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A Review on Dispersible Tablets: A Novel Drug Delivery System for Pedietrics and Geriatrics

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ABSTRACT

Novel Drug Delivery system offer great chance to invent new drug delivery system for the betterment of the life. Oral dispersible tablets are modern day technology and extensively used for those formulations which are required for pediatrics and geriatrics. Dispersible tablet disintegrates rapidly into the mouth in presence of saliva, as they don't require water for disintegration. Such rapid disintegration is helpful for the person having problem of dysphasia. Dispersible tablet requires a key ingredient called supradisintegrants for such rapid and effective disintegration. There are various methodologies used for preparing such effective dispersible tablets like – Compaction method, Freeze Drying, Molding Method, Sublimation, all such methods are effective to make dispersible tablets. There is need of evaluation of each and every tablet after manufacturing which requires evaluation parameters such as weight variation, Disintegration test, Dissolution Test, Hardness, and Thickness.

This article discuss about dispersible tablets, methods of preparation for dispersible tablets, evaluation parameters and advantages and disadvantages.

Keywords: *Dispersible Tablets, Dysphasia, Supradisintegrants*

1. INTRODUCTION

Oral route is considered as the most common and preferred for drug delivery of both solid and liquid dosage forms. However, solid dosage forms have the many advantages like being cheaper than other dosage forms, administration is easy, accuracy in dosing, self- medication and most importantly the patient compliance; these all makes solid dosage forms most popular. Tablets and capsules solid dosage forms are most prominent. Both tablets and capsules are classified into various categories on the basis of their application.[1, 2, 3]

However, a lot of people come across the problem in swallowing of tablets and hard gelatin capsules. This difficulty in swallowing is called dysphasia. Dysphasia has been faced in wide variety of patients, but it seeks especial attention in pediatric and geriatric patients. As a result, high incidence of non- compliance and ineffective therapy is caused by conventional dosage forms.[1, 2, 3, 4]

To overcome these patient issues, a novel oral drug delivery dosage form called as dispersible tablets was formulated by pharmaceutical scientists, which break down rapidly in saliva in few seconds without the ease of water. This early disintegration of tablets triggers the dissolution and absorption of drug and on the virtue of this, onset of pharmacological action and bioavailability gets improved, remarkably improved than conventional dosage forms. Dispersible Tablets are also known as mouth dissolving tablets, rapid dissolving tablets, fast disintegrating tablets and of course orodispersible tablets. [1,2,3,4]

A fast disintegrating tablet is a type of dispersible tablet that disintegrates in water or other liquid and disperse immediately inside the mouth. Such tablets are efficiently used to bypass the first pass metabolism, a convenient dosage regimen for pediatrics and geriatrics.[5]

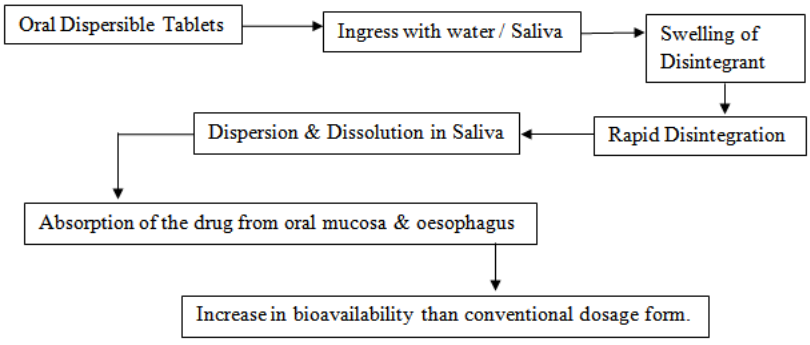


Diagram 1.1: Working of Dispersible tablets

According to British Pharmacopoeia, dispersible tablets are the uncoated tablets, which when placed in the mouth disperse readily within 3 minutes before swallowing. USP has also approved this dosage form as dispersible tablets. Hence, these are the solid unit dosage forms as like conventional tablets, but are formulated with superdisintegrant, which helps in disintegrating and dissolving the tablet within minutes in oral cavity in presence of saliva and counters the problem of dysphasia.[2]

Dispersible Tablets have a lot of advantageous points to offer like absorption takes place directly from mouth, which enhances the bioavailability of drug by bypassing first pass metabolism. Dispersible tablets releases the active medicament in mouth for absorption via local tissues of oral mucosa and through pre-gastric (oral cavity, pharynx & oesophagus), gastric [stomach] and post gastric (Intestines) segments of GIT. Dispersible tablets are becoming more popular day by day because of its various advantages.[2, 3]

