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A COMPREHENSIVE REVIEW ON ORAL DISPERSIBLE TABLET

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ABSTRACT

Now – a – days, dispersible drug delivery systems are extensively used to improve bioavailability and patient compliance. Over the past three decades, dispersible tablets have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better patient compliance, improved solubility and stability profiles. Dispersible tablets could be preferred choice especially with those drugs sensitive to GI fluids, for masking bitter taste of drug and for patients under category of pediatrics , geriatrics, bedridden , postoperative and who may have difficulty in swallowing the conventional tablets and capsules .

The convenience of administration and improved patients compliance are important in the design of oral drug delivery s system which remains the preferred route of drug delivery inspite of various disadvantage.one such problem can be solved in the novel drug delivery system by formulating oral disintegrating tablets which disintegrates rapidly without water within few seconds in the mouth due to action of super disintegrants in the formulation.

Keywords: Oral dispersible tablets, super disintegrants , Fast dissolving tablets

INTRODUCTION

In order to prevent the dysphagia and improve patient compliance, orodispersible tablets are introduced as a

substitute in oral DDS, designed to disintegrate in mouth without the aid of water. These orodispersible tablets (ODT)

can be administered to any patients having difficulty in swallowing [1].

The basic aim behind development of any drug delivery system (DDS) is to achieve a safe and effective therapy for the human being. For decades oral drug delivery has become the major segment in the global pharmaceutical market. It is growing day by day because of being a favorite route for drug administration. A large number of developments in the field of pharmaceutical technology have made manufacturing of tablet a science. In recent days tablets become the most favorable dosage form as compared [2] other available dosage forms. The popularity of this dosage form is because of common advantages such as ease of manufacturing, convenience in administration, and high accuracy in dosage, stability and safety. Despite all the advantages, conventional tablets generally do not prove useful in certain situations. The elderly face difficulties in taking conventional oral dosage forms because of hand tremors and dysphagia. Swallowing is also a problem in the young individuals because of their underdeveloped muscular and skeletal system. Other groups experience problems using conventional oral dosage forms include mentally ill, developmentally disabled patients and patients who are

uncooperative or who are suffering from severe nausea [3-5].

Prerequisite of fast disintegrating tablets

There are some prerequisites for fast disintegrating tablets which are mentioned as follows. Tablet must disintegrate and disperse in oral cavity without water intake. It can hold high drug quantity. It should be compatible with taste masking agents and excipients and have optimum sensation effect. Leave minimum to no residue after administration. It should have optimum capacity to remain intact in formulation processes. It should be stable at the range of temperature and humidity. It should be adaptable and amenable to existing processing and packaging machinery. It should be manufactured at low cost [24, 25].

Suitability of drugs for fast disintegrating tablets:

For developing FDT of a specific drug several factors should be kept in mind while selecting drug, excipients and formulation method. These are as follows: Drugs to be used for sustained action are not suitable candidates for FDT. Drugs having very disagreeable taste are not suitable like clopidogrel. Patients suffering from Sjogren's syndrome and those with less saliva secretion are not suitable for FDT dosage form. Drugs of very short half life

and requiring frequent dosing are not appropriate candidate. Patients on anticholinergic therapy are not suitable for FDT. Drugs showing altered pharmacokinetic behavior if formulated in such dosage form with respect to their conventional dosage form are not suitable, like selegiline, apomorphine and buspirone. Drugs producing considerable amounts of toxic metabolites on first pass metabolism and in GIT and having substantial absorption in oral and pregastric areas are good candidates. Drugs permeable to upper GIT and oral mucosal epithelial cell lining are considered good candidates for FDT [26].

