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Orally Disintegrating Tablets: Formulation Strategies, Evaluation Parameters, Manufacturing Technologies and Future Perspectives

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Abstract: ***Orally disintegrating tablets (ODTs), also known as orodispersible, mouth-dissolving or fast-disintegrating tablets, are patient-centric solid oral dosage forms designed to disintegrate rapidly in the oral cavity with saliva and without the need for water. They are particularly useful for pediatric, geriatric, psychiatric, travelling and dysphagic patients, and for therapeutic situations where rapid onset, convenience and improved compliance are desired. The performance of an ODT depends on the physicochemical properties of the active pharmaceutical ingredient, the concentration and mechanism of the superdisintegrant, the solubility and mouthfeel of excipients, tablet porosity, compression force, taste-masking strategy and packaging protection. This review manuscript summarizes the concept, advantages, limitations, formulation components, mechanisms of disintegration, manufacturing technologies, patented platforms, quality-control evaluation parameters, stability concerns and future perspectives of ODTs. Direct compression remains the most widely used method because of its simplicity, economy and scalability; however, technologies such as lyophilization, molding, sublimation, spray drying, melt granulation, cotton-candy process and three-dimensional printing provide additional opportunities for drugs with special requirements. Evaluation of ODTs should include pre-compression and post-compression parameters, especially weight variation, hardness, friability, wetting time, water-absorption ratio, in-vitro disintegration time, dispersion behavior, drug content, dissolution profile, taste acceptability and stability. Modern ODT development increasingly uses quality-by-design, risk assessment, design of experiments, artificial-intelligence assisted formulation screening and personalized manufacturing. Overall, ODTs represent a valuable and expanding dosage-form platform capable of improving patient adherence and therapeutic performance when formulation and process variables are scientifically optimized.***

Keywords: orally disintegrating tablets; orodispersible tablets; mouth-dissolving tablets; superdisintegrants; direct compression; taste masking; patient compliance; quality by design.

I. INTRODUCTION

The oral route remains the most preferred route for drug administration because it is non-invasive, convenient, economical, and generally acceptable to patients. Conventional tablets and capsules, however, are not ideal for every patient population. Many pediatric and geriatric patients, patients with neurological disorders, psychiatric patients, bedridden patients, and individuals with dysphagia experience difficulty swallowing intact tablets or capsules. Some patients also avoid tablets because water may not be available during travel, work, nausea, acute migraine attacks, allergic episodes or emergency situations. These issues can reduce compliance and lead to therapeutic failure, particularly in diseases that require rapid or regular medication administration.[1]

Orally disintegrating tablets were developed to address these limitations. An ODT is placed on the tongue, where it rapidly disintegrates or disperses in saliva, producing a suspension or solution that can be swallowed without additional water. According to the United States Food and Drug Administration guidance, an ODT is a solid dosage form containing medicinal substances that disintegrates rapidly, usually within seconds, when placed on the tongue. The guidance recommends an in-vitro disintegration time of approximately 30 seconds or less using the United States Pharmacopeia disintegration test or an equivalent method . This definition differentiates ODTs from chewable tablets, conventional oral tablets and tablets that merely dissolve slowly in the mouth.[2]

The commercial and clinical interest in ODTs has grown due to their convenience, portability and patient-friendly nature. They are used in therapy areas such as allergy, migraine, nausea and vomiting, pain management, psychosis, depression and pediatric fever.

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ODTs are particularly beneficial when rapid administration is important or when patients are unwilling or unable to swallow a conventional tablet. In addition to improved compliance, ODTs may provide faster onset of action for some drugs because the dosage form disintegrates quickly and drug particles become available for dissolution earlier than from a conventional compressed tablet. Certain drugs may also undergo partial pregastric absorption from the oral cavity, pharynx or esophagus, which can reduce first-pass metabolism and improve bioavailability; however, this advantage depends strongly on drug solubility, permeability, residence time and formulation design.[3]

