

A Review on Use of Glidants in Formulation of Pharmaceutical Solid dosage Forms

¹Mr.Sumedh Paralkar, ²Dr.Yogesh Thorat, ³Dr.Balkirshna Tiwari, ⁴Ms.Laxmi Kawade, ⁵Ms.Rutuja Kinagi

¹Assistant Professor, ²Associate Professor, ³Vice Principal, ⁴Co-author, ⁵Co-author

¹ Department of Pharmaceutics, ² Department of Pharmaceutics, ³ Department of Medicinal Chemistry

²D. S. T. S Mandal's College of Pharmacy, Shivdhare Campus, Shrikant Nagar, Jule Solapur

^{1,3,4,5} Amepurva Fourm's Nirant Institute of Pharmacy, Solapur, Maharashtra, India

Abstract: Glidants are the substances that enhance the flow characteristics of powder mixture. To get desired effect, these are added as a dry powder before the compression process. Glidants can show their effect at certain optimum concentration only. Above certain concentration glidants itself inhibit or decreases the good flow or flow properties. Glidants act by decreasing the overall surface charge present on the blend decreasing friction between particles and filling the gaps on the surface, thus further enhancing the rate of movement and flow. Glidants are additive materials that are used to improve a powder's flowability by lowering surface charge, cohesion, and interparticle friction all of which lower the angle of repose. Angle of repose is the maximum angle between the free standing surface of powder and horizontal plane. Smaller angle indicates a good flow property compared to bigger angle. Glidants also show impact on the flow properties, product quality, granulation, particle size, uniform distribution, tablet die cavity. Glidants play vital role in pharmaceutical industry for better quality of products. Various glidants used in pharmaceutical industry are Talc, Magnesium oxide, Magnesium silicate, Silicon dioxide, etc.

Key words: Glidants, Flow property, Surface charge, Cavity filling, etc

1.INTRODUCTION:

The objective of the pharmaceutical development is to design a quality product as well as a manufacturing process for assuring the consistent production of the required quality product. The knowledge and information obtained from manufacturing experience and pharmaceutical development studies impart the scientific understanding to establish the specifications, design space, and manufacturing controls. Several components of pharmaceutical product development should be included in the drug development protocol.^[1] The drug substance and excipients are two main components of drug products, which are discussed below in detail:

1.1 Drug Substance:

The pharmaceutical product's active element, the medications, is what gives the disease condition(s) its therapeutic effects. When developing a new product, the drug's physiological and biological characteristics are crucial. Solubility, water content, melting and boiling points, particle size, crystal characteristics, optical activity, pH, pKa value(s) (negative log of the dissociation constant), partition coefficient, and other physicochemical characteristics must all be monitored during the pharmaceutical development process.^[2] Biological activity, drug permeability, and other biological characteristics need to be monitored. For the product to be more effective, these physicochemical and biological qualities—which may be reliant on one another—should be taken into account.^[3]

1.2 Excipients:

Other than the main medication, chemicals utilized in pharmaceutical dosage forms are known as pharmaceutical excipients. Excipients are regarded as inert chemicals, meaning that while they don't play an active part in treatments, they can aid in the production of a successful product.^[4]Pharmaceutical dosage forms serve as an adequate and suitable approach when certain active ingredients or medications are difficult for the human body to give and absorb. Excipients are crucial to the formulation of dosage forms. The kind and quantity of excipients, for instance, have an impact on the disintegration rate, disintegration time, and other aspects of tablets. They offer uniformity in the drug compositions.^[5]Excipients can be classified into binders, cosolvents, fillers, disintegrates, lubricants, glidants, surfactants, emulsifying agents, suspending agents, antimicrobials, preservatives, etc. based on the roles they perform. The medication product specification and the selection and calibre of the excipients include dosage forms in greater amounts than active pharmaceutical ingredients (API) and can account for up to 90% of the overall mass or volume of pharmaceutical products.^[6, 7]Based on safety data, pharmaceutical excipients were divided into two classifications by the International Pharmaceutical Excipient Council (IPEC): "new chemical excipients" and "established excipients." ^[8]

Pharmaceutical excipients are materials that are included in a finished pharmaceutical item in form or incorporated into the assembling process but are not the pharmacologically active medication or prodrug.^[9,10]Excipients have a variety of beneficial roles in medicinal dosage forms, such as:

