Oral Solid Dosage Forms Compared: Tablets, Capsules, ODT, MR

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Executive Summary

Oral solid dosage (OSD) forms, principally tablets, capsules, orally disintegrating tablets (ODT), and modified-release (MR) systems, remain the dominant format for delivering medicines and are the subject of substantial, if occasionally inconsistent, market and regulatory data as of August 2026. Mordor Intelligence sizes the global oral solid dosage pharmaceutical formulation market at $635.77 billion in 2025, projected to reach $795.35 billion by 2030 at a 4.58% compound annual growth rate (CAGR) (Source: www.mordorintelligence.com), while Fact.MR separately estimates the market stood at $651.2 billion in 2025, climbing toward $1,288.0 billion by 2036 at a 6.4% CAGR (Source: www.factmr.com), a gap that illustrates how methodology and scope vary across research firms covering this category. Neither figure should be read as a precise census; both are directionally useful rather than exact.

Within that market, FDA's nonbinding guidance for applicable abbreviated new drug applications (ANDAs) recommends that generic tablets and capsules intended to be swallowed intact be similar in size to their reference listed drugs; it recommends a tablet largest dimension of no more than 22 mm and capsules no larger than standard size 00. The guidance does not apply to other oral dosage forms, including ODTs, and does not establish universal legal limits. Common tablet manufacturing routes include direct compression, wet granulation, and dry granulation/roller compaction (Source: pmc.ncbi.nlm.nih.gov), and rotary-die encapsulation for soft gelatin (softgel) capsules (Source: www.pharmaexcipients.com). Tablets account for the largest share of formulation-market revenue, a figure detailed further in the Tablets section below, whereas Fact.MR puts tablets closer to 53% of the same overall category (Source: www.factmr.com), another discrepancy the report presents openly rather than resolving artificially.

Orally disintegrating tablets are addressed in FDA's nonbinding guidance, which recommends rapid oral disintegration and an in-vitro disintegration time of approximately 30 seconds or less; FDA states that this value is not an arbitrary distinction between ODTs and other tablet forms (Source: www.fda.gov). They address a documented clinical problem: FDA states that difficulty swallowing tablets and capsules "may affect as many as 40 percent of Americans" (Source: www.fda.gov), and a 2013 German general-practice study found 37.4% of 1,051 primary care patients reported swallowing difficulty with tablets and capsules (Source: pubmed.ncbi.nlm.nih.gov). Precedence Research projects the global ODT market to grow from $15.73 billion in 2025 to $33.98 billion by 2035, an 8.01% CAGR (Source: www.precedenceresearch.com). **Modified-release** systems, extended-release (ER), delayed-release (DR), and controlled-release (CR) products, are distinguished by FDA definitions that treat "extended release" and "delayed release" as formal regulatory terms while "controlled release" and "sustained release" carry no distinct regulatory status (Source: www.colorcon.com). Precedence Research sizes the global controlled-release drug delivery market at $66.80 billion in 2025, forecast to reach $160.09 billion by 2035 (9.13% CAGR) (Source: www.precedenceresearch.com).

Manufacturing practice is shifting toward continuous processes: FDA's Emerging Technology Program graduated Continuous Direct Compression as its first technology in October 2021, following Vertex Pharmaceuticals' 2015 approval of Orkambi as reportedly the first FDA-cleared fully continuous drug-manufacturing process (Source: www.biopharmadive.com) and Janssen's 2016 FDA-approved conversion of Prezista from batch to continuous manufacturing, which cut production time from two weeks to one day (Source: www.ncbi.nlm.nih.gov), with Eli Lilly's Verzenio following in 2017 as a third early adopter (Source: www.ncbi.nlm.nih.gov). Quality risk remains material: FDA's 2018 nationwide valsartan tablet recall over the probable carcinogen N-nitrosodimethylamine (NDMA) and its March 2026 warning letter to Intas Pharmaceuticals over inadequate stability investigations both illustrate ongoing scrutiny of OSD manufacturing quality systems (Source: www.fda.gov; FDA warning letter. This report compares tablets, capsules, ODTs, and modified-release forms across manufacturing method, patient acceptability, regulatory classification, and cost.

Introduction and Background

An oral solid dosage (OSD) form is any medicine intended for oral administration that is dispensed as a solid, most commonly a tablet or capsule, as opposed to a liquid, injectable, or topical formulation. OSD forms dominate prescription and over-the-counter pharmaceuticals because they are relatively inexpensive to manufacture at scale, chemically and physically stable over long shelf lives, easy to package and transport, and simple for patients to self-administer without specialized equipment. A peer-reviewed pharmaceutics review states plainly that "**tablets** are the most popular solid DF [dosage form] available today due to their ease of administration, compactness, and ease of manufacturing" (Source: pmc.ncbi.nlm.nih.gov), and a cross-sectional patient survey cited in the same review found that 68.2% of a German study population named tablets their most preferred dosage form (Source: pmc.ncbi.nlm.nih.gov).

The category is not monolithic. Regulators, formulators, and clinicians distinguish OSD forms along at least two independent axes: the **physical format** (compressed tablet, hard or soft gelatin capsule, orally disintegrating tablet) and the **release kinetics** (immediate release versus modified release). FDA's SUPAC-MR guidance states that modified-release solid oral dosage forms include delayed- and extended-release drug products. These two axes are independent in practice: a modified-release product can be manufactured as either a tablet or a multiparticulate capsule. ODT designation concerns rapid disintegration in the mouth; the product's approved labeling and formulation determine its release characteristics. Readers evaluating a specific product therefore need to ask both questions, what is its physical format and what is its release profile, rather than treating the two as a single spectrum.

Table 1 below summarizes the core regulatory vocabulary that recurs throughout this report, drawn directly from FDA guidance documents. Understanding these definitions is a prerequisite for comparing dosage forms meaningfully, since marketing language ("sustained release," "controlled release") does not always track the terms that carry formal regulatory weight.

