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Technological Approaches and Quality Assessment of Mini-Tablets: A Review

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ABSTRACT

The mini-tablets are a new solid oral dosage form, which is supposed to fulfill the emerging requirements of personalized drugs, particularly in the pediatric and geriatric patient groups. Mini-tablets can be characterized as a smooth tablet with a diameter of up to 3 mm; thus, it presents various benefits, such as excellent swallowability, flexibility in the dosing range, and excellent patient adherence. They may be manufactured to conventional processes, direct compression, dry and wet granulation with adaptations to suit their small size and low dose content. Mini- tablets may be prepared as immediate, sustained or pulsatile release systems, or formulated as biphasic release systems. They can also be coated to mask bitter tastes or deliver drugs specifically to various locations. They are used also in bioadhesive systems and floating and orally disintegrating formulations. Improved 3D printing and smart dispensing technologies also allow patient-specific dosing, digital health platform cross-over, and increased therapeutic success. The technological advancement of packaging like a stick pack, blister pack, capsule filling aids in maintaining a hygienic and precise dispensing. Nevertheless, issues like low drug payload, excellent production tolerance, and new, complicated packaging specifications shall have to be resolved. Nevertheless, despite these challenges, mini-tablets are a potentially valuable platform to deliver an individualized, safe, and efficient drug, a very positive step in the sphere of modern pharmaceutics.

INTRODUCTION

Medicines are often present as solid dosage form mainly tablets. Tablets are often manufactured at large industrial scale with high productivity and reproducibility. The efficacy of the solid dosage form has led to the lower prices and greater access to medicines for the world's Population. Solid dosage forms are nowadays manufactured using conventional unit operation practices which has limited dose flexibility, which has to be further addressed to fulfil the growing demand for personalized therapy (1,2). This personalized therapy aims at a higher individualized therapy specifically altered to the needs and requirement of the individual patients; these includes the factor such as age, weight, height, race, gender and diseased state are precisely tailored for the oral delivery form to produce oral delivery system. In order to produce the pediatrics patient with the dosage requirement is to prepare an oral liquid suspension or the dividing the tablets (3,4). Due the physiological factors stability, drug solubility issues and liquid oral dosage forms are very limited but the dividable tablets have much difficulties in breaking, inaccuracy in dosing and loss of drug loaded mass (5). Later due to these difficulties a number of new technologies has emerged for improving the dose flexibility and ease of swallowing -these includes films, multi-particulates, chewable and mini- tablets. In such cases, it is reasonable to develop a new design to pediatric formulation such as solid formulation such as 'mini compartments' like mini-tablets and pellets (6,7). These mini-tablets easily allow appropriate dosage form for abroad age range of children based on the multiplication of dosage form. Mini-tablets are small sized solid tablets which has a diameter equal or smaller Than 3mm. Studies have shown that the mini-tablets are quite effective and easily swallowable from the age of 6 months (8). Under several trails, it is found that the preschool ages children have the acceptability and swallowability of mini-tablets as a solid dosage form (9,10). The modified release formulation can be designed in single or multiple dosage forms. The single dose form consists of an active pharmaceutical ingredient within a single tablet or a capsule. In multiple dosage form comprises of multiple discrete particles

which are combined into single dosage unit. These can exist in the form of pellets, granules, sugar seeds and mini-tablets. This is apparently used in sustained release single unit dosage form (11-13). Mini-tablets are produced on conventional tablet pressed equipment with multiple tooling with the production of tablets under the diameter of <3mm. Mini-tablet's production process is same as that of the production of standard tablet but requires excellent flow properties due to the small dies and exact control process of the formulation's parameters and special caution during tablet press assembly in order to avoid tool damage (14,15). Mini-tablets are mainly developed in order to improve personalized medicines as they offer to improve swallowing and flexible dosing and active components in one system (16).

Table 1: Comparative Analysis of Minitablets, Pellets, and Tablets.

