



An Overview on Disintegrates Used in Solid Orals

Ms. Rajeshwari G. Khairnar^{1}, Ms Pradnya Chavan², Dr.Rupali R. Tasgaonkar³*

^{1*}Assistant Professor in Pharmaceutics, Yadavrao Tasgaonkar Institute of Pharmacy, University of Mumbai, Mumbai.

²Bachelor of Pharmacy, Yadavrao Tasgaonkar Institute of Pharmacy, , University of Mumbai, Mumbai.

³ Principal and Professor in Pharmaceutics, Yadavrao Tasgaonkar Institute of Pharmacy, University of Mumbai, Mumbai.

prajeshwari91@gmail.com

ABSTRACT;

Disintegration is a complex phenomenon observed across various domains, ranging from social structures to physical processes. This abstract explores the multifaceted nature of disintegration, examining its manifestations, underlying mechanisms, and implications. In social contexts, disintegration refers to the breakdown of cohesive bonds within communities, institutions, or relationships, often leading to fragmentation and discord. Psychological disintegration involves the deterioration of an individual's mental faculties, resulting in cognitive impairments and emotional instability. On a macroscopic scale, physical disintegration encompasses the decay or breakdown of materials, such as rocks, biological tissues, or technological systems, influenced by factors like environmental stressors and chemical processes. Understanding the dynamics of disintegration requires interdisciplinary perspectives, integrating insights from sociology, psychology, physics, chemistry, and engineering. By elucidating the causes and consequences of disintegration, researchers can develop strategies to mitigate its negative effects and foster resilience in complex systems. Disintegrant is one of the most important components in a typical tablet dosage form. It is responsible for ensuring that the tablet matrix breaks down after taking. Shredders operate by different mechanisms, and many factors will affect their performance. It is important for formulators to understand the role of disintegrants so they can use them intelligently to create optimized formulations. If manufacturers want to determine quality by design when creating tablet formulations, it is important to consider the impact of different ingredients and processes on tablet performance (especially the effects of tablet disintegration). Therefore, a better understanding of the disintegrating process and tablet disintegration mechanism is essential for effective product development. The purpose of this review is to provide an overview of tablet shredders and disintegration processes, focusing on factors affecting shredder performance. An updated summary of the different methods used to measure separation and separation time is also provided.

KEYWORDS; Factors affecting, swelling capacity, compatibility, tablet/ capsule properties, cost effective, regulatory c, fast disintegrating tablet, super disintegrate

Introduction

Tablet disintegration is the disaggregation of the compressed tablet into multiple particles. A thorough disintegration is beneficial when poorly soluble active pharmaceutical ingredients (APIs) are incorporated.[1] Tablets should disintegrate in the digestive tract for better medication absorption. The primary measure for evaluating disintegrants in tablet formulations is the measuring the time of disintegration.[3] Tablet disintegration is the breaking up of a crushed tablet into numerous particles. When incorporating poorly soluble active pharmaceutical ingredients (APIs), complete disintegration is recommended. As particle size decreases, so does the surface area accessible for dissolving, leading to an increase in dissolution rate.[4]. Oral drug delivery is recommended for its ease of ingesting, reduced discomfort, adaptability, and, most importantly, Patient compliance.[6] The drug delivery method is crucial for preventing adverse reactions. Patient compliance is based on how easily the medicine is administered. Delivered into the body without compromising efficacy or inconvenience for the patient.[8] Creating an orally disintegrating tablet involves extensive research to ensure sufficient porosity. Compressed tablets can be dissolved or melted quickly while keeping mechanical strength. [8] Creating .Tablets and capsules remain the most often used method for administering active pharmaceutical ingredients (API) to patients. Within this Group disintegrating tablets are the most common pharmaceutical product. [10]; Disintegrants in tablet formulations work by promoting the tablet's breakage or disintegration when it comes into contact with fluids, most commonly in the gastrointestinal tract. This promotes the release of the active pharmaceutical ingredient (API) for absorption. Types of excipients used in tablet formulations include disintegrants, fillers, binders, lubricants, lubricants, antioxidants, UV absorbers, dissolution modifiers, absorbents, flavoring agents, colorants, humectants, Humectants and preservatives. Learn about its functions and methods of disintegrates is crucial for selecting them.