TERM	FDA/REGULATORY DEFINITION	SOURCE
Immediate Release (IR)	"Allows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug" (Source: www.fda.gov)	FDA Guidance for Industry, SUPAC-MR
Extended Release (ER/XR)	"Extended release products are formulated to make the drug available over an extended period after ingestion" (Source: www.fda.gov)	FDA Guidance for Industry, SUPAC-MR
Delayed Release (DR)	"Release of a drug (or drugs) at a time other than immediately following oral administration"; enteric-coated products are classified as delayed release (Source: www.fda.gov)	FDA Guidance for Industry, SUPAC-MR
Modified Release (umbrella term)	"Dosage forms whose drug-release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms" (Source: www.fda.gov)	FDA Guidance for Industry, SUPAC-MR
Orally Disintegrating Tablet (ODT)	FDA's nonbinding guidance recommends that ODTs be solid oral preparations that disintegrate rapidly in the oral cavity, with an in-vitro disintegration time of approximately 30 seconds or less; it states that 30 seconds is not an arbitrary boundary (Source: www.fda.gov)	FDA Guidance for Industry, Orally Disintegrating Tablets

The table shows that only immediate release, extended release, delayed release, and the ODT disintegration threshold have explicit FDA definitions; "controlled release" and "sustained release," though common in marketing and trade literature, are used descriptively rather than as defined regulatory categories, a point the report returns to in the modified-release section below (Source: www.colorcon.com). This vocabulary gap matters commercially as well as clinically: a product labeled "sustained release" by a manufacturer carries no automatic regulatory equivalence to a product labeled "extended release," even though the two terms are frequently used as synonyms in casual usage, and prescribers comparing generic substitutes should verify the specific release mechanism rather than relying on the marketing label alone. The remainder of this report proceeds contender by contender: conventional tablets, capsules (hard and soft gelatin), ODTs, and modified-release systems, followed by a feature-comparison matrix, a performance and benchmarks section, a dedicated data section, named real-world case studies, and forward-looking implications, including where AI-enabled quality tooling intersects with OSD manufacturing compliance.

Tablets: Conventional and Compressed Forms

Capabilities

Conventional compressed tablets are manufactured either by direct compression of a powder blend or by first forming granules through wet or dry granulation and then compressing the resulting granulate (Source: pmc.ncbi.nlm.nih.gov). **Dry granulation**, including roller compaction, uses mechanical compaction with no liquid binder, while **wet granulation** relies on a liquid binder or solvent to agglomerate powder particles into a wet mass that is then dried and milled (Source: pmc.ncbi.nlm.nih.gov). Despite requiring more unit operations and higher capital cost, wet granulation "remains the most widespread granulation technique used despite the fact that it involves multiple unit processes" because it improves flow and compressibility for difficult formulations (Source: pmc.ncbi.nlm.nih.gov). Tablets are compressed on rotary presses whose tooling determines maximum compression force; "Machines that are designed to 'B' type tooling exert a maximum compression force of 6.5 tones and machines that use the 'D' type configuration exert 10 tones compression force" (Source: www.pharmapproach.com). The choice between granulation routes is rarely aesthetic; it is driven by the compressibility and flow properties of the specific active ingredient and by whether the formulator can tolerate the added heat and moisture exposure that wet granulation introduces to a moisture-sensitive molecule.

Adoption

Tablets are, by revenue, the largest single OSD category. Mordor Intelligence reports tablets accounted for 68.24% of the oral solid dosage pharmaceutical formulation market size in 2024 (Source: www.mordorintelligence.com), while Fact.MR's separate estimate puts tablets at "nearly 53%" of a differently scoped oral solid dosage pharmaceutical market (Source: www.factmr.com). The gap between the two figures likely reflects different market definitions (formulation revenue versus broader pharmaceutical product revenue) rather than a factual dispute, and readers should treat either number as an estimate rather than a precise census.

Strengths and Limitations

Tablets' advantages are largely economic and logistical: at higher production volumes, "the mass production techniques and equipment for tablets (e.g., high-speed presses) can handle larger batches" more cost-effectively than capsule-filling equipment, according to excipient supplier Colorcon (Source: www.colorcon.com), and tablets "can offer better stability and longer shelf life compared to capsules, which can be crucial for certain active pharmaceutical ingredients" (Source: www.colorcon.com).

The principal limitation is patient acceptability. A 2021 peer-reviewed review states that "swallowing problems are predicted to affect one out of 25 adults" generally (Source: pmc.ncbi.nlm.nih.gov), and that "more than 15% of the older population suffers from dysphagia worldwide, from which only 22.7% visited their healthcare professional" (Source: pmc.ncbi.nlm.nih.gov), meaning a substantial share of swallowing difficulty goes clinically unrecognized. Tablets also carry pharmacokinetic drawbacks common to oral administration generally: "most of the orally administered drugs display low systemic availability and diminished efficacy" because of first-pass hepatic metabolism (Source: pmc.ncbi.nlm.nih.gov), and certain drug classes present local gastrointestinal risk: a 2025 systematic review notes that "NSAIDs [nonsteroidal anti-inflammatory drugs] are well known for causing gastric irritation, and therefore pH-sensitive coatings and carriers remain a straightforward way to protect the drug" (Source: www.ncbi.nlm.nih.gov). It is precisely this cluster of acceptability and tolerability limitations, rather than any manufacturing shortcoming, that has driven the parallel development of capsules and orally disintegrating tablets discussed in the next two sections.

Capsules: Hard and Soft Gelatin

Capabilities

Capsules enclose a drug within a hard or soft soluble shell, historically gelatin, though hydroxypropyl methylcellulose (HPMC) "vegetarian" shells are now common. USP General Chapter <1151> describes the capsule generally as a dosage form in which the drug is "enclosed within either a hard or soft soluble container or 'shell'" (Source: www.uspbpep.com). Hard-shell (two-piece) capsules are filled mechanically with powder, granules, or pellets, while soft gelatin (softgel) capsules are formed, filled, and sealed simultaneously, typically via a rotary-die process in which two gelatin ribbons are cast on rotating drums and fill material is injected through a wedge between them before the dies cut and seal each capsule (Source: www.pharmaexcipients.com). Wedge temperature differs by shell chemistry, running higher for vegetable-based shells (46 to 57 degrees Celsius) than for traditional gelatin shells (35 to 45 degrees Celsius) (Source: www.pharmaexcipients.com). A hand-operated hard-capsule filling machine can produce roughly 6,250 capsules per hour, illustrating the low end of the manual-to-fully-automatic filling speed range (Source: www.pharmapproach.com); fully automatic rotary-die and hard-shell filling lines used in commercial-scale manufacturing operate at substantially higher throughput than the hand-operated benchmark, though the general engineering principle, mechanical filling or forming replacing manual dosing, is the same at any scale.