Parameter	Minitablets	Pellets	Tablets
Definition	Conventional tablet form having diameter1- 4 mm.	They are small beads like structure which are filled inside the capsule.	A compressed solid dosage form containing medicament with or without excipients.
Solvent	Doesn't require any solvent for the preparation which overcome stability.	They require solvent for the preparation.	They don't require solvent for the preparation.
Process	Conventional compression method	Fluidized bed dryer extrusion required.	Tablets manufacturing involves several steps including compression, coating, blending, blending and compressed into tablets.
Physical characterization	They possess same size, shape and uniformity.	Spherical in size and non-uniform in nature.	They possess same size, shape, colour and uniform in nature.
Coating	Perforatedpan coated.	Coating is done with wuster coating	Tablet coating is commonly done through the process of sugar coating and film coating.
Packing	Easily be packed into capsule sachets.	Dispersed into the capsules.	Tablet are typically packed using blister packing and bottle packing.

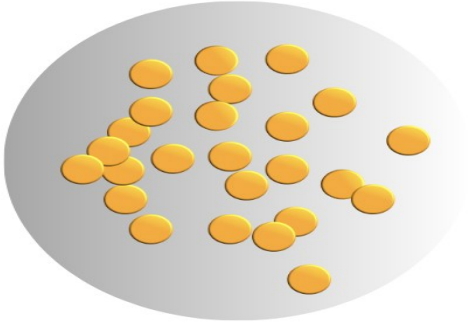

Fig1: Minitablet

Materials & Methods:

Chemicals (Materials):

Xylitol, PVP K30, magnesium stearate, croscarmellose, drug (API), and Aerosol were the ingredients and chemicals employed in the formulation of the minitablets (17).

Pre-formulation study:

Pre-formulation investigations including differential scanning calorimetry (DSC), Fourier transform infrared spectroscopy, and melting point determination were carried out for Minitablets (17).

Melting point:

A small sample of the API was put in a capillary tube with one end closed and it was then put in Thiele's melting point apparatus to find the API's melting point (17).

Drug-Excipient Compatibility study:

Carefully choosing the excipients is essential to the successful formulation of an appropriate and efficient solid dosage form. To aid in administration and encourage steady drug release and absorption, excipients are added. Researching how well excipients work with the medication is essential (17).

To look into and forecast any physicochemical interactions between the formulations' constituent parts and choose appropriately suitable excipients, the melting point, thermal analysis, and FTIR spectroscopy were employed (17).

Fourier transform infrared spectroscopy:

Potassium bromide powder was combined with the drug sample. After applying dried KBr for the base line correction of the FTIR(4100Jasco), the powder was placed in the light path and the sample was scanned throughout the 4000–400 cm range to capture the spectra of a dried mixture of the drug and KBr (17).

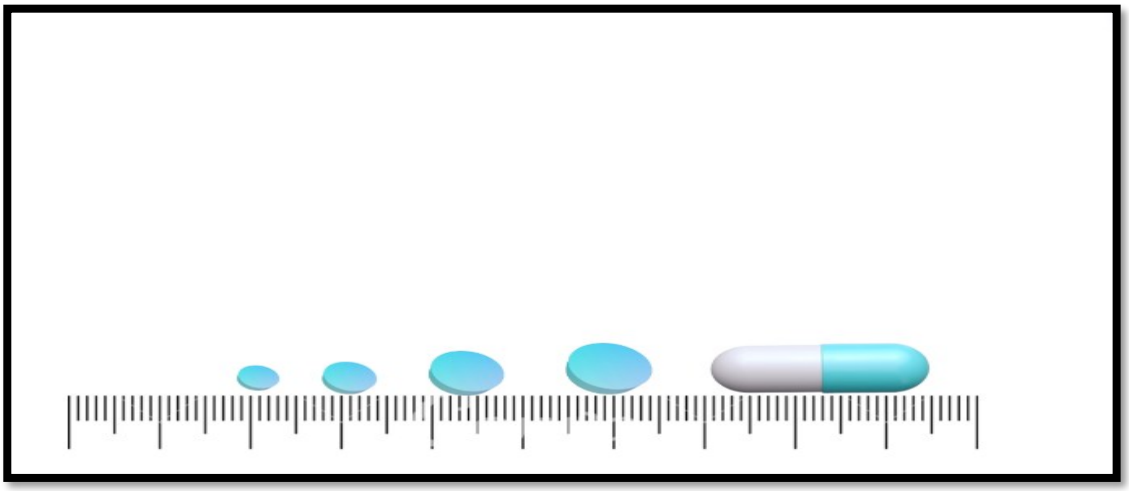

Fig 2: Various sizes of minitablets

Methods Of Manufacturing Mini-Tablets:

Some the methods that can be used for the preparation of minitablets include:

Dry Granulation, Wet Granulation, Direct Compression.

