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Innovations in Orally Disintegrating Tablets Technology: Formulation Principles, Taste Masking Mechanisms, and Biopharmaceutical Considerations

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Abstract

Orally disintegrating tablets (ODTs) have become a key patient centric oral dosage form that is designed to dissolve quickly in the mouth without the need of water, which aids in improving oral adherence (in pediatric, geriatric, dysphagic and other special care patients). This review looks at a broad review of how ODT technology has evolved over the decades, from early lyophilized and moulded systems to modern robust systems that make use of direct compression, particle engineering and additive manufacturing techniques. The discussion focuses on key formulation principles such as critical quality attributes, excipient functionality and process considerations including a special emphasis on achieving the best balance between fast rate of disintegration, mechanical strength and palatability. Advanced taste masking approaches, including microencapsulation, hot melt coating, cyclodextrin inclusion complexes, nanotechnology based systems and 3D printing based designs are critically reviewed to explain the efficacy and limitations of the taste masking methods. Furthermore, biopharmaceutical aspects of saliva mediated drug release, kinetics of absorption, solubility permeability issues, lack of dependence on food and water intake, and biopharmaceutical regulatory are highlighted to offer a holistic view. Emerging innovations of personalized and precision oral drug delivery such as 3D printing, smart ODTs and multifunctional excipients are driving the future of personalized and precision oral drug

delivery, with new developments and possibilities for customized therapeutic regimens. In summary, ODT technology is evolving as a versatile and clinically relevant technology that fills therapeutic and patient needs that are lacking.

Keywords: Orally disintegrating tablets; Formulation of taste masking; Patient centered drug delivery; Biopharmaceutical considerations of taste masking; 3D printing

Introduction

Orally disintegrating tablets (ODTs) form one of the most significant patient centric solid oral dosage form developments that allow fast disintegration of a tablet in the oral cavity without access to water. Evolving since their commercial debut in the late 1980s, ODTs have grown rampant with the increased demand for convenient, palatable and easily administered formulations. This exigency is particularly strong for pediatric, geriatric, dysphagic, psychiatric, and traveling patient cohorts for whom conventional tablet swallowing is very difficult. Early ODTs were mostly based on lyophilized, highly porous matrices with the design that their dissolution occurs in a few seconds, although they were the origin of the fast dissolved technologies, their use was limited due to the low mechanical strength, the poor drug loading, and the high manufacturing cost [1].

The technological course of ODTs grew significantly when techniques for direct compression were developed or novel functional excipients became available. Co processed excipients that are designed specifically to rapidly disintegrate, are more easily compressed and have improved mouthfeel enabled the scalable cost effective ODT production. As a result, safety has shifted from wafer like structures that were easily damaged to stronger, mechanically stable, palatable and patient acceptable tablets. The addition of super disintegrants, matrix forming agents, taste masking polymers and multifunctional excipients further refined the formulation possibilities and made it possible to use a wider range of active pharmaceutical ingredients (APIs) such as those being poorly soluble or have a pronounced bitterness.

Contemporary ODT technology is still advancing fast and is led by advancements in particle engineering, nanotechnology, polymer science and additive manufacturing. Breakthrough innovations like 3D printed ODTs, nano enabled drug carriers and hybrid taste masking systems allow for unprecedented tablet structure, disintegration behaviour and sensory characteristics to be controlled. These developments have led ODT design to a more scientific and precision based paradigm of combined biopharmaceutical principles, patient experience, and manufacturability [2]. At the same time, regulatory authorities have placed an increased focus on quality, safety, sensory assessment and performance consistency, which has led to the use of sound formulation approaches and cutting edge predictive tools. As ODTs cross genres of therapeutics requiring a higher dosing, improved bioavailability and stability, the mastering of basic formulation principles, taste masking mechanisms, and biopharmaceutical issues is indispensable. This review provides an autopsy of traditional, contemporary, and future innovations of ODT technology to outline their role in servicing the unmet clinical needs and an important evolution of patient centric drug delivery [3].

Evolution of Orally Disintegrating Tablets: From Traditional to Modern Technologies

The evolution of orally disintegrating tablets (ODTs) has been an ongoing process that has passed through different technological eras each overcoming the limitations of the previous design while simultaneously enhancing the convenience of administration, dosing, mechanical integrity, and ease of manufacturing. This evolutionary path seeks for improvement in excipient engineering, process optimization, particle design, and patient centers dosage form expectation of regulatory bodies [4].