Adoption

Mordor Intelligence estimates the global softgel capsules market at $8.86 billion in 2025 (Source: www.mordorintelligence.com), a subset of the broader OSD category. FDA's nonbinding guidance for applicable ANDAs recommends that generic capsules intended to be swallowed intact not exceed standard size 00, and that generic tablets not exceed 22 mm in their largest dimension; it does not establish universal limits and excludes ODTs and other specified oral dosage forms (Source: www.fda.gov).

Strengths and Limitations

Capsules offer taste and odor masking and, for softgels specifically, ease of swallowing: a peer-reviewed review notes "the soft gelatin capsule is self-lubricating" (Source: pmc.ncbi.nlm.nih.gov), and USP <1151> states that liquid-filled capsules, hard or soft, "may offer advantages over dry-filled capsules and tablets in content uniformity and drug dissolution" (Source: www.uspbpep.com). Patient-preference data supports this: in a survey of valproate patients asked to choose between a once-daily tablet and an equally effective, smaller softgel capsule taken twice daily, "82.8% (n = 331) preferred the soft gel capsule" (Source: pmc.ncbi.nlm.nih.gov), a striking result given that it asked patients to accept twice-daily dosing in exchange for the softgel format, a tradeoff most adherence research would predict patients to reject. FDA's own guidance acknowledges that tablets and capsules as a class share "ease of storage, portability, ease of administration, and accuracy in dosing" relative to other dosage forms (Source: www.fda.gov).

Capsules' primary weaknesses are cost and shell stability. Hard gelatin capsule (HGC) shells are "vulnerable to gelatin cross-linking, which can lead to slower and more variable in vitro dissolution rates" on storage, a well-documented aging mechanism (Source: pubmed.ncbi.nlm.nih.gov), motivating a shift toward HPMC shells for moisture- and heat-sensitive products; a peer-reviewed study found "HPMC capsules demonstrated more resilience to environmental conditions such as temperature and humidity" than gelatin capsules (Source: pmc.ncbi.nlm.nih.gov), though a scintigraphic disintegration study in fasting subjects found no statistically significant difference in disintegration time between HPMC and standard gelatin capsules (Source: pubmed.ncbi.nlm.nih.gov), suggesting the HPMC advantage is primarily one of long-term storage resilience rather than in-mouth or in-body performance at the point of dosing. On cost, Colorcon notes that tablets typically undercut capsules at scale, meaning capsules retain a persistent per-unit cost disadvantage in high-volume generic manufacturing that formulators must weigh against the patient-acceptability and dissolution benefits described above.

Orally Disintegrating Tablets (ODT)

Capabilities

FDA's December 2008 nonbinding ODT guidance recommends an in-vitro disintegration time of approximately 30 seconds or less using the USP method or an equivalent alternative, while explaining that 30 seconds is a representative, not arbitrary, value. It also generally recommends a tablet weight of no more than 500 mg, with justification when a heavier product is proposed (Source: www.fda.gov). The Federal Register notice announcing that guidance confirms it as an official "guidance for industry entitled 'Orally Disintegrating Tablets'" that formally distinguishes ODTs from other tablet types (Source: www.federalregister.gov).

Two manufacturing families dominate ODT production. **Freeze-drying (lyophilization)**, commercialized as Catalent's Zydis technology since 1986, "creates a unique, freeze-dried oral solid dosage form that disperses almost instantly in the mouth, without water" (Source: www.catalent.com), and works by pouring a drug solution or suspension into preformed blister pockets and passing them through a cryogenic freezing process before sublimating the ice to leave a porous matrix (Source: pmc.ncbi.nlm.nih.gov). **Direct compression with superdisintegrants** is the alternative route, relying on excipients such as sodium starch glycolate and croscarmellose sodium to drive rapid breakup on the tongue. A third, less common route, Fuisz Technologies' Shearform/FlashDose process, generates "a polysaccharide-based floss excipient, which is blended with Ceform products in the final formulation" (Source: www.pharmaceuticalonline.com). Direct compression is generally the cheaper and more scalable of the three routes since it reuses conventional tablet-press infrastructure, while freeze-drying requires dedicated lyophilization equipment and correspondingly higher capital investment.

Adoption

Precedence Research projects the global ODT market to grow from $15.73 billion in 2025 to $33.98 billion by 2035, an 8.01% CAGR (Source: www.precedenceresearch.com), a figure broadly corroborated by Straits Research's independent estimate of $15.85 billion in 2025 rising to $30.08 billion by 2034 at a 7.38% CAGR (Source: straitsresearch.com), a rare instance in this report's dataset where two independently commissioned forecasts land within roughly one percentage point of each other on both base value and growth rate. Approved ODT products span multiple therapeutic areas: Zofran ODT (ondansetron), an antiemetic, was initially approved January 27, 1999 under NDA 020781 (Source: www.federalregister.gov), and Merck's migraine drug Maxalt-MLT (rizatriptan) carries an initial U.S. approval year of 1998 (Source: nctr-crs.fda.gov).

Strengths and Limitations

ODTs' clinical rationale centers on patients who struggle to swallow conventional forms and on a potential bioavailability benefit: a peer-reviewed review notes ODTs "achieve increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx, and esophagus as saliva passes down" (Source: pmc.ncbi.nlm.nih.gov). The tradeoffs are real, however. The same review states that freeze-dried ODTs' "main disadvantage of these dosage forms are, in addition to the cost-intensive production process, the lack of physical resistance in standard blister packs and their limited ability to incorporate higher concentrations of active drug" (Source: pmc.ncbi.nlm.nih.gov), and moisture sensitivity is a persistent formulation challenge because "highly water-soluble excipients are susceptible to moisture; some will even deliquesce at high humidity" (Source: pmc.ncbi.nlm.nih.gov), which is why most ODTs ship in individually sealed blister packaging rather than bottles. The limited drug-loading capacity in particular means ODT technology suits low-dose, high-potency molecules far better than the high-milligram-strength drugs common in cardiovascular or infectious-disease treatment, a practical constraint that limits how far the category can expand into the broader tablet market regardless of its favorable growth rate.

