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Orofast Disintegrating Tablet: A Modern to The Drug Delivery System

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ABSTRACT

The most recommended and appropriate route in terms of patient compliance is the delivery of drugs by the oral route. Oral drug tablets are solid dosage forms that disintegrate in the mouth in less than 60 seconds and dissolved rapidly in the saliva without the need of water. Oro dispersible tablets have benefits such as accurate dosing, easy transportability, fabrication, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients. Generally, super disintegrants are used in the solid dosage form at a low concentration, typically 1-10% by weight relative to the total dosage unit weight, different type of super disintegrants such as synthetic, semisynthetic, natural and co-processed blends etc., have been used to publish successful super disintegrants and to short out the constraint of traditional method of tablet dosing. Usually, elderly people experience difficulty in swallowing the conventional dosage forms like capsules, tablets, solutions and suspensions because of tremors of allergic attack or coughing, and an unavailability of water, swallowing conventional tablets may be difficult. In recent past, several manufacturing technologies such as spray drying technique, sublimation technique etc., are immersed to overcome the limitations of conventional tablet dosage forms. The review explains various aspects of mouth dissolving tablet formulation, soluble tablets and technologies developed for it.

Keywords: Mouth dissolving tablets, patient compliance, super disintegrants, dispersible tablets, bioavailability.

INTRODUCTION:

The core aim of developing a drug delivery system is to achieve effective and safe therapy for individuals. [1] Even with substantial advances in drug delivery technology, the oral route remains the best option for administering therapeutic agents owing to its low cost, ease of administration, precise dosing, self - medication potential, pain – free nature, and versatility, which contribute to high levels of patient compliance. [2]

A significant number of patients take conventional tablets, but some such as pediatric, geriatric, bedridden, mentally ill, and uncooperative individuals, struggle to swallow them because of their systemic abnormalities. Sometimes these orodisinegrating tablets are crushed and added to tea, which is administered to the psychiatric patients, when they deny the administration of oral dosages [3]. Research concluded that 50% of patients face these repercussions, leading to substantial noncompliance and ineffective treatments. [4]

Overcoming these challenges has been made possible through innovative developments in drug delivery systems. [5] Solid dosage forms containing medicinal substances or active ingredients that disintegrate rapidly within a few seconds when placed on the tongue''.[3]

Orally disintegrating tablets with a pleasant taste increase the acceptance of bitter drugs among diverse population groups, merging the benefits of both solid and liquid dosage forms.[6]

Super disintegrants like croscarmellose sodium, crospovidone, sodium starch glycolate, and PVP are commonly used in ODT formulations. The chosen super disintegrant should be compatible with the drug and not interfere with its therapeutic impact. [4]

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Ideal characteristics: [7,8]

To be distinct from conventional dosage forms, ODTs should possess certain ideal characteristics; • The formulation needs to be sufficiently compactable to produce durable tablets.

- It should ensure quick disintegration.
- They should dissolve or disintegrate quickly in the mouth, typically within a few seconds, without necessitating water.
- Minimal or no residue should remain in the mouth after oral administration.
- Effective taste masking should be achievable with these tablets.
- They must give a pleasing sensation when taken orally.

Advantages of Oral Dispersing tablets: (ODTs)

The advantages of ODTs include. [5,8]

- Tablets can be manufactured using standard processing and packaging equipment at low cost.
- Capable of masking taste effectively while delivering a pleasing mouth sensation.
- Oral administration of conventional formulations avoids the risk of choking or suffocation due to physical blockages, thereby enhancing safety.
- Ensuring administration for patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients with renal failure, and those who refuse to swallow, including pediatric, geriatric, and psychiatric patients.
- Dosing is more precise compared to liquid alternatives.
- Tablets can be taken orally without water.
- Achieve increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx & oesophagus as saliva passes down.
- Orally disintegrating tablets (ODTs) support the sustained and controlled release of active compounds.
- No residue in the oral cavity after administration.

Disadvantages of Oral Dispersing tablets: (ODTs)

The disadvantages of ODTs include. [9,2]

- Concurrent use of ODTs and anti-cholinergic drugs is not recommended.
- Drugs with site-specific absorption cannot be administered via these dosage forms.
- It is difficult to formulate drugs with moderately larger doses in FDTs.
- The hygroscopic nature of the formulation necessitates additional moisture protection through specialized packaging to ensure product stability and safety. □ Drugs which have large doses, can cause problems to formulate them into ODTs.

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Mechanism of action:

As per the European pharmacopoeia the ODT disperses or disintegrates in less than three minutes. The process of development of ODT makes use of super disintegrants such as Sodium starch glycolate, carboxymethyl cellulose, polyvinylpyrrolidone etc., which offers rapid disintegration of tablet when offers rapid disintegration of the tablet when released in saliva after administration of drug through mouth. [10]

The dispersion or disintegration of the tablets include a release pattern depending on the super disintegrants used in it.

Mechanism of super disintegrant:

The dispersion conveys its action by 4 mechanisms.

- Swelling
- Porosity and capillary action[wicking]
- Due to disintegrating particle
- Deformation [4]

Swelling:

The general mechanism which is widely accepted for tablet disintegration is swelling force.[5] When disintegrants come in contact with water they start to swell and break apart.

