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# A CRITICAL REVIEW ON WET AND DRY GRANULATION IN PHARMACEUTICALS

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**ABSTRACT**
Granulation is a vital processing step in pharmaceutical manufacturing that converts loose, fine powders into larger, mechanically stronger, and more flowable granules. This transformation improves powder handling, ensures uniformity of drug content, enhances compressibility, and supports the production of high-quality tablets. Among the various methods available, wet granulation and dry granulation are the two most widely used techniques, each offering specific benefits based on the characteristics of the drug and excipients involved. Wet granulation relies on the incorporation of a liquid binding medium to promote particle adhesion and controlled agglomerate growth, making it suitable for formulations requiring robust granule strength and superior content uniformity. In contrast, dry granulation employs mechanical pressure either by roller compaction or slugging to consolidate powders without the use of moisture, making it ideal for heat-sensitive or moisture-sensitive active pharmaceutical ingredients (APIs).
This project presents a comprehensive comparison of wet and dry granulation methods, discussing their operating principles, process parameters, advantages, limitations, and industrial relevance. The review also highlights key research contributions, current manufacturing challenges, and emerging innovations such as continuous granulation, automation, and AI-assisted process control. Together, these insights underline the essential role of granulation in ensuring consistent product quality and in advancing modern pharmaceutical manufacturing practices.

**KEYWORDS**
Wet Granulation, Dry Granulation, Roller Compaction, Particle Agglomeration, Flowability

## INTRODUCTION

### Definition and Importance of Granulation

Granulation is a fundamental operation in the production of solid oral dosage forms. It involves converting fine, loosely packed powders into larger, coherent granules. These granules exhibit improved flow properties, better compressibility, and enhanced mechanical strength - qualities essential for producing tablets with consistent weight, uniform drug distribution, and satisfactory physical integrity. [1]
The process is crucial because most pharmaceutical powders, in their raw state, possess poor flowability and low bulk density, making them unsuitable for direct compression. This ensures that each tablet contains the correct dose of the active pharmaceutical ingredient (API), fulfilling regulatory and therapeutic demands. Therefore, granulation directly influences product quality, patient safety, and manufacturing efficiency. [1,2]

### Overview of Tablet Manufacturing

Tablet manufacturing remains the most common method for delivering oral medications, accounting for more than half of the pharmaceutical dosage forms produced worldwide. The typical workflow includes raw material testing, powder blending, granulation, sizing or milling, lubrication, compression, and packaging. [3] Granulation sits at the center of this workflow, as the properties of the granules determine the success of downstream operations. Properly prepared granules ensure smooth die filling, adequate compaction, and minimal tablet defects such as capping or lamination. As a result, selecting an appropriate granulation technique is a strategic decision that influences the stability, performance, and manufacturability of a tablet formulation. [3]

### Granulation Techniques

Granulation can be carried out through several approaches, but wet granulation and dry granulation are the two dominant and widely adopted techniques in pharmaceutical manufacturing. Each method influences the physical, mechanical, and flow properties of the resulting granules, ultimately affecting tablet quality and process efficiency. This section provides a detailed explanation of both techniques, their operational steps, and the variables that govern their performance. [3]