Types of disintegrants;

1. Include physical disintegration, which breaks down structures into smaller bits.

2. Chemical Disintegration: The decomposition of things into simpler chemical components.
3. Social disintegration: The breakdown of social institutions, norms, or relationships.
4. Emotional Disintegration: Emotional breakdown or disintegration.
5. Technological Disintegration: A failure or breakdown of technological systems.
6. Political Disintegration: The division or collapse of political entities or institutions.

Each type is characterized by a breakdown or fragmentation process within its specific domain.

Factor Affecting Performance Of Disintegrants

Temperature, pressure, and the material's characteristics can all have an impact on disintegration. Additionally, environmental factors and external forces can have an impact on the disintegration process. A disintegrant's performance is affected by its particle size, techniques of inclusion, particularly for wet granulation, applied compression force, moisture content, and reworking.

1. Formulation Composition: The use of binders, disintegrants, and other excipients.
2. Particle Size: Smaller particles disintegrate faster.
3. Tablet Hardness: Tablets that are harder may degrade slower.
4. Moisture Content: Excess moisture can cause disintegration.
5. pH Level: pH can affect the breakdown of certain formulations.
6. Storage Conditions: Temperature and humidity might cause disintegration over time.
7. Excipient Interactions: Compatibility of excipients and active substances.
8. Tablet Geometry: Shape and surface area influence disintegration rates.
9. Manufacturing Process: Method and Conditions for Tablet Production[.2]

Examples Of Disintegrate with their nature:

Sufficient C Starches include cornstarch, potato starch, and modified starches such as sodium starch glycolate. They absorb water and swell, promoting pill disintegration.

Cellulose derivatives include microcrystalline cellulose (MCC), carboxymethylcellulose sodium (CMC), and croscarmellose sodium (Ac-Di-Sol). They absorb water and facilitate pill disintegration.

Cross-linked polymers include crospovidone (polyplasdone) and croscarmellose sodium. When they come into touch with water, they rapidly inflate, which aids in disintegration.

Pre-gelatinized starch is a modified starch that easily absorbs water, enabling tablet disintegration.

Sufficient CD Disintegrants are chemicals that are often employed in pharmaceutical formulations to aid in the breakdown or disintegration of tablets or capsules in the gastrointestinal system, hence improving medication solubility and absorption.

Amongst these some frequent disintegrants are:

Croscarmellose sodium Crospovidone Sodium starch glycolate Cross-linked polyvinylpyrrolidone (PVP) Microcrystalline cellulose Sodium carboxymethyl cellulose (CMC-Na).

Mechanisms Of Action

It discusses the mechanisms through which disintegrants work, such as wicking, swelling, and deformation, leading to tablet/capsule breakup when exposed to aqueous environments.

Effects on Formulation and Performance: The article explores how different disintegrants affect formulation characteristics (e.g., tablet hardness, friability, and dissolution rate) and the overall performance of the dosage form.

Selection Criteria: It outlines factors to consider when selecting a disintegrant, including compatibility with the active pharmaceutical ingredient (API), manufacturing process requirements, cost-effectiveness, and regulatory considerations.

Recent Advances: The review may also highlight recent advances in disintegrant technology, such as novel materials, improved understanding of disintegration mechanisms, and formulation strategies for enhancing disintegration and drug release.

Applications and Future Directions: It discusses current applications of disintegrants across various dosage forms (e.g., tablets, capsules, orally disintegrating tablets) and potential future directions in disintegrant research and development.

Role of disintegrants in formulations:

Disintegrants are crucial in pharmaceutical formulations to promote the breakup and dissolution of tablets or capsules in the digestive tract. Here are some common formulations of disintegrants:

Croscopovidone (Polyplasdone): This is a widely used disintegrant known for its rapid swelling and high water uptake capacity, which helps in tablet disintegration.

Sodium Starch Glycolate (Explotab, Primogel, Vivastar): It's a cross-linked starch derivative that swells rapidly in water, aiding in tablet disintegration.

Croscarmellose Sodium (Ac-Di-Sol): Another cross-linked polymer that rapidly swells in water, leading to efficient tablet disintegration.