Ideal characteristics of ODT:

- Ideal Characteristics of ODT's: [6, 7] Exhibit low sensitivity to environmental conditions as humidity and temperature.
- Should dissolve or disintegrate in the mouth rapidly without aid of water in matter of seconds and without swallowing.
- Should maintain physical integrity and possess no friable loss with sufficient mechanical strength should have a pleasant mouth feel.
- Should leave minimum or no residue in the mouth after oral administration .
- Should exhibit low sensitive to environmental condition as temperature and humidity.
- Should allow high drug loading capacity.
- Should be adaptable and amenable to the existing processing and packaging machinery at low costs.
- Small to moderate molecular weight.
- Good solubility in water and saliva. Partially non – ionized at the oral cavity pH.
- Ability to diffuse and partition in to the epithelium of the upper GIT logp more than or preferably more than 2.
- Ability to permeate oral mucosal tissue The fast disintegration usually means disintegration of tablets in less than 1 minute, but it is preferred to have disintegration as soon as possible.
- The excipients should have high wettability , and the tablet structure should also have a highly porous network for fast dissolution The disintegrated tablet should become a soft paste or liquid suspension , which can provide good mouth feel and smooth swallowing

- A pleasant taste inside the mouth becomes critical for patient acceptance.
- Unless the drug is tasteless or does not have an undesirable taste, taste – masking techniques should be used. An ideal taste – masking Pharmaceutical Research and Development technology should provide drugs without grittiness and with good mouth feel.

Specific Features of Dispersible tablet:

Dispersible are not intended to be chewed or swallowed whole. They should not be dispersed in carbonated drinks or milk due to foaming or slow dispersion. The purpose of dispersible tablets is to provide a unit dosage form of medication which can be easily administered to infants and children or to elderly, who may have difficulty in swallowing an intact tablet [8, 9].

Advantages of Dispersible tablet:

1. Onset action compared with conventional tablets because of improved bioavailability.
2. Suitable for children and elderly persons with

swallowing difficulties (Dysphagia)

3. More convenient for API's with insufficient stability in water.
4. More easy for transportation (less volume , less weight)
5. Dispersible tablets remain solid until administration. This aids the stability of the pharmaceutically active agent, the dose accuracy, storage of the tablets.

Criteria of selection of drug ODT: [29]

The ideal characteristics of a drug for in vivo dissolution from an FFDT include

- No bitter taste
- Dose lower than 20mg
- Small to moderate molecular weight
- Good stability in water and saliva
- Partially non ionized at the oral cavities pH
- Ability to diffuse and partition into the epithelium of the upper GIT (log P>1, or preferably>2)
- Ability to permeate oral mucosal tissue

- Passive diffusion drug absorption
- Bes-class 2
- Molecular weight below 500 da

Drugs which can be integrated in the fast dissolving tablets:

A variety of drugs are being incorporated in FDTs. Examples of drug candidates in various classes are mentioned in **Table 1** [27, 28].

Formulation of dispersible tablets

The tablets were prepared by wet granulation and direct compression method using formula as given in the **Table 1 and 2** respectively. The drug and excipients were passed through a # 60 size mesh prior to the preparation of the dosage form. The entire ingredients were weighed separately and mixed thoroughly for 10 minutes to ensure uniform mixing in geometrical ratio.

Excipient used in Dispersible Tablet:

Table 1: Drug can be integrated in fast dissolving tablet

Category	Drugs
Analgeses and anti-inflammatory agents	Piroxicam, thuprofen, keroprofeo, sulindar, phenylburazane, naproxenacid, azapropazone
Antiepileptic's	Carbamazepine, methsuximide, phenytoin, pyrimidine, phenobarbitalbazepirne
Antifungal agents	Clotrimazole, amphotericin, griseofulvin, ketoconazole, miconazole,
Antimalarial	Chlorquine, mefloquine, proquanil, pyrimethamine
Antigout agents	Allopurinol, probenecid, sulphinpyrazone
Anrthypertensive agents	Amlodipine,diltiazem ,valsartan,nifedifin,
Antibacterial agent	Triclosan, triclocarban, and benzalkonium chloride.
Antineoplastic agents	Busulfan, melphalan, cyclophosphamide, dacarbazine, cytarabine, fluorouracil, carboplatin
Diuretics	Aldactone (spironolactone) Bumex (bumetanide) Demadex (torsemide) Esidrix (hydrochlorothiazide) Lasix (furosemide) Zaroxolyn (metolazone)
Antiparkinsonism agents	Carbidopa-levodopa.