Despite these benefits, formulation of ODTs is challenging. The dosage form must disintegrate rapidly but remain strong enough to withstand handling, packaging, transport and administration. It should have acceptable taste, smooth mouthfeel, low grittiness, minimal residue, adequate dose uniformity and stability against moisture. Many active pharmaceutical ingredients are bitter, poorly soluble, high-dose or moisture-sensitive, which complicates ODT development. Therefore, successful ODT design requires rational selection of the API, excipients, superdisintegrants, taste-masking systems and manufacturing process.[4]

II. NEED AND SIGNIFICANCE OF ODTS

ODTs are important because they convert the benefits of solid dosage forms into a more patient-friendly format. Unlike liquids, they generally provide better dose accuracy, lower risk of microbial contamination, easier transport and improved stability. Unlike conventional tablets, they can be administered without water and do not require swallowing of an intact unit. This makes them valuable for patients who experience choking fear, dry mouth, nausea, vomiting, dysphagia or lack of cooperation.[5]

The significance of ODTs can be summarized under four major aspects. First, ODTs improve convenience. Patients can take the medication at any time without arranging water, which increases adherence to therapy. Second, ODTs improve acceptability for pediatric and geriatric patients, who often dislike or cannot swallow large tablets. Third, they may provide rapid drug release and faster pharmacological action for immediate-release medicines. Fourth, ODTs provide lifecycle-management opportunities for pharmaceutical companies by improving existing molecules through patient-centric dosage-form design.[6]

ODTs are also relevant to public health because non-adherence is a major reason for poor treatment outcomes in chronic and acute conditions. A dosage form that is easier to take can improve regularity of administration. This is especially useful in psychiatric diseases, where patients may refuse conventional tablets, and in acute conditions such as migraine, allergy and vomiting, where rapid, convenient administration is desirable. For rural areas and during travel, ODTs also provide practical advantages because administration does not depend on drinking water.[7]

3. Ideal Characteristics of Orally Disintegrating Tablets

An ideal ODT should rapidly wet, disintegrate and disperse in saliva while producing a pleasant mouthfeel. It should not require water for administration and should leave minimal residue in the oral cavity. The tablet must possess adequate hardness to tolerate manufacturing, packaging and handling, and friability should remain within acceptable pharmacopoeial limits. The dosage form should be stable under normal storage conditions, compatible with common packaging materials and resistant to humidity-related softening or premature disintegration.[8]

From a patient perspective, palatability is as important as pharmacotechnical performance. Bitter or irritating drugs must be taste masked without delaying disintegration or dissolution. The tablet should be small, light and easy to place on the tongue. The FDA guidance recommends that tablet weight generally should not exceed 500 mg unless the product can be justified based on performance. For high-dose drugs, this requirement becomes difficult because a large tablet may leave more residue and reduce patient acceptability. Therefore, ODTs are often more suitable for low to moderate dose drugs with acceptable potency and manageable taste[9]

Table: Ideal characteristics of orally disintegrating tablets.

Characteristic	Desired expectation
Disintegration	Rapid disintegration in saliva; target commonly 30 seconds or less for FDA-labelled ODTs.
Administration	No requirement of water, chewing or prior dispersion.
Mechanical strength	Sufficient hardness for handling with low friability.
Palatability	Acceptable taste, smooth mouthfeel and minimal residue.
Dose accuracy	Uniform weight and drug content.
Stability	Resistance to humidity, temperature and handling stress.
Manufacturability	Scalable process with reproducible critical quality attributes.

From a manufacturing perspective, an ideal ODT should be reproducible, scalable, economical and compatible with conventional manufacturing equipment where possible. It should show low weight variation, good content uniformity, satisfactory flow and compressibility of powder blend, predictable disintegration time and robust dissolution performance. The formulation should also tolerate minor processing variations without significant changes in critical quality attributes.[10]

III. DRUG CANDIDATE SELECTION FOR ODTS

Selection of an appropriate drug candidate is a critical early decision in ODT development. Drugs administered in low doses are generally preferred because large doses increase tablet weight and may compromise mouthfeel. Drugs with high bitterness require effective taste-masking strategies such as coating, complexation, ion-exchange resin, granulation, use of flavors and sweeteners, or lipid/polymer-based systems. Drugs with poor aqueous solubility may show slow dissolution even after rapid disintegration; such drugs may require particle-size reduction, solid dispersion, inclusion complexation, salt formation, nanosizing, surfactants or solubilizing excipients.[11]