Microcrystalline Cellulose (Avicel, Emcocel): Although primarily used as a binder and filler, microcrystalline cellulose also contributes to disintegration due to its ability to absorb water and swell.

Sodium Carboxymethyl Cellulose: It's a cellulose derivative that helps in disintegration by forming a gel-like structure when in contact with water.

Pregelatinized Starch:

This starch has been processed to rupture its granules, making it readily soluble in water and aiding in tablet disintegration.

DISINTEGRATION TEST APPARATUS:



Figure 1: Disintegration Test Apparatus

The Disintegration Tester is a solid-state tool that accurately estimates tablet disintegration time based on IP/USP standards. The equipment can simultaneously test two batches of six pills. The unit is particularly valuable in the pharmaceutical industry. It is used in quality assurance and research and development to determine. The tablet and capsule must meet the disintegration requirements outlined in USP/BP/IP standards. The instrument utilizes cutting-edge microprocessor technology and engineering techniques for improved accuracy and reproducibility.

Quality Assurance: It helps ensure that pharmaceutical products disintegrate properly, allowing for accurate dosing and absorption in the body, thus maintaining product quality and efficacy. **Compliance:** By testing the disintegration time of tablets and capsules, it ensures compliance with regulatory standards set by agencies such as the FDA, ensuring that products meet required dissolution criteria.

Process Control: It enables manufacturers to monitor and optimize their manufacturing processes, ensuring consistency and reliability in the production of pharmaceutical products. **Cost Savings:** By identifying potential issues early in the manufacturing process, disintegration testing helps prevent costly product recalls and rejections, ultimately saving companies money. **Customer Satisfaction:** Ensures that consumers receive pharmaceutical products that meet quality standards, leading to increased trust and satisfaction with the brand.



Figure 2: Disintegration Test Apparatus front view

The shaft goes up and down by 50-60mm at a rate of 28-32 strokes per minute. A horizontal strip with clamps on either side was put onto the shaft's upper end. Glass vessel clamps use stainless steel wire gauge and rubber rings at the lower end that dip in water. Two 125 watt hot plates are installed on the top of the cabinet, with 1000 ml beakers filled with water. The temperature is maintained at 37°C with a 1°C accuracy using independent switches and neon indicators on a panel for motor hot plates. The mains fuse, along with a two-meter mains wire and socket, allows for work on 220 volt A.C. Mains. Includes a digital temperature controller, cum indication, and timer. The Disintegration test is a solid-state apparatus that accurately estimates tablet disintegration time according to IP/USP standards. This instrument is designed to test two batches of six pills at once. The unit is very beneficial for pharmaceutical firms. Disintegration Machin is Available in: This disintegration test machine is available with single basket. And also the disintegration test machine is available with double basket, in this machine there is presence of single basket and double basket. [9]

Swelling Capacity

Crospovidone (Polyplasdone) is a common disintegrant known for its quick swelling and high water uptake capacity, facilitating tablet breakdown.

Disintegrants are chemicals that are added to pharmaceutical formulations to encourage the breakage or disintegration of tablets or capsules in the gastrointestinal tract, which aids in medication dissolving and absorption. A disintegrant's swelling capacity refers to its propensity to absorb water and swell, which causes the tablet or capsule to break apart more easily when exposed to fluid in the digestive system. Swelling capacity is an important attribute of disintegrants because it influences disintegration and, eventually, dissolution of the medicinal product. Crospovidone and cross-linked sodium carboxymethylcellulose (crosscarmellose sodium) are examples of disintegrants with high swelling capacity.

Compatibility with Active Pharmaceutical Integrate

The compatibility of active pharmaceutical substances with disintegration processes, most commonly in reference to dissolution or breakdown in pharmaceutical formulations. To obtain the desired therapeutic results, pharmaceutical developers must ensure that the active components dissolve appropriately. This process can be affected by a variety of parameters, including formulation excipients, dose form, pH, and ambient conditions. Conducting compatibility studies ensures maximum performance and safety of the final product.

