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REVIEW ARTICLE

REVIEW ON MINI TABLETS

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ABSTRACT:
The goal of controlled drug delivery systems is to reduce dosing frequency and increase drug efficacy. Multiple unit dosage forms (MUDF) such as pellets, granules, and minitablets are the most common in oral controlled drug delivery systems compared to single unit dosage forms (SUDF). Because we can control drug release and provide solutions. On current topics in the pharmaceutical industry. Mini tablets have many advantages, including providing accurate dosages and their relative ease of manufacture. No solvents are required for manufacturing, which maintains product stability and provides great flexibility in formulation and development. The mini-tablets are easy to swallow, so children and the elderly will love them. Minitablets are an effective alternative to unit dosage forms. Dose dumping and local irritation can be avoided by using mini-tablets. This review focuses on different aspects of the mini tablet. It can also be filled into capsules like other multiple unit dosage forms. Therefore, it is an excellent alternative to pellets and granules. Within this framework, there have been some major advances recently. This review describes the various benefits of minitablets, types, manufacturing processes, formulation options, and general minitablet evaluation trials.

Keywords: *Multiple unit dosage forms (MUDFs), Single unit dosage forms (SUDFs), Mini-tablets, Pellets.*

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INTRODUCTION:

Among all drug delivery routes, the most convenient and common route of administration is oral drug delivery. The primary goal of any dosage form is to maintain therapeutic levels of drug at target sites with minimal toxicity and side effects by providing loading and maintenance doses. Tablets are the most common solid dosage form, and there are always ways to push the boundaries of tablets, such as: Precise dosing, stability, and controlled release patterns have been achieved in production and use (1-4). Tablets are the most common solid dosage form, and there are always ways to push the boundaries of tablets, such as: B.: But there are also some drawbacks. The expected therapeutic effect or drug concentration at the site of action cannot be achieved due to first-pass metabolism (5-7). A challenge associated with minitablets is the development of a pediatric dosage form (PDF). This is primarily due to differences in children's swallowing abilities, dosage form requirements, and taste preferences (8-9). To date, the most commonly prescribed dosage forms for the pediatric population are liquid dosage forms due to their ease of administration. Liquid dosage forms are the most commonly prescribed dosage form in

pediatrics because they are easy to consume. The excipients, preservatives, and solvents used in PDF also have limitations (10-12). According to a recently published study, minitablets are superior to syrups when administered to children, including infants, using flexible single or combined multi-unit drug delivery devices. Therefore, mini-tablets represent a promising alternative to liquid formulations given to children of different age groups. Traditional solid dosage forms such as tablets and capsules are considered unsuitable because they are difficult for small children to swallow. Due to lack of stability, dose accuracy, and dosing errors, special attention has been paid to the advancement of minitablets to overcome these problems with the aim of improving drug delivery to children. . Minitablets represent a new development in the design of solid dosage forms and can be used as flexible single or multiple drug delivery units. In addition, mini-tablets with well-controlled quality attributes could be a viable option for administering solid dosage forms of low-potency drugs such as capsules and stick packs (13). The difference between full-size compression and mini-tablets lies in the type of tools required. Tablet presses for producing mini-tablets are usually manufactured on standard ram or rotary tablet presses with single or multi-point dies. Certain modifications to the press and tooling may be required depending on your tableting needs. Multi-tip tools must meet specific requirements regarding accuracy and mechanical stability. Mini-tablet tools are easily damaged and should be handled with minimal care (14-15). Excessive force applied to the tool can damage the punch, and the small diameter of the punch makes it prone to deformation and breakage. Multi-tip tools have to meet stricter machining and mechanical stability requirements than larger tray tools. Multi-chip tooling reduces the time required for production.

TYPES OF MINI TABLETS:

Mini tablets can be categorized based on the target site, process of manufacturing, which includes:

1. Bioadhesive mini tablets
2. Gastroretentive mini tablets
3. Paediatric mini tablets
4. Oral disintegrating mini tablets
5. Biphasic mini tablet.