The stability profile of the API is also important. Hygroscopic or moisture-sensitive drugs may not be ideal for porous ODTs unless protective packaging and suitable excipients are selected. Drugs unstable in saliva or at oral pH may require protective technologies. Drugs causing local irritation, numbness or unpleasant aftertaste may reduce acceptability. The API should be compatible with commonly used ODT excipients such as mannitol, lactose, microcrystalline cellulose, crospovidone, croscarmellose sodium, sodium starch glycolate, sweeteners and flavors[12]

ODTs are most suitable for immediate-release drugs where rapid availability is desired. However, modified-release ODTs have also been explored using coated pellets, multiparticulates, ion-exchange complexes and polymeric systems. In such systems, the ODT disintegrates quickly in the mouth, but drug release is controlled by the embedded multiparticulate system after swallowing.[13]

IV. FORMULATION COMPONENTS OF ODTS

ODT formulations contain the API and several excipients that together control disintegration, mechanical strength, taste, stability and patient acceptability. The main excipient classes include superdisintegrants, diluents, binders, lubricants, glidants, sweeteners, flavors, saliva-stimulating agents, taste-masking agents, surfactants and sometimes effervescent components.[14]

Superdisintegrants are the key functional excipients in most ODTs. They promote rapid tablet breakup by mechanisms such as swelling, wicking, deformation recovery and particle repulsion. Common synthetic superdisintegrants include crospovidone, croscarmellose sodium and sodium starch glycolate. Crospovidone is valued for capillary action and minimal gel formation; croscarmellose sodium promotes swelling and wicking; sodium starch glycolate swells rapidly but may form a viscous gel at high levels. The optimal concentration varies with formulation, but excessive superdisintegrant can sometimes reduce tablet strength, increase friability, create grittiness or prolong disintegration due to gel formation[15]

Diluents and fillers contribute to tablet bulk, mouthfeel and compressibility. Mannitol is widely used because it provides a pleasant cooling sensation, sweetness, low hygroscopicity and good mouthfeel. Lactose, microcrystalline cellulose, dibasic calcium phosphate, xylitol, sorbitol and directly compressible co-processed excipients may also be used. Microcrystalline cellulose improves compressibility and wicking but may produce a slightly gritty mouthfeel if used at high concentration.[16]

Binders provide mechanical strength. In ODTs, binder level must be carefully controlled because excessive binding can slow water penetration and disintegration. Lubricants such as magnesium stearate reduce friction during compression and ejection, but over-lubrication can make tablet surfaces hydrophobic and delay wetting. Glidants such as colloidal silicon dioxide improve powder flow. Sweeteners and flavors improve taste, while saliva-stimulating agents such as citric acid and malic acid may accelerate wetting and improve patient sensation. Taste-masking agents are essential for bitter drugs and must be selected so that they do not reduce immediate-release performance.[17]

V. MECHANISMS OF DISINTEGRATION

The rapid disintegration of ODTs occurs when saliva penetrates the tablet matrix and weakens interparticulate bonds. Several mechanisms operate simultaneously. In the swelling mechanism, the superdisintegrant absorbs water and increases in volume, generating internal pressure that breaks the tablet apart. In the wicking mechanism, water enters the porous tablet by capillary action, replaces air in the tablet voids and reduces the bonding forces between particles. Crospovidone and microcrystalline cellulose can support this mechanism by maintaining porous channels.[18]

