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Orally Disintegrating Film: A Prevailing Expansion in Drug Delivery System

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ABSTRACT

In the course of years, propensity towards creative medication conveyance frameworks has significantly expanded endeavors to ensure efficacy, safety, and patient acceptability. Regarding the oral route of drug administration, many substitutes have consistently been introduced by utilizing recent novel technologies for pediatrics, geriatrics, nauseous and non-compliance patients. Orally dissolving films (ODFs) provide a quick release of an active pharmaceutical ingredient (API) when placed on the tongue. ODFs provide an alternative to orally disintegrating tablets. These dose structures are put on a patient's tongue or any oral mucosal tissue. At the point when wet by salivation, the film quickly hydrates and follows onto the site of utilization. It quickly disintegrates and dissolves to deliver the medication for mucosal ingestion or with adjustments, takes into account oral gastrointestinal assimilation with fast-dissolving properties. Therefore, research in developing orally disintegrating systems has been designed at exploring different excipients as well as techniques to meet these faces. An assortment of measurements structures like tablets, films, wafers, biting gums, microparticles, nanoparticles, and so forth have been created for improving the exhibition credits in the orally disintegrating systems.

[A] INTRODUCTION:

Orally disintegrating films (ODF) have recently become one of the most popular forms of drug administration due to their excellent patient convenience and compliance. The primary benefit of the measurement structure emerges from quick deterioration: it tends to be put on the tongue without the need for water. Intraoral route is the most liked because of its comfort and rapid onset of activity. Intraoral dose structures have developed as an option in contrast to conventional tablets, capsules, and fluid formulation. Of the intraoral dosage forms, quick-dissolving dosage forms have acquired a lot of consideration because of working on persistent consistency and simplicity of organization. Issues related to customary measurements structures like disintegration and bioavailability of drug molecules can be overwhelmed with details expected for progastrin conveyance [1].

The upside of utilizing ODF is the high effectiveness of assimilation of certain mixtures by oral by means of without the need of water for swallow, being an option in contrast to bioactive regulated in tablets and pills [1,2], and in addition the ingestion through the buccal epithelium, without contact with a gastrointestinal parcel which could corrupt some sensible compounds [3].

The administration of ODFs enjoys various benefits and some of them are as per the following:

i. Easy transportation.

ii. Ease of swallowing for geriatrics and pediatrics

iii. Convenient and accurate dosing need of water for administration.

iv. Convenient for dysplasia patients having difficulty in swallowing tablets and capsules.

v. Rapid onset of action with increased bioavailability due to bypassing hepatic first-pass effect and stability

No costly lyophilization, high mechanical strength, rapid disintegration are the quality credits of ODF that have accomplished momentous importance in the drug industry for the explanation of having special properties and quick disintegration, time going from seconds to one moment ODFs configuration grants to fuse an assortment of medications for their

pharmacological effects e.g., anti-tussive, anti-epileptic, anti-asthmatic, expectorant, etc. High temperature and moisture [4].

Disadvantages:

1. Dose uniformity is a technical challenge.

2. Hygroscopic in nature.

3. High doses cannot be incorporated (<40 mg/4cm^2 piece)

4. Require special packaging for products stability and safety.

[B] FORMULATION:

ODFs are fast disintegrating thin films having an area vacillating from 5 to 20 cm^2 in which drug is integrated into the form of a matrix using hydrophilic polymer. The active pharmaceutical ingredient can be included up to 15 mg with other excipients i.e., plasticizers, colorants, sweeteners, taste-masking agents, etc. Plasticizer increases the workability, spreadability, and flexibility of films. [5]

Table- 1: Composition

Components	Conc. (%)
Active pharmaceutical ingredient	1–25
Hydrophilic polymer	40–50
Plasticizer	0–20
Colour, filler, flavor	0–40

[B.1.] Active pharmaceutical ingredient:

Various classes of drugs can be incorporated into ODFs e.g., anti-histamine, anti-diarrheal, anti-depressants, vasodilators, anti-asthmatic, anti-emetic, etc [6]. Dimenhydrinate can also be incorporated into ODFs for taste masking. drugs incorporated into ODFs are salbutamol sulfate, rizatriptan benzoate, verapamil, ondansetron, dexamethasone, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc.

[B.2.] Hydrophilic polymers:

The improvement of an ODF is an element of advocated choice and convergence of polymers as the mechanical strength of films is emphatically connected with these elements. The veracity of fast dissolving oral films is dependent upon careful selection of polymer nature and concentration. Generally, polymer concentration used in preparing ODFs is around 45% w/w of the total weight of dry thin strips, though, it can be increased up to 60–65% w/w to accomplish the film of characteristics and attributes. [7]

Properties

- Non-irritant
- Should not hinder the disintegration time of ODF
- Non-toxic
- Non-irritant
- Affordable
- Should possess adequate shelf-life
- Should possess good spreadability
- Should exhibit sufficient tensile strength
- Should have good mechanical properties

[B.3.] Plasticizers

In general, mechanical properties, for example, rigidity and percent extension are improved by adding a plasticizer to the definitions. The convergence of plasticizers ordinarily goes from 0% to 20% w/w. Normal instances of plasticizers are PEG, glycerol, diethyl phthalate, triethyl citrate, tributyl citrate, and so forth.