Traditional ODT Technologies

Initial ODTs came through lyophilization, molding and sublimation that resulted in very porous, sponge like matrices that were capable of disintegrating in seconds. The Zydis® platform, a ground breaking lyophilized system with outstanding results in disintegration

speed and ease of administration paved the way to establish ODTs as a potential dosage form for vulnerable patient groups. Nonetheless, these systems were lacking in mechanical robustness that would be required for bulk handling, required therefore, specialized packaging and drug loading was limited typically less than 400mg. In addition, a high production cost as well as susceptibility to moisture limited the widespread utilization. Yet, these early platforms laid the basis for defining such attributes as rapid disintegration, pleasant mouthfeel, and taste acceptability [5].

Intermediate Generation ODTs

With the advent of direct compression technologies, the breadth and the commercialization of ODTs were greatly expanded. This generation used superdisintegrants like crospovidone, croscarmellose sodium and sodium starch glycolate along with fillers like mannitol and MCC for fast dispersion and palatability. The introduction of coprocessed excipients such as F-Melt®, Ludiflash® and Pharmaburst® had a further impact on the compressibility, flowability and uniformity and thereby made industrial scale manufacturing possible on standard tableting equipment. These systems produced hard wearing tablets with acceptable levels of hardness, decreased friability and good sensory characteristics, and overcome many of the deficiencies of past technologies [6].

Advanced and Modern ODT Manufacturing Technologies

Contemporary ODT innovation applies new materials and advanced manufacturing processes in this endeavor to better drug loading, mechanical strength, stability and sensory experience.

Particle Engineering based ODTs

Particle engineering methods, such as spray drying, coacervation, microencapsulation, and solid dispersion formation, produce extremely porous, taste masked and quickly dispersible drug particles. These systems allow for poor or bitter APIs to be incorporated and resulting mouthfeel to be maintained at an acceptable level. Engineered particles also enhance the compressibility as well as help to control the disintegration behavior [7].

3D Printed ODTs (Aprecia's ZipDose® Platform)

Additive manufacturing is a revolutionary milestone in the technology of ODT. Aprecia's FDA approved ZipDose® platform uses binder jet 3D printing to print highly porous structures that provide ultra rapid disintegration and unheard of drug loading (more than 1g). This technology enables dose personalization, multi COPD treating API combinations, as well as programmable tablet architecture, making 3D printed ODTs potential candidates for precision medicine [8].

Freeze Granulation and Cryo Extrusion

Freeze granulation is used to obtain spherical porous granules through the rapid solidification of drug excipients slurries, while cryo extrusion is used to obtain matrices of low density through frozen extrusion. Both techniques yield formulations that have rapid hydration and good disintegration and maintain tablet strength. These methods enjoy the advantage of accommodating moisture sensitive and thermolabile APIs, in line with modern quality by design requirements [9].

Hot Melt Extruded ODTs

Hot melt extrusion (HME) combines APIs in polymeric carriers to improve solubility, taste masking and stability. When extruded material is milled and directly compressed from ODTs it allows for a controlled porosity and fast dispersion without compromising mechanical integrity. HME based ODT's are especially suitable for BCS Class IV drugs, which require simultaneous solubility enhancement and taste suppression [10].

Formulation Principles of ODTs

Formulation of orally disintegrating tablets requires the integration of excipient functionality, processing science and biopharmaceutical performance. ODTs have to achieve rapid disintegration in the oral cavity whilst still maintaining mechanical integrity, taste acceptability and stability during storage and distribution. As patient centric dosage forms, they must be designed so that they are easy to administer, especially for pediatric and geriatric patients as well as dysphagic patients. Modern ODT formulation is based on Quality by Design (QbD) strategy, which involves systematic risk evaluation, critical material attributes (CMAs) and critical process parameters (CPPs) evaluation [11]. In addition, sensory parameters, such as color, odor and taste have received regulatory focus as they are fundamental to adherence. Taking advantage of recent improvements in excipient design and particle configuration, ODTs have become robust and scalable solid dosage forms which rival conventional tablets in ease of manufacture while excelling them in ease for the patient [12].