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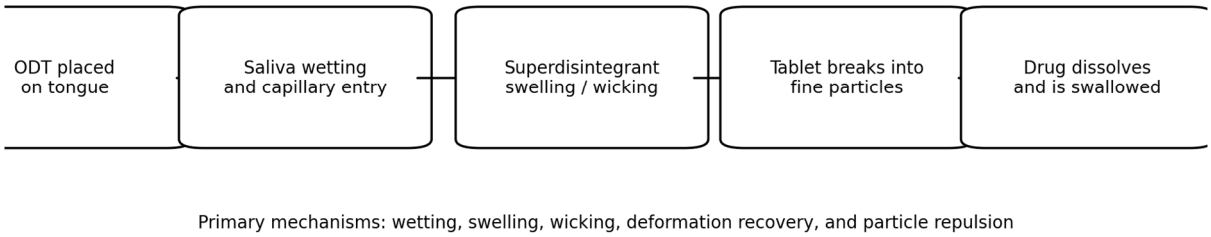

Figure . Mechanism of rapid disintegration and drug release from an orally disintegrating tablet.

In deformation recovery, particles that were deformed during compression recover their original shape when exposed to moisture, producing disruptive stress within the compact. Particle repulsion may also contribute when hydrated particles repel each other and accelerate breakup. Effervescent systems use acid-base reactions to generate carbon dioxide, promoting rapid tablet dispersion and pleasant mouthfeel, but they require moisture-protective packaging.[19]
The mechanism that dominates depends on the nature of the superdisintegrant, tablet porosity, compression pressure, binder level, hydrophobic excipients, particle size and saliva volume. High compression pressure can improve hardness but reduce porosity and slow disintegration. Conversely, very low compression may produce fragile tablets with poor handling properties. Thus, optimization of compression force is a critical step in ODT development[20]

VI. MANUFACTURING TECHNOLOGIES FOR ODTS

Several conventional and advanced technologies have been used to prepare ODTs. The choice of method depends on API properties, desired disintegration time, dose, cost, scalability and stability requirements. Direct compression is the most common and economical method. The API is blended with directly compressible fillers, superdisintegrants, lubricants, flavors and sweeteners and compressed into tablets. This method uses conventional tablet equipment, is suitable for large-scale production and avoids water or heat. However, direct compression requires powders with good flow and compressibility and may not achieve the extremely rapid disintegration seen with highly porous lyophilized tablets.[21]

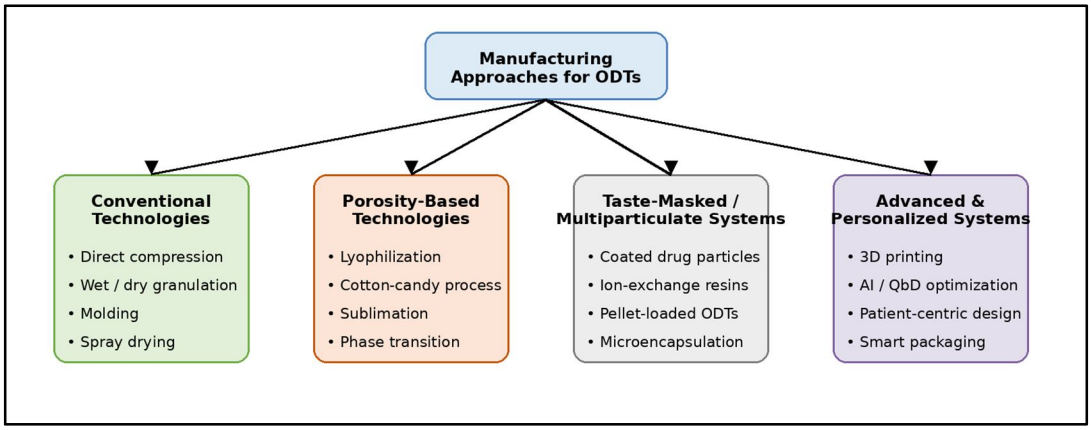

Fig: Manufacturing Technologies for ODTs

Lyophilization or freeze drying produces highly porous tablets with very rapid disintegration. The API is dispersed or dissolved in a matrix-forming solution, filled into blister pockets and freeze dried. The resulting product often disperses almost instantly in the mouth. However, lyophilized tablets are fragile, moisture-sensitive and expensive to manufacture; they usually require special blister packaging. Molding produces tablets from a moist mass or suspension that is molded and dried.