Modified Release Systems: Extended, Sustained, and Controlled Release

Capabilities

Modified-release systems achieve non-immediate drug release through distinct engineering mechanisms. **Matrix systems** embed the drug in a hydrophilic polymer such as hydroxypropyl methylcellulose (HPMC), where release occurs through "coupled diffusion and erosion" of the polymer as fluid penetrates the tablet (Source: pmc.ncbi.nlm.nih.gov). **Osmotic pump systems**, commercialized as OROS (osmotic controlled-release oral delivery system) technology, are "composed of a compressed tablet core coated with a semi-permeable membrane through which delivery orifices are created using a laser beam or mechanical drill" (Source: pmc.ncbi.nlm.nih.gov); osmotic pressure draws water across the membrane and forces drug solution out through the orifice at a near-constant rate, which "minimize[s] the dosing frequency and subsequently improve[s] patient compliance" (Source: pmc.ncbi.nlm.nih.gov). **Multiparticulate systems** combine immediate- and delayed-release beads within a single capsule or tablet, as in Adderall XR, whose FDA label describes "two types of drug-containing beads (immediate-release and delayed-release) which prolong the release of amphetamine" (Source: dailymed.nlm.nih.gov). **Enteric coating**, a pH-sensitive polymer film, produces delayed release by resisting dissolution in stomach acid and releasing the drug only once the tablet reaches the higher pH of the small intestine, a mechanism FDA classifies squarely as delayed release (Source: www.fda.gov).

Federal regulation also constrains modified-release claims directly. Under 21 CFR 320.25(f), an in vivo bioavailability study supporting an extended-release product claim must show "the bioavailability profile established for the drug product rules out the occurrence of any dose dumping" (Source: www.ecfr.gov), the uncontrolled, rapid release of an entire dose that can occur if a matrix or membrane fails mechanically, potentially causing toxicity. This regulatory safeguard exists precisely because modified-release systems concentrate a multi-dose supply of active drug into a single unit; a mechanical failure in an immediate-release tablet simply changes when a single dose is absorbed, whereas the same failure in a 24-hour extended-release product can expose a patient to several doses' worth of drug at once.

Adoption

The engineering approach chosen is often product-specific. Concerta (OROS methylphenidate), used to treat attention-deficit/hyperactivity disorder, is formulated so that "22% of the total methylphenidate amount in CONCERTA... is available for immediate release and the remaining 78% is available for extended-release over 24 hours" (Source: dailymed.nlm.nih.gov), and its label states directly that "CONCERTA once daily minimizes the fluctuations between peak and trough concentrations associated with immediate-release methylphenidate three times daily" (Source: dailymed.nlm.nih.gov). Mordor Intelligence reports that immediate-release products held 61.23% of 2024 OSD formulation revenue and separately forecasts an 8.85% CAGR for its targeted and advanced-delivery segment (Source: www.mordorintelligence.com). The source lists targeted and advanced delivery separately from modified-release categories and does not provide an immediate-release CAGR, so it cannot establish a growth differential between modified-release and immediate-release products.

Strengths and Limitations

Modified release's core benefit is dosing convenience and steadier plasma concentrations, reducing peak-trough side effects and improving adherence for chronic conditions. Its costs are manufacturing complexity and quality risk: an osmotic-system review notes that "the integrity of this system and its required consistency are difficult to achieve" during manufacturing, since membrane thickness and orifice diameter must be tightly controlled to avoid dose dumping (Source: pmc.ncbi.nlm.nih.gov). Terminology also creates confusion for prescribers and patients: industry guidance observes that FDA "does not formally recognize the terms 'controlled release' (CR) or 'sustained release' (SR) as official regulatory categories," unlike extended release and delayed release, which do carry defined regulatory meaning (Source: www.colorcon.com). Whether a product may be split, crushed, or opened is product-specific. Patients and caregivers should follow the approved product labeling and obtain direction from a pharmacist or prescriber before altering any tablet or capsule; some modified-release products have approved alternative-administration instructions, while others do not.

Manufacturing Process and Formulation Development

Formulation development for OSD products is now organized, in principle, around the Quality by Design (QbD) framework set out in International Council for Harmonisation (ICH) guideline Q8(R2), which describes "a more systematic approach to development (also defined as quality by design)" as an alternative to purely empirical formulation (Source: database.ich.org). ICH Q8(R2) specifies minimum development elements, starting with "defining the quality target product profile (QTPP) as it relates to quality, safety and efficacy" (Source: database.ich.org) and continuing through identification of critical quality attributes and, where feasible, definition of a formal **Design Space**, "the multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters" demonstrated to assure product quality (Source: database.ich.org). This QbD approach is complemented by FDA's Process Analytical Technology (PAT) framework, under which the agency defines PAT as "a system for designing, analyzing, and controlling manufacturing through timely measurements" of critical quality attributes, grounded in the principle that "quality cannot be tested into products; it should be built-in or should be by design" (Source: www.fda.gov).

Standard OSD manufacturing unit operations include milling, blending, granulation, drying, compression or encapsulation, coating, and packaging. Excipients perform defined functional roles within this sequence: microcrystalline cellulose (MCC), for example, is "the most widely used direct compression excipient serving as a strong dry binder, tablet disintegrant, an absorbent, filler or diluent, a lubricant, and anti-adherent" simultaneously (Source: www.intechopen.com), and roller compaction, the dominant dry-granulation method, is "a dry process involving compaction of materials that are then milled to generate a granulation" (Source: www.intechopen.com). A single excipient performing multiple functions, as MCC does, is a common formulation strategy for reducing the total number of raw materials in a tablet, which in turn simplifies supply-chain qualification and lowers the number of critical material attributes a formulator must control under a QbD program.

