range of viscosity types are commercially available.The viscosity of solutions ranges from 75 mPa s–6500 mPa s depending upon The polymer grade

**Melting point-**. It softens at 130°C; chars at 260–275 °C

**3.Starch and modified starch:**

**Synonym -**Amido, amylum, PharmGel, Fluftex W, Instant pure- Cote, Melogel etc.

**Description-** It is an odorless, tasteless,fine, white powder.

**Molecular weight-**50,000–160,000

**Solubility**- Starch is insoluble in cold water and ethanol. It swells inwater by about 5 to 10% at 37 °C

**Film forming -** Modified starches

**Capacity-** property to form quick Dissolving films.

**Viscosity-**2%w/v aqueous dispersion of starch provides 13mPa s Viscosity

**Melting point-** It decomposesat 250 °

4. **Carboxy methyl cellulose-**

**Synonym -**Akulell, Blanose, Aquasorb,CMC sodium

**Description**- It is white, odorless powder

**Molecular weight**- 15,000-90,000 , 250,000-700,000

**Solubility**- It is easily dispersed in water to form a clear or colloidal solution.

**Film forming-**The enzymatically modified.

**Capacity-** carboxymethyl cellulose has Good film forming property

**Viscosity-** The 1%w/w aqueous solution has viscosities in the range of 5–13,000 mPa s.

**Melting point-** Browns at 227°C and chars at 252 °C

**5. Gelatin**

**Synonym -Citrus pectin, Methopectin, pectin, pectinic acid.**

**Description**- It occurs as a yellowish-white, odorless powder with mucilaginous taste.

**Molecular weight**-30,000–100,000

**Solubility**- It is soluble in water but insoluble in most of the organic solvents.

**Film forming-**It has a very good film

**Capacity- Formin g ability.**

**Viscosity-**4.3–4.7mPa s for a 6.67%w/v Aqueous solution at60 °C.

**6. Pectin**

**Synonym -Citrus pectin, Methopectin, pectin, pectinic acid.**
**Description-** It occurs as a yellowish-white, odorless powder with mucilaginous taste.
**Molecular weight-** 30,000–100,000
**Solubility-** It is soluble in water but insoluble in most of the organic solvent.

**PLASTICIZER**

A vital part of the quickly dissolving films is plasticizer. Plasticizer aids in enhancing the strip's elasticity and decreases the films' brittleness. It substantially reduces the and hence enhances the film forming characteristics. The polymer's glass transition temperature. The substance composition and quantity of plasticizers are important. significant contribution to easing the glass transition the polymers' temperature. deciding which plasticizer to use depending on how well it works with the polymer and in addition the kind of solvent used in the casting of the film.

The usage of plasticizer improves the flow of polymer and increases the polymer's strength. Propylene glycol, glycerol, and low molecular weight. Dimethyl phthalate derivatives, polyethylene glycols, and Diethyl and dibutyl phthalates, compounds of citrate like Castor oil,tributyl, triethyl, acetyl citrate, triacetin, and a few of the excipients used as plasticizers most frequently. Typically, the concentration of plasticizers utilized is 0–20%; weight/weight of thedried polymer. However, improper plasticizer use could result in film cracking. The strip is breaking and coming apart. Additionally, reports state the usage of specific plasticizers could have an impact on the drug's rate of absorption.

**SWEETENING AGENTS-**

Sweeteners are currently an essential part of formulations meant to dissolve or disintegrate in the mouth and teeth. Sweeteners are typically utilized in the whether alone or in combination, a concentration of 3 to 6%w/w Combination. Both artificial and natural sweeteners in order to make these fast food products, sweeteners are used. Vanishing flicks. Alcohols that are polyhydric, like sorbitol, Mannitol and isomalt can be used combined because additionally offer cooling and a pleasant mouth feel sensation. But it should be promoted that the utilization of such preparations need to limit natural sugars. Individuals who are diabetic or those who are on a dieted patient.

Artificial sweeteners have risen in popularity in culinary and pharmaceutical preparations as a result. Aspartame, cyclamate, and saccharin are the artificial sweeteners of the first generation were followed by Sucralose, acesulfame-K, alitame, and neotame, which fall under the Second- generation artificial sweeteners are those. Sucralose and acesulfame-K have over 200 and 600 respectively. Time is sweet. Alitame and neotame both contain more than 2000 and 8000 times the sweetening power of sucrose. Oral rehydration salts were prepared using aspartame. The valdecoxib strips. Neotame and sucrose were reported. to be used in order to mask the unpleasant flavor of quick Diclofenac and Ondansetron dissolve film respectively

.