Molded tablets can provide good mouthfeel and rapid dissolution because they are less compact than compressed tablets. Their limitation is low mechanical strength and higher drying requirements. Sublimation involves incorporating volatile materials such as camphor, ammonium bicarbonate or menthol into the tablet blend and then removing them by sublimation to create pores. Increased porosity accelerates saliva penetration and disintegration.[22]

Table: Manufacturing technologies for ODTs.

Technique	Principle	Advantages	Limitations
Direct compression	Blend API with excipients and compress.	Simple, economical, scalable.	Needs good powder flow and compressibility.
Lyophilization	Freeze drying of drug-containing matrix.	Very rapid disintegration and excellent mouthfeel.	Fragile, costly and moisture-sensitive.
Molding	Mold wet mass or suspension and dry.	Porous tablets with good dispersion.	Low strength and drying requirement.
Sublimation	Remove volatile material to create pores.	Improved porosity and rapid wetting.	Extra processing step and potential stability concerns.
Spray drying	Produce porous excipient-drug particles.	Good compressibility and fast disintegration.	Requires process control and suitable solvents.
Melt granulation	Use meltable binder to granulate powder.	Can improve taste masking and flow.	Not suitable for heat-sensitive drugs.
3D printing	Print porous/personalized tablets layer by layer.	Personalized dosing and geometry control.	Scale-up, regulatory and throughput challenges.

Spray drying can generate highly porous, compressible excipient matrices containing gelatin, mannitol, disintegrants and other components. Melt granulation uses a meltable binder to agglomerate powders and may improve taste masking and compressibility. Mass extrusion can be used for taste masking by mixing the API with a softening agent and polymer, then extruding and cutting the mass into particles that are compressed into tablets. Cotton-candy or flash-dose technology produces floss-like saccharide matrices that can be milled, blended with the drug and compressed. Three-dimensional printing is an emerging technology for ODTs because it enables personalized dose, complex geometry and porous structures. 3D-printed ODTs can be designed to disintegrate rapidly by controlling infill, pore size, binder distribution and tablet geometry. However, regulatory acceptance, print speed, excipient selection, dose uniformity and scale-up remain important challenges.[23]

VII. PATENTED AND COMMERCIAL TECHNOLOGIES

Several patented technologies have contributed to the development of ODT products. Zydis technology is based on freeze drying and produces highly porous tablets that dissolve rapidly in the oral cavity. It is suitable for low-dose drugs but usually requires moisture-protective packaging and careful handling. OraSolv technology uses effervescence and taste-masked drug particles in lightly compressed tablets. DuraSolv technology improves mechanical strength compared with earlier lightly compressed systems and can be packaged more conveniently for certain products. WowTab technology uses saccharides with different moldability and dissolution characteristics to balance hardness and rapid disintegration. FlashDose technology uses a floss-like matrix created from saccharides by a cotton-candy process. Although these technologies differ, they share the same development goal: achieving rapid disintegration while maintaining palatability, dose uniformity, stability and manufacturability. Selection of patented technology depends on the drug dose, taste, solubility, stability and desired product positioning. For generic development, direct compression is often preferred due to lower cost and easier scale-up, whereas patented platforms may provide superior disintegration and mouthfeel for specific drugs.[24]

VIII. EVALUATION PARAMETERS OF ODTS

Evaluation of ODTs includes both pre-compression and post-compression studies. Pre-compression evaluation assesses the suitability of the powder blend for tablet manufacture. Key parameters include bulk density, tapped density, angle of repose, Carr's index and Hausner's ratio.