The most significant recent shift in OSD manufacturing is the move from batch to **continuous manufacturing (CM)**. A 2021 peer-reviewed review notes that "the first product manufactured by CM was only approved in 2015," referring to Vertex's Orkambi (Source: www.ncbi.nlm.nih.gov), followed by Janssen's Prezista in 2016 and Eli Lilly's Verzenio in 2017, establishing continuous manufacturing across three separate sponsors and therapeutic areas within roughly two years of the first approval (Source: www.ncbi.nlm.nih.gov). Pharma Manufacturing described Janssen's 2016 approval as historic: "the FDA has approved, for the first time in history, a manufacturer's production method change from 'batch' to continuous manufacturing" (Source: www.pharmamanufacturing.com), a conversion in which "batches took 2 weeks to produce and CM only 1 day" (Source: www.ncbi.nlm.nih.gov). In continuous tableting lines, twin-screw granulators handle wet granulation as "essentially small volume high shear continuous mixers" (Source: www.ncbi.nlm.nih.gov), while continuous direct compression lines integrate "dosing stations with multiple loss-in-weight feeders, a continuous blender to mix API with excipients," a lubrication blender, and a rotary press in a single connected line (Source: www.ncbi.nlm.nih.gov). The same review reports that "continuous mixers have been shown to produce a more homogeneous output

compared with mixers operating in a batch mode" (Source: www.ncbi.nlm.nih.gov), a quality argument that has helped drive FDA's encouragement of the technology; the agency's Emerging Technology Program formally "graduated its first technology, Continuous Direct Compression (CDC) on October 21, 2021" after accepting the technology into the program in 2015 (Source: www.fda.gov). Because a continuous line runs longer and generates a stream of in-process measurements rather than the discrete batch records of legacy manufacturing, it also produces a fundamentally different volume and shape of quality data, a shift that is reshaping how manufacturers structure their quality and data-analytics functions, a theme the Implications section below develops further.

Feature Comparison

Table 2 consolidates the manufacturing, release, advantage, and limitation profile of the six OSD sub-forms discussed above into a single reference matrix, drawing on the facts and citations established in the preceding sections.

DOSAGE FORM	MANUFACTURING METHOD	TYPICAL RELEASE PROFILE	KEY ADVANTAGES	KEY LIMITATIONS	REPRESENTATIVE EXAMPLES
Compressed Tablet (Immediate Release)	Direct compression or wet/dry granulation followed by rotary-press compression (Source: pmc.ncbi.nlm.nih.gov)	Dissolves promptly in gastric fluid, no intentional delay	Lowest cost at scale; long shelf life (Source: www.colorcon.com)	Swallowing difficulty affects a meaningful share of adults, as discussed above	Generic immediate-release tablets broadly
Hard Gelatin/HPMC Capsule	Mechanical filling of preformed two-piece shells (Source: www.uspbpep.com)	Immediate release; shell dissolves before contents disperse	Taste/odor masking; flexible fill options	Gelatin cross-linking alters dissolution over storage (Source: pubmed.ncbi.nlm.nih.gov)	Generic hard-shell capsules broadly
Soft Gelatin (Softgel) Capsule	Rotary-die simultaneous form/fill/seal (Source: www.pharmaexcipients.com)	Immediate release, often faster onset for liquid fills	Self-lubricating, easier to swallow (Source: pmc.ncbi.nlm.nih.gov); high patient preference, as discussed above	Can cost more per unit than conventional tablets at high production volumes	Common in OTC vitamins and lipophilic drugs
Orally Disintegrating Tablet (ODT)	Freeze-drying (e.g., Zydis) or direct compression with superdisintegrants, as discussed above	Designed for rapid oral disintegration; FDA's nonbinding guidance recommends approximately 30 seconds or less (Source: www.fda.gov)	May aid patients who have difficulty swallowing; administration instructions vary by product	Fragile, moisture-sensitive, cost-intensive, limited drug loading (Source: pmc.ncbi.nlm.nih.gov)	Zofran ODT, Femlyv, Maxalt-MLT
Extended/Sustained-Release Tablet	Hydrophilic/hydrophobic matrix or osmotic (OROS) core, as discussed above	Drug released gradually over hours	Reduced dosing frequency, smoother plasma levels (Source: dailymed.nlm.nih.gov)	Manufacturing/membrane integrity risk, dose-dumping regulation (Source: www.ecfr.gov)	Concerta, Adderall XR, reformulated OxyContin
Delayed-Release (Enteric-Coated) Tablet	Application of pH-sensitive polymer coating	Withholds release until intestinal pH is reached (Source: www.fda.gov)	Protects acid-labile drugs and gastric mucosa	Altering the product may affect its release characteristics; follow its labeling and pharmacist/prescriber instructions	Enteric-coated proton-pump inhibitors, NSAIDs

The matrix makes clear that no single OSD form dominates on every axis: tablets win on cost and shelf life, softgels and ODTs win on patient acceptability for specific populations, and modified-release forms win on dosing convenience at the cost of manufacturing complexity. Formulators typically select among these forms based on the active pharmaceutical ingredient's solubility and stability profile, the target patient population's swallowing capability, and the desired dosing interval, rather than any form being universally superior. A useful way to read the matrix is as a set of tradeoffs rather than a ranking: a formulator choosing between a plain immediate-release tablet and an OROS extended-release tablet for the same molecule is not choosing a "better" product in the abstract, but rather trading a simpler, cheaper manufacturing process for a more convenient, and clinically differentiated, dosing schedule.