Table 2: Available marketed drug product of fast dissolving tablet

Product	Generic	Company
Nimulid MD	Nimedulide	Panacea Biotech , New Delhi , India
Feldene fast melt	Piroxicam	Pfizer Inc. , NY , USA
Zyrof meltab	Rofecoxib	Zydus Cadila , India
Pepcid RPD	Famotidin	Merck and Co. , NJ , USA
Romilast	Montelukast	Ranbaxy Labs Ltd. , New Delhi , India
Torex MT	Rofecoxib	Torrent Pharmaceuticals , India
Zofran ODT	Ondansetron	Glaxo Wellcome , Middlesex , UK
Mosid – MT	Mosapride citrate	Torren pharmaceuticals , India
Febrectol	Paracetamol	Prographarm , Chateaufneuf , France
Zelapar TM	Selengiline	Amarin Corp. , London , UK
Benadryl fast melt	Diphenhydramine	Pfizer

Table 3: Excipients In The Preparation Of Dispersible Tablet

Excipients	Function	example
Diluents	Make required bulk of tablet, improve cohesion , flow compatibility . stability	Lactose , Spray lactose , Mannitol , Dibasic phosphate . dried MCC . Sorbitol , calcium
Binder	Impart cohesive Qualities to powder materials.	Gelatin . lactose , HPMC , Povidone , Sodium alginate , CMC , Acacia . MC , glucose EC starch
Super disintegrant	They facilitate tablet breakingwhen it comes in contact with waterin oral cavity/GIT	Crospovidone , starch . Croscarmellose sodium . SSG , Sucralose Aspartame
Lubricants	Prevent adhesion of tablet material to surface of dies and punches . inter friction . reduces particulate	Insoluble- Steric acid , Magnesium stearate , Tale , Paraffin , Soluble SLS , Sodium benzoate , PEG .
Glidant	Improve flow characteristics of Powder mixture	Colloidal dioxide , Corn Tale etc. Silicon starch
Antiadherent	Prevent adhesion of tablet material to punches and dies .	Talc
Sweeteners	Produce a palatable dosage form Improve taste of	Sucrose , Saccharin , etc. Sucralose , Aspartame
Flavours	Improve taste of dosage form	Peppermint , Orange , Cinnamon , Mango BananaStrawberry , Vanilla , Fruit essence
Colours	These are added for better of dosage form appearance	Sunset yellow (supra)

1. Superdisintegrants: [30]

As ODT require faster disintegration. So, pharmacist needs to formulate Disintegrates i.e.

Superdisintegrants which are effective at low concentration and have greater disintegrating efficiency and they are intra granularly. But have one drawback that it is hygroscopic therefore not used with moisture sensitive drugs. And this super disintegrants act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst. So more effective or the accelerated absorption of water leading to an enormous increase in the

volume of granules to promote disintegration.

Selection of super-disintegrates [29]

The ideal superdisintegrant should have

- Poor solubility.
- Poor gel foration.
- Good hydration capacity.
- Good molding and flow properties
- No tendency to form complexes with thedrugs
- Good mouth feel.
- It should also be compatible with the other
- excipients
- And have desirable tableting properties.

Example	Supper disintigrant	Mechanism of action	Special comment
Crosslinked cellulose	Disintegrants Crosscarmellose” Ac-Di-Sol” PrimelloseVivasol	Swells 4-8 folds in k 10 seconds. Swelling and wicking both	Swelling is in two dimensions. Direct compression or granulation Starch free
Crosslinked PVP	Crosspovidone	Swells 7-12 folds in <30 seconds	Swells in three dimensions and high level serve as sustain release matrix
Crosslinked starch	Sodium starch glycolate	Swells 7-12 folds in <30	Swells in three dimensions

		seconds	and high level serve as sustain release matrix
Cross linked alginic	Alginic acid NF	Rapid swelling in aqueous medium or wicking action	Promote disintegration in both dry or wet granulation
Natural super Disintegrates	polysaccharides Soya	Rapid Dissolving	Does not contain any starch or sugar. Used in nutritional products.

METHOD OF PREPARATION OF DISPERSIBLE TABLETS:

1. Spray drying: Spray drying is one of the oldest forms of drying and one of the few technologies available for the conversion of a liquid, slurry, or low – viscosity paste to a dry solid (free – flowing powder). The spray – drying process is carried out in three fundamental stages. The first stage is: atomization of a liquid feed into fine droplets . In the second stage, spray droplets mix with a heated gas stream and the dried particles are produced by the evaporation of the liquid from the droplets. The final stage involves the separation of the dried powder from the gas stream and collection of these powders in a chamber. The components included supporting agents like non hydrolyzed and hydrolyzed gelatin, a bulking agent like mannitol and a volatilizing agent [10, 11].