- Modulating solvency and bioavailability of APIs,
- Increasing the security of dynamic fixings in dose frames,
- Helping dynamic fixings keep up favored polymorphic structures or adaptations
- Maintaining the pH or osmolarity of the fluid details,
- Acting as cell reinforcements, emulsifying specialists, airborne charges, tablet fasteners, and tablet disintegrants.
- Preventing accumulation or separation (e.g. of protein and polysaccharide actives),
- Modulating immunogenic reactions of dynamic fixings (e.g. adjuvant), and the sky is the limit from there ^[10]

2. PROPERTIES OF GLIDANTS :

Glidants are additive materials that are used to improve a powder's flowability by lowering surface charge, cohesion, and interparticle frictionall of which lower the angle of repose. Frequently, they are mixed in as a dry powder right before direct compression. Because glidants cannot lower the friction on the die wall, they are typically applied in conjunction with a lubricant. The amount of glidant employed is important since too much could hinder the powder mixture's flowability, which would severely affect its flow characteristics. Colloidal silicon dioxide, or colloidal silica, is the most widely used glidant and can be employed at concentrations as low as 0.2 w/w%. Fumed silica, magnesium carbonate, magnesium stearate,

and talc are few other examples. It is worth noting that some glidants, such as Syloid 244 FP and Syloid XDP silica, could also provide the added benefits of moisture absorbance and taste-masking".^[11]

Glidants are compounds that improve a powder's flowability, inhibiting adhesion and facilitating more efficient processing across a range of industries. These substances are used in food, medicine, and powder metallurgy. In the production of tablets and capsules, glidants are frequently employed in the pharmaceutical industry to enhance the flow characteristics of excipients and active pharmaceutical ingredients (APIs). Reducing interparticle friction helps to ensure uniform powder dispersion and avoid clumping, which is one of glidants' main purposes. This is especially crucial for pharmaceutical formulations where accurate dosing is necessary. Popular glidants that are frequently added in trace amounts to powdered formulations are talc and colloidal silicon dioxide. Glidants help the food industry handle powdered materials more effectively, avoiding caking and guaranteeing a constant texture in goods like spice mixes and powdered beverages. Additionally, in powder metallurgy, glidants aid in the production of metal powders with improved flow characteristics, facilitating their use in various manufacturing processes like powder compaction and sintering.

In sectors that depend on powdered formulations, the precise selection and inclusion of glidants is essential for streamlining manufacturing procedures and guaranteeing the caliber and uniformity of the finished goods.^[12]By reducing interparticle friction and cohesion, glidants—a non-toxic, pharmacologically inert material—are used to improve the flow characteristics of tablet granulation or powder materials. Only specific glidants, like 5% talc, may be effective at a given range of concentrations. Glidant generally inhibits flow characteristics above a specific concentration.^[13]



PROPERTIES OF DOSAGE FORMS ENCHANCE BY GLIDANTS INDUCLES;

- Smooth flow of granules or powder during solid dosage from production; Assists in preserving the homogeneity of the API and/or excipient powder mixture.
- Prevent weight fluctuation indirectly. ^[13]

3.

- To enhance the flow characteristics of powders or granulates, glidants are added to solid dosage forms^[14]
- These are excipients that adsorb particles of other excipients or active pharmaceutical ingredients from the powders' surface during mixing (the creation of the tableting mixture).
- Glidants lessen friction between particles and between particles and the hopper wall during the phase of dumping the tableting mixture from the hopper into the tableting press die.
- As a result of reducing friction, or increasing mixture flowability, the powder mixture is uniformly die-filled, guaranteeing that the generated tablets have the appropriate weight and content. Additionally, glidants stop pressed powders from adhering to compression thorns and tablet capping [15]
- The addition of glidants to capsules guarantees a uniform distribution of active substances and great metering accuracy. The precise mechanism is a matter of debate, although two possibilities have been proposed.
- Two ways that glidant powders work are as follows: first, they coat the relatively bigger host powders, increasing interparticle distance and decreasing interparticle forces; second, they behave like ball bearings, reducing friction on rough surfaces. ^[15]

4. DISADVANTAGES OF GLIDANTS :

- There is a concentration range at which only a glidant will function. The glidant will impair flow characteristics above a particular concentration.
- Moreover, they are powerless to lessen die wall friction ^[13].
- Excessive usage of glidants will have a negative impact and slow down or impede the flow ^[16].