1. Bioadhesive mini tablets:

Bioadhesive mini-tablets are mainly used for vaginal drug delivery to deliver drugs precisely. Over time, the mini-tablet dose is divided into multiple units for even distribution in the vaginal cavity with enhanced exposure at the vaginal epithelium. Bioadhesive mini-tablets work by swelling and forming microgels to release drugs in a controlled manner, thereby enhancing bioavailability (16). The most common problems with using other dosage forms available for vaginal drug administration are creams, ointments, gels, and tablets. This means leaks, confusion, poor patient compliance, and reduced retention times. Bioadhesive or hydrophilic polymers can be used to overcome the above problems. They dissolve and adhere readily when exposed to moisture, and their low concentrations and high viscosities allow them to adhere quickly to surfaces. Solid dosage forms are stable and accurate over time, whereas conventional intravaginal tablets have a very slow disintegration process and are quickly eliminated due to the self-cleaning of the vagina. This can be reduced by using bioadhesive polymers in the formulation (17). Bioadhesive mini-tablets made of hydroxypropyl cellulose and HPMC report adequate mechanical and bioadhesive properties. Vaginal pH varies with the age of the woman. To withstand these pH conditions, bioadhesive vaginal mini-tablets using

nonionic cellulose ethers with bioadhesive properties should be developed (18).

2. Gastro retentive mini tablets:

Gastric-retentive mini-tablets were designed to release drugs in the stomach over a longer period of time. It has to be formulated, and when it comes in contact with food, CO2 is produced, the gas produced is trapped in a swelling hydrocolloid, the tablet floats, and the stomach stays in it. Single-unit tablets have a lower drug load due to the higher polymer used for flotation. For mini-tablets, they can be coated with the gas-generating agents sodium bicarbonate or calcium carbonate, replacing the swellable polymer with a Eudragit coating to increase drug loading efficiency. Fluid bed processors are commonly used to coat mini-tablets (19).

3. Paediatric mini tablets:

There are a variety of dosage forms for children, and the most commonly preferred dosage forms are liquid dosage forms (syrups) and solid dosage forms (tablets and capsules). Liquid dosage forms are easy to administer but have many drawbacks, such as stability and palatability issues (20). Tablets are bulky, difficult to swallow, difficult to titrate, and sometimes have to be split in half to reduce their size, resulting in a loss of activity and currently poor patient compliance. one Another problem Compared to conventional dosage forms, all these problems can be overcome by mini-tablet formulations, potentially resulting in better patient compliance. It is a more convenient and easily accepted dosage form for children than other dosage forms such as syrups, tablets, and capsules (21).

4. Oral disintegrating mini tablets:

Orally disintegrating tablet synonyms are some of the commonly used synonyms such as orodispersible tablet, orally dissolving fast disintegrating tablet, fast disintegrating tablet, fast disintegrating tablet (22). It is also defined as a tablet that dissolves quickly in the mouth before being swallowed. Orodispersible tablets (ODTs) must dissolve in the mouth without additional water, offering the following advantages: Due to its feasibility and convenience, ODT has been statistically proven to have several advantages over conventional tablets for improving patient compliance and acceptance (23). Nearly 50% of the pediatric and geriatric population suffers from difficulty swallowing when taking tablets and hard gelatin capsules, large tablets to overcome these problems. , orally disintegrating tablets, and mini tablets (ODT) have been developed as alternative oral dosage forms. Tablets that disintegrate in the mouth may be preferred even by those who do not suffer from swallowing difficulties. ODT technology has developed rapidly over the past decade. There is a new generation of his ODT that has evolved to overcome the limitations of previous products (24-25). Another reason for ODT's promise is its route of administration, which has so far been oral only. This unique factor allows other companies to obtain approval for generic drugs. The ODT mini-tablet composition includes sodium salicylate, prosolv ODT, and magnesium stearate. Sodium salicylate served as a model drug compound (26). Excipients include microcrystalline cellulose, crospovidone, mannitol, colloidal silicon dioxide, and fructose.

5. Biphasic mini tablet:

Biphasic mini-tablets consist of two parts, a rapid-release part and a sustained-release part. The intent of a biphasic delivery system is to release the drug at two different rates or two different time periods. They are either fast/slow or slow/fast. Fast/sustained release systems provide an initial burst of drug release followed by controlled release over a period of time, while slow/fast release systems provide reverse release. This type is useful for drugs used in high blood pressure that can reduce repeated dosing. Various drugs can be compressed into mini-tablets and filled into the same capsule to treat a variety of ailments (27-28).

ADVANTAGES OF MINI-TABLETS:

a) Easy to make mini-tablets.
b) Regular shape, smooth surface and good size uniformity.
c) Combining the advantages of multiple unit dosage forms with well-known manufacturing techniques in tableting, showing less necking compared to extrusion or spheronization.
d) Mini-tablets are relatively easy to manufacture and represent an alternative to pellets as equal proportion and weight dosage forms with smooth and regular surfaces are produced in a reproducible and continuous manner. (29).
e) It also offers high drug loading, broad release rate design and fine tuning of these release rates.
f) Mini-tablets have a low risk of dose dumping and are highly distributed in the gastrointestinal area, minimizing the risk of high local drug concentrations.
g) Mini-tablets are easier to manufacture due to equal proportions, equal weight, smooth and regular surface compared to pellets.
h) Mini-tablets are excellent coating substrates due to their excellent size uniformity, regular shape and smooth surface.
i) Unlike pellets, mini-tablets do not require solvents for manufacturing. As a result, stability issues can be avoided.
j) Mini-tablets eliminate local side effects and eliminate systemic side effects (30).
k) minimizing drug accumulation and improving therapeutic efficacy with long-term administration.
l) take advantage of superior properties; B. Sustained-release aspirin for morning relief of arthritis by administration before bedtime (31).