1. **Porosity and capillary action: [wicking]**

Before the tablets are administered, they are dissolved in small amount of liquid or water. Due to this the tablets are broken into minute particles as the water penetrates easily [4]. The uptake of water depends on the hydrophilicity of the drug or excipient and the conditions involved in tableting.

2. **Due to disintegrating particles:**

based on the observation that the non-swelling particles can also disintegrate the tablet particles and this theory was proposed by Guyot-Herman.

3. **Deformation:**

During tablet compression, the particles get deformed, these particles when they come in contact with aqueous media or water they get back to their normal structure.[8]

Challenges in the product design, formulation and manufacture of oral disintegrating tablets: 1) Disintegrating time and mechanical strength:

Maintenance of a good mechanical strength is a prime challenge in the formulation of ODTs as they are formulated such that the disintegration time is usually less than a minute. There are chances of breakage of the fragile ODTs during their packaging, handling and transport. Increase in the mechanical strength leads to delay in disintegration time. So, a perfect compromise is needed between these two parameters.[11]

1) Taste masking:

Since most of the drug are bitter in taste, the formulator should have a matter of concern on the palatability of an orally administered drug. A suitable taste masking agent should be used to mask the taste of the drug [4]. A tablet having bitter drug dissolution or disintegration in oral cavity will affect the patient compliance and acceptance of the drug. Masking of bitter drugs should be effective so that the taste of drug is not felt in the oral cavity.

2) Mouth feel:

The particles produced after disintegration of the ODT should be as small as possible. After oral administration of ODTs, they should leave minimal or no residue in the mouth. Incorporation of flavours and cooling agents like menthol enhance the mouth feel.[10]

Sensitivity to environmental conditions.

The ODTs are usually meant to dissolve in less quantity of water. Hence ODTs should exhibit low sensitivity to environmental conditions such as temperature and humidity.[12]

3) Aqueous solubility:

Water soluble drugs form a eutectic mixture causing depression in freezing point and glassy solid formation which may break after drying during sublimation process due to lack of supporting structure. The use of matrix-forming excipient like mannitol can avoid such consequences by imparting crystallinity and rigidity to amorphous composite.[13]

4) Hygroscopicity:

Various oral dispersible tablets are hygroscopic and cannot retain their physical integrity under temperature and humidity conditions. Therefore, OTDs should be provided with specialized packaging.

5) Friability:

ODTs are made of either very porous or soft moulded matrices or tablets with low compression force to allow rapid disintegration of the tablet in the oral cavity. It usually requires specialized peel-off blister packing.[1]

6) Amount of drug:

In lyophilized dosage form the drug dose should be less than 60mg for soluble drugs and less than 400mg for insoluble drugs.[4]

7) Cost:

The formulation technology adopted for ODT should be acceptable regarding the cost of final product. [9]

Methods of preparation: I.

Direct compression:

The basic principle involved in the direct compression of dosage form is the addition of optimum concentration of super disintegrants to achieve rapid disintegration with a pleasant mouth feel. This method is easy to implement, use of conventional equipment and easily available excipients and cost effectiveness [7].

Moulding:

This method involves the preparation of moulded tablets using water- soluble ingredients to achieve a complete and rapid dissolution of the tablets. The blended powder is moistened with a hydro-alcoholic solvent and then moulded into tablets under a pressure lesser than that used in the conventional compression method. It is then air dried to remove the solvent. Moulded tablets have lesser compactness than compressed tablets and the dissolution is enhanced due to these porous structure [14].

II. Freeze drying/ lyophilization:

Lyophilization technique is most commonly used for thermolabile drugs as it employs lower temperature for drying the drug. The moisture present in the drug escapes through sublimation. In this method the drug is placed in a water-soluble matrix, which is then passed through a freezing tunnel for drying. The product disintegrates in a matter of seconds because of its porous nature, thus enhancing its bioavailability.

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III.Spray drying:

This method is employed to achieve an extremely porous and fine powder. Gelatin is used as a supporting agent and mannitol as a bulking agent. To improve dissolution and disintegration effervescent agents can also be employed. Finally, the prepared mass is spray dried to form a porous powder [4].

IV.Sublimation:

In this method inert volatile substance like camphor, napthalene, urea, urethane are added to the excipients. Pores are created in the tablet structure due to the removal of volatile material by sublimation. Due to the porous structure , tablet dissolves when it comes in contact with saliva. Also, some solvents like benzene or cyclohexane can be used to form pores [15].

V. Nanonization:

Nanonization involves reduction of particle size to nano particle size by employing wet grinding technique. The nano particles thus formed are stabilized to prevent agglomeration by physically attaching to the inert material surface. This technique is suitable for water insoluble drugs with lower bioavailability, a cost-effective process and hold wide range of dose (greater or equal to 200mg) [16].

VI.Mass extrusion:

The active blend of solvent mixture of water soluble polyethylene glycol and methanol is softened. Now this mass is placed into a syringe or an extruder to get a cylindershaped product which is then cut into small fragments to form tablets [17].