5. CLASSIFICATION OF GLIDANTS:

They have no such established classification but they are also two types :

Based on Solubility Glidant are two types: A) Hydrophilic

B) Hydrophobic

A] Hydrophilic: For example, hydrophilic silica and hydrophilic colloidal silicon dioxide ^[17].

B] Hydrophobic: For example, hydrophobic silica and hydrophobic colloidal silicon dioxide.

6. VARIOUS GLIDANTS CAN USED:

Nature of Glidants	Glidants	Concentration (%)
Natural	Calcium stearate	0.5 - 2
	Cellulose powdered	1 - 2
	Magnesium carbonate	1 - 3
	Magnesium oxide	1 - 3
	Starch	2 - 10
	Talc	1 - 10
Synthetic	Magnesium silicate	0.5 - 2
	Silicon dioxide, colloidal	0.05 - 0.5

Table no 1: Various Glidants and their concentration ^[18]

8. MECHANI<mark>SM</mark> OF WO<mark>RK</mark>ING OF GLIDANTS:

Glidants are additive materials that are used to improve a powder's flowability by lowering surface charge, cohesion, and interparticle friction—all of which lower the angle of repose. Frequently, they are mixed in as a dry powder right before direct compression. ^[11] Glidants have a straightforward method of operation; they encourage flow through the following mechanisms:

- a. Reducing Friction
- b. Reducing Surface Charge

A] Reducing Friction: Friction reduction: Glidants work by lowering the blend's total surface charge, which reduces friction between the blend's particles and closes surface gaps, increasing the velocity of flow and movement. ^[19]

B] Reducing Surface Charge:Glidants function as spacers between particles and have been linked to a decrease in van der Waals forces as the primary mechanism of action on flowability. However, additional modes of action, including friction or surface energy alteration, could change the flow.^[20]

IJNRD2404416

9. FUNCTIONS OF GLIDANTS:

- To improve powder flow
- To reduce interparticle friction
- Decreasing surface charge
- To reduce cohesion^[13,21]
- Help to prevent weight variation

10. MONOGRAPHS OF GLIDANTS:

10.1Calcium Stearate

- i. **Synonyms -** Calcii stearas; calcium distearate; calcium octadecanoate; Deasit PC; HyQual; Kemistab EC-F; octadecanoic acid, calcium salt; stearic acid, calcium salt; Synpro.
- ii. Chemical Name- Octadecanoic acid calcium salt
- iii. Empirical Formula and Molecular Weight C36H70CaO4 607.03 (for pure material)
- iv. Structural Formula -



- v. Functional Category Tablet and capsule lubricant.
- vi. Applications in Pharmaceutical Formulation or Technology- Calcium stearate is mostly utilized at concentrations of up to 1.0% w/w as a lubricant in pharmaceutical formulations for the production of tablets and capsules. Calcium stearate has poor glidant qualities despite having good lubricant and antiadherent qualities. In addition, calcium stearate is utilized in food and cosmetic applications as an emulsifier, stabilizing agent, and suspending agent.
- vii. **Description** -Calcium stearate occurs as a fine, white to yellowish-white, bulky powder having a slight, characteristic odor. It is unctuous and free from grittiness
- viii. **Method of Manufacture -** The sodium salts of stearic and palmitic acids are combined with calcium chloride to create calcium stearate. To get rid of any sodium chloride, the calcium stearate that has formed is gathered and rinsed with water.
- ix. **Solubility** Practically insoluble or insoluble in ethanol (95%), ether, chloroform, acetone, and water. Slightly soluble in hot alcohol, and hot vegetable and mineral oils. Soluble in hot pyridine.
- x. Melting point -149-160 ⁰ C

xi. **Stability and Storage Conditions** - Calcium stearate is stable and should be stored in a well-closed container in a cool, dry place.^[22]

10.2Magnesium Carbonate

- **i. Synonyms** -Carbonic acid, magnesium salt (1:1); carbonate magnesium; Destab; E504; hydromagnesite; magnesii subcarbonas levis; magnesii subcarbonas ponderosus.
- ii. Chemical Name Magnesium carbonate anhydrous
- iii. Empirical Formula and Molecular Weight MgCo3 and 84.3139 g/mol^[22]
- iv. Structural Formula -