**Table 2 : Relative sweetness of commonly used sweeteners (Sharma and Lewis, 2010)**

| **Sweetening agent** | **Relative sweetness** | **Comment** |
|---|---|---|
| Aspartame | 200 | Not very stable in solution |
| Acesulfame Potassium | 137-200 | Bitter after taste if used inhigher concentration |
| Cyclamate | 40 | Banned |
| Glycerrhizin | 50 | Moderately expensive |
| Lactose | 0.16 | Large amount required |
| Mannitol | 0.60 | Negative heat of solution |
| Saccharin | 450 | Unpleasant after taste |
| Sucrose | 1 | Most commonly used |
| Sucralose | 600 | Synergistic sweetening |
| Sativoside | 300 | Bitter after taste if high conc. |

**SALIVA STIMULATING AGENT**

Saliva stimulating agent increases the production of saliva that would aid in the faster disintegration of the rapid dissolving strips formulation. Acids that in general, salivary stimulantscan be made from acids that are used in meal preparation.

As an example, lactic acid, ascorbic acid, citric acid, malic acid, acid tartaric. These substances can be utilized singly or in combination. Combination of 2 to 6 weights per weight of the strip.

**Table 3 : Comparison between various salivary stimulants**

| **Stimulants** | **Molarity** | **Flow rate (ml/min)** | **Time required for returning to initial flow rate (min)** |
|---|---|---|---|
| Citric acid | 0.26 | 1.68 | 7.3 |
| Glucose | 1.17 | 0.52 | 6.7 |
| Fructose | 1.17 | 0.97 | 8.7 |
| Sucrose | 1.17 | 0.74 | 6.3 |
| Aspartame | 0.034 | 0.82 | 6.8 |
| Sodium saccharin | 0.42 | 1.04 | 10.5 |

**FLAVORING AGENT**

About 10% w/w flavors is added in the OFDF formulations. The acceptance of oral disintegrating film is highly depending on the initial flavor and quality which is observed in firstfew seconds after product has been consumed. This taste is last for at least about 10 min. The specific type of medicine to be included in the formulation will determine what flavor is chosen. Age was found to be a significant factor in taste. Affection Elderly people prefer mint or orange younger generations prefer flavors like fruit raspberry, punch, etc.

**COLORING AGENTS**

Orally fast dissolving films are made using FD & C approved coloring chemicals, although not in concentrations more than 1% (w/w). as in titanium dioxide.

**STABILIZING AGENT AND THICKENING AGENT:**

Before casting, the strip preparation solution or suspension is given a boost in viscosity and consistency using stabilizing and thickening agents. natural gums, such as Carrageenan, xanthan gum, locust bean gum, and derivatives of cellulosic materials can be used as thickening agents inconcentrations up to 5%w/w. same stabilizing substances. other components, including surfactants. To enhance the strips quality emulsion, emulsifying agents are also added in modest amount.

**METHOD OF PREPARATION:**

Sometimes one or more than one methods are used for the preparation of oral disintegrating films.

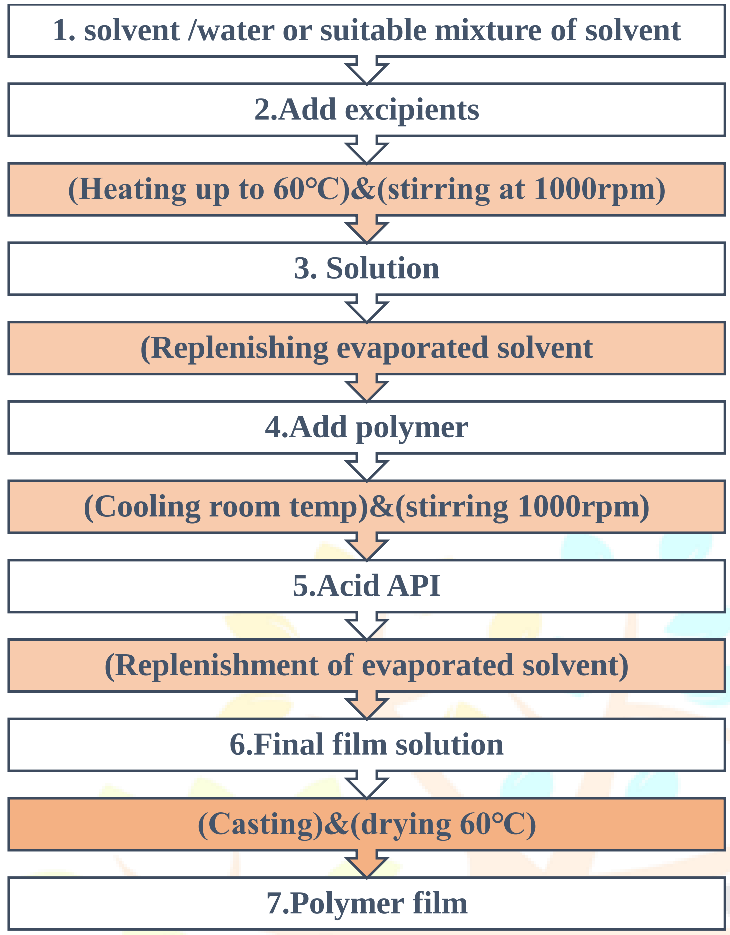
1) Solvent casting
2) Semisolid casting
3) Hot melt extrusion
4) Solid dispersion extrusion
5) Rolling