Cotton candy process:

This process involves the formation of polysaccharide matrix by simultaneous action of flash melting and spinning. The candy floss matrix thus formed is recrystallised partially to enhance the flow property and compressibility and then milled and mixed with active ingredient along with excipients and compressed to form dispersible tablets.

In this method high dose of drug can be accommodated [1].

EVALVATION PARAMETER:

Pre-compression parameter:[10]

- **Hausner's ratio:** It is the ratio of number that is correlated to the flow ability of a powder or granular material.

$$Hausner's\ ratio = \frac{\text{unsettled apparent volume}}{\text{final tapped volume}}$$

- **Angle of repose:** The steepest angle of dip relative to the horizontal plane to which a material can be plied without slumping. The range of angle of repose is from 0 to 90 degree.

$$tan\theta = \frac{\text{height}}{\text{radius}}$$

- **Tapped density:** It is increased bulk density attained after mechanically tapping containing the powder sample in container. Tapped density is obtained by the mechanically tapping a vessel that contain powder sample.

$$Tapped\ density = \frac{\text{Mass}}{\text{Final tapped volume}}$$

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POST – COMPRESSION EVALVATION PARAMETER:

 Weight variation: Individually selected randomly twenty tablets and all together, the average percentage and weight deviation were calculated. The percentage difference in the weight variation should be within (±7.5%) permissible limits. This is calculated by using the below formula.**[6]**

$$\%\ deviation = \frac{\text{individual weight} - \text{average weight}}{\text{individual weight}}$$

 Hardness: The force which is applied across the diameter of the tablet in order to break it is called as Hardness. The capacity of the tablet to develop resistance to breaking during storage transformation and handling depends on Hardness of the tablet.[18]

 Thickness: The strip thickness can be usually measured by using micrometer screw gauge, vernier's caliper, electronic digital micrometer or scanning electron microscopy (SEM) images. Plasticizer increase the thickness of the film slightly. The thickness should be usually less than 5%.[19]

 Friability: It is a challenge for a formulator to achieve the percentage friability within 0.1- 0.9%. Friability can be measured in "Electro lab friabilator". 10 tablets which are Pre-weighed are rotated at 25rpm upto 100 revolutions or total of 4 minutes. Percentage loss of weight is calculated using the following formula [20].

$$F = \frac{\text{W (initial)} - \text{W (final) x100}}{\text{W(initial)}}$$

 Wetting time: It is measured by making use of fine circular tissue papers with a diameter of 10cm. they are placed in a petridish and add ten milli litres of water-soluble dye like cosign solution.[21]

 Dissolution test: the formulation of dissolution methods for ODTs aligns with the technique used for conventional tablets and is largely the same. USP 1 and USP 2 are used as dissolution apparatus. USP 2 apparatus is chosen because, despite the various application of USP 1, tablet fragment become lodged in the basket at the optimal and most frequently used method for ODTs utilizing a paddle at 50rpm. Due to the rapid dissolution of ODTs under USP monograph conditions, a reduced speed can be applied to applied to achieve the desired dissolution profiles [22].

 Uniformity of dispersion: 2 tablets are kept in 100ml water and gently stirred for 2 min. This dispersion is made to pass through #22 meshes. If the residue remained on the screen, then the tablets pass the test [23].

Excipients:

Fast disintegrating tablets contain excipients such as super disintegrants, lubricants, diluents, and optionally swellings agents, sweeteners, flavoring agents and permeators. Major excipients are present in percentage [16].

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Table 1. List of excipients used in formulation of dispersible tablet.[1]

Sl no	Excipients	Functions	Examples
1	Glidants	• To improve the flow characteristics of a powder mixture and optimise the particle size distribution.	• Silicon dioxide • Starch • Talc
2	Sweeteners	• Sweeteners are added to mask the taste of the active ingredient.	• saccharine • sucrose
3	Colours	• They are added for good appearences.	• Sunset yellow (supra)
4	Diluents	• Helps in the flow compatibility and stability.	• Calcium phosphate • MCC
5	Lubricants	• Prevents the inter particulate friction	• Paraffin • Sodium benzoate
6	Flavors	• Mask the bitter taste of dosage form	• Orange Banana
7	Super disintegrants	• They helps the tablet to break when they come in contact with GIT/oral cavity.	• Croscarmellose sodium • Crospovidone • Starch • SSG

Name of the excipients and Percentage Used:[24]

- Diluents 0 to 85%
- Binder 5 to 10%
- Antistatic Agent 0 to 10%
- Disintegrants 1 to 15%

Conclusion:

These are the conventional dosage form which are used while there is a difficulty in swallowing the tablet in geriatric and paediatric patients. In this dosage form, the route of administration results in rapid onset of action which enhances bioavailability and patient compliance. Fast disintegrating tablets are type of dosage form which requires no water and the tablet disintegrates within 60secs. The different methods used to formulate FDTs are; direct compression, sublimation method, freeze drying technique etc., The basic approach to be followed by all oral disintegrating tablet is to maximise the porous structure of the tablet matrix, so that the rapid disintegration of tablet can be achieved in the oral cavity along with good taste, ideal properties and good mechanical strength.

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