1.1. ADVANTAGES

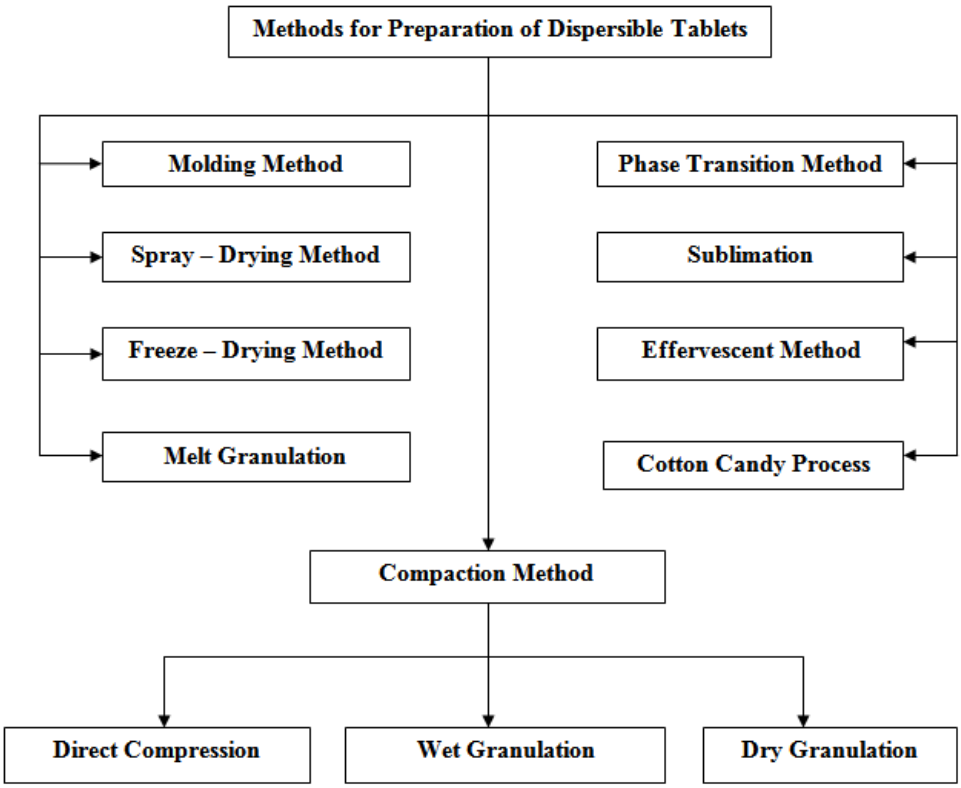
1. Dispersible tablets allow ease in administration to patients who are unable to swallow (Dysphasia). Like the geriatric stroke victims and bedridden patients who couldn't swallow e.g.; renal failure patients. It can also be used for very young children; Pediatrics (0-6 Years).
2. It requires very less amount of water or no water (Can be dispersed in saliva), which allow extensive use of such type of medication for bedridden patients.
3. Dispersible tablets possess the property of good mouth feel (Due to the addition of flavors and sweeteners), which thus changed the traditional view of medication as "bitter pill" and increases the patient acceptability towards the tablets.
4. Dispersible tablets have more convenience in drug administration and exact dosing as compared with the liquid formulations and the conventional tablets. It has benefits over liquid medication as well as conventional tablet medications.
5. It provides Convenience to active pharmaceutical ingredients with insufficient stability towards water.
6. It provides rapid absorption from mouth, which produces rapid onset of pharmacological action and provides instant relief.
7. It bypasses first pass metabolism as it absorbs from buccal cavity and the esophagus, increases the absorption and bioavailability.
8. Dispersible tablets are easy to manufacture and their production cost is less as compared to the conventional tablets, which makes them more affordable than other liquid dosage forms.
9. Easy to transport and they generate less handling and transportation cost.

1.2. DISADVANTAGES

1. Dispersible tablets are hygroscopic (sensitive towards moisture) in nature so it must be kept in dry place.
2. They pose less physical strength then conventional tablets.
3. They have less mechanical strength; they show high friability and less hardness.
4. Occasionally, if tablets are not formulated properly, they may leave grittiness after drug administration.
5. To maintain its stability, dispersible tablets require special packaging.
6. Uniformity in dosing is quite difficult.