Impact on Tablet /Capsule Properties:

Tablets and capsules' qualities, particularly disintegration, can be influenced by a variety of factors such as formulation ingredients, manufacturing processes, storage conditions, and environmental influences. Moisture, temperature, and pH all have an impact on disintegration, potentially affecting the solubility and absorption of active substances. Furthermore, changes in excipient concentrations or particle size distribution might affect disintegration rates. Consistent product performance requires strict adherence to regulatory standards and quality control systems.

Effect of storage on disintegration.

The impact of storage on disintegrant activity. Tablet disintegration performance can be influenced by storage conditions. Disintegrants in dry tablets can absorb water when exposed to moisture, potentially resulting in "pre-activation" of the disintegrant expansion (i.e. swelling and/or shape recovery) and a

loss of disintegrant power during storage. Furthermore, all other substances in the tablets can contribute to tablet hardness or softening, which may impair disintegration.

Cost Effectiveness

To determine the cost-effectiveness of disintegration, you would normally weigh the costs of the disintegration process, including equipment, energy, and labor, against the advantages, such as enhanced efficiency, reduced waste, or improved product quality. It's critical to assess the total impact on operations and determine whether the benefits will outweigh the expenses over time. To determine the cost-effectiveness of disintegration, consider the initial investment in disintegration equipment, operating costs such as energy consumption and maintenance, labor requirements, savings from improved efficiency or reduced waste, and the potential for increased product quality or revenue generation. A detailed cost-benefit analysis can evaluate if disintegration is economically feasible for your situation.

Disintegration can apply to a variety of processes, hence the cost-effectiveness will vary depending on the context. Disintegrating waste materials for disposal can be cost-effective by considering initial equipment investment, operational costs, and potential savings on disposal fees.

SUPER DISINTEGRANT:

These forms are highly effective and have low concentrations, resulting in faster dissolution and increased therapeutic efficacy. These interact with saliva to provide hydrostatic pressure and volume expansion, allowing for faster pill disintegration.

Selecting a super disintegrate would depend on several factors including its power output, efficiency, , safety features, ease of use, cost, and compatibility with your specific application or requirements. It's essential to thoroughly research and compare different models, consider expert recommendations, and possibly consult with professionals in the field to make an informed decision.

Super disintegrants are excipients commonly used in pharmaceutical formulations to promote the rapid disintegration of tablets or capsules upon ingestion, facilitating drug dissolution and absorption in the body. Examples include croscarmellose sodium, and sodium starch glycolate. They work by rapidly absorbing water, swelling, and generating pressure within the dosage form, leading to its breakup into smaller particles for easier dissolution. Super disintegrants are excipients used in pharmaceutical formulations to promote the rapid breakup or disintegration of tablets and capsules upon contact with moisture or saliva in the mouth, facilitating drug dissolution and absorption in the gastrointestinal tract. Common super disintegrants include croscarmellose sodium, sodium starch glycolate, and cross-linked PVP (polyvinylpyrrolidone). They are particularly useful for drugs with poor solubility or those requiring rapid onset of action.

The addition of superdisintegrants primarily alters the rate of disintegration, and hence the dissolution.

Concentrating the disintegrants can help to speed up tablet disintegration. Disintegration time of tablets below critical concentrations is inversely proportional to disintegrant concentration.

Above the critical.

However, at the concentration level, disintegration time remains roughly constant or even increases. To ensure effective formulation, it's crucial to carefully pick superdisintegrants depending on key parameters [18]. The disintegrant should have quick wicking action to provide hydrostatic pressure for quicker disintegration. Smaller particles are preferred over larger ones. The latter produce a gritty mouthfeel. Gel-forming superdisintegrants are often avoided due to patient non-compliance. To avoid friability, use a more compactable superdisintegrant.[19]

Factors For Selection Of Super Disintegrant :

1. Disintegration
2. Compatibility
3. Mouthfeel

Selection Of Super Disintegrants ;

1. 1.Less solubility.
2. Low gel formation.
3. Excellent hydration capacity.
4. Good molding and flow qualities.
5. Improved taste conformity.
6. Be compatible with other excipients and have adequate tableting qualitie the disintegration mechanism of super disintegrant material.

Super Disintegrant Classes

Swelling Disintegrants: These disintegrants absorb water rapidly, causing swelling and subsequent disruption of the tablet matrix. Examples include croscarmellose sodium (CCS) and crospovidone (CP).