Critical Quality Attributes (CQAs)

CQAs are used as benchmarks to ensure that ODTs achieve therapeutic, functional, and patient centric goals. Disintegration time, which is usually less than or equal to 30 seconds, depends on porosity, wicking efficiency and physicochemical behaviour of super disintegrants. Advanced ODTs often fully disintegrate in less than 10 seconds through the use of engineered pore networks and optimized excipient ratios, helping to improve compliance and patient experience. Mechanical strength is also equally important. Highly porous tablets break apart easily but can chip or break when packaged, therefore tensile strength specifications which aim to maintain structural integrity without disintegrating. Taste masking performance makes up a major CQA owing to the prolonged oral residence [13]. The extent and durability of taste masking coating, efficiency of bitterness suppression, and flavor interaction have to be evaluated using accelerated stability testing and sensory profiling. Mouthfeel attributes (e.g. smoothness, no grittiness, cooling sensation) are highly determinants of acceptability. These attributes are dependent on filler selection, particle size distribution, and uniformity of coating. Wetting time and water absorption ratio are key predictors of in mouth performance and rapid wetting indicates good capillary mechanisms. The stability issue continues to be of paramount importance due to excipient hygroscopicity as well as dedicate microstructures. ODTs often need unique packaging to prevent such softening of moisture or taste reduction of moisture, and pesticide degradation.

Role of Excipients

Excipients make up the architects of ODT functionality. Their choice determines disintegration behavior, palatability, texture, structural strength and manufacturability. Given the fact that ODTs are highly dependent on excipient performance and do not necessarily rely on the API's performance alone, formulators will carefully formulate the excipient matrix based on the best possible porosity, optimization of flow, and taste quality. Excipients also determine compatibility as well as moisture sensitivity and long term characteristics of mouthfeel. Emerging excipient technologies are based on providing multifunctional benefits, rapid hydration, enhanced compressibility, textural enhancement, and taste uniformity, and simplification of production for high throughput tableting equipment [14].

Super disintegrants

Super disintegrants are key components in ODT performance because of their ability to absorb saliva in a short period of time and to rupture the tablet matrix in a spontaneous manner. Croscarmellose sodium is multidirectional swelling, which produces large amounts of disruptive force. In contrast, Crospovidone performs wicking instead of swelling from moisture that is absorbed into deep matrix layers to make it appropriate for highly porous ODTs. Sodium starch glycolate combines the two properties (swelling and gel formation), allowing controlled yet rapid swelling gratified at low concentrations [15].

Fillers and Matrix Formers

Fillers add bulk, improves organoleptic properties and improves compressibility. Mannitol is highly popular for its sweetness, non hygroscopic properties, and cooling effect, and therefore favors high acceptance sensory profiles. Microcrystalline cellulose (MCC)

enhances internal porosity and structural integrity to make it an indispensable part for direct compression ODTs. The combination of mannitol and MCC often results in tablets that are excellent in hardness but that will disintegrate too rapidly. Fillers need to be chosen with flow characteristics, taste masking layer compatibility and impact of dissolution. Emerging matrix formers such as porous sugar alcohols and co crystallized mannitol grades, are further optimizing the ODT performance by increasing the salivary penetration [16].

Lubricants

Lubricants make tableting smooth but they can affect the disintegration of ODT if used incorrectly. Magnesium stearate produces hydrophobic films surrounding particles that inhibit saliva penetration, especially with high porosity matrices and, therefore, the lowest possible lubricant incorporation and strict blending times are required. Sodium stearyl fumarate (SSF) is becoming the material of choice for its water dispersible potential and negligible effect on disintegration kinetics. Glyceryl behenate and other lipid based lubricants provide other taste masking advantages and stabilize APIs that are prone to hydrolysis, however they must be used sparingly to avoid negative consequences of API wetting behaviour [17].

Co-Processed Excipients

Co processed excipients revolutionize the manufacturing process of ODT by combining ideal ratios of super disintegrants, fillers and binders in one ingredient. Their engineered particle architecture provides for uniform porosity as well as improved flow properties with little segregation, which is ideal for direct compression. For example, the apparent pea size mannitol grain of Ludiflash® incorporates three polymers, crospovidone and polyvinyl acetate into a synergistic structure that ensures quick disintegration and high mechanical stability [18]. F-Melt® has multifunctional performance with enhanced hydration that is valuable for use with low solubility APIs. Pharmaburst® provides excellent mouthfeel, fast dispersion and compressibility, which allows faster production cycles.