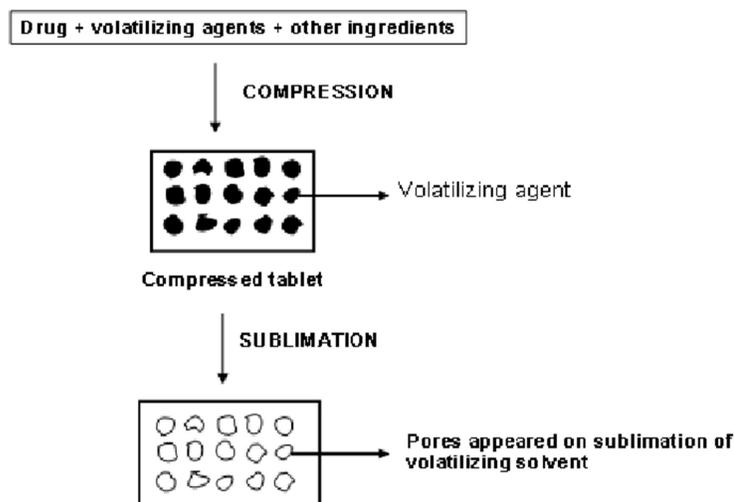
2. lyphilization or freeze drying : It is a process in which solvent is removed from a frozen drug solution or a suspension containing structure forming excipients .

Freeze drying process normally consists of three steps:

- A) Material is frozen to bring it below the eutectic point,
- B) Primary drying to reduce the moisture around 4 % w / w of dry product and
- C) Secondary drying to reduce the bound moisture up to required final volume.

The resulting tablets are usually very light and have highly porous structures that allow rapid dissolution or disintegration. This process may result in a glassy amorphous structure of excipients as well as the drug substance leading to the enhanced dissolution rate [10, 11, 12].

3.Sublimation: In this technique, highly volatile substances like camphor , urea and urethane are added to the blend before compression . When highly volatile substances are compressed, they can be easily removed by sublimation. This improves the dissolution rate as the end product is a porous structure due to the evaporation of the volatile substances [10, 13].



4. Molding: The powder blend is moistened with the solvent and the tablet is molded. This process is called solvent molding. The low compression pressure used results in a porous structure which leads to enhanced dissolution rate; the powder blend is generally passed through a very fine screen. The major drawback of the molded tablets is that they lack the mechanical strength. The molded forms have also been prepared directly from a molten matrix in which the drug is dissolved or dispersed (known as heat molding) or by evaporating the solvent from a drug solution or suspension at ambient pressure (no – vacuum lyophilisation) [10].

5. Cotton candy process: Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed partially

recrystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to dispersible tablets. This process can accommodate high dose of drug and high process temperature limits the use of this process [14, 15].

6. Wet granulation method

The wet granulation method was carried out using two binding agents viz. PVP K – 30 and starch. PVP K – 30 in isopropyl alcohol in different concentrations such as 1 %, 2 %, 3 % and 4 %. The other binding agent starch was used in different concentrations.

7. Granulation method

In dry granulation method all the ingredients were passed through # 60 mesh separately. The drug and the diluents were mixed in small portion of

both each time and blending it to get a uniform mixture and kept aside. The other ingredients were weighed and mixed in geometrical order.

Evaluation parameters: (1)

Pre – compression parameters The pre – compression parameters like

- **Angle of repose :**

$$= \tan^{-1} h / r$$

Where, is angle of repose, h is the height of the pile and r is the radius of the pile .

- **Compressibility Index (Carrs Index) is given by**

$$1 - (1 - V_t / V) \times 100$$

Where,

V_t – tapped volum,

V – Bulk volume

Hausner's ratio is given by:

$$H = D / D_0$$

- **Evaluation of the Compressed Tablet “**

Post compression parameters [16]

All the formulations of Cefixime prepared were evaluated for following physical and chemical parameters.