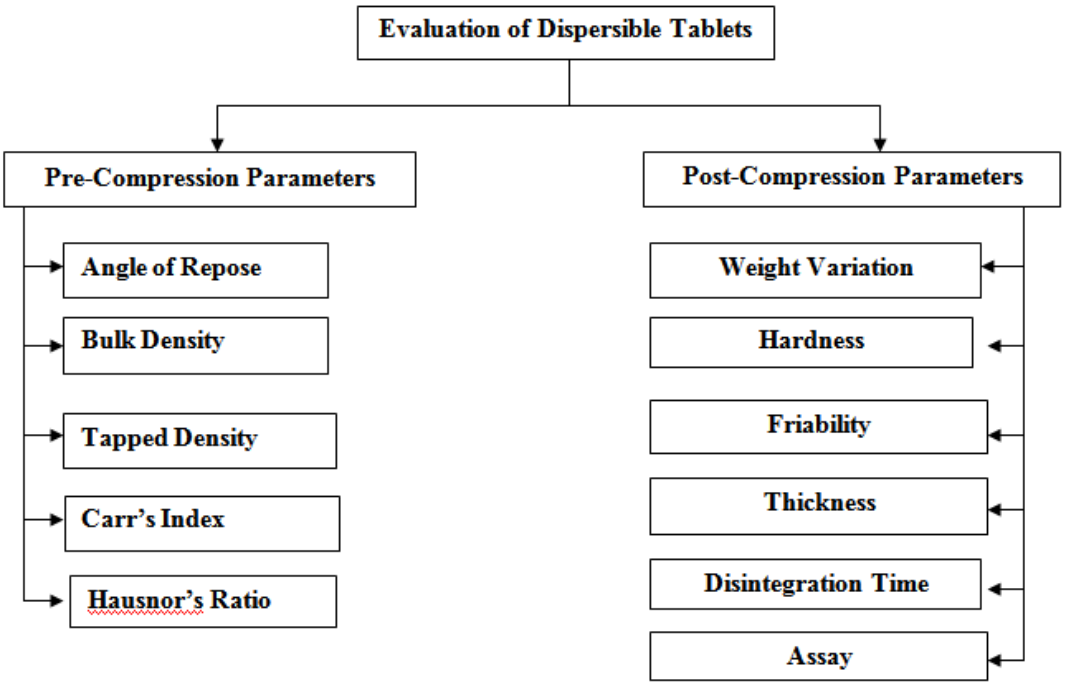
1.3. VARIOUS METHODS FOR PREPARATION OF DISPERSIBLE TABLETS

There are number of methods for the preparation of dispersible tablets but the prepared products vary in their properties like mechanical strength of tablets, swallow ability, and bioavailability, drug dissolution in saliva, stability and to some extent of taste.



1.4. EVALUATION OF DISPERSIBLE TABLETS

Evaluation of dispersible tablet is mandatory as it provides consistent quality attributes



1.4.1. Pre-Compression Parameters

1. Angle of Repose: is a parameter commonly used for the evaluation of interparticle force, it is the maximum slope angle of non-cohesive (Free-Flowing) granular material. It is the angle between a horizontal plane and the cone slope of such material.

Procedure: Weigh accurately 30g of granules; pass it through the funnel placed on 10cm distance from the base. Now mark the circle manually around the heap and adjust the tip of the funnel in such a manner so that it just touches the top of the heap. Calculate the height of the heap and radius and calculate the angle of repose by using the following formula.

$$\text{Angle of repose } (\theta) = \tan^{-1}\left(\frac{h}{r}\right)$$

Table 1.3: Angle of Repose

Flow Property	Angle of Repose (θ)
Excellent	25 – 30
Good	31 - 35
Fair	36 – 40
Passable	41 – 45
Poor	46 – 55
Very Poor	56 – 65
Extremely Poor	> 65

2. Bulk Density: The bulk density of a material is the ratio of the mass to the volume (including the interparticulate void volume) of an untapped powder sample.