- v. **Functional Category** -Adsorbent; antacid; tablet and capsule diluent.^[22]
- vi. **Applications in Pharmaceutical Formulation or Technology** -Magnesium carbonate is primarily utilized as an excipient in quantities up to 45% w/w as an immediately compressible tablet diluent. Tablets made with heavy magnesium carbonate have good disintegration qualities, minimal friability, and a high crushing strength^{23–26]}Magnesium carbonate, however, can affect stability and dissolution in different ways.^[27, 28]To stabilize proteins that are encapsulated, magnesium carbonate has been added to microsphere formulations.^[29] Moreover, it has been coencapsulated in formulations of poly(lactide-co-glycolide) microspheres to counteract acidity and improve the immunogenicity of a peptide vaccine for contraception.^[30]Moreover, flavours and other liquids are absorbed by magnesium carbonate during the tableting process. In addition, magnesium carbonate is utilized as a food ingredient and as a medication as an antacid.
- vii. **Description** -Magnesium carbonate can be found as a large, white powder or as light, friable masses. Although it is odourless and has a slightly earthy flavour, magnesium carbonate can absorb smells due to its high absorptive capacity.
- viii. Solubility Practically insoluble in water but soluble in water containing carbon dioxide. Insoluble in ethanol (95%) and other solvents. Magnesium carbonate dissolves and effervesces on contact with dilute acids.
 - ^{ix.} **Method of Manufacture -** Depending upon the manufacturing process used, the composition of the magnesium carbonate obtained may vary from normal hydrated magnesium carbonate to basic hydrated magnesium carbonate.^[22]

Research Through Innovation

10.3 Magnesium Oxide

- i. **Synonyms -** Calcined magnesia; calcinated magnesite; Descote; E530; Magcal; Magchem 100; Maglite; magnesia; magnesia monoxide; magnesia usta; magnesii oxidum leve; magnesii oxidum ponderosum;Magnyox; Marmag; Oxymag; periclase.
- ii. Chemical Name Magnesium oxide
- iii. Empirical Formula and Molecular Weight MgO and 40.30[22]
- iv. Structural Formula –



- v. Functional Category Anticaking agent; emulsifying agent; glidant; tablet and capsule diluent^[22]
- vi. **Applications in Pharmaceutical Formulation or Technology** To change the pH of tablets, magnesium oxide is used as an alkaline diluent in solid dosage forms.^[31]It can be used to bind extra water in solid-dosage formulations and maintain the granulation's dryness. Magnesium oxide can be employed as an additional glidant in conjunction with silica.^[32]It's also used as an antacid, either by itself or in combination with aluminum hydroxide, and as a food additive. In addition, magnesium oxide is taken as a supplement to address deficient situations and as an osmotic laxative.
- vii. **Solubility** -Soluble in ammonium salt solutions and weak acids Magnesium oxide is used as an alkaline diluent in solid dosage forms to adjust the pH of tablets.^[31] It can be used to keep the granulation dry and bind excess water in formulations for solid dosages. When used with silica, magnesium oxide can be used as an extra glidant.^[32]It's also used as a food additive and as an antacid, either on its own or in conjunction with aluminum hydroxide. Magnesium oxide is sometimes utilized as an osmotic laxative and supplement to treat deficiencies. Very slightly soluble in pure water (0.0086 g/100 mL at 308C;solubility is increased by carbon dioxide); practically insoluble in ethanol (95%).
- viii. Melting point 2800° C
 - ix. **Boiling point** 3600° C
 - x. **Method of Manufacture** Magnesium oxide occurs naturally as the mineral periclase. It can be manufactured by many processes. Limestone containing the mineral dolomite is calcinated at high temperatures to produce dolime which then reacts with magnesium chloride-rich sea water to produce magnesium hydroxide and calcium chloride.^[33] The magnesium hydroxide is then calcinated to produce magnesium oxide and water. In another process, mined magnesite (MgCO3) is calcinated to produce magnesium oxide and carbon dioxide.^[33] Purification methods include crushing and size separation, heavymedia separation, and froth flotationHeating concentrated brine from the Dead Sea containing magnesium chloride is the procedure used to produce magnesium oxide from sea water.Hydrochloric acid and magnesium oxide are the byproducts of the breakdown of magnesium chloride ^[33] The thermal breakdown of magnesium chloride, magnesium sulfate, magnesium sulfite, nesquehonite, and the basic carbonate 5MgO4CO25H2O can also provide magnesium oxide. Purification of the magnesium oxide produced through thermal degradation is carried out by filtration or sedimentation.
- xi. **Stability and Storage Conditions-** At standard pressures and temperatures, magnesium oxide is stable. In the presence of water, it transforms into magnesium hydroxide, though. Due to its hygroscopic nature, magnesium oxide absorbs carbon dioxide and water in the air more quickly in the light form than in the heavy form. The bulk material needs to be kept dry and cool in an airtight container^[22]