The solvent casting method involves dissolving excipients in water, adding water-soluble polymers, and adding a drug, stirring to form a homogeneous solution, which is then cast onto a Petri plate and dried.

Films can be prepared either by hot melt extrusion method or solvent casting technique. In the extrusion process the API and other ingredients are mixed in dry state, subjected to heating process and then extruded out in molten state. In this process, solvents are completely eliminated. The strips are further cooled and cut to the desired size. Hence, generally the solvent cast methodis employed for manufacture of strips.typically, it includes the preparation of the base material which involves the mixing of stripforming excipients and the API mixed together in a suitable solvent or solvent system. The selection of solvent essentially depends on the API to be incorporated into the strip.The physicochemical properties of the API like heat sensitivity, shear sensitivity, the polymorphic form of the API employed, compatibility of the API with solvent and other strip excipients are to be critically studied. The significant elements in this are liquid rheology, desired mass to be cast and content or dosage uniformity. Solvents used for the preparation of solution or suspension should ideally be selected from ICH Class 3 solvent list.

**SOLVENT CASTING 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




**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 controlleddrums. Gel mass is obtained by adding solution of film forming to a solution of acid insolublepolymer in ammonium or sodium hydroxide.Acid-insoluble polymers used to prepare films include: cellulose acetate phthalate, celluloseacetate butyrate. Acid insoluble polymer and film forming polymer should be used in the ratio of 1:4.

**EXTRUSION OF HOT MELT**

In the hot melt extrusion procedure, the medication and carriers are first combined in solid form.The granular substance is then dried. placed within the extruder. You should set the screwspeed. At 15 rpm, the granules inside the mixture are processed. barrel of the extruder for about three to four minutes. The processing temperatures of 800C (zone 1) and 1150C are recommended.650C is in zone 4, 1000C is in zone 3, and so forth. A extrudate (T = 650C) was then pressed into a cylinder calendar in chronological order. to acquire a movie.

The use of hot melt has some advantages.

1. Less operational units
2. Better homogeneity of content.

**SOLID DISPERSION EXTRUSION**

Immiscible components are extruded with the medication in this process, and solid dispersions are subsequently made. Finally, dies are used to mold the solid dispersions into film.

**ROLLING METHOD**

The rolling approach involves preparing a medication solution or suspension with a film-formingpolymer before putting it through the roller. The suspension or solution needs to have certain rheological analysis. primarily comprised of water and alcohol and water combined. On the, the film has dried. Cut into the desired shapes and sizes using rollers.

**EVALUATION TESTS**

1) Mechanical properties.
2) Thickness
3) Dryness/tack test
4) Tensile strength
5) Percent elongation
6) Young‘s modulus
7) Tear resistance
8) Folding endurance
9) Organoleptic test
10) Swelling test
11) Surface pH test
12) Contact angle
13) Transparency
14) Assay/ Content Uniformity
15) Disintegration test
16) In-vitro Dissolution test
17) Tack testing and dryness tests

**1.MECHANICAL PROPERTIES**

There are about eight phases in the drying process for films, and these include set to touch, dust- free, and tack-free. Dry to the touch, hard, and through (surface) (dry to handle), (dry to recoat), and (dry print free). Despite the fact that paints films are the focus of these tests. Most studies can be elaborately modified to evaluate health care OFDF. The specifics of how these were evaluated parameters are beyond what can be checked elsewhere. the range of this analysis. The tenacity with which a tactician. The strip is attached to a sheet of paper or other accessory. has being pushed up against the strip. Instruments also accessible for this research.