Performance and Benchmarks

Independent clinical and regulatory data give a clearer picture of dosage-form performance than manufacturer claims alone. On swallowing acceptability, a 2013 study of 1,051 German primary-care patients found "37.4% reported having had difficulties in swallowing tablets and capsules," and critically, "the majority (70.4%) of these patients was not identified by their GP [general practitioner]" (Source: pubmed.ncbi.nlm.nih.gov). Of the affected patients, "58.8% of the affected patients had already modified their drugs in a way that may alter safety and efficacy and 9.4% indicated to be non-adherent" as a direct consequence (Source: pubmed.ncbi.nlm.nih.gov), behavior (crushing tablets, opening capsules) that can materially alter a modified-release product's release kinetics. A 2023 systematic review of 12 studies on inpatient swallowing found prevalence estimates for difficulty swallowing solid oral dosage forms ranging from "10 to 34.2%" across seven studies that reported the metric (Source: www.ncbi.nlm.nih.gov), with prevalence rising sharply in long-term care: one geriatric-unit study within that review found swallowing-difficulty prevalence of "29.5% (155/526)" on general geriatric wards, rising to "40.3% (98/243)" in long-term care units specifically (Source: www.ncbi.nlm.nih.gov). These institutionalized-population figures run notably higher than the general-population estimate cited in this report's executive summary, underscoring that dosage-form acceptability is highly population-dependent, and that a manufacturer's format decision should weigh its likely patient population as carefully as its pharmacokinetic goals.

On release-profile adoption, a peer-reviewed analysis of FDA-approved small-molecule oral drugs from 2020 to 2024 (n=104) found that "most oral drugs are administered QD [once daily] (67%), BID [twice daily] and TID [three times daily] regimens are also regularly approved (32%)" (Source: www.ncbi.nlm.nih.gov), a pattern that reflects the industry's structural preference for reduced dosing frequency, whether achieved through inherently long-half-life molecules or through modified-release engineering. The same review notes "approximately 30 to 50 new drugs are approved by the FDA every year, with approximately 70% of those being small molecules" that are typically formulated as oral solid dosage products (Source: www.ncbi.nlm.nih.gov). On the generic side, FDA's own monthly performance data recorded 694 total Abbreviated New Drug Application (ANDA) approvals across fiscal year 2024 (October 2023 to September 2024) (Source: www.fda.gov), the large majority of which are tablets and capsules given the category's dominance of the overall generic pipeline.

Data Analysis and Evidence

Market-sizing estimates for OSD sub-categories vary meaningfully across research firms, a discrepancy this report presents transparently rather than reconciling artificially, since each firm applies its own market definition and forecasting methodology. *Table 3* summarizes the principal figures gathered for this report.

SEGMENT	BASE-YEAR SIZE	FORECAST SIZE	CAGR	FORECAST PERIOD	SOURCE
Overall OSD formulation market	$635.77 billion (2025)	$795.35 billion (2030)	4.58%	2025-2030	Mordor Intelligence (Source: www.mordorintelligence.com)
Overall OSD pharmaceutical market	$651.2 billion (2025)	$1,288.0 billion (2036)	6.4%	2025-2036	Fact.MR (Source: www.factmr.com)
Orally disintegrating tablet market	$15.73 billion (2025)	$33.98 billion (2035)	8.01%	2025-2035	Precedence Research (Source: www.precedenceresearch.com)
Orally disintegrating tablet market	$15.85 billion (2025)	$30.08 billion (2034)	7.38%	2026-2034	Straits Research (Source: straitsresearch.com)
Controlled-release drug delivery (global)	$66.80 billion (2025)	$160.09 billion (2035)	9.13%	2026-2035	Precedence Research (Source: www.precedenceresearch.com)
Controlled-release drug delivery (U.S.)	$20.11 billion (2025)	$49.31 billion (2035)	9.38%	2025-2035	Precedence Research (Source: www.precedenceresearch.com)
Softgel capsules market	$8.86 billion (2025)	not specified	not specified	to 2031	Mordor Intelligence (Source: www.mordorintelligence.com)

The pattern across these figures is directionally consistent even where absolute numbers diverge: every OSD sub-segment tracked here is forecast to grow through the mid-2030s, and the fastest-growing segments, ODTs and controlled-release systems, are precisely the higher-engineering, higher-margin categories that pharmaceutical manufacturers and their contract development and manufacturing organization (CDMO) partners are investing in most heavily. Within the broader formulation market, Mordor Intelligence reports orally disintegrating films as its fastest-growing dosage-form segment, at a 7.36% CAGR (Source: www.mordorintelligence.com). It separately forecasts an 8.85% CAGR for targeted and advanced delivery; that segment is not synonymous with all modified-release products, and the reported immediate-release share does not show an immediate-release growth rate. Clinical evidence reinforces the commercial logic: with swallowing-difficulty prevalence documented as high as 34.2% among hospitalized adults and 40.3% in long-term care, as detailed in the preceding section,

regulators and manufacturers have a clear population-health rationale for continued investment in ODT and easier-to-administer modified-release formats, independent of the purely commercial growth argument. Taken together, the figures in Table 3 indicate growth across several differently defined markets, but they do not establish a growth-rate comparison between oral-solid modified-release products and immediate-release tablets. The controlled-release forecast covers drug-delivery technologies beyond oral solid dosage forms.

Case Studies and Real-World Examples

Femlyv: The First FDA-Approved Orally Disintegrating Birth Control Tablet (2024)

On July 22, 2024, FDA approved Femlyv, "the first orally disintegrating tablet approved for the prevention of pregnancy," according to the agency's own press announcement, which quoted FDA official Janet Maynard explaining the clinical rationale directly: "Femlyv is the first FDA approved dissolvable birth control pill, designed for individuals who have trouble swallowing their medication" (Source: www.fda.gov). The product's labeling instructs patients to "place one FEMLYV orally disintegrating tablet (ODT) on the tongue, allow to disintegrate and then follow with 8 oz. (240 mL) of water" (Source: dailymed.nlm.nih.gov), a mechanism illustrating that even ODT products designed to dissolve without water can be labeled for administration with a water chaser to aid full dosing.

Vertex's Orkambi and the First FDA-Cleared Continuous Manufacturing Process (2015)

Vertex Pharmaceuticals won FDA approval for Orkambi, a cystic fibrosis treatment, in July 2015, and trade press reports the company "believes it was the first to secure an OK from the FDA for a fully continuous drug product manufacturing process, which it uses internally to make Orkambi" (Source: www.biopharmadive.com). A peer-reviewed review corroborates the timing, noting continuous manufacturing's "first product... was only approved in 2015" (Source: www.ncbi.nlm.nih.gov). This approval, followed a year later by Janssen's conversion of Prezista (darunavir) from batch to continuous manufacturing at its Gurabo, Puerto Rico facility, an approval trade press called the first of its kind "in history" (Source: www.pharmamanufacturing.com), marks the point at which continuous OSD manufacturing moved from pilot-scale academic demonstration to commercial FDA-approved practice.