Dry Granulation:

This is the method of preferred for producing drug MTs with moisture sensitivity and thermolabile properties. Compression machines are utilized in conjunction with instruments such as roller compactors and chilsonators. Premixed powder is formed into athinribbonor sheet by passing it between rollers that rotate counter to one another. This fragile sheet is reduced to a precise size to create granules, which are then compressed into tablets using a compression machine (18,19).

Wet Granulation:

In the pharmaceutical industry, this is the granulation method that is most frequently utilized. Using this method, a moist dough mass is formed by adding a binder solution. The wet powder particles are bound together by the added liquid through a combination of capillary and viscous forces. After passing through a filter once again to create granules, it is dried. Agglomerates are created when drying causes more robust bonding to occur. Afterwards, a traditional compression machine is used to finally compress the granules into the tablet (20,21).

Direct Compression:

The practice of compressing tablets straight from a blend (powder) that contains the active pharmaceutical ingredient (API) and appropriate or compatible excipients is known as direct compression. To achieve the necessary hardness in the tablet, direct compression uses components that are of compression grade, or immediately compressible. When comparing tablets made by wet granulation process to tablets made by direct compression, stability-related problems are far less common (21,22).

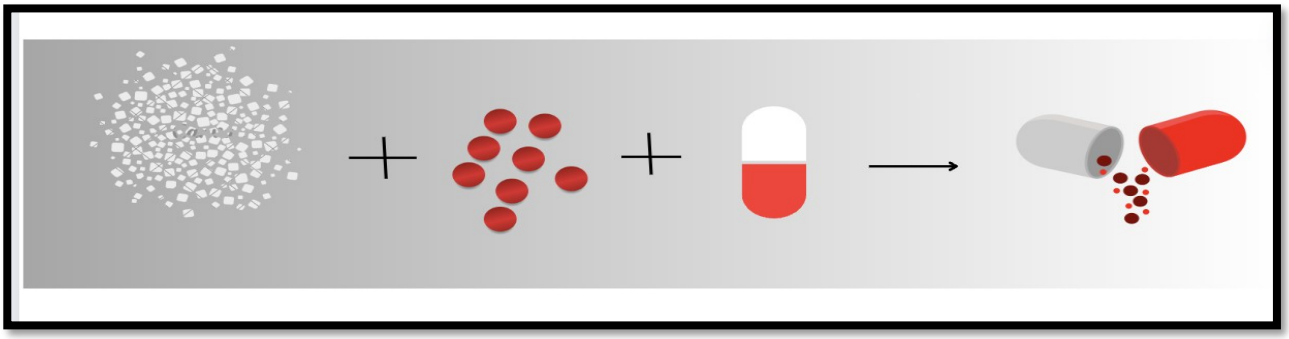

Fig 2: Method of preparing minitablet

Evaluation of Minitablets:

Friability:

Ten mini tablets from each formulation were precisely weighed and Putina friabilator drum that revolved at 25 rpm for four minutes. Next, the tablets were meticulously cleaned and weighed again. Friability was determined by calculating the % loss in weights (23).

Weight variation:

Ten mini tablets from each formulation were chosen atr and om and weighed in order to determine the mean weight (23).

Thickness:

A micrometer was used to measure the thickness of the mini tablets, and the mean thickness of 10 minitablets from each formulation was computed (23).

Swelling studies:

At room temperature, gravimetric analysis was used to examine the swelling index or water intake. The weighed minitablets were placed on top of a filter paper that was submerged in simulated lacrimal fluid within a Petri dish. The weight of the wet, swollen minitablet was measured using a digital balance at 15,30,60,120,180,240, and 300minutes until the weight of the minitablet did not increase. Minitablet surfaces with extra simulated lacrimal fluid were carefully absorbed using filter paper. The formula was used to compute the swelling index.

$$Swelling\ Index(\%) = \frac{\text{final weight - Initial weight}}{\text{Initial weight}} \times 100$$

In addition, the area under the mean swelling index curve from 0 to 300 minutes (AUCSI0-300) was calculated using the linear trapezoidal method and used to compare the swelling qualities derived from the formulations under study. The mean swelling index was plotted against time in minutes (23).