## LITERATURE REVIEW

1. Pradhan and co-authors present a detailed comparison of wet and dry granulation by outlining the influence of each process on material flow, compressibility, and processing needs. The review notes that wet granulation builds strong granule structures through binders, giving superior flow properties, whereas dry granulation is more economical and suitable for heat- and moisture-sensitive drugs. Ultimately, the selection of granulation method depends on formulation requirements and processing limitations. [4]
2. Kulyadi summarizes manufacturing obstacles relating to granulation, especially during scale-up. Wet granulation is highlighted for achieving good dose uniformity in formulations containing very small amounts of drug, while dry granulation is recommended for drugs that cannot tolerate excess heat or moisture. Variations in flow, compressibility and friability across methods are also discussed. [5]
3. Shaikshanik et al. studied on this review explains the fundamental stages of wet granulation— nucleation, growth and consolidation— and compares common techniques like high-shear, low-shear and fluid-bed systems. The authors point out that wet granulation provides greater control over the final granule structure than dry granulation due to its binder-driven agglomeration mechanism. [6]
4. Muralidhar and colleagues examine both conventional and advanced granulation technologies, including steam granulation, foam granulation and moisture-activated dry granulation. Wet granulation is viewed as versatile but energy-intensive, whereas dry granulation is faster but challenged by poor powder flow. The new technologies aim to minimize solvent use while improving energy efficiency. [7]
5. Intelligent Pharmacy reported this extensive analysis compares 11 wet granulation techniques with multiple dry granulation approaches. The paper emphasizes that continuous twin-screw granulation provides a middle ground, reducing the need for liquid while maintaining performance, and notes a growing trend toward continuous processes in industry. [8]
6. PubMed Comparative study on the investigates roller compaction, twin-screw, high- shear and fluid-bed granulation. Results show that stronger granules from wet granulation do not automatically produce stronger tablets, revealing an inverse connection between granule strength and tablet tensile strength. Roller compaction unexpectedly resulted in good tablet ability. [9]
7. PharmaTutor review this paper describes the moisture-activated dry granulation (MADG) technique, which uses minimal added water while still promoting binding. By reducing drying steps associated with wet granulation, MADG supports the production of strong granules and is a viable choice for moderately moisture-sensitive actives. [10]
8. Thalari reviews novel dry granulation methods, with a focus on pneumatic granulation, which minimizes dust and enhances uniformity compared with traditional dry granulation. It also offers improved potential for continuous manufacturing. [11]
9. Indurevati the review identifies common shortcomings of dry granulation such as dust formation and poor compressibility. In contrast, wet granulation yields granules with superior mechanical properties. The paper suggests using enhanced excipients to overcome binding limitations in dry granulation. [12]
10. Ries and colleagues propose a continuous wet granulation method that does not require externally added liquid. Instead, the excipient releases water during processing, drastically decreasing drying energy. The produced granules showed excellent compactibility and tablet tensile strength. [13]
11. Khan & Nasir review centers on binder behavior in wet granulation and how binder solubility and viscosity modify granule hardness and friability. The authors emphasize that selecting an unsuitable binder type is one of the most frequent causes of formulation failure.[14]
12. Patel & Singh the authors review scale-up issues for both granulation processes. Wet granulation scale-up is complicated by moisture variation across the batch, whereas dry granulation is mainly dependent on ensuring consistent compaction force. They recommend using PAT-based monitoring to achieve consistent process performance. [15]
13. Chatterjee examines the principles of particle engineering during granule formation and concludes that wet granulation gives better control over porosity than dry granulation. Since porosity strongly affects disintegration anddissolution, wet granulation is advantageous when rapid drug release is required. [16]
14. Subramanian & Rao study compares dissolution profiles of tablets prepared using both granulation methods. Wet-granulated tablets exhibited faster dissolution due to improved wettability and internal porosity. Tablets made by dry granulation needed additional disintegrates to match the dissolution behavior. [17]
15. Onwuneme et al. the authors study the effect of granule size distribution on tablet weight uniformity. Wet granulation achieved a narrower size distribution and resulted in highly consistent tablet mass. Dry granulation generated more fine particles, contributing to variations in both tablet hardness and weight. [18]

## WET GRANULATION PROCESS

### Definition and Principle

Wet granulation involves the addition of a liquid binder to a powder blend to promote agglomeration. When a binding solution comes in contact with powder particles, it forms temporary liquid bridges that hold the particles together. As drying progresses, these bridges transform into solid bonds, producing granules with superior strength, improved uniformity, and better flow characteristics. This method is especially suited for formulations that require enhanced improved drug distribution. [1,2]


**Fig. no. 1 : Wet Granulation Process**

**Step-by-Step Wet Granulation Procedure**

Step 1: Weighing and Initial Mixing

All formulation components—such as the API, diluents, disintegrates, and binders— are accurately weighed. These powders are then mixed using appropriate blending equipment (planetary mixers, ribbon blenders, or drum mixers) to ensure homogeneity before binder addition.

Step 2: Preparation of Binder Solution

A binder, such as PVP, HPMC, gelatin, or gum acacia, is dissolved in a suitable solvent (commonly water or alcohol). The binder concentration typically ranges between 5–20%, depending on the formulation's binding strength requirements.

Step 3: Wet Massing

The binder solution is added gradually to the powder blend under continuous mixing. High- shear mixers or planetary mixers are typically used. This stage continues until a cohesive, moldable wet mass is formed-one that holds its shape without crumbling or becoming overly sticky.

Step 4: Wet Screening

The wet mass is forced through a sieve (6–12 mesh) to break it into smaller granules. The chosen mesh size influences the initial granule size and affects later drying and compression behavior.