10.4 Magnesium Silicate

- i. **Synonyms -**E553a; synthetic magnesium silicate.
- ii. Chemical Name Silicic acid, magnesium salt
- iii. Empirical Formula and Molecular Weight MgOSiO2xH2O and 100.387 g/ mol
- iv. Structural Formula –



- v. Functional Category Anticaking agent; glidant.
- vi. **Applications in Pharmaceutical Formulation or Technology -**Magnesium silicate is utilized as a glidant and anticaking agent in food products and oral medicinal formulations.
- vii. **Description -** Magnesium silicate occurs as an odorless and tasteless, fine, whitecolored powder that is free from grittiness.
- viii. **Method of Manufacture -**Sodium silicate and magnesium sulfate can be combined to create magnesium silicate. Moreover, the silicate can be found in nature as the minerals parasepiolite, sepiolite, and meerschaum.
- ix. Solubility Practically insoluble in ethanol (95%), ether, and water.
- x. Stability and Storage Conditions Magnesium silicate should be stored in a well-closed container in a cool, dry place.^[22]

10.5 Talc

- i. **Synonyms** Altalc;E553b; hydrous magnesium calcium silicate; hydrous magnesium silicate; Imperial; Luzenac Pharma; magnesium hydrogen metasilicate; Magsil Osmanthus; Magsil Star; powdered talc; purified French chalk; Purtalc; soapstone; steatite; Superiore; talcum
- ii. Chemical Name Talc
- iii. **Empirical Formula and Molecular Weight -** Talc is a purified, hydrated, magnesium silicate, approximating tobthe formula Mg6(Si2O5)4(OH)4. It may contain small, variable amounts of aluminum silicate and iron.
- ^{iv.} **Functional Category-** Anticaking agent; glidant; tablet and capsule diluent; tablet and capsule lubricant.^[22]
- v. Applications in Pharmaceutical Formulation or Technology -Talc was once widely used in oral solid dosage formulations as a lubricant and diluent, ^[34-36] although today it is less commonly used. However, it is widely used as a dissolution retardant in the development of controlled-release products.^[37-39] Talc is also used as a lubricant in tablet formulations; ^[37] in a novel powder coating for extended-release pellets; ^[40] and as an adsorbant.^[41] In topical preparations, talc is used as a dusting powder, although it should not be used to dust surgical gloves.Since talc is a natural material, it should be sanitized before using it as a dusting powder as it frequently contains bacteria. Because of its lubricating qualities, talc is widely utilized in culinary and cosmetic items as well as to clarify liquids.
- vi. **Description** -Talc is a very fine, white to grayish-white, odorless,impalpable,unctuous, crystalline powder. It adheres readily to the skin and issoft to the touch and free from grittiness.
- vii. Solubility Practically insoluble in dilute acids and alkalis, organic solvents, and water.
- viii. **Method of Manufacture -** To remove various impurities including asbestos (tremolite), carbon, dolomite, iron oxide, and numerous other magnesium and carbonate minerals, naturally existing talc is extracted, ground, and then floated. After that, the talc is ground into a fine powder, exposed to diluted hydrochloric acid, rinsed with water, and allowed to dry. Agglomerated talc's processing parameters have a significant impact on its physical properties. ^[42-45]

ix. **Stability and Storage Conditions**- Talc is a stable material and may be sterilized by heating at 1608C for not less than 1 hour. It may also be sterilized by exposure to ethylene oxide or gamma irradiation^[46]. Talc should be stored in a well-closed container in a cool, dry place.