Tablet Strength (Hardness):

Using a Texture Analyzer, a total of twenty mini-tablets that were chosen at random were tested to determine the maximum force required to shatter the tablet (23).

Content Uniformity:

Ten tablets total, chosen at random, were finely ground and dissolved in ten milliliters of methanol. After shaking the contents of the flask continuously, 3mL of filtered samples were taken out

and subjected to spectrophotometric analysis at a wavelength of 362 nm using a spectrophotometer. The calibration curve of AB in methanol (linearity in the range of 20–160g/mL,R2=0.9985) was used to determine the AB content. Microsoft Excel was used for both data gathering and analysis. The studies were carried out in triplicate (23).

Dissolution Studies:

Three dissolution investigations (n = 3) using ten mini-tablets as the sample size each were carried out in a basket apparatus. 900 mL of pH 6.0 phosphate buffer, tempered at 37± 0.5 ºC, was selected as the dissolving media. This medium was used to replicate the oral cavity medium for the dissolving investigations of the film-coated mini-tablets, which were intended to mask flavor, as it is suggested in Ph. Eur. 2.9.25 for the dissolution test for medicated chewing gums. Sampling was done by hand while the baskets were rotating at a speed of 60 to 65 rpm. After centrifuging the samples, the assay for content uniformity was used to analyze them using HPLC (24,25).

Applications of minitablets:

Pediatrics:

Pediatrics comprehends the mental health, physical health and overall wellness of the children. The pediatric care involves the medicinal heed of infants, children and young adults under the age of18.most of the pediatrics include liquid and solid dosage forms which are pre eminent in acceptability and ease of administration (26-30). Syrups are versatile liquid preparations with the advantage of dose alteration and swallowability which is being used worldwide held for oral administration apart from these syrups considered to have the stability issues and also does not prefer for controlled release (31,32). Tablets are one of the most commonly used dosage forms administered by all the age group people but has the disadvantage of swallowing in respect to size and shape od the tablet (33,34). In contrary to this the evolution of minitablets assess with number of advantages which overcomes all the limitations of oral dosage forms such as easy administration respective of size and shapes compared to tablets, swallowability, acceptability of dose, palatability, effective therapy against various diseases such as, candidiasis, viral infections, respiratory issues such as acute respiratory infections and also neurological disorders (35-38).

Oral disintegrating minitablets:

Oral disintegrating mini tablets or odmts are then ovel drug dosage forms which can be disintegrated in the mouth within seconds to improve the patient compliance including pediatrics and geriatrics (39,40). The novelistic design in odmt overcomes the limitations of conventional tablets in size ≤4mm and definite shapes. The various synonyms of odmt include
fast disintegrating, rapidly disintegrating, fast dissolving, rapid dissolving fast melting and Oro dispersible tablets (17,20,41).

An ideal characteristic of odmt:

An orally dispensable mini tablet (ODMT) is expected to have a few important features to be efficient and able to support patient adherence. It ought to be able to pass through the oral mucosa easily so as to enable its fast absorption and action. The encompassing should allow improved dispersing and diffusion in the oral cavity. The active pharmaceutical ingredient (API) must preferably be 50 mg or below to get the best mucosal uptake. To increase the acceptability of the ODMT particularly in pediatric and geriatric subsets, it should possess an agreeable and acceptable smell and taste. In some applications, shorter half-life of the drug may be desired to permit controlled frequent dosing. To increase shelf life and efficacy, formulation should be very stable in an assortment of conditions. Also, it ought to be compatible with chosen excipients and pack national materials in order to provide integrity and effectiveness. Finally, ODMTs must be cost-effective to produce and have them available so that they could be manufactured in large quantities and made accessible (42).