**2.THICKNESS**

The thickness of film is crucial for drug content uniformity, and can be measured using micrometer screw gauges or calibrated digital Vernier Calipers at strategic locations.

**3.DRYNESS/TACK TEST**

Eight stages of film drying process have been identified: set-to-touch, dust-free, tack-free, dry- to-touch, dry-hard, dry-through, dry-to-handle, dry-to-recoat, and dry print-free. These tests are primarily used for paint films but can be adapted for pharmaceutical OFDF evaluation.

**4.TENSIL STRENGTH**

Tensile strength is the maximum stress applied to a strip specimen at breakage, calculated by dividing the applied load at rupture by the strip's cross-sectional area.

**5.PERCENT ELONGATION**

Strain, the deformation of a strip divided by its original dimension, increases with increased plasticizer content, resulting in a stretch in the strip.

% Elongation = Increase in length ×100 Original length

**6.YOUNG'S MODULUS**

Young's modulus measures strip stiffness by comparing applied stress to strain in elastic deformation region. Hard and brittle strips have high tensile strength and small elongation.

**7.TEAR RESISTANCE**

Tear resistance of plastic film is a complex function based on its ultimate rupture resistance, measured at a low loading rate of 51 mm/min and recorded in Newton's.

**8.FOLDING ENDURANCE**

The folding endurance value is calculated by counting the number of times the film is folded without breaking.

**9.ORGANOLEPTIC EVALUATION**

Special controlled human taste panels and in-vitro methods are used for high-throughput taste screening of oral pharmaceutical formulations, utilizing taste sensors, specially designed apparatus, and modified pharmacopoeia methods.

**10.SURFACE PH OF FILM**

The films' surface pH was determined by placing them on a 1.5% w/v agar gel and placing pH paper on them, observing the color change.

**11.SWELLING PROPERTY**

The study uses simulated saliva solution to study film swelling. Film samples are weighed, placed in a mesh, and submerged in a 15ml medium. The swelling degree is calculated using parameter

**α = wt - wo/wo**

Where, Wt is weight of film at timet; wo is weight

## 13.ASSAY/ CONTENT UNIFORMITY

Content uniformity is determined by estimating API content in individual strips using standardassay methods, with a limit of 85-115 percent.

## 14.DISINTEGRATION TIME

Orally fast dissolving films require USP disintegration apparatus, with a disintegration time limit of 30seconds or less. Typically, 5-30 seconds, no official guidance available for oral fast disintegrating Film strips.

## 15.DISSOLUTION TEST

Dissolution testing using standard basket or paddle apparatus, selected based on sink conditionsAnd API dose, can be challenging due to strip floatation on medium.

**TABLE NO 5 : POTENTIAL CANDIDATES ELIGIBLE FOR INCORPORATION IN ODF**

| Molecule | Therapeutic category | Dose (mg) |
|---|---|---|
| Nicotine | Smoking cessation | 1-15 |
| Zolmitriptan | Antimigraine | 2.5 |
| Sumatriptan | Antimigraine | 35-70 |
| Loratidine | Antihistaminic | 5-10 |
| Oxycodone | Opoid analgesic | 2.5-10 |
| Ketoprofen | Anti-inflammatory | 12.5-25 |
| Acrivastine | Antihistaminic | 8 |
| Cetrizine | Antihistaminic | 5-10 |
| Famotidine | Antacid | 10 |
| Omeprazole | Proton pump inhibitor | 10-20 |
| Flurazepam | Anxiolytic, Anticonvulsant | 15-30 |
| Dextromethorphan HCl | Cough suppressant | 10-20 |
| Azatidine maleate | Antihistaminic | 1 |
| Diphenhydramine HCl | Antihistaminic | 25 |
| Nitroglycerin derivatives | Vasodilator | 0.3-0.6 |
| Chlorpheniramine maleate | Anti-allergic | 4 |
| Odenswetron | Vomiting | 4 |
| Riztrptane benzoate | acute attack for migraine | 5 |

**CONCLUSION:**

Many pharmaceutical companies are moving away from ODTs and toward OSTs as a more consumer-friendly product brand. Additionally, this technological choice may offer a strong foundation for patents. respecting the evolution of the product. OST permits brand expansion forgoods. A useful tool for managing the product life cycle is the OST. extending the patent life of currently available compounds or goods. In contrast to certain costly and intricate procedures like (lyophilization).The OST is comparatively simple to create when it comes to making ODTs; lowering thetherapy's overall cost in the process. Using OTF has expanded beyond the buccal rapid dissolving method to include opens up new possibilities for use, such as topical, gastro retentive, sublingual, implanted delivery methods

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