Process Considerations

Process parameters have a great impact on the structural and functional properties of ODTs. Blending must be done to homogeneity without degradation of super disintegrants, excessive lubrication or mixing may result in formation of hydrophobic layer which prolong disintegration. Low shear blending and control addition order is a must for reproducibility. Granulation is used selectively where API flow properties are poor; where moisture addition has to be limited to avoid collapse of pores. Advanced methods such as fluid bed granulation make porous granules with a superior hydration kinetic profile. Spray granulation has the ability to incorporate taste masked particles without the loss of fast disintegration behavior. Compression involves fine tuning. Excessive compression results in a low porosity, while lack of compression results in fragile tablets [19]. The speed of compression as well as the dwell time determine the density gradients and lamination tendencies. Modern ODTs have the benefit of multi tip tooling and shorter resulting dwell times in order to retain porosity. Environmental control is very important because of moisture sensitivity hence hygroscopic excipients or coated particles may degrade in high humidity requiring less than 40% RH processing conditions. Packaging also plays a vital role here. ODTs often need moisture impervious blisters, cold form foils, or strip packaging to prevent softening, sticking, or masking of taste failure with time.

Advanced Taste Masking Mechanisms in ODT Technology

Traditional Taste Masking Approaches

Traditional taste masking approaches used in orally disintegrating tablets (ODTs) were mostly based on the inclusion of sweeteners, flavourants and primitive coating methods to reduce the disagreeable taste of many active pharmaceutical ingredients (APIs). Sweeteners like mannitol, aspartame and sucralose had not only given a positive sweetness but also brought a cooling effect to which they partially compensated the bad taste profiles, concomitantly, aromatic flavourants had a secondary masking effect. In addition, simple film coatings based on hydrophobic polymers and complexation with ion exchange resin were used for drug retarding dissolution in the oral cavity [20]. While these measures were satisfactory for drugs with moderate bitterness, they were inadequate for highly soluble or highly bitter APIs, hence the need to develop more elaborate technologies.

Modern Taste Masking Technologies

Contemporary taste masking systems attempt to control drug exposure to saliva by introducing complex and sophisticated physical and chemical barriers into the saliva. These approaches combine polymer science and particle engineering as well as the principles of controlled release to prevent contact of the API with taste buds until the time of swallowing. Techniques such as microencapsulation, hot melt coating, cyclodextrin complexation and nanotechnology provide a way to finely tune the kinetics of dissolution while retaining a rapid disintegration. Collectively all these methods improve stability and reduce bitterness perception while increasing the overall palatability without reducing its bioavailability [21].

Microencapsulation

Microencapsulation is the means of adding drug particles to polymeric membranes that are not broken down in the saliva, but are readily broken down with exposure to gastric fluids. Polymers like Eudragit®, hydroxypropyl methylcellulose (HPMC) and cellulose derivatives are protective shells to limit the solubilization by saliva. Figure.1 depicts the microencapsulation release of drug in the stomach [22]. This technique has a benefit not only in suppressing the bitterness, but also the moisture resistance, flowability and mouthfeel. The controlled release presented by the microcapsules ensures that taste masking without delaying absorption after ingestion is ensured.

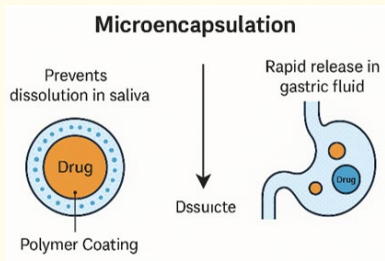

Figure 1: Microencapsulation.

Hot Melt Coating

Hot melt coating is done by coating of lipids or thermoplastic polymers in molten form onto the drug particles, this leads to the formation of hydrophobic coats that would prevent dissolution in the oral cavity. Figure. 2 shows the hot melt coating of drug. Lipids like glyceryl behenate and stearic acid are common ingredients in this gain and provide solvent free stable coatings [23]. This method is especially suitable for moisture sensitive APIs and produces smooth and non gritty particles favorable to ODT matrices.