10.6 Starch

- i. **Synonyms** -Amido; amidon; amilo; amylum; C*PharmGel; Eurylon; fecule; Hylon; maydis amylum; Melojel; Meritena; oryzae amylum; Pearl; Perfectamyl; pisi amylum; Pure-Dent; Purity 21; Purity 826; solani amylum; tritici amylum; Uni-Pure.
- ii. Chemical Name -Starch
- iii. Empirical Formula and Molecular Weight (C6H10O5)n where n = 300-1000 and 342.297 g/mol
- iv. Structural Formula -



- v. **Functional Category** Tablet and capsule diluent; tablet and capsule disintegrant; tablet binder and thickening agent .
- vi. **Applications in Pharmaceutical Formulation or Technology** Starch is a multipurpose excipient that is mostly employed as a disintegrant, diluent, and binder in oral solid-dosage formulations. Starch serves as a diluent in the production of standardized triturates of powerful medications, colorants, and herbal extracts, which makes future mixing or blending procedures in manufacturing operations easier. Additionally, starch is employed in dry-filled capsule formulations to increase powder flow and alter the fill matrix's volume, particularly when dried starches are used. 3–10% w/w starch can be used as a lubricant and antiadherent during the tableting and capsule filling processes.

Freshly made starch paste is employed as a binder for wet granulation in tablet formulations at a concentration of 3-20% w/w (often 5-10%, depending on the kind of starch).

- vii. **Description**-Starch occurs as an odorless and tasteless, fine, white to off-white powder. It consists of very small spherical or ovoid granules or grains whose size and shape are characteristic for each botanical variety.
- viii. **Solubility** -Practically insoluble in cold ethanol (96%) and in cold water. Starch swells instantaneously in water by about 5–10% at 378C.Starch becomes soluble in hot water at temperatures above the gelatinization temperature. Starches are partially soluble in dimethylsulfoxide and dimethylformamide.
- ix. **Method of Manufacture -**In accordance with its botanical provenance, starch is extracted from plant sources using particular procedures. Steeping (corn), wet milling (corn, potato), dry milling (wheat), or sifting and physical separation using hydrocyclones are typical industrial procedures. Usually, the final stage of production involves hot air drying after the starch slurry is separated using a centrifuge. Sulfur dioxide or peroxides can be used as a processing aid in the starch separation process to improve both the separation process and the microbiological quality of the finished product.

^{x.} **Stability and Storage Conditions -**If shielded from excessive humidity, dry starch remains stable. Under typical storage circumstances, starch is thought to be chemically and microbiologically inert. Since starch pastes and solutions are easily broken down by microorganisms and are physically fragile, they should always be made fresh for wet granulation. It is recommended to keep starch in an airtight container in a dry, cool environment. ^[22]

11. EFFECT OF GLIDANT ON FLOW PROPERTIES:

The course of Adding glidants, such as talc, magnesium stearate, and starch, increases the powder's properties. Angle of repose is used to measure flow properties. It is the greatest angle that may be formed between a horizontal plane and a powder surface that stands alone. The glidant's purpose is to improve the powder's flow characteristics. Angle of repose is the maximum angle between the free standing surface of powder and horizontal plane. The objective of the glidant is to increase the flow property of powder.^[47]

Glidants have often been selected by subjective or indirect methods such as measurement of the angle of repose. As a result, several materials have been empirically classified as glidants .Many of the more widely used glidants actually decreased the flow rate. Glidants which lowered the angle of repose did not necessarily increase the flow rate and marked changes in flow rate were not always detectable by angle of repose measurement.^[48]Smaller angle indicates a good flow property compared to bigger angle. Several factors that influence the angle of repose is also determined which are the particle size, particle shape, cohesiveness and the method by which the angle is measured. Smaller particles have a bigger angle of repose due to the cohesiveness. This cohesivity causes a poor flow. Mixture of particles with various sizes also gives a bigger angle of repose owing to the friction. Besides the angle of repose is also gravity-dependant. The flow of the materials is improved with the addition of a glidant at low concentration. The glidant only work at a certain range of concentration.