[B.4.] Sweetening Agent

Sweeteners have developed an imperative part of the food products as well as pharmaceutical products projected to be disintegrated or dissolved in the oral cavity. Natural sweeteners, as well as artificial sweeteners, are used to increase the palatability of the mouth's dissolving formulations.

Table 2: Types of Sweetening agent.

Sweetening agent	Example
Natural	Glucose, fructose, dextrose, sucrose, and isomaltose
Artificial	Acesulfame-K, sucralose, and neotame

[C] CONVENTIONAL APPROACHES FOR MANUFACTURING OF ODFS:

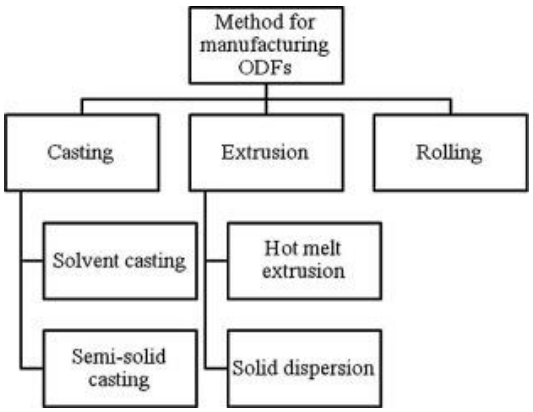

Fig. No.1. Conventional approaches for manufacturing ODFs.

[C.1] Solvent casting method

Solvent casting is the most generally utilized strategy for the planning of ODFs utilizing water solvent excipients, polymers, and medication which are broken down in de-ionized water; thusly, a homogenous combination is gotten by applying high shear powers produced by a shear processor. Then, at that point, the solution is poured onto the Petri plate and the dissolvable is permitted to dry by presenting it to high temperature to achieve great quality film. [8]

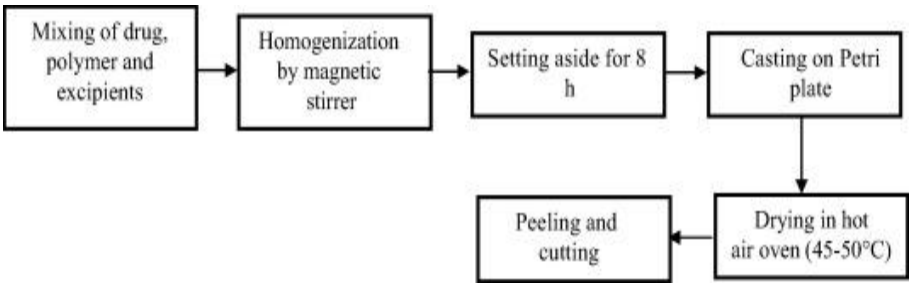

Fig. No.2. Flow chart of solvent casting method

[C.2] Semi-solid casting method

In this method, a solution of water-soluble film-forming polymer is assorted to the solution of acid-insoluble polymer to form a homogenous viscous solution (e.g. cellulose acetate phthalate and cellulose acetate butyrate).

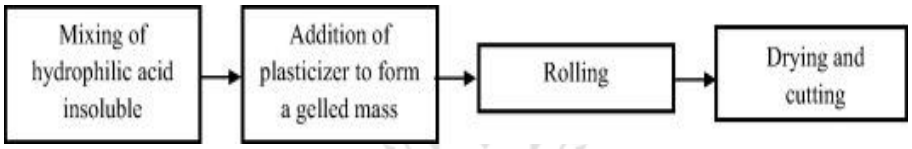

Fig. No.3. Flow map of semi-solid casting method

[C.3] Hot melt extrusion

Processing films by this technique involves shaping a polymer into a film via the heating process rather than through the traditional solvent casting technique.

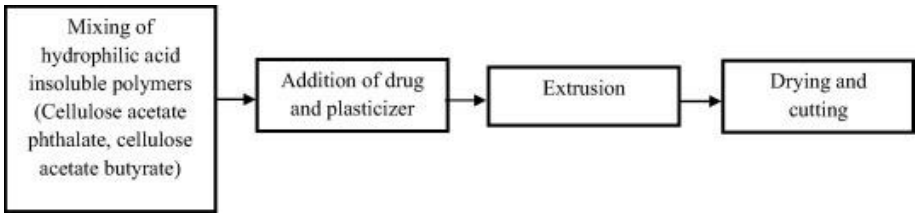

Fig. No.4. Flow chart of hot-melt extrusion method.