Step 5: Drying

The wet granules are dried in tray dryers, fluidized-bed dryers, or vacuum dryers. Controlled drying is essential to prevent thermal degradation of sensitive drugs. The ideal final moisture content is typically maintained around 2–5% to balance granule hardness and compressibility.

Step 6: Dry Screening (Sizing)

Once dried, the granules are passed through a finer sieve (14–20 mesh) to achieve uniform particle size distribution suitable for compression.

Step 7: Final Blending and Lubrication

Lubricants (e.g., magnesium stearate or talc) and glidants are blended with the dried granules. This step must be gentle and brief to avoid overmixing, which could impair tablet hardness or dissolution.

Step 8: Compression

The final granules are compressed into tablets using single-punch or rotary tablet presses. Proper granule flowability and uniformity ensure consistent tablet weight and mechanical strength. [6]

**Critical Process Parameters**

Several variables directly influence wet granulation outcomes: Binder concentration and type,amount of liquid added, Mixing speed, and duration Granule size before and after drying, drying temperature and time Final Moisture Level [6]

**DRY GRANULATION PROCESS**

**Definition and Principle**

Dry granulation converts powder blends into granules without the use of liquid binding agents. Instead, powders are compacted under high pressure, forming large sheets or slugs. These compacts are then milled to obtain granules of the desired size. This method is particularly beneficial for moisture-sensitive or thermolabile APIs that cannot withstand the conditions of wet granulation. [19,20]

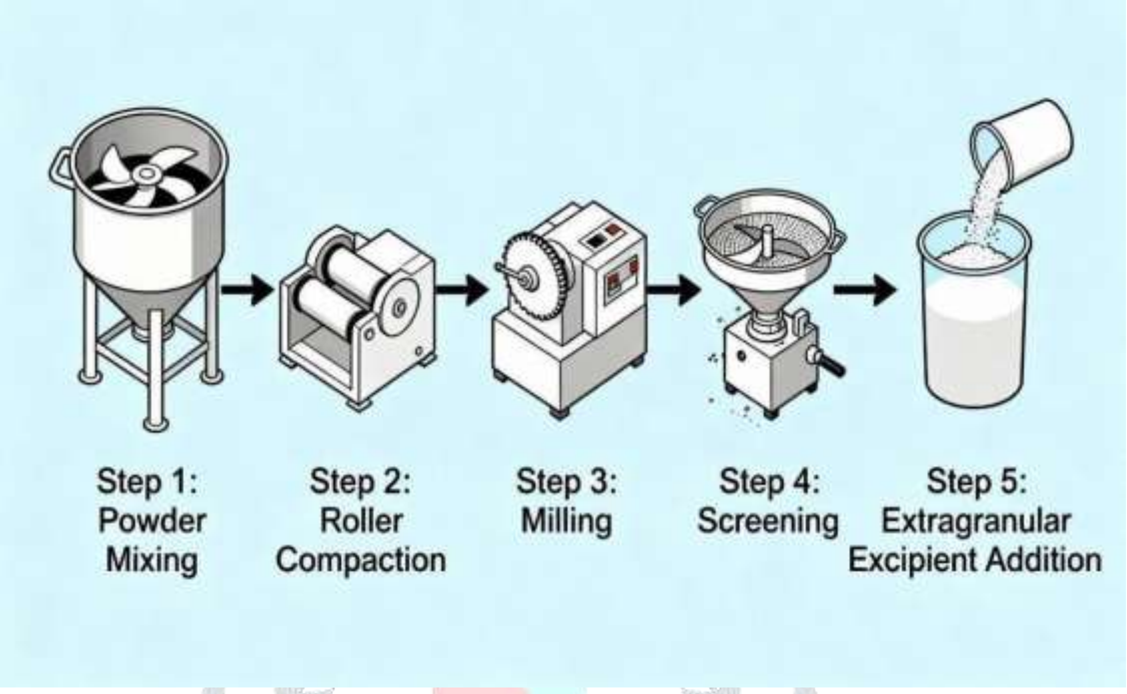


**Fig. no. 2: dry granulation process**

**Types of Dry Granulation**

1. Slugging Method

In slugging, powder blends are compressed into large, flat tablets known as slugs. These slugs are subsequently milled and screened to produce granules. While simple, slugging has limitations such as low throughput, inconsistent compaction, and higher dust formation.