Procedure: Weigh accurately 30g of the granules and transfer it to the graduated cylinder, mark the volume occupied by the bulk in the cylinder and calculate the bulk density by using the following formula.

$$\text{Bulk Density } (D_b) = M/V_b$$

Where,
D_b = Bulk Density
M = Weight of the dried granules
V_b = Bulk Volume

3. Tapped Density: The tapped density of a material is a ratio of the mass to the volume of the tapped powder sample.

Procedure: Weigh accurately 30g of the granules and transfer it to the graduated cylinder, mark the volume occupied by the bulk in the cylinder and calculate the bulk density by using the following formula.

$$\text{Tapped Density } (D_T) = M/V_T$$

Where,
D_T = Tapped Density
M = Weight of the dried granules
V_T = Tapped Volume

4. Carr's Compressibility Index: It is the indication of compressibility of the powder/ granules. It is a percentage proportion calculated by using the following formula.

Carr's Index (% Compressibility) = $\frac{(V_b - V_t) \times 100}{V_b}$

Where,
V_b = Bulk Volume
V_t = Tapped Volume

Table 1.4: Carr's Compressibility Index

% Compressibility	Relative Flowability
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair
23 – 28	Slightly Poor
28 – 35	Poor
35 – 38	Very Poor
>40	Extremely Poor

5. Hausnor's Ratio: is generally used to determine the flow character of the powder/ granule. It the ratio between bulk volume to the tapped volume.

Hausnor's Ratio = V_b/ V_t
Where,
V_b = Bulk Volume
V_t = Tapped Volume

Table: 1.5 Hausnor's Ratio

Hausnor's Ratio	Flow Character
1.00 – 1.11	Excellent
1.12 – 1.18	Good
1.19 – 1.25	Fair
1.26 – 1.34	Passable
1.35 – 1.45	Poor
1.46 – 1.59	Very Poor
>1.60	Very Very Poor

1.4.2. Post Compression Parameters

1. Weight Variation: is carried out to ensure that each tablet shall contain adequate amount of medicament.

Procedure:
20 tablets have been weighed individually on analytical weighing balance and average has been calculated and percentage weight variation determined by using the formula:

% Wt. Variation = $\frac{\text{(Individual Wt. – Average Wt.)} \times 100}{\text{Average Wt.}}$

Monograph	Average weight	Deviation [%]
IP/BP	<80 mg	10
	Between 80 and 250 mg	7.5
	>250 mg	5
USP	<130 mg	10
	Between 130 and 325 mg	7.5
	>325 mg	5

2. Hardness: it is a technique used to find out breaking point and structural integrity of the tablet. It is the measure to check out the strength between the granules. Monsanto hardness tester is used to check the hardness of the tablets. Hardness of dispersible tablets kept lower than ordinary tablet. Hardness around 3-5 kg/cm2 is thought to be acceptable for uncoated tablets.

3. Friability: It is the % weight loss by the tablet due to mechanical action during the test. Roche friabilator is utilized for finding the friability of the tablets. Friabilator comprise of a plastic chamber that spins at 25 rpm and dropping the tablets at a tallness of 6 creeps in every upset. Pre-measured example of tablets was set in the friabilator and was subjected to 100 revolutions. Tablets were de-tidied using a delicate muslin fabric and reweighed

% Friability = $\frac{(W1 - W2) \times 100}{W1}$

W1 = Initial Weight of the Tablets
W2 = Weight of tablets after the test

4. Thickness: It permits accurate measurement and provides information on the variation between tablets. Six tablets were taken and the thickness was measured using a Vernier caliper. The tablet thickness should be controlled within a ± 5% variation of a standard value. It is expressed in millimeters (mm).

5. Disintegration Test: It determines whether the tablets disintegrate properly when placed in the liquid medium.

Procedure:
Six tablets were taken and placed in the tubes of disintegration test apparatus (Apparatus was filled with dispersion medium i.e. pH 6.8 Phosphate Buffer at a temperature of 37°C ± 5°C), operate the disintegration test apparatus until no residue of the tablet remains onscreen.

6. Dissolution Test: This check is intended to see compliance with the dissolution demand for solid indefinite quantity forms that area unit administered orally. It is an important test as the drug-release profile can be obtained by performing this test. Both the USP dissolution test apparatus can be used. Dissolution of orodispersible tablets is very fast. Therefore, USP type-2 apparatus at 50-100 rpm is used for dissolution study. USP Type I basket apparatus have a limitation, that the some tablet residue stick to the spindles whereas no such problem occurs in USP type-2 apparatus. Thus type-2 apparatus is more preferred due to reproducible-dissolution profile.

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