12. EFFECT OF GLIDANTS ON GRANULATION:

Glidants reduce particle friction, which promotes the flow of tablet granulation. The size and form of the glidants' and granules' particles determine how they affect the flow of the granules. Both lipophilic and hydrophilic glidants perform better on different types of granules. Hydrophilic glidant materials behave better on hydrophilic granules. In a certain formulation, the glidants ensure that enhancing granules move in the direction of a specific ideal concentration. A drag action could occur if the glidant is applied at a higher concentration because the flow rate would drop. ^[49]The formulation of tablets either by wet or dry granulation requires the addition of extragranular excipients like glidants to the granules before tablet compression. Two different glidants, talc, and CSD were used either singly or in combination to assess the impact of glidants on the granular, compaction, and tableting properties. The granule properties were found to be similar, implying that varying the glidant used did not produce a wide variation in granule properties. All the formulations of granules had similar properties, possibly because the composition of the granules and process of granulation were kept constant for all the formulations. The formulation variable across the formulations was related to the type of glidant used, but this was not enough to cause a wide variation in the properties of granules before the addition of extragranular excipients. ^[50]

13. EFFECT OF GLIDANTS ON PRODUCT QUALITY:

Product quality is always dependent on smooth & trouble-free manufacturing operations. If there is any problem during the manufacturing process it will seriously affect the product quality.

IJNRD2404416

For Example;

Let's take the example of the tablet compression process in which we add powder or granules in the hopper of the compression machine & from the hopper these powders or granules travel in the direction of the feeder to fill it.

If there is a flow problem of powders or granules, it may result in the following defects,^[51]

- Weight Variation
- Low Hardness

14. MIXING ORDER OF GLIDANTS:

In the final blending step, first we add other excipients & mix them with powders or granules depending on the formulation. Glidants and lubricants are the two excipients that are employed in the end. Glidants are added just before the lubricants or in simple words, glidants are added at the 2nd last number."^[51]In our formulation, glidants are introduced during the wet granulation, dry granulation, or direct compression process's last blending stage. Since sieving increases surface area, we add glidants after sieving.^[51]

Glidants are used in the following processes to enhance the flow of powders or granules.

We use glidants to improve the flow of powders or granules during the following process,

- During Tablet Compression
- During Capsule Filling
- During Dry Powder Suspension Filling
- Dry Powder Sachet Filling

As we mentioned in the example above, low hardness tablets are compressed in the same way during the capsule, dry suspension, and sachet filling processes, which causes flow issues during compression and weight variation in filling weight. To address this issue, we use glidants in our formulations.^[51]

References:

- 1. Dadfar, H., Dahlgaard, J.J., Brege, S., Alamirhoor, A/Linkage between organisational innovation capability,product platform development and performance: the case of pharmaceutical small and medium enterprises in/Iran. Tot. Qual. Manag. Bus. Excell/ 2016 / 24 (78) / 819834.
- 2. Gleeson, M.P., Hersey, A., Montanari, D., Overington, J/Probing the links between in vitro potency, ADMET and physicochemical parameters/ Nat. Rev. Drug Discov / 2011 / 10 (3), 197
- 3. Cartwright, A.C., Matthews, B.R. (Eds.) / International Pharmaceutical Product Registration /2016 / vol. 200. CRC Press.
- 4. Dureja, H., Kumar, D / Pharmaceutical excipients: global regulatoryissues/ Ind. J. Pharm / 2013 / Oct (1), 215221.
- Johnson, L.M., Li, Z., LaBelle, A.J., Bates, F.S., Lodge, T.P., Hillmyer, M.A / Impact of polymer excipient molar mass and end groups on hydrophobic drug solubility enhancement / Macromolecules /2017 / 50 (3), 11021112.