2. Roller Compaction Method

Roller compaction is the modern and preferred dry granulation technique. Powders are fed between counter-rotating rollers that apply high pressure, producing a continuous sheet or ribbon. This compacted ribbon is milled andscreened to yield granules. Roller compaction offers advantages such as: Higher throughput, Better process control

Reduced dust generation

Suitabilityfor continuous manufacturing [19,21]

**Step-by-Step Dry Granulation Procedure**

Step 1: Pre-Mixing

The API and excipients are weighed and blended to achieve a uniformpowder mixture with adequate flow properties suitable for roller compaction.

Step 2: Compaction

The powder is compacted between rollers or compressed into slugs. The degree of compaction is controlled through roller pressure, roller gap, and feed rate.

Step 3: Milling

The compacted ribbons or slugs are milled using a hammer mill or oscillating granulator to break them into uniform-sized granules.

Step 4: Screening

Granules are passed through sieves to obtain the desired size distribution. Oversized or undersized material may be recycled.

Step 5: Lubrication

Lubricants are added in a final blending step to enhance flowability and reduce friction during tablet compression.

Step 6: Compression

The resulting granules are compressed into tablets using appropriate tablet presses. [19]

## COMPARATIVE OVERVIEW OF WET AND DRY GRANULATION [22]

| CHARACTERISTIC | WET GRANULATION | DRY GRANULATION |
|---|---|---|
| Granulating Agent | Liquid binder (aqueous/non - aqueous) | No liquid; mechanical compression |
| Equipment Complexity | High (requires dryer, mixer, mill) | Moderate (requires compactor, mill) |
| Processing Time | Longer | Shorter |
| API Sensitivity | Not suitable for moisture-sensitive APIs | Ideal for moisture-sensitive APIs |
| Granule Density | Medium to high | Variable (controllable) |
| Granule Porosity | Low to moderate | High, porous structure |
| Process Scalability | Excellent | Excellent |
| Energy Requirements | High (drying consumes significant energy) | Lower (no drying required) |
| Environmental Impact | Moderate(solvent disposal concerns) | Low (no solvents) |
| Cost | Higher | Lowe |
| Waste Generation | Moderate (potential solvent waste) | Low |
| Industry Adoption | 90% of pharmaceutical applications | 10% of pharmaceutical applications |

## ADVANTAGES AND DISADVANTAGES OF WET GRANULATION

### Advantages Of Wet Granulation

1. Improves Powder Flowability:

Binder solution helps convert fine powders into cohesive, free-flowing granules.

2. Enhances Compressibility:

Produces strong granules that compress easily into robust tablets.

3. Reduces Segregation:

Uniformgranules prevent separation ofAPI and excipients during handling.

4. Suitable for Low-Dose & High-Dose Drugs:

Ensures uniformcontent even whenthe API is present insmallamounts.

5. Better Granule Size Control:

Achieves a smooth and consistent particle size distribution.

6. Improves Dissolution & Bioavailability:

Binders, wetting agents, and porosity improve wettabilityand dissolution rate.

7. Minimizes Tablet Manufacturing Defects:

Reduces capping, lamination, and weight variation issues. [22]

### Disadvantages Of Wet Granulation

1. Not Suitable for Moisture- or Heat-Sensitive Drugs: APIs may degrade during wetting or drying.
2. Multiple Processing Steps:

Mixing → Wet Massing → Drying → Milling → Blending (time-consuming).

3. High Cost of Equipment & Operation:

Requires dryers, high-shear mixers, fluid-bed systems.

4. Risk of Over-Wetting or Under-Wetting:

Improper binder amount affects granule qualityand tablet hardness.

5. Longer Processing Time:

Drying step significantly increases production time.

6. Larger Space Requirement:

More equipment and utilities required compared to dry granulation. [23]

## ADVANTAGES AND DISADVANTAGES OF DRY GRANULATION

### Advantages Of Dry Granulation

1. Ideal for Moisture- and Heat-Sensitive Drugs:

No water or heat used, preventing API degradation.

2. Simple and Fast Process:

Shorter steps: compaction → milling → blending.

3. Lower Cost of Production:

No need for drying equipment, reducing energy use and cost.

4. Improves Flow Properties:

Roller compaction or slugging forms strong granules with better flow.

5. Better Control Over Density:

Produces granules with consistent density suitable for uniformdie filling.

6. Environmentally Friendly: Reduces water and solvent usage.
7. Suitable for Continuous Manufacturing:

Easier to integrate into modern automated lines. [24,25]

### Disadvantages OfDry Granulation

1. Lower Granule Strength Compared to Wet Granulation: May result in weak compacts or friable tablets.
2. Poor Binding for Some Formulations:

Hard to granulate powders withpoor inherent cohesiveness.