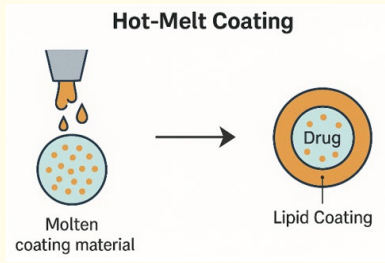

Figure 2: Hot Melt Coating.

Cyclodextrin Inclusion Complexes

Cyclodextrins encapsulate drug molecules in their hydrophobic cavities and hence decrease direct interaction with the taste receptors. These complexes are very effective in bitterness masking and at the same time, increase solubility and stability. Figure. 3 shows the method of formation of complexes. Their rapid dispersion in saliva means that uncomplexed API cannot be exposed in mouth providing a pleasant mouthfeel without uncomplexed API exposure [24].

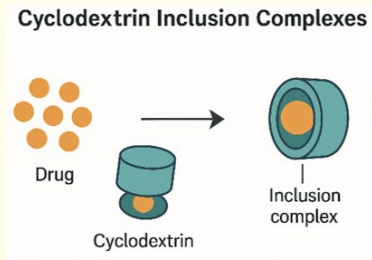

Figure 3: Cyclodextrin Inclusion complexes.

Nanoparticle based Taste Masking

Nanoparticle systems are API delivery systems whereby APIs are presented in nanoscale carriers, thereby forming strong diffusion barriers that retard release activity in saliva. Nanostructured lipid carriers, polymeric nanoparticles, and nanosuspensions offer homogeneous coating, low grittiness and excellent taste. They also provide better dissolution once in the stomach, which has a particular benefit for poorly soluble drugs.

3D Printing enabled Taste Masking

3D printing allows for the precise segregation of APIs in porous matrices in space and time, thus delaying exposure to saliva using the matrix design, not chemical modification. This ability has enabled customized taste masking intensity, high drug loading, and customizable disintegration behaviour, and is a transformative development in the design of ODTs.

Palatability Optimization

Palatability optimization is not limited to taste masking, it also includes influences of organoleptic properties all of which need to be taken into account. Smooth fillers like mannitol and a controlled particle size distribution and flavor modulators are used for improving oral comfort. Sensory analysis tools including electronic tongue technology, human taste panels are used in formulation refinement. Integration of saliva stimulating agents and flavor sweetener synergies further enhances acceptability, which would ensure good compliance in the patient [25].

Biopharmaceutical Considerations in ODT Formulation

Absorption Kinetics

Absorption kinetics in ODTs are determined by their individual oral disintegration behavior that allows a limited degree of pre gastric absorption. Unlike conventional tablets that are only dependent on gastrointestinal dissolution, ODTs release drug particles in the oral cavity where mucosal uptake is possible by buccal, sublingual or oropharyngeal routes, depending on the physicochemical characteristics of the API. Moderately lipophilic drugs (Log P 1-3), those of low molecular weight, and those that are partially unionized at salivary pH are shown to have more of a propensity for uptake by the oral mucosa. This phenomenon can dampen the first pass effect and increase the onset time especially for such APIs as ondansetron, zolpidem, rizatriptan and certain benzodiazepines. There

is still a limitation to the degree of buccal absorption, as most of the dose is swallowed pretty quickly after it is disintegration and then goes through the normal process of absorption in the gut [26]. The short time of residence, combined with limited absorptive surface area and low salivary volume result in further limitations on systemic delivery through the oral mucosa. Consequently, although it is possible that ODTs will alter the absorption kinetics for suitable APIs, the overall pharmacokinetic profiles of ODTs are quite similar to standard oral tablets, unless they have been developed with a need for substantial mucosal targeting.