Capillary Action Disintegrants: These disintegrants function by wicking water into the tablet interior through capillary action, leading to rapid disintegration. Sodium starch glycolate (SSG) is a commonly used capillary action disintegrant.

Mechanical Disintegrants: These disintegrants work by providing mechanical stress within the tablet matrix, leading to its breakup upon contact with water. Examples include microcrystalline cellulose (MCC) and powdered cellulose.

Table 1: Example of super disintegrant

S. No.	Super disintegrant	Mechanism of action	Specific properties
1.	Gollan Gum	Good Swelling property whenever contacted with the water.	Anionic polysaccharide, good super-disintegrant.
2.	Xanthan Gum	Extensive Swelling Property	Greater Hydrophilicity, Very Low Gelling tendency & Water Solubility.
3.	Cross-linked alginic acid	Hydrophilic Colloidal substance	Swelling and Wicking action.
4.	Soy Polysaccharide	Rapid dissolution	These products are used in Diabetics due to absence of Sugars and Starch.
5.	Sodium-Starch Glycolate	Good Swelling Property	Rapid absorption of water causes 6% of Swelling & High concentration causes Gelling.
6.	Cros-povidone	Swelling & Wicking Action	Efficacy Concentration 1-3%. It is available in Micronized Grades, Rapid dispersion and swells in water.

CONCLUSION:

Fast disintegrating tablets with mouth dissolving properties provide optimum bioavailability for therapeutic efficacy and patient compliance, particularly in geriatric and paediatric populations Patient safety. Various technologies are used to create super or quick disintegration tablets. These products are easy to manufacture, have high mechanical strength, are easy to administer, have a quick onset of action, and have a large market reach due to successful dosage form formulations.

Disintegration is a critical quality control test today. Disintegration testing may become a release test for formulations with API-controlled dissolution. Disintegration testing is a cost-effective and time-saving solution for pharmaceutical QC departments. As a result, demand among patients and Advancements in technology have led to increased acceptance of oral disintegrating tablets, extending drug patents.

Some technologies provide FDT formulations with high mechanical strength and rapid disintegration in the mouth without water. These tablets breakdown quickly in saliva, typically within 5-50 seconds. I try my best to explain the quick

Disintegrating medication delivery methods, tablet processing, and tablet disintegration apparatus

REFERENCES;

1. <http://informahealthcare.com/phd> ISSN: 1083-7450 (print), 1097-9867 (electronic) Pharm Dev Technol, Early Online: 1–12 ! 2015 Informa Healthcare USA, Inc. DOI: 10.3109/10837450.2015.1045618
2. P. J. Antony and N. M. Sanghavi* Pharmaceutical Division, University Department of Chemical Technology, Matunga, Bombay, 400 019, India
3. International Research Journal of Modernization in Engineering Technology and Science (Peer-Reviewed, Open Access, Fully Refereed International Journal)Volume:05/Issue:05/May-2023 Impact Factor- 7.868 www.irjmets.com www.irjmets.com @International Research