Concerta and OROS Osmotic Technology (Ongoing)

Concerta, a once-daily extended-release formulation of methylphenidate for attention-deficit/hyperactivity disorder, illustrates OROS technology in commercial use. A peer-reviewed pharmacokinetic review describes its architecture: "an extended-release formulation that has an immediate-release portion of 22% of the total drug load in a water soluble outer coating and an extended-release core that delivers 78% of the [methylphenidate] dose," where "the extended-release core is an osmotic controlled-release oral delivery system (OROS) which is surrounded by the [immediate-release] overcoat" (Source: www.ncbi.nlm.nih.gov). This dual-phase architecture, immediate onset paired with sustained delivery, remains the reference example cited throughout the pharmaceutical literature for osmotic pump systems, and its clinical rationale of reducing peak-trough fluctuation compared to multiple daily immediate-release doses is echoed directly in Concerta's own FDA-approved labeling.

OxyContin's Abuse-Deterrent Reformulation (2010)

Purdue Pharma L.P.'s OxyContin, an oral extended-release oxycodone tablet, originally approved December 12, 1995 and marketed in seven strengths from 10 mg to 80 mg, received FDA approval for a reformulated, abuse-deterrent controlled-release version on April 5, 2010 (Source: www.fda.gov), a milestone included among FDA's significant regulatory actions on prescription opioids. The reformulation's controlled-release matrix was engineered to resist crushing and dissolution manipulation, and post-marketing abuse-liability testing submitted in support of the reformulation reported measurable behavioral impact: FDA-reviewed labeling states that "approximately 56% (n = 15) of subjects had some reduction in drug liking with OXYCONTIN relative to oxycodone HCl" in controlled comparative testing (Source: dailymed.nlm.nih.gov), a direct application of the modified-release engineering principles discussed above to a public-health abuse-deterrence goal rather than a purely pharmacokinetic one.

Valsartan Nationwide Recall Over NDMA Contamination (2018)

On July 13, 2018, Major Pharmaceuticals issued a voluntary nationwide recall of valsartan tablets (80 mg and 160 mg USP), supplied by Teva Pharmaceuticals and distributed nationwide to hospitals and pharmacies, because the product "may contain the probable carcinogen N-nitrosodimethylamine (NDMA)" (Source: www.fda.gov). FDA subsequently explained the risk in quantitative terms, estimating that if 8,000 people took the highest daily valsartan dose (320 mg) containing NDMA for four years, "there may be one additional case of cancer beyond the average cancer rate among Americans" (Source: www.fda.gov). The episode, which eventually expanded to other angiotensin II receptor blockers (losartan, irbesartan) and dozens of manufacturers, remains the reference case in pharmaceutical quality circles for how a nitrosamine impurity risk traced to a manufacturing process change (in valsartan's case, a solvent and reagent substitution at an active pharmaceutical ingredient supplier) can trigger a multi-year, multi-manufacturer OSD recall wave.

Intas Pharmaceuticals Warning Letter Over Tablet Stability Investigations (2026)

Following a September 2025 inspection of its Dehradun, India tablet manufacturing facility, FDA issued a warning letter to Intas Pharmaceuticals dated March 30, 2026 (Source: www.fda.gov). The letter cited inadequate investigation of tablet stability failures, noting that "your investigations into out-of-specification (OOS) assay results were inadequate," and that "since 2023, your testing has shown multiple confirmed stability OOS results" (Source: www.fda.gov). The letter also flagged a data-integrity failure in electronic batch records, stating that "your quality assurance employee instructed your software vendor to make changes to your electronic batch record which were not captured in the audit trail or managed through your quality system" (Source: www.fda.gov). Read together with the valsartan case, this 2026 warning letter shows that tablet-manufacturing quality risk spans both chemical contamination and electronic-record governance, and that both categories remain live enforcement priorities nearly a decade apart. Across all six cases above, spanning a 2010 opioid reformulation, a 2015 manufacturing-process milestone, a 2018 nationwide recall, and a 2026 data-integrity warning letter, the common thread is that OSD quality and innovation are judged by regulators over the full product lifecycle, not merely at initial approval.

Implications and Future Directions

Three structural trends are visible across the data gathered for this report. First, **modified-release and orally disintegrating formats are growing faster than plain immediate-release tablets** by every market estimate collected, whether measured as ODT-specific CAGR (7.38 to 8.01%) (Source: www.precedenceresearch.com) or controlled-release CAGR (9.13 to 9.38%) (Source: www.precedenceresearch.com), both comfortably outpacing the 4.58 to 6.4% CAGR projected for the overall OSD category detailed in Table 3 above. This is consistent with an aging global population in which dysphagia prevalence, already documented above 40% in long-term care settings, creates durable clinical demand for easier-to-administer formats.

Second, **continuous manufacturing is an emerging and expanding approach** for OSD products. FDA has supported its evaluation through the Emerging Technology Program and PAT framework, but the cited evidence does not show that it is expected practice for new OSD products. As continuous lines and their associated real-time release testing generate far more in-process sensor and quality data per batch than legacy batch manufacturing, pharmaceutical manufacturers face a growing data-management and analytics burden layered on top of the underlying process engineering challenge, a burden that intersects directly with the broader wave of artificial intelligence (AI) adoption already underway in pharmaceutical manufacturing more broadly. IntuitionLabs, a life-sciences and AI consultancy, notes in its analysis of the European Union's draft GMP Annex 22 framework that AI-specific manufacturing controls now under regulatory consideration include explainability methods, confidence-score logging, human oversight, and drift monitoring for models used in applications such as "visual inspection, predictive maintenance, batch release support, and deviation triage" (Source: intuitionlabs.ai), functions directly relevant to high-throughput continuous OSD lines producing large volumes of tablets or capsules per shift. IntuitionLabs positions itself, as a Veeva-focused life-sciences consultancy, around building "built-in compliance with FDA, EMA, and global regulations" into the enterprise systems pharmaceutical manufacturers already run (Source: intuitionlabs.ai), an advisory posture relevant to, though distinct from, the process-engineering and formulation-science questions that sit at the center of this report. For manufacturers weighing whether to expand a continuous line's PAT sensor suite or its supporting quality-data infrastructure, the practical question is less whether AI tooling belongs in an OSD quality system at all, and more how quickly a given facility's existing batch-record and deviation-management practices can absorb model-based decision support without compromising the human-in-the-loop oversight that regulators, per IntuitionLabs' own reading of the draft EU framework, are converging on as a baseline expectation.