Size and Shape: The tablets formulated were circular in shape with 12 mm diameter

Organoleptic property:

Colour – the tablets were found I to be uniformly light yellow in colour

Taste -All tablets prepared was tested for taste and odour. It was found that all the

formulations gave sweet taste and pleasant odour.

Weight variation: Twenty dispersible tablets were selected randomly from the lot and weighed individually to check for weight variation. IP limit for weight variation in case of tablets weighing 130-324 mg + 7.5 % and more than 324 mg 5 %.

Hardness: The hardness of the dispersible tablet was determined using a Monsanto hardness tester. It is expressed in Kg / cm²

Thickness: The thickness of the tablets was measured using digital vernier caliper scale. It is expressed in millimeter and was found to be within + 0.2mm

Friability: All dispersible tablets were tested for friability using Roche friabilator

20 tablets were weighed initially and transferred to the friabilator. The Instrument was set at 25rpm for 4min.

The resulting tablets were weighed and the % loss was calculated using

Formula

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Uniformity of dispersion:

All the formulations prepared were tested for uniformity of dispersion. Two tablets were placed in water and stirred gently until a smooth dispersion is

obtained which was passed through a sieve screen with nominal mesh of 710 μ m. All the formulations prepared have complied with uniformity of dispersion.

Disintegration time: The disintegration time for dispersible tablet was determined

in accordance with USP disintegration apparatus. The water was maintained at a temperature of 37.0 \pm 0.5 $^{\circ}$ C and time taken for all the tablets to disintegrate completely was noted.

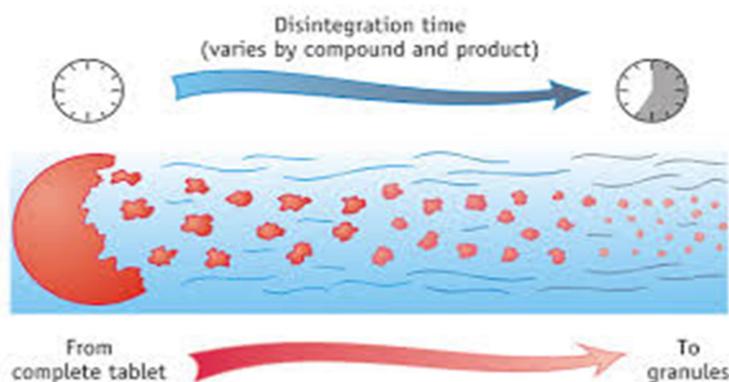


Figure 1: Disintegration time

Wetting time: A method was used to measure wetting time and capillarity of the dispersible tablets. The tablet was placed in a petridish of 5.5 cm in diameter, containing 10 ml of water at room temperature, and the time for complete wetting was recorded. The measurements were carried out six times.

Content Uniformity test: [17]

Ten tablets were used in this test, where each one was crushed and transferred into a 100 ml volumetric flask. The flasks were brought to volume by phosphate buffer pH 6.8. The flasks were placed onto a sonicator till complete dissolution;

1 ml of the solution was filtered through a Millipore filter of 0.45 μ m pore size then introduced into a 25 ml volumetric flask which was completed to volume by phosphate buffer. The absorbance of the solution was measured UV – visible using a spectrophotometer against the blank buffer. The tablets meet the test if the mean drug content lies within the specified range of the labelled potency.

Weight variation test:

20 tablets are selected at random and weighed individually. The average weight of the tablet is then determined. NMT 2 of the individual weights deviates from the average weight by more than the

percentage given in the pharmacopoeia and none deviates by more than twice the percentage [22].

Water absorption ratio: A piece of tissue paper which is folded twice is kept in a petri dish (i.d. – 6.5 cm) containing 6 ml of water and place the tablet on the tissue paper. Observe the time taken for complete wetting of the tablet. Thus, wetted tablet was weighed. Now the water absorption ratio R is calculated using the formula

$$R = 100 \times \frac{W_a - W_b}{W_b}$$

W_b is the weight of the tablet before absorption,

W_a is the weight of the tablet after absorption,

The procedure should be followed for three times (three trial) for each formulation and standard deviation is also calculated from the obtained results [23].