These tests indicate flowability and compressibility and help predict weight variation during compression. Post-compression evaluation begins with appearance, thickness, diameter, weight variation, hardness and friability. Hardness indicates mechanical strength, while friability evaluates the ability of tablets to resist abrasion during handling. For ODTs, hardness should be sufficient for handling but not so high that it delays disintegration. Weight variation and drug-content uniformity are essential for dose accuracy.[25]

ODT-specific tests include wetting time, water absorption ratio, in-vitro disintegration time, in-vitro dispersion time, mouthfeel, taste evaluation and residue assessment. Wetting time provides information about how fast saliva can penetrate the tablet. Water absorption ratio reflects the ability of the tablet to take up fluid. In-vitro disintegration time is a critical quality attribute; FDA guidance recommends approximately 30 seconds or less for products labeled as ODTs. However, some pharmacopoeial or regional definitions use different limits; therefore, the target should be aligned with the intended market and regulatory pathway.[26]

Dissolution testing determines how rapidly the drug becomes available in solution after disintegration. For immediate-release ODTs, rapid dissolution is generally expected, but dissolution depends on drug solubility, particle size, wetting agents, taste-masking coatings and formulation matrix. Taste evaluation can be performed using human taste panels where ethically acceptable, electronic tongue systems or in-vitro drug-release studies in simulated salivary fluid. Stability studies are essential because many ODTs are moisture-sensitive. Parameters such as appearance, hardness, friability, disintegration time, drug content, dissolution and microbial quality should be monitored during storage.[27]

IX. TASTE MASKING APPROACHES

Taste masking is one of the most important requirements for successful ODT development because the dosage form remains in the mouth during disintegration. Bitter drugs can cause poor patient acceptance even if the tablet disintegrates rapidly. A suitable taste-masking method should reduce bitterness in the oral cavity without delaying drug release in the stomach or intestine[28]

Simple taste masking may be achieved using sweeteners such as aspartame, sucralose, saccharin sodium, stevia or sugar alcohols and flavors such as mint, orange, strawberry or vanilla. These approaches are useful for mildly bitter drugs but insufficient for intensely bitter APIs. Complexation with cyclodextrins can reduce free drug concentration in saliva and improve solubility for selected drugs. Ion-exchange resins form drug-resin complexes that remain relatively stable in saliva but release the drug in the gastrointestinal environment. Polymer coating of drug particles using ethyl cellulose, Eudragit polymers or other film-formers can reduce exposure of taste buds. Granulation, melt coating, lipid coating and microencapsulation are also widely used.[29]Taste masking must be integrated with disintegration and dissolution design. A thick coating may mask taste effectively but delay drug release. A soluble sweetener may improve mouthfeel but increase hygroscopicity. Therefore, formulation scientists must balance taste, disintegration, dissolution, stability and manufacturability.[30]

X. QUALITY-BY-DESIGN APPROACH IN ODT DEVELOPMENT

Quality-by-design (QbD) is a systematic approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding. In ODT development, the quality target product profile may include immediate release, disintegration within 30 seconds, acceptable taste, adequate hardness, friability below 1%, dose uniformity, stability and suitable packaging. Critical quality attributes include disintegration time, dissolution profile, hardness, friability, assay, content uniformity, taste and microbial quality. Critical material attributes include API particle size, API solubility, superdisintegrant grade and concentration, filler type, lubricant level, moisture content and taste-masking particle size. Critical process parameters include blending time, granulation variables, drying temperature, compression force, turret speed and packaging conditions. Risk assessment tools such as Ishikawa diagrams and failure mode and effects analysis can identify variables most likely to affect ODT performance.[31]

Design of experiments can be used to study the effects of superdisintegrant concentration, binder concentration and compression force on responses such as hardness, friability, wetting time, disintegration time and dissolution. Response-surface methodology helps identify the design space where tablets meet all performance requirements. Modern computational tools, machine learning and artificial neural networks are increasingly being explored to predict ODT disintegration and optimize formulations with fewer experimental trials.[32]

XI. STABILITY AND PACKAGING CONSIDERATIONS

Stability is a major concern for ODTs because rapid disintegration often depends on high porosity, hydrophilic excipients and low compression force. These same characteristics can make the tablet sensitive to humidity and mechanical damage. Moisture uptake may soften the tablet, reduce hardness, increase friability, alter disintegration time, initiate effervescence or degrade moisture-

sensitive drugs. Therefore, excipient hygroscopicity, packaging type and storage conditions are critical. Blister packaging with aluminum-aluminum protection, peelable blisters, desiccant-containing containers and moisture-barrier films may be used depending on product sensitivity. Lyophilized ODTs often require special blister packs because they are fragile. Directly compressed tablets may be packaged in bottles if they possess adequate strength and humidity resistance, but desiccants are often necessary. Stability studies should assess appearance, odor, hardness, friability, assay, degradation products, disintegration time, dissolution and microbial limits under accelerated and long-term conditions.[33]