S.NO	Brand name	Generic name	Drug classes
1	Ambien	Zolpidem	Non benzodiazepine hypnotics.
2	Benadryl fast melt	Diphenhydramine	Antihistamines
3	Claritine	Loratadine	Antihistamines (second generation)
4	Furosemide	Furosemide	Loop diuretics
5	Imodium	Loperamide hydrochloride	Antidiarrheal agent
6	Nurofen	Ibuprofen	NSAIDS
7	Pepcid rpd	Famotidine	Histamineh2blockers
8	Ratio pharm	Ondansetron	Serotonin5ht receptor Antagonists
9	Prev acid	Lansoprazole	Proton pump inhibitors
10	Risperdal	Risperidone	Antipsychotic
11	Romi last	Montelukast	Leukotriene receptor Antagonists

Table 2: List of orally disintegrating mini-tablets

Floating Mini tablets For Git Systems:

Floating dosage forms is one of the novel drug delivery systems. In this system which the API or active ingredient gets encapsulated into the swellable polymer (43). It was introduced due to the prolonged release and sustained release in the git despite local ph in the stomach, gastric contents, poor bioavailability by increasing the gastric retention time or gastric residence time. Compared to conventional oral dosage forms this as longer gastric retention time thereby producing sustained release (44,45). The floating systems work by constant buoyancy motion because of the incorporation of gas liberating agents such as co2 into the formulation. When comes in contact with the surface Gi fluid the polymer starts swelling causing decrease in the density lesser than Gi contents produces targeted sustained drug release (46).

Extended release:

In extended-release formulations, the active ingredient in the drug produces long term term effect continuously and results in sustained drug release. This can be achieved by matrix systems and osmotic system (47,48).

Pulsatile release: (pdds)

Pulsatile drug release system is a time dependent drug delivery system works by releasing the api according to the circadian rhythm or physiological conditions (49-52). Pulsatile drug releases the drug very rapidly at the predetermined time i.e. Lag time it plays a major role in chrono therapeutics in treating asthma, copd, peptic ulcer, cardiac diseases, hypertension, diabetes mellites etc. And also improves the patient compliance by reducing the dosing frequency and side effects (53,54).

Bio adhesive minitablets:

The polymers such as polyacrylic acid, carbapol etc. can be used as bio adhesive polymers. These polymers usually work by adhesion forces such that they may stick to the surface of the mucosal layer or moisture content (vaginal mucosa) and provide their action for a prolonged period of time (55,56). In consideration with vaginal allergies or infections the conventional dosage forms are widely prescribed but has large no. of limitations including decreased patient compliance because of dosing frequency, side effects, irritations, etc. The introduction of

minitablets can be very useful in the advancement of the therapy by manufacturing the mini tablets coated by bio adhesive polymers for the controlled release (57-60).

Biphasic minitablets:

Biphasic drug delivery system involves two mechanisms one is slow releasing the other one is fast releasing (61-63). It works by slow/quick action or vice versa which means the faster leasing portion will be released first and then the other portion releases very slowly producing controlled release at the target site it is mostly used in the treatment of hypertension (64-68).

Table 3: Commercially available mini tablets.