MANUFACTURING METHODS FOR MINI TABLETS:

A portion of techniques that can be utilized for the manufacturing of mini tablets are:

1. Direct compression,
2. Dry granulation,
3. Wet granulation,
4. Melt- extrusion.

1. Direct Compression Method:

In the direct compression process, a powder mixture containing excipients and active pharmaceutical ingredients is directly compressed from the powder mixture into mini-tablets. Hardness depends on the degree of direct pressing of the auxiliary material. The powdered mixture flows into a die and the top and bottom punches of the tablet press compress the material under high pressure to produce mini-tablets. In this process, a powder mixture containing active pharmaceutical ingredients, excipients, and lubricants is compressed. This makes the product simple and easy to process, with no other additional processing steps required. The direct compression method is the most commonly used as it is the least time consuming and is the most effective and easiest way to create mini tablets. Less stability issues compared to wet granulation (32).

2. Dry Granulation Method:

The dry granulation process is a logical approach to mini-tablet manufacturing. In these processes, granules are formed by beating. Thermolabile and moisture sensitive pharmaceuticals are suitable for mini-tablet production using this method. In this process, a roller compactor is used as processing equipment. In this process, pre-mixed powders are compressed into mini-tablets under extreme pressure between two counter-rotating rollers (32).

3. Wet Granulation Method:

In wet granulation, active ingredients, diluents and disintegrants are mixed well to form granules, which are further compressed in a compression machine to produce mini-tablets. Various grades of polyvinylpyrrolidine are used as binders in this process (32).

4. Melt-Extrusion Technique:

In the melt extrusion method, the powders (drug + excipients) were premixed. This

premixed powder is then transferred to an extruder for melting. In a melt extruder, parameters such as temperature, screw speed and feed rate are set within the melting point range of the material. After processing, the extrudate is processed and screened. The granules obtained are then compressed into mini-tablets using a compression machine (32).

FORMULATION OF MINI TABLET IN CAPSULE SYSTEMS:

The formulation development of Mini Tablet in Capsule Systems can be classified into three essential stages:

- The formulation/production of mini-tablets,
- Coating of these mini tablets with appropriate coating polymer,
- Filling of coated mini tablets into HPMC or hard gelatine capsules (33) .

MINI TABLETS TO BE ADMINISTER BY SUBSEQUENT METHODS:

Direct management as individual units: Mini-tablets can be administered directly as is. It comes in a bottle that allows you to easily take the amount you need. The previously compressed mini-tablets are further compressed to obtain conventional-sized tablets.

Filling into hard gelatin capsules: Mini-tablets are difficult to handle and are generally administered in hard gelatin capsules (34).

Automatic dosing device: Based on the individualization of the mean dose for the patient population, it is necessary to determine whether the dose is significant. This is because giving the right drug in the wrong dose can lead to side effects and reduced efficacy. Tablets are commonly used, but partial strengths are available for administration. An automatic dose dispenser can be used to dispense the required dose of tablets.

EVALUATION TESTS FOR MINI TABLETS :

1. **Angle of repose:**

Weighed amount of powder mix was taken, allowed to pass through the funnel to form a pile on paper at lower end of the funnel. The height (h) of the pile and distance across of the cone was noted. From the diameter, radius (r) was calculated. The angle of repose (Θ) can calculated by following condition.

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

Where,
h = height of pile
r = radius of base of the pile

2. **Bulk density:**

Bulk volume occupied by the mixed blend is noted using measuring cylinder. Bulk density is determined utilizing following formula Bulk density (35).

(BD) = Mass of the mix / Bulk volume of the mix

3. **Tapped density:**

Tapped density is calculated by weighed amount of powder mix is filled the graduated cylinder, which is then tapped for 500 taps. Tapped density is determined by utilizing following formula Tapped density

(TD) = Mass of mix/ Tapped volume of the mix

4. **Compressibility index:**

Compressibility index indicate the tendency of formulation for binding. It shows the stream properties of the mix. Compressibility index was determined from the readings of bulk and tapped densities(35).