Packaging should also support patient usability. ODTs that are too fragile may break when pushed through conventional blisters; therefore, peel-off blisters may be required. For elderly patients, packaging must be protective but not excessively difficult to open. Thus, final packaging selection should be based on both stability and patient handling requirements.[34]

XII. ADVANTAGES AND LIMITATIONS

The major advantages of ODTs include ease of administration, no need for water, improved patient compliance, faster disintegration, suitability for dysphagic patients, convenience during travel and potential for rapid onset of action. They also reduce the risk of choking associated with conventional tablets and may be useful for patients who are uncooperative or bedridden. However, ODTs also have limitations. Many formulations are moisture-sensitive and require special packaging. Some ODTs have low mechanical strength and may break during handling. Bitter drugs require taste masking, which can increase formulation complexity and cost. High-dose drugs are difficult to formulate because large tablets may not disintegrate rapidly and may leave unpleasant residue. Hygroscopic excipients and effervescent components can create stability problems. In addition, in-vitro disintegration may not always predict in-mouth performance because saliva volume, tongue movement and patient behavior vary among individuals. These limitations can be reduced through careful drug selection, use of co-processed excipients, optimized compression force, advanced taste masking, protective packaging and patient-centered evaluation. The goal is not only rapid disintegration but also a complete product experience that includes taste, mouthfeel, safety, manufacturability and stability.[35]

XIII. RECENT ADVANCES AND FUTURE PERSPECTIVES

The future of ODTs is moving toward patient-centric, personalized and digitally supported formulation development. Co-processed excipients designed specifically for ODTs can improve flow, compressibility, mouthfeel and disintegration. Nanocrystals, solid dispersions, inclusion complexes and lipid-based particles are being investigated to improve dissolution of poorly soluble drugs. Multiparticulate systems can allow taste masking or modified release while maintaining rapid tablet disintegration.

Three-dimensional printing is a promising platform for personalized ODTs. It can produce porous structures, individualized dose strengths and complex release profiles. This may be valuable in pediatrics, geriatrics and precision medicine, where fixed commercial strengths may not meet patient needs. Artificial intelligence and machine learning can support formulation screening by predicting the influence of excipient concentration, porosity and compression force on disintegration and dissolution.

Another important future direction is the development of more biorelevant evaluation methods. Conventional USP disintegration and dissolution tests provide useful quality control, but they may not fully simulate in-mouth conditions. Improved tests using small saliva volumes, controlled agitation, oral-cavity models and electronic taste systems may improve prediction of patient experience. Finally, sustainability is becoming important; future ODT packaging should combine moisture protection with reduced environmental impact.[36]

XIV. CONCLUSION

Orally disintegrating tablets are a valuable patient-friendly dosage form that combines the stability and dose accuracy of solid tablets with the convenience of administration without water. They are particularly useful for pediatric, geriatric, dysphagic, psychiatric and travelling patients, and in therapeutic situations where rapid administration is desirable. Successful ODT formulation requires careful balancing of rapid disintegration, mechanical strength, palatability, drug release, stability and manufacturing feasibility.

Superdisintegrants are central to ODT performance, but their selection and concentration must be optimized with fillers, binders, lubricants, sweeteners, flavors and taste-masking systems. Direct compression remains the most practical manufacturing approach, while lyophilization, molding, sublimation, spray drying, patented platforms and 3D printing offer specialized advantages. Evaluation should include conventional tablet tests as well as ODT-specific tests such as wetting time, water absorption ratio, disintegration time, dispersion behavior, taste and mouthfeel.