Name of the drug	Brand name	Manufacturer	Indications	Application	Reference
Donepezil hydrochloride	Aricept	Eisai	Alzheimer's' Disease	Uses to treat memory Loss and confusion	(69)
Levonorgestrel or ethinyl estradiol	Alessi	Wyeth- Ayerst	contraceptive s	Treatment of menopausal symptoms, gynecological disorders and some cancers that were hormone sensitive	(70)
Galantamine hydrobromide	Raza dyne ER	Johnson and Johnson	Alzheimer	Used to treat mild to moderate Alzheimer's treated confused behavior	(71)
Warfarin sodium	coumadin	Bristol- Myers Squibb	Anticoagulant	Used intreating blood Clotting and disrupting their growth	(72)
Hydromorphone HCL	Exalgo	Mallinckrodt Inc	Moderate to severe pain	Used in relieving pain in opioid tolerant patients	(73)
Sumatriptan and naproxen sod	Treximent	Gsk	Migraine	Used to treat acute migraine in adult	(74,75)
olanzapine	Zyprexa	Eli Lilly and co a	schizophrenia	Used in treatment of distinct mental/emotional disorders such as bipolar disorder and schizophrenia in addition to this prevents depression And hallucinations.	(76)
Feno fibric acid	Trilipix	Abbviel fierce pharma	Lipid regulating agent	Used to treat severe hypertriglyceridemia and primary hypercholesterolemia, dyslipidemia	(77)
zafirlukast	Accolate	AstraZeneca	Asthma	Used to prevent respiratory diseases and to cure the symptoms Of asthma allergic rhinitis etc.	(78)
Prasugrel	Effient	Activez live sciences Indiapvtltd	Blood clotting	Prevents the platelet adherence and to treat acute coronary syndrome undergoing percutaneous coronary intervention and Prevent strokes.	(79,80)
Vorapaxar	zontivity	Sun pharma	Antiplatelet agent	Inhibits the platelet aggregation which can be used for reducing the possibility of cardiovascular thrombotic condition in patients with myocardial infarction and peripheral vascular diseases	(81)
pancrelipase	ultresa	Aptalis pharmaus	Exocrine pancreatic insuffiency	Helps in food digestion with chronic pancreatitis and cystic fibrosis	(82)
pancreatin	pan keratan	Novartis	Pancreatic insuffiency	Used to treat pancreatic exocrine insufficiency.	(83)
pancreatin	Lefax	Bayer	Dyspepsia	used in treatment of hyperacidity, and assess in proper digestion and proficient absorption of nutrition.	(84)
Terbinafine hydrochloride	Lamisil	Novartis	Antifungals	Used widely in treatment of fungal skin infections like athletes foot , jock itch and ringworm	(85)

Sodium valproate	Orifiril Long	desitin	Epilepsy	Bipolar disorder and mania	(86)
Propafenone hydrochloride	Rhythma l Sr	Gsk	Anti arrhythmic	Control of Supraventricular and ventricular arrhythmias.	(87,88)

Packaging Systems for Minitablets:

Minitablets, due to their small size and unit-dose nature, require specialized packaging solutions that ensure dose accuracy, stability, and patient safety (89,90). Common packaging options include bottles, stick packs, sachets, blister packs, and capsules (91-93). Stick packs and sachets are widely used in pediatric care, allowing pre-measured unit doses, improving compliance, and minimizing contamination risks (94). Blister packs, while effective for moisture protection and dose tracking, often require adapted equipment due to the small tablet size (95). Capsule filling enables combination therapy and fixed dosing (96,97). These systems aim to support product integrity and ease of administration across diverse patient populations, particularly children and the elderly (98-100).

Dispensing Innovations and Challenges:

Innovative dispensing systems, such as integrated multi-dose dispensers (e.g., Philips-Medisize), allow users to accurately dispense a preset number of minitablets without handling, thereby improving hygiene and dose consistency. These systems are particularly beneficial in personalized medicine, enabling flexible, error-free dosing. Emerging technologies like smart electronic dispensers are being explored to track adherence and connect patients to digital health platforms. Despite these advancements, challenges remain in achieving high counting precision, child resistance, and compatibility with existing pharmaceutical machinery. Effective design of dispensing systems enhances usability and supports regulatory and therapeutic goals.

Future Trends and Innovations in Minitablets

1. 3D Printing and Personalized Drug Delivery

Advances in 3D printing, particularly fused deposition modeling (FDM) and inkjet printing, are revolutionizing minitablet production. These technologies enable precise control over tablet geometry, size, and active pharmaceutical ingredient (API) distribution for tailored therapeutic regimens. 3D printing allows for patient-specific dosages, enabling on-demand production of minitablets with individualized release profiles. This flexibility is valuable for pediatric, geriatric, and rare disease therapies, where conventional dosage forms fall short. Notable successes include personalized hydrocortisone minitablets for children, designed with either immediate or sustained release, demonstrating the feasibility and promise of digitally manufactured minitablets.

2. Smart Dispensing and Digital Health Integration

The integration of smart dispensing technologies addresses adherence, safety, and accuracy in minitablet delivery. Electronic dispensers, often Bluetooth-enabled or linked to smartphone applications, provide scheduled dosing reminders, real-time adherence tracking, and automated dose adjustments tailored to the patient. These systems simplify complex regimens, reduce user errors, and transmit usage data to caregivers and clinicians. By embedding sensors and digital connectivity, manufacturers pave the way for interconnected healthcare, bridging the gap between medication delivery and digital health management platforms.