3. Higher Risk of Segregation:

Less effective in preventing API–excipient separation.

4. Requires High Pressure:

Roller compaction demands expensive, high-pressure equipment.

5. MayProduce Dusty Granules:

Increased fines can affect flow and cause weight variation.

6. Denser Granules MayAffect Dissolution:

Highcompaction force leads to hard granules with slower disintegration.

7. Not Suitable for All Formulation Types:

Struggles with very fluffy, low-density, or oily powders. [26]

## CHALLENGES AND LIMITATIONS

Both wet and drygranulation methods play essential roles in tablet manufacturing, but each is associated with several operational and technical challenges. These limitations influence process efficiency, granule quality, regulatory compliance, and overall manufacturing cost. This section outlines the major challenges linked to both techniques and broader industry-wide limitations. [6]

### Challenges in Wet Granulation

1. Scale-Up and Process Transfer Difficulties

Scaling a wet granulation process from laboratory to commercial production can be challenging. Changes in equipment size, mixing intensity, and binder addition patterns often alter granule characteristics. As a result, formulations that behave predictably on a small scale may require significant re- optimization during scale-up.

2. Moisture Level Optimization

Controlling residual moisture content is critical. Excess moisture can soften granules and compromise tablet hardness, whereas insufficient moisture can lead to weak granules that crumble during compression. Maintaining the ideal moisture range requires continuous monitoring and experienced judgement.

3. Batch-to-Batch Variability

Wet granulation processes are typically batch-based, making them prone to inconsistencies. Small deviations in drying time, binder distribution, or mixing speed can lead to variations in granule size and compressibility.

4. Operator-Dependent Factors

Determining the optimal wet mass endpoint often relies on operator experience. Over-wetting or under-wetting during binder addition can compromise granule quality, making operator training a critical factor.

5. Equipment Complexityand Maintenance

Multiple pieces of specialized equipment—mixers, dryers, granulators—are required. Each unit demands maintenance, calibration, and validation, increasing both operational complexity and cost. [6,27]

**Challenges in Dry Granulation**

1. Requirement for Good Initial Flowability

Powder blends must exhibit sufficient initial flow to be consistently fed into roller compactors. Poor-flowing powders may bridge in the hopper or feed unevenly, resulting in inconsistent ribbon density.

2. Uneven Density Distribution

The compaction step often produces ribbons with non-uniform density across their width. This variation leads to inconsistent granule strength, affecting tablet weight, hardness, and dissolution.

3. Dust Generation During Milling

Breaking compacted ribbons into granules requires milling, which can generate dust and create environmental or health concerns. Effective dust extraction systems are necessary to maintain safety and cleanliness

4. Limited Applicability for Low-Dose APIs

Dry granulation may not provide the level of uniformity needed for low-dose or highly potent APIs. Poor mixing and segregative tendencies can result in tablets with inaccurate drug content.

5. High Compression Stress on APIs

Some active ingredients degrade or undergo polymorphic changes when exposed to the high pressure used during roller compaction, limiting the technique's applicability.

6. Equipment Availability

Not all manufacturing facilities possess roller compaction equipment, which may limit the adoption of dry granulation in certain settings. [25,27]

**FUTURE SCOPE**

The landscape of pharmaceutical granulation is rapidly evolving as industries adopt smarter, more efficient, and sustainable technologies. Future advancements are expected to enhance process control, reduce manufacturing costs, and improve the overall quality of oral solid dosage forms. The following subsections outline the major innovations that will shape the future of granulation. [19]

**Continuous Granulation Technology**

1. Growing Industrial Adoption

Pharmaceutical manufacturing is gradually shifting from batch-based processes to continuous production systems. Recent industrial surveys indicate that a majority of new granulation equipment installations now support continuous operation. This trend is driven by the need for higher efficiency, reduced downtime, and better product consistency.

2. Advances in Processing Techniques

Modern continuous granulation platforms—such as twin-screw granulators and advanced roller compactors—allow seamless processing with minimal manual intervention. These systems provide superior mixing intensity, precise control over material flow, and consistent granule formation, even with moisture- sensitive APIs.

3. Improved Qualityand Reproducibility

Continuous granulation enables real-time control of critical parameters such as moisture content, spray rate, torque, and powder feed rate. With steady-state operation, batch-to-batch variability is minimized, resulting in reproducible granule properties and enhanced product uniformity. [28]

**Integration of Artificial Intelligence (AI) and Machine Learning**

1. Real-Time Monitoring of Critical Parameters

AI-driven Process Analytical Technology (PAT) tools can monitor key attributes— including particle size, density, and moisture—during production. Machine learning models analyze this data to detect process deviations before they escalate, ensuring consistent quality.