Impact of Saliva on Drug Release

Saliva is the main medium involved in the initial disintegration and dissolution of ODTs and the physicochemical properties of saliva directly determine the rate and pattern of release. The low fluid environment of typical resting salivary volumes (0.3-1 mL) under constrained aqueous conditions gives rise to the dissolution in these fluids. This reduced volume results in difficulties of solubilization of poorly soluble drugs and faster release of highly soluble, bitter APIs results in saliva as envied dissolution process becomes a determinant for taste perception and can vary upon the drug. Salivary pH normally leaving from 6.2 to 7.4, modulate the degrees of solubility and degree of ionization of ionizable drug during early stage of dissolution. Variability in salivary flow among patients, e.g. in geriatric or xerostomia patients, of disintegration time and onset of drug release is important, and emphasizes the importance of ODT matrices being designed with robust wicking properties to compensate the reduction of saliva production. Salivary composition especially mucins, enzymes and electrolytes may further affect dispersion of the drug and stability of the coating [27]. Hence, formulators have to engineer ODTs to rapidly hydrate and disperse under minimal salivary conditions and reduce premature dissolution of bitter APIs by protective coatings or solubility modifying excipients.

Solubility and Permeability Challenges

Solubility and permeability are among key biopharmaceutical issues in ODT formulation and most problematic for BCS Class II and IV drugs. Due to the nature of ODTs (initiation of dissolution in the low fluid oral cavity), poorly soluble APIs cannot always be appropriately wetted or dissolved for swallowing and may not be bioavailable. Strategies such as amorphous solid dispersions, nanocrystals, cyclodextrin complexes, and lipid based carriers have been used more frequently to increase dissolution rates in saliva as well as gastric fluids. To avoid causing intense bitterness as a result of rapid solubilization in the mouth, these approaches need to be optimized. Permeability considerations also play a role in ODT biopharmaceutics, local supersaturation phenomenon produced in the disintegration process may have a transient effect on increasing mucosal absorption for lipophilic APIs although contribution to the systemic circulation will usually be modest. For highly permeable drugs, rapid dissolution in saliva and subsequently absorption pre-gastric may cause a slightly more rapid Tmax resulting in clinical advantages. Nevertheless, irritant or acidic APIs require a dedicate formulation to avoid mucosal discomfort. Therefore, to solve the problems of solubility and permeability includes balancing the increase in dissolution, efficiency of taste masking and patient comfort, and to ensure the consistency of exposure to the system [28].

Food and Water Independence

ODTs are designed for administration without water thus increasing convenience for pediatric, geriatric, traveling, and dysphagic populations. Their water independence makes them different from conventional tablets that need the absurd fluid quantity for swallowing and dissolution. Nonetheless, gastrointestinal absorption is still dependent upon physiological processes that are vulnerable to meal composition as well as gastric emptying. High fat meals may cause a delay in stomach transit or enhance absorption of lipophilic drugs irrespective of the formulation of the ODT, which requires testing the effect of food during the clinical development of the drug. Water independence also increases the need for better disintegration performance under low saliva conditions, patients with xerostomia and dehydration can have slow disintegration rates, therefore formulations with fast acting wicking agents and porous architectures might be needed to ensure better disintegration. Additionally, ODTs may reduce variability related to incorrect co ingestion of volumes of water that regularly occurs in the case of conventional tablets. Overall, food and water independence not only helps increase patient accessibility, but requires rigorous evaluation of downstream pharmacokinetic effects [29].

Regulatory and Biowaiver Considerations

Regulatory agencies classify ODTs as oral solid dosage forms but enforce special requirements developing as disintegration time, palatability, mechanical strength and usability by the patients. To be considered an ODT, pharmacopoeial standards require a disintegration time of 30 seconds or less, although many of the approved products disintegrate faster than that. Increasing quality focus on patient centric attributes regulatory submissions have to include sensory evaluation data demonstrating good taste masking and acceptable taste. Biowaivers may be granted for ODTs of BCS Class 1 and 3 drugs which are allowed to have dissolution profiles similar to reference products in several media, and where the formulation features do not change the kinetics of absorption. However, taste masking coatings, encapsulation systems or some novel excipients may be subject to further regulatory scrutiny to ensure that they do not alter in vivo performance. Inclusion of nanotechnology or coatings with advanced polymers needs exhaustive safety evaluations because of the possible effect on the release kinetics. Stability studies should include investigating moisture sensitivity because variations in the amount of moisture present could result in a loss of disintegration and of taste masking integrity. As such, regulatory pathways for ODTs require robust characterization of the biopharmaceutical performance, acceptability for the patient and robustness of the formulation [30].