3. Modular and Multi-Unit Tablet Systems

Modular minitablet systems enable combination therapies with precisely controlled immediate, delayed, or pulsatile drug release profiles in a single administration. By blending minitablets containing different drugs and release characteristics, clinicians can tailor therapies for complex, chronic, or multi-morbidity cases. This approach also reduces the risk of dose dumping and improves therapeutic outcomes, offering a significant advancement over single-unit conventional tablets.

4. Automation, Robotics, and Sustainable Manufacturing

Automated manufacturing using robotics is enhancing the scalability, precision, and efficiency of minitablet production. High-speed rotary presses with multi-tip tooling, automated counting systems, and machine vision inspection minimize defects and ensure consistent quality. Innovations extend to the use of greener excipients and eco-friendly packaging, addressing both environmental sustainability and regulatory requirements.

5. Regulatory, Clinical, and Market Evolution

Pharmaceutical regulatory agencies, such as the EMA and FDA, are evolving their guidance to foster innovation in age-appropriate and personalized dosage forms. Clinical trials increasingly support the safety, acceptability, and efficacy of minitablets, driving their adoption in commercial markets. As these trends converge, minitablets are expanding rapidly in use for pediatrics, geriatrics, and chronic-disease management, reinforcing the movement toward individualized, patient-centric therapies.

Challenges And Limitations of Minitablets

Despite their considerable advantages, minitablets present several challenges and limitations that must be addressed for broader clinical and commercial adoption. One major constraint is their limited drug loading capacity; due to their small size—typically 2–3mm in diameter—minitablets can only contain a minimal amount of active pharmaceutical ingredient. As a result, achieving therapeutic doses for drugs requiring high quantities often necessitates the administration of multiple minitablets per dose, which can affect patient compliance and add complexity to treatment regimens.

Additionally, the production of minitablets demands exceptionally high manufacturing precision. The consistency of both size and weight across each mini-unit is crucial, as even minimal deviations can lead to dosing inaccuracies. This requirement for precision translates into stringent quality control measures and frequently calls for advanced or specialized manufacturing equipment, escalating operational and capital costs compared to conventional tablets.

Packaging presents another significant challenge, especially for home-based dispensing. The accuracy of dispensing multiple minitablets, along with the necessity to minimize handling and ensure child resistance, complicates packaging design. Solutions such as integrated dispensers, stick packs, or specialized blister packs help address these issues, but often involve complex machinery or new material requirements, adding further to production costs and logistical considerations. Collectively, these limitations highlight the need for continued investment in formulation science, process optimization, and smart packaging innovations to fully realize the potential of minitablets in personalized and widespread therapy.

CONCLUSION

Mini-tablets have emerged as a promising solid oral dosage form that bridges the gap between patient-specific therapy and large-scale pharmaceutical manufacturing. With their small size (≤3 mm), they offer enhanced dose flexibility, improved swallowability, and high patient acceptability, particularly in pediatric and geriatric populations. Unlike conventional tablets or liquid formulations, mini-tablets can be accurately dosed, easily coated, and efficiently packed, while also minimizing issues related to drug stability and dosing errors. Advances in 3D printing technologies have further enabled precise customization of mini-tablets with tailored release profiles, supporting personalized medicine initiatives. Additionally, innovative packaging and dispensing systems enhance usability and adherence by enabling hygienic, accurate, and automated dosing. Despite ongoing challenges in manufacturing precision and regulatory adaptation, mini-tablets hold immense potential for sustained drug delivery, chrono-therapeutic systems, and complex combination therapies, making them a key advancement in modern drug delivery strategies.

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Conflict of interest:

The authors declare no conflict of interest.

Author Contributions:

Vetrivel R contributed to the literature review, data curation, writing of the original draft, and evaluation. Saraswathi T.S contributed to conceptualizing it and conducting the critical evaluation. Damodharan Narayanasamy provided guidance and reviewed the manuscript

Declaration of generative AI and AI assisted writing tools:

For manuscript preparation, the authors utilized Quillbot Premium and Grammarly to enhance the clarity readability. The authors have also used Biorender for the preparation of images. The final version of the manuscript has been properly checked, verified and approved by all the authors.

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