$Compressibility\ index = (TD-BD) \times 100/TD$

Where,
TD = Tapped density
BD = Bulk density

5. **Hausner's ratio:**

Hausner's ratio specifies the stream properties of the powder mix and is estimated by the proportion of tapped density to bulk density.

Hausner's ratio = Tapped density/Bulk density

6. FTIR studies:

IR spectra for pure drug and mini tablets formulations were verified in a Fourier transform infrared (FTIR) spectrophotometer (35).

7. DSC studies:

A differential scanning calorimetry (DSC) study was performed on the pure drug formulation and the optimal mini-tablet formulation. Perforated and sealed aluminum pans were used for all samples for analysis. Temperature calibration was implemented using indium as the standard. An empty pan sealed in a manner similar to that used for the samples was used as a reference. All samples were run from 50 to 3000 °C with a scan rate of 100 °C/min (35).

Table 1: MARKETED PREPARATIONS:

Sr. No	Brand Name	Drug Name	Indication	Manufacturer	Dosage Form	uses
1	Aricept	Donepazail hcl	Alzheimers /Dementia	Eisai	Mini-Tablets	To treat mild,moderate and severe alzemiers disease
2	Alesse	Levonorergosterol and ethinyl estradiol	Contraceptive	Wyeth-Ayerst	Mini-tablets	For birth control
3	Accolate	Zafirlukast	Asthma	AstraZeneca	Mini-Tablets	Control the symptoms of asthma
4	Coumadin	Warfarin sodium	Anticoagulant	Bristol-Myers Squibb	Mini-Tablets	Treating blood clots and prevents formation of new clots
5	Exalgo	Hydomorphone Hcl	Moderate to severe pain	Mallinckrodt Inc	Mini-Tablets	To treat moderate to severe pain
6	Effient	Prasugrel tablets	Prevent blood clotting	Activz Livesciences India Pvt Ltd	Mini-Tablets	Preventing platelets from clumping together into blood clots
7	Razadyne ER	Galantamine HBr	Alzemiar	Johnson and Johnson	Mini-Tablets	To treat mild to moderate confusion related to Alzheimer disease
8	Treximet	Sumatriptan and Naproxen Sod.	Migraine	GSK	Mini-Tablets	To treat acute migrain headache with or without aura in patients 12 years of age and older

9	Trilipix	Fenofibric Acid	Reduce abnormal blood lipid level	AbbViel FiercePharma	Mini-Tablets	To treat cholesterol in the body by lowering the total amount of triglycerides and LDL cholesterol and increasing the HDL cholesterol
10	Zyprexa	Olanzapine	Schizophrenia	Eli Lilly and Co.	Mini-Tablets	To treat schizophrenia
11	Lamisil	Terbinafina Hcl	Antifungal	Novartis	Capsule	Indicates the treatment of ringworm
12	Orifiril long	Sodium valproate	Epilepsy	Desitin	Capsule	Treatment of generalized forms of epilepsy
13	Pankeratan	Pancreatin	Pancreatic insufficiency	Novaritis	Capsule	_
14	Enzyme-Lefax	Pancreatin	Indigestion	Bayer	Capsule	Relief symptoms of osteoarthritis of the hip or knee
15	Rythmol SR	Propafenone HCL	Antiarrhythmic	GSK	Capsule	Help prevents certain types of serious irregular heartbeat
16	Ultresa	Pancrelipase	Pancreatic insufficiency	APTALIS PharmaUS	Capsule	Muscle ache, backpain, joint pain, menstrual cramps and toothache
17	Zontivity	Vorpaxar tablet	Antiplatelet agent	Sun Pharmaceutical	Capsule	Prevent complication from blood clots.

CONCLUSION:

From this overview, we can conclude that pharmaceutical mini-tablets offer many advantages over unit dosage forms. Minitablets can be processed into tablets, filled into capsules, or used as sachets, so they are advantageous in terms of both ease of production and cost, and are also an excellent alternative to granules and pellets. They have well-defined size, shape, surface, low porosity and high mechanical strength. By combining different mini-tablets, it is possible to administer drugs that cannot be used together or to effectively treat concomitant diseases. Especially in geriatric and pediatric patient groups, the chances of successful treatment are very high. Ultimately, mini-tablets improve overall treatment outcomes, patient compliance, and convenience. Because of their great advantages, they can be prescribed along with most available and appropriate medications. Studies have shown that minitablets adapt to a variety of modified release patterns, including: B. Prolongation,

delay, pulsatile, bimodal release, and colon targeting. Therefore, mini-tablet development has become an interesting research topic for oral controlled solid dosage forms.

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