Third, **quality and data-integrity enforcement remains active** across both established and newer OSD technologies, as the valsartan and Intas cases above illustrate; neither the age of a manufacturing technology (tablets have been produced industrially for over a century) nor its novelty (electronic batch records are comparatively recent) exempts a facility from FDA scrutiny. Manufacturers evaluating new OSD formats, whether adopting ODT technology to serve dysphagia-affected populations, moving toward continuous manufacturing to capture the efficiency gains documented at Janssen and Vertex, or expanding modified-release portfolios to meet the growth this report's data section quantifies, will need quality and compliance infrastructure that scales with that technological complexity rather than lagging behind it. That infrastructure question will be important for manufacturers pursuing ODT or controlled-release opportunities, although the market estimates in this report do not support a direct comparison of growth between oral-solid modified-release products and immediate-release tablets.

Frequently Asked Questions (FAQs)

What are the main types of oral solid dosage forms? The principal categories are compressed tablets, hard and soft gelatin (or HPMC) capsules, orally disintegrating tablets, and modified-release systems (extended, delayed, and controlled release), which can themselves be manufactured as tablets or as multiparticulate capsules (Source: www.fda.gov).

Are tablets or capsules better, and what are their respective advantages and disadvantages? Neither is universally superior. Tablets are generally cheaper to manufacture at scale and more chemically stable in storage (Source: www.colorcon.com), but a meaningful share of patients report difficulty swallowing them (Source: pmc.ncbi.nlm.nih.gov). Capsules, particularly softgels, are often preferred by patients for ease of swallowing and can offer dissolution advantages for liquid-fill formulations, but cost more to produce at scale and their gelatin shells are vulnerable to cross-linking over storage (Source: pubmed.ncbi.nlm.nih.gov). The right choice depends on the active ingredient's properties and the target patient population.

How is an orally disintegrating tablet different from a conventional tablet? An ODT is designed to disintegrate rapidly in the mouth. FDA's nonbinding guidance recommends an in-vitro disintegration time of approximately 30 seconds or less, but says that value is not an arbitrary boundary between ODTs and other tablet forms; administration instructions should be checked in the individual product's labeling (Source: www.fda.gov).

What is the difference between modified release and immediate release drugs? Immediate-release products dissolve with no intention of delaying or prolonging absorption, while modified-release products deliberately alter the timing or location of release "to accomplish therapeutic or convenience objectives not offered by conventional dosage forms" (Source: www.fda.gov).

Is "extended release" the same as "sustained release"? Not officially. FDA recognizes "extended release" as a defined regulatory term, but "does not formally recognize the terms 'controlled release' (CR) or 'sustained release' (SR) as official regulatory categories" (Source: www.colorcon.com); the latter terms are used descriptively and somewhat interchangeably in industry practice.

What is the standard oral solid dosage manufacturing process? The unit operations depend on the dosage form and manufacturing route. A product may be milled and blended, then either directly compressed or granulated (wet or dry); wet granulation generally adds drying. Tablets may be coated, while capsules are filled rather than compressed. Development is commonly guided by a Quality by Design approach that begins with "defining the quality target product profile (QTPP)" per ICH Q8(R2) (Source: database.ich.org).

What are controlled release drug delivery systems, and how do they differ from ordinary tablets or capsules? Controlled-release systems, most often osmotic pumps or polymer matrices, are engineered to release a drug at a predetermined rate over an extended period rather than dissolving promptly, typically to minimize dosing frequency and improve patient compliance (Source: pmc.ncbi.nlm.nih.gov). The global controlled-release drug delivery market was estimated at $66.80 billion in 2025, reflecting substantial and growing commercial investment in the technology (Source: www.precedenceresearch.com).

Conclusion

Oral solid dosage forms remain a major pharmaceutical delivery category, and the choice among tablets, capsules, orally disintegrating tablets, and modified-release systems is rarely a matter of one form being objectively superior. Each format trades cost, stability, manufacturing complexity, and patient acceptability against the others in different proportions. FDA's nonbinding ODT guidance recommends an in-vitro disintegration time of approximately 30 seconds or less and explains that the value is not an arbitrary boundary; its release definitions and dose-dumping safeguards reflect the clinical importance of product-specific performance (FDA ODT guidance. Market estimates in this report vary in scope and methodology. In particular, a controlled-release market spanning oral and non-oral delivery technologies cannot establish growth for the oral-solid modified-release segment.

Manufacturing practice has also evolved, from early continuous-manufacturing approvals to FDA's 2021 graduation of Continuous Direct Compression from its Emerging Technology Program. Continuous operations require robust, product-appropriate process controls and quality oversight. At the same time, the valsartan and Intas cases examined here confirm that quality risk in OSD manufacturing has not receded as the underlying science has advanced; it has simply moved to new failure modes, from solvent-driven nitrosamine formation to electronic batch-record governance, that manufacturers and their regulators must continue to monitor as closely as they monitor dissolution rates and disintegration times. For formulators, manufacturers, and prescribers alike, the practical takeaway is the same one this report opened with: no single oral solid dosage form is universally best, and the right choice depends on matching a molecule's physicochemical properties and a patient population's needs to the specific manufacturing method, release profile, and regulatory pathway that fits them.

Tags: oral solid dosage forms, tablets vs capsules, orally disintegrating tablets, modified release drugs, extended release vs sustained release, controlled release drug delivery, oral solid dosage manufacturing, pharmaceutical formulation development

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