- Journal of Modernization in Engineering, Technology and Science[6129] A REVIEW ON DISINTEGRANT-TABLET Dushyant Unde*1, Asst. Prof. Vikas Wamane
4. International Journal of Pharma Research & Review, Jan 2016;5(1):50-62 ISSN: 2278-6074 Mandeep Dahiya et.al, IJPRR 2016; 5(1) 50 Review Article Oral Disintegrating Tablets: A Review Parijat Pandey, Mandeep Dahiya* Department of Pharmaceutical Sciences, Maharshi Dayanand University, Rohtak, India
 5. Current developments in orally disintegrating tablet technology Amit Kumar Nayak* and Kaushik Manna Department of Pharmaceutics, Seemanta Institute of Pharmaceutical Sciences, Mayurbhanj-757086. Orissa, India *Email:amitkrnayak@yahoo.co.in
 6. Review article : mechanisms of drug release from tablets and capsules. I: Disintegration C. D. MELIA & S. S. DAVIS Department of Pharmaceutical Sciences, University of Nottingham, University Park, Nottingham, UK
 7. FAST DISINTEGRATING TABLETS- A REVIEW T. Anjali1 *, P. S. S. Prasanna Kumar1 , Srinivas Nandyala2 , V. Venkatalakshmi1 , D. Virginia1 , B. Tulasi Krishna1 , P. Tulasi Naga Durga1 , D. Lakshmi Sowmya1 and S. Durga Dinesh*
 8. Vaishali Chauhan, Kapil Kumar, Deepak Teotia. Fast Dissolving Tablets: A Promising Approach for Drug Delivery. Universal Journal of Pharmaceutical Research, 2017; 2(1): 58-64. 9
 9. Ved Parkash, Saurabh Maan, Deepika, 1 Shiv Kumar Yadav, 2 Hemlata, and Vikas Jogpal. Fast disintegrating tablet. Opportunity in drug delivery system, 2011; 2(4): 223–23510 Aheth Smita S.1*, Saudagar R. B. 1, Shinde Mayuri S, Review. Fast Dissolving Tablet. Int J Cur Pharm Res, 2018; 10(2): 5-12.
 10. R.D. Rahane*, Dr. Punit R. Rach. Fast dissolving tablet. Journal of Drug Delivery and Therapeutics, 2018; 8(5): 50-55.
 11. Ashish Masih, Amar Kumar, Shivam Singh*, Ajay Kumar Tiwari. Fast Dissolving Tablets. International Journal of Current Pharmaceutical Research, 2012; 9(2): 10-18.
 12. Debjiit Bhowmik*, Chiranji. B, Krishna kanth, Pankaj, R. Margret Chandrika. Fast Dissolving Tablet. Journal of Chemical and Pharmaceutical Research, 2009; 1(1): 163-177.
 13. Md. Nehal Siddiqui*, Garima Garg, Pramod Kumar Sharma. Fast Dissolving Tablets: Preparation, Characterization and evaluation. International Journal of Pharmaceutical Sciences Review and Research, 2010; 4(2): 015: 92-95.
 14. Desai PM, Liew CV, Heng PWS. Understanding disintegrant action by visualization. J Pharm Sci 2012;101:2155–2164
 15. Guyot-Hermann AM. Tablet disintegration and disintegrating agents. STP Pharma Sci 1992;2:445–462.
 16. Nogami H, Nagai T, Fukuoka E, Sonobe T. Disintegration of the aspirin tablets containing potato starch and microcrystalline cellulose in various concentrations. Chem Pharm Bull 1969;17: 1450–1455.
 17. Khan KA, Rhodes CT. Water-sorption properties of tablets disintegrants. J Pharm Sci 1975;64:447–451.
 18. Shangraw R, Mitrejev A, Shah M. A new era of tablet disintegrants. Pharm Technol 1980;4:49–57.
 19. Lowenthal W. Mechanism of action of starch as a tablet disintegrant. V. Effect of starch grain deformation. J Pharm Sci 1972;61: 455–459.
 20. Erdo's S, Bezegh A. Studies on the mechanism of disintegration. Pharm Ind 1977;39:1130–1135.
 21. Quodbach J, Kleinebudde P. Performance of tablet disintegrants: impact of storage conditions and relative tablet density. Pharm Dev Technol. 2014. [Epub ahead of print]. doi:10.3109/ 10837450.2014.9203.
 22. WERNER LOWENTHAL ,REVIEW ARTICLE Disintegration of Tablets , Journal of Pharmaceutical hl. sciences NOVEMBER 1972 VOLUMB 61 NUMBER 11, 1972 0 1695
 23. Parind Mahendrakumar Desai, Celine Valeria Liew, Paul Wan Sia Heng ,Review of Disintegrants and the Disintegration Phenomena , P.M. Desai et al. / Journal of Pharmaceutical Sciences xxx (2016) 1e11.
 24. Quodbach, J. and Kleinebudde, P., 2016. A critical review on tablet disintegration. Pharmaceutical Development and Technology, 21(6), pp.763-774
 25. C Mallikarjuna Setty, D.V.K Prasad, V.R.M Gupta, B Sa. "Development Of Fast Dispersible Aceclofenac Tablets: Effect Of Functionality Of Superdisintegrants." Indian journal of pharmaceutical sciences. 2008, 70(2): 180-185
 26. <https://electronicsindia.co.in/product/disintegration-test-apparatus-2901>