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The future of ODTs lies in quality-by-design, co-processed excipients, advanced taste-masking, biorelevant testing, personalized dose manufacture and computational formulation tools. With proper scientific design and regulatory alignment, ODTs can significantly improve patient adherence, therapeutic convenience and overall drug-delivery performance.

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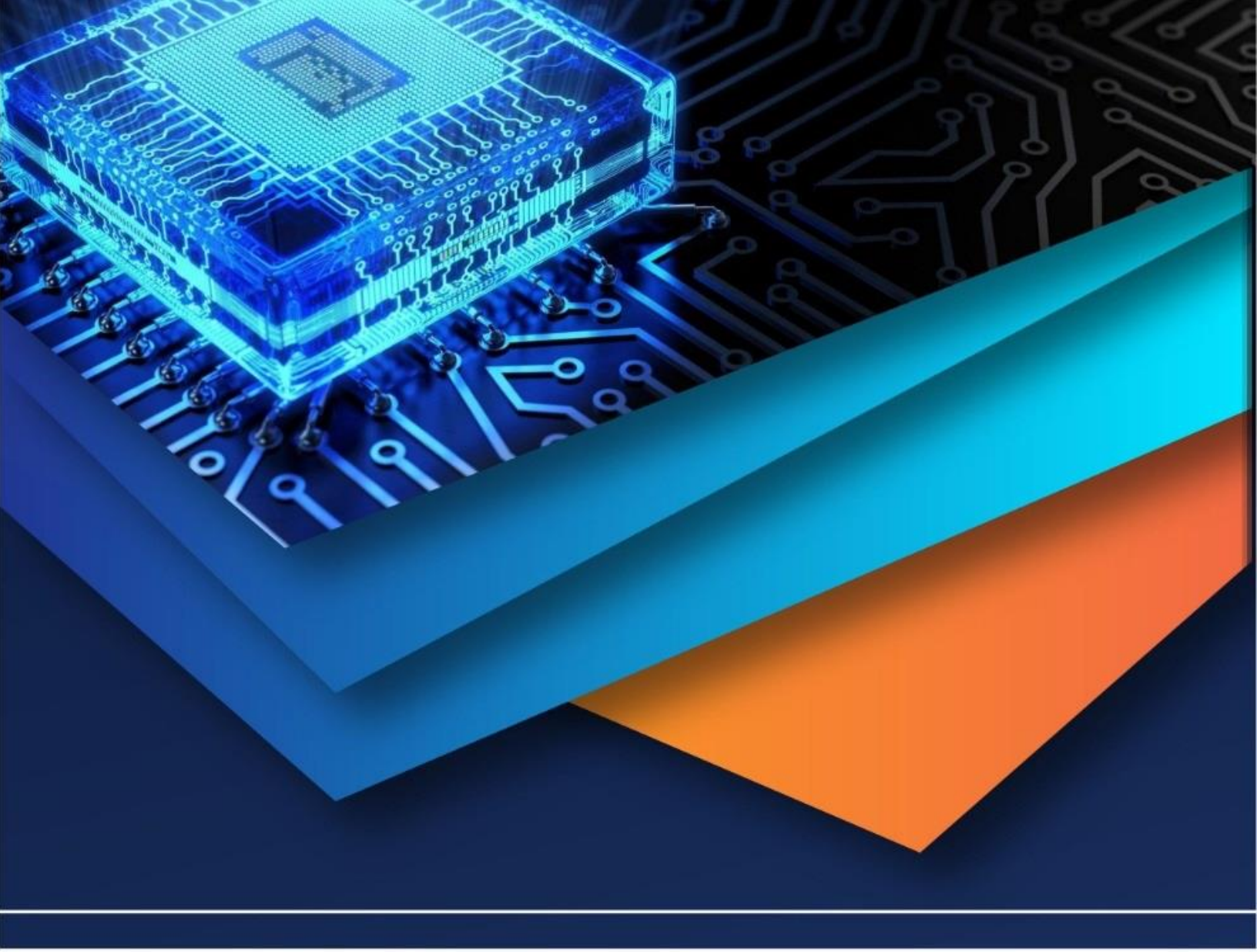

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