This is a solvent-free process, notwithstanding, the handling of thermolabile substances is a significant disadvantage of this cycle because of the utilization of high temperature during extrusion. [9]

[D] CHARACTERIZATION AND EVALUATION:

1. Organoleptic evaluation

An exceptional controlled human taste bud is utilized for such a reason. This in vivo taste assessment is done on human volunteers. In-vitro taste assessment of ODFs is performed by utilizing taste sensors for screening. In vitro taste evaluating techniques and advancements are proper and adequate for high-throughput taste detecting of such dose structures. Both in vivo and in vitro strategies dissect the taste concealing capacity and pleasantness level of taste covering specialists.

2. Thickness test

The thickness of a film is controlled by utilizing an adjusted advanced micrometer and afterward hence mean average is determined. Three readings from every one of the batches are determined. The weight variation of a film is determined three-fold by cutting the film and deciding the load of each film. Consistency in thickness is critical to however sure as it seems to be straightforwardly relative to the portion exactness of the film.

3. Tensile strength

Tensile strength is characterized as the greatest pressure applied at which the film breaks. Essentially, this test is performed to gauge the mechanical strength of films. It tends to be determined from the applied burden at break partitioned by the strip cross-sectional region given in the equation below:

Tensile strength = (load at failure / strip thickness * strip width) * 100

4. Percentage elongation:

When the sample films are subjected to tensile stress, deformation of the films occurs resulting in stretching or elongation of the sample. It is performed to predict the ductility of polymers using a texture analyzer. It is calculated by the formula:

% Elongation = Increase in length ×100 / Original length

5. Swelling property:

Simulated saliva solution is used to check the swelling studies of films. The initial weight of the film is governed and is located in pre-weighed stainless steel wire mesh. This mesh containing film is then dipped into a simulated saliva solution. An increase in the weight of the film is observed at constant pre-determined time intervals until no more increase in weight. The degree of swelling is defined by these parameters:

Degree of swelling = final weight (wt) –Initial weight (w0)/ Initial weight (w0)

Wt = weight of film at time interval t, w0 = weight of film at time 0.

6. Transparency

The transparency of a strip is decided by using a UV-spectrophotometer. This test is accomplished for the visual appearance of the formulation. Film specimens are cut into rectangular shapes and positioned on the internal side of the photometer cell. The transmittance of the film is functioned out at 600 nm wavelength.

Transparency=(logT600)/b=-€c

T600 = transmittance at 600 nm, *b* = film thickness (mm), and *c* = concentration.

7. Content uniformity

Contents of a film are resolved by a standard assay method specified for the specific drug in the different pharmacopeia. This test is performed on 20 samples using analytical techniques. The acceptance value of the test is less than 15% in accordance with Japanese pharmacopeia. According to USP27, the contents should reach from 85% to 115% with a standard deviation of less than or equal to 6%.

8. Disintegration time

The disintegration apparatus quoted in official pharmacopeias is used for governing the disintegration time of a film. Normally, the disintegration time is the function of the composition of film as it varies with the formulation and generally reaches from 5 to 30 s. Mostly, the USP disintegration apparatus is used for this test. There are two methods for determining the disintegration time of film:

Slide frame method

A drop of distilled water is poured onto the film clamped into slide frames placed on a petri dish. Time taken by the film to dissolve is noted. [10]

Petri dish method

A film is placed onto 2 ml distilled water taken in a petri dish. Time taken by the film to dissolve completely is considered as the disintegrating time.[11]

9. *In-vitro* dissolution test:

Standard official basket or paddle apparatus is used for directing dissolution studies on films. Sink conditions should be retained during dissolution. Sometimes while performing this process, the film floats over the medium making it difficult to perform the test properly. This problem is more likely to occur in the case of the paddle method thus the basket apparatus is mostly preferred. The media used are 6.8 pH phosphate buffer (300 ml) and 0.1 N HCl (900 ml). Temperature is maintained at 37 ± 0.5 C and rotation speed of 50 rpm is usually adjusted. Samples of drug dissolved are collected at pre-determined intervals and are analyzed by using UV-spectrophotometer. [12,13]

[E] CONCLUSION:

The current survey shows that ODFs are one of the novel approaches in the field of pharmaceutical sciences. They have further developed acknowledgment and patient consistency without any danger of gagging related to better wellbeing and viability comparison with ordinary dose structures. The fundamental thought behind the plan of ODFs was to adapt to the trouble in gulping ordinary oral dosage structures among pediatric, geriatric, and mental patients with dysphagia. Presently, ODFs are generally accessible for hypertension, acridity, sensitivity, torment, and so on mirroring their significance. Significant benefits of such dose structure are their organization without the utilization of water satisfying the need of target populace looking for accommodation in drug administration alongside bypassing the hepatic digestion, therefore, prompting worked on restorative reaction.

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