Emerging Technologies and Innovations in ODT Development

Emerging technologies in the development of ODT are challenging performance boundaries and the advancement of patient centric oral delivery. Modern innovation focuses on the importance of precision engineering, improved taste masking, drug loading and personalized dosing. Advanced particle engineering (like nanocrystals, amorphous dispersions and microencapsulated drug particulates) helps enable rapid disintegration of superior palatability and bioavailability. Additive manufacturing and especially 3D printing allows for the architecture of the tablet to be custom made, allowing for ultra porous architectures, high drug loading and appropriate release kinetics to be designed. Novel co processed excipients further optimize the manufacturing process as innovative development of optimized porosity, compressibility and mouthfeel within multifunctional matrices. In addition, smart technologies that include biosensors and programmable dissolution patterns are being developed as next generation ODT systems [31].

Emerging Technology	*Key Features*	*Advantages*	*Applications*
Particle engineering techniques, (Nanocrystals, Amorphous Solid Dispersions, Microencapsulation)	Increase Solubility, Reduces particle size, enhance taste masking	smooth mouthfeel, Improved bioavailability,	BCS Class II/ IV drugs, bitter APIs
3D Printing (Zip-Dose® Technology)	Fabrication of ultra porous tablet architecture, made by layer by layer fabrication technology.	High drug loading, with the ability to formulate doses to the users specifications	3D printed Personalized medicine, high dose ODTs
Advanced Co processed Excipients	combines the role of filler, binder and disintegrant in one material.	Superior compressibility, rapid disintegration	Direct compression, ODT manufacturing
Hot Melt Extrusion (HME) Based ODTs	API embedded in polymeric carriers by thermal processing	Taste masking and solubility enhancement	Poorly soluble and thermally stable APIs

Smart ODTs (Sensor or Trigger Responsive)	Triggered reactions can be programmed to release their payload according to changes in pH or enzymatic activity.	controlled release in combination with rapid disintegration	Future platforms for personalized therapy

Table 1: Emerging technology of ODT Development.

Challenges and Limitations

Despite great progress, this ODT technology still has a number of scientific and industrial challenges. Achieving a very efficient taste masking for intensively bitter APIs, fast dissolving APIs or high dose APIs is still challenging, often requiring complex systems of coating or encapsulation that may have disintegration time disadvantages. Balancing quick disintegration with adequate mechanical strength is the other major limitation; highly porous tablets are by nature very fragile and easily break during handling and packaging. In addition to this, ODTs have a greater sensitivity to moisture and require specialized packaging and stringent environmental controls in manufacturing [32]. High drug loading is often limited due to the compressibility and mouth feel to the extent that not every API can be formulated in ODT. Variability in volume of patient saliva, especially in geriatric, pediatric and xerostomia populations may affect performance of disintegration and sensory experience. Process challenges like uniformity of the blend, segregation and sensitive optimization of compression forces make large scale production even more complicated [33]. These limitations highlight the need for ongoing innovation in the areas of excipients, processing and design strategies.

Future Perspectives

Future innovations on ODT technology will be aimed at personalizing it further, increasing bioavailability and combining it with intelligent formulation strategies. Advances in 3D printing and additive manufacturing will make it possible to dose medications per patient, as multi drug combinations, and to create architecturally optimized porous matrix for ultra rapid disintegration. Nanotechnology and polymer engineered taste masking systems will revolutionize the delivery of poorly soluble and bitter APIs. Smart ODTs with responsive polymers or biosensors may allow to achieve controlled release in a fast disintegrating platform. Sustainable, solvent bounce free manufacturing and next generation co processed excipients will further reduce the process [34]. Collectively, these developments will increase the range of therapeutic application and ODTs will continue to be a hallmark of patient centric drug delivery.

Conclusion

Orally disintegrating tablets has evolved into highly sophisticated, and patient centric dosage forms due to its advances in excipient engineering, particle design and cutting edge manufacturing technologies. Contemporary ODTs fulfill fast disintegration, excellent palatability and improved bioavailability as well as high mechanical integrity, thus addressing the requirements of the variable needs within patient populations. Notwithstanding difficulty in taste masking, stability and accommodating high drug loads, continuous innovation as seen in nanotechnology and 3D printing and next generation co processed excipients are expanding their potential for therapeutics. As formulation science grows more and more sophisticated in terms of smart materials and predictive modeling, ODT's are likely to represent a foundation of a platform for the next generation of personalized and accessible oral drug delivery.

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