2. Predictive Equipment Maintenance

AI-based predictive algorithms can forecast equipment wear and potential failures. This helps schedule maintenance at optimal times, reducing unplanned downtime and improving equipment lifespan.

3. Automated Optimization

Machine learning systems can automatically determine optimal binder concentration, roller pressure, and other parameters. By evaluating large datasets from previous batches, AI models enhance process efficiency and minimize waste. [29]

**Sustainable and Green Manufacturing Practices**

1. Reduction of Solvent Use

Future granulation methods will continue to focus on avoiding hazardous organic solvents. Water-based processes, lower solvent volumes, and dry granulation techniques align with green chemistry principle.

2. Improved Energy Efficiency

Innovations such as microwave-assisted drying, heat recovery systems, and low-energy fluidized dryer designs aim to significantly reduce energy consumption in wet granulation processes.

3. Waste Minimization and Recycling

Advanced granulation systems are being designed to minimize material wastage. Off-size granules can be efficiently reprocessed without compromising product quality, supporting sustainable manufacturing. [30,31]

**Modular and Flexible Manufacturing**

1. Plug-and-Play Process Units

Future processing plants will incorporate modular equipment designs that allow rapid configuration changes. Manufacturers will be able to switch between wet granulation, dry granulation, and direct compression with minimal downtime.

2. Personalized and Small-Batch Manufacturing

As personalized medicine grows, flexible systems that support small-batch, high- precision granule production will be essential. Modular equipment will enable quick product changeovers and efficient scale-up or scale-down. [32]

**Advancements in Excipient Technology**

1. Smart and Functional Excipients

New excipients with multifunctional roles—such as binding, disintegration, and flow enhancement—will simplify formulations and improve granulation performance under varying conditions.

2. Enhanced Fillers and Binders

Future excipients may provide better mechanical strength, enhance drug solubility, or enable controlled-release properties directly during granulation.
[33]

**Regulatory Developments**

1. Evolving Guidelines

Regulatory agencies like the FDA and EMA are progressively updating guidelines to support continuous granulation, QbD (Quality by Design), and PAT-driven approaches. Clearer frameworks will help manufacturers adopt modern technologies more confidently.

2. Risk-Based Validation Strategies

Next-generation validation protocols will likely emphasize risk assessment, real-time monitoring, and reduced reliance on end-product testing. This shift will streamline approval processes and enhance compliance efficiency. [33]

## CONCLUSION

Granulation remains a central and indispensable operation in the manufacturing of solid oral dosage forms. By transforming fine, poorly flowing powders into robust, free- flowing granules, the process enhances blend uniformity, improves compressibility, and supports stable tablet production. The two primary techniques— wet granulation and dry granulation—each provide unique advantages tailored to different formulation needs, processing environments, and drug stability requirements. Wet granulation continues to be the method of choice for achieving superior content uniformity, enhanced flow properties, and high mechanical strength in tablets. Its ability to accommodate complex formulations and improve the dissolution of poorly soluble drugs reinforces its relevance in modern pharmaceutical development. However, its complexity, longer processing time, and incompatibility with moisture- or heat-sensitive ingredients highlight the necessity of alternative approaches.

Dry granulation, driven by roller compaction technology, offers an efficient solution for sensitive APIs and large-scale continuous manufacturing. With fewer processing steps, lower operational costs, and environmental benefits, it has become increasingly important in achieving faster, cleaner, and more streamlined tablet production. Although challenges such as density variation and limitations with low-dose drugs remain, advancements in equipment design and process control continue to expand its applicability.

Looking ahead, the evolution of granulation will be shaped by continuous manufacturing, AI-assisted monitoring, sustainable practices, modular flexibility, and advanced excipients. These innovations promise to overcome current limitations, improve process predictability, and support the industry's shift toward high-efficiency, data-driven production. As pharmaceutical science continues to advance, a deep understanding of granulation principles will remain essential for formulators, process engineers, and quality professionals alike.

Ultimately, both wet and dry granulation will continue to play vital roles in ensuring that tablets—one of the most widely used dosage forms in the world—are safe, effective, and manufactured to the highest-quality standards.

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**CONFLICT OF INTEREST**
The authors declare no conflict of interest.

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