In- vitro Disintegration test:

The disintegration time was measured using disintegration test apparatus. One tablet was placed in each tube of the basket. The basket with the bottom surface made of a stainless steel screen which was immersed in water bath at 37 ± 0.5 °C. The time required for complete disintegration of the tablet in each tube was determined using a stop watch. To be

complied with the Pharmacopocial standards, dispersible tablets must disintegrate within 3 min when examined by the disintegration test for tablets.

Modified Dissolution apparatus for Disintegration time: [18]

Three tablets per batch were evaluated for disintegration time by employing a modified dissolution apparatus. Apparatus. Instead of the disintegration apparatus described in JP XII, a modified dissolution apparatus (JP XII paddle method) was employed. Simulated salivary fluid (900 ml), maintained at 37 ± 0.5 °C was stirred with a paddle at 100 rpm. Disintegration time was recorded when all the fragments of the disintegrated tablet passed through the screen of the basket

In – vitro dispersion test [19]

This test is performed to ensure disintegration of tablets in the salivary fluid, if it is to be used as an orodispersible tablet. In vitro dispersion time was measured by dropping a tablet in a measuring cylinder containing 6ml of simulated salivary fluid of pH 6.8. Five tablets from each formulation were randomly selected and in – vitro dispersion time was performed.

Mechanism of drug release [20, 21]

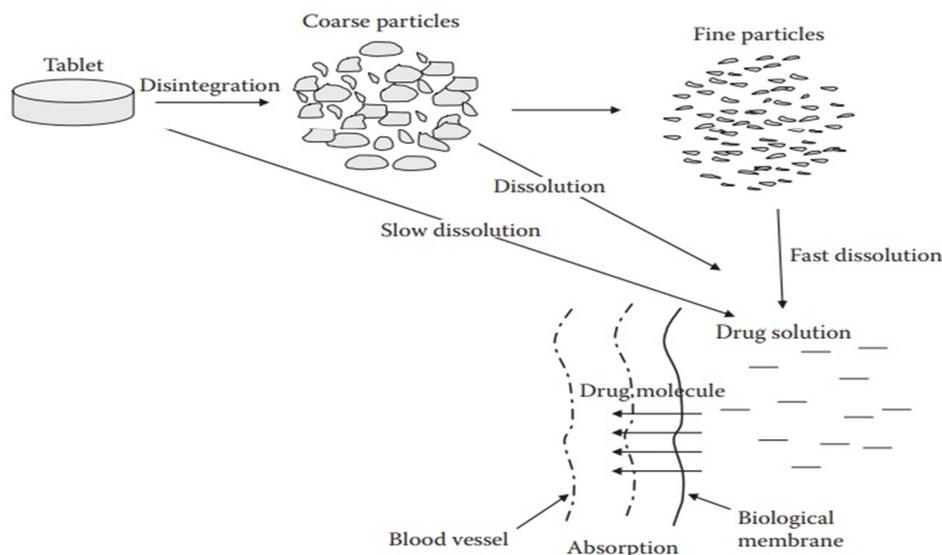


Figure 2: Mechanism of drug release

Disintegration take place when a tablet breaks into fragments when comes in contact with the fluid. This is followed by de-aggregation, disintegration beyond the original granule size into the primary particles. Dissolution occurs more rapidly from primary particles since the available surface area is large, but to a limited extent from the intact tablet, and the aggregates generated during tablet disintegration. The RDT should be disperses or disintegrates in less than three minutes. The fundamental methodology used in development of RDT is the use of superdisintegrants like Carboxy methyl cellulose, Poly vinyl pyrrolidine, sodium starch glycolate.

CONCLUSION

At the present time these tablets are gaining more significance in

pharmaceutical industry directing especially pediatrics, geriatrics and all age groups. Dispersible tablets have potential advantages over conventional dosage forms, with better patient compliance; convenience. Bioavailability and speed of action have attracted the attention of many manufacturers for a decade .The introduction of dispersible dosage forms has solved some of the problems encountered in administration of drugs to the pediatric and elderly patients, which constitutes a large proportion of the world's population.

The number of formulation related factors contributes to the significant amount of non compliance and hence there is a need to design patient – oriented drug delivery system. Dispersible tablets are ideal for many groups of patients.

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