- 6. Abrantes, C.G.; Duarte, D.; Reis, C.P/ An Overview of Pharmaceutical Excipients: Safe or Not Safe / J. Pharm.Sci / 2016 / 105, 2019–2026. [CrossRef] [PubMed]
- Haywood, A.; Glass, B.D / Pharmaceutical excipients—Where do we begin? / Aust. Prescr/ 2011 / 34, 112–114.[CrossRef]
- 8. Elder, D.P.; Kuentz, M.; Holm, R /Pharmaceutical excipients—Quality, regulatory and biopharmaceutical considerations / Eur. J. Pharm. Sci / 2016 / 87, 88–99. [CrossRef] [PubMed]
- 9. Ansel H.C., Allen L.V., and Jr., Popovich N.G./ Pharmaceutical Dosage Forms &Drug Delivery Systems / 8th ed; Lippincott Williams & Wilkins / 2005 /121-145.
- 10. Aulton M.E / Pharmaceutics The Science of Dosage Form Design / 2005 / 113-138.
- 11. Atheer Awad, Sarah J. Trenfield, Abdul W., Basit /Chapter 19 Solid oral dosage formsRemington (Twentythree Edition)/The Science and Practice of Pharmacy2021/ Pages 333-358
- 12. https://pediaa.com/what-is-the-difference-between-lubricant-glidant-and-anti-adherent/13
- 13. https://pharmaeducation.net/difference-between-lubricant-and-glidant/
- JONAT,S.,HASENZAHL,S.,DRECHSLER,M.,ALBERS,P., WAGNER, K. G .SCHMIDT, P. C /Investigation of compacted hydrophilic and hydrophobic colloidal silicon dioxides as glidants for pharmaceutical excipients / Powder Technology / 2004 / vol. 141/ pp. 31-43.
- MANGAL, S., MEISER, F., LAKIO, S., MORTON, D., LARSON, J /The role of physico-chemical andbulk characteristics of co-spray dried L-leucine and polyvinylpyrrolidone on glidant and binder properties in interactive mixtures / International Journal of Pharmaceutics / 2015 / vol. 479 / pp. 338-348.
- 16. https://www.pharmainform.com/2022/10/glidants.html
- 17. Ahmad Fahmi Bin Ruzaidi, Uttam Kumar Mandal Bappaditya Chatterjee / Glidant effect of hydrophobic and hydrophilic nanosilica on a cohesive powder: Comparison of different flow characterization techniques / Particuology / April 2017 / Volume 31 / Pages 69-79
- 18. Lachman L, Lieberman A, Kinig JL. 4th ed. Bombay: Varghese Publishing House; 1991. The Theory and Practice of Industrial Pharmacy.
- "Maria-C. Jiménez Garavito" Maria-G. Cares Pacheco, Fabien Gerardin, and Véronique Falk / "Silica Nanoparticles as Glidants for Industrial Processing: A Statistical Approach" / Ind. Eng. Chem. Res / 2022 / 61, 44, 16517–" 16528"
- 20. https://www.pharmainform.com/2022/10/glidants.html
- 21. https://www.slideshare.net/sachinUttarwar/lubricants-and-glidents-in-pharmaceuticals
- 22. Handbook of pharmaceutical excipients Edition 6th, editated by Raymondcrowe paul J shekey and Marian E Quinn, Publisher- Pharmaceutical press.
- 23. Haines-Nutt RF / The compression properties of magnesium and calcium carbonates / J Pharm Pharmacol / 1976 / 28: 468-470
- 24. Armstrong NA, Cham T-M / Changes in the particle size and size distribution during compaction of two pharmaceutical powders with dissimilar consolidation mechanisms / Drug Dev Ind Pharm / 1986 / 12: 2043–2059.
- 25. Cham T-M. / The effect of the specific surface area of heavy magnesium carbonate on its tableting properties / Drug Dev Ind Pharm / 1987 / 13(9–11) / 1989–2015.
- 26. Peterson CL et al./ Characterization of antacid compounds containing both aluminum and magnesium. II: Codried powders / Pharm Res / 1993 / 10(7): 1005–1007.
- 27. Tabata T et al. /Manufacturing method of stable enteric granules of a new antiulcer drug (lansoprazole) / Drug Dev Ind Pharm / 1994 / 20(9): 1661–1672.

- 28. Hashim F, El-Din EZ. Effect of some excipients on the dissolution of phenytoin and acetazolamide from capsule formulations. Acta Pharm Fenn 1989; 98: 197–204.
- 29. Sandor M et al. / Effect of lecithin and MgCO₃ as additives on the enzymatic activity of carbonic anhydrase encapsulated in poly(lactideco-glycolide) (PLGA) microspheres / Biochim Biophys Acta / 2002 / 1570(1): 63–74.
- 30. Cui C et al. / Injectable polymer microspheres enhance immunogenicity of a contraceptive peptide vaccine / Vaccine 2007 / 25(3): 500–509.
- 31. Patel H et al. / The effect of excipients on the stability of levothroxine sodium pentahydrate tablets / Int J Pharm / 2003 / 264: 35–43
- Kirk RE, Othmer DF / Encyclopedia of Chemical Technology / 4th edn,/ vol. 1: New York: Wiley / 1995 / 107.
- 33. Kirk RE, Othmer DF / Encyclopedia of Chemical Technology / 4th edn, / vol. 15: New York: Wiley / 1995 / 703–707.
- 34. Dawoodbhai S, Rhodes CT / Pharmaceutical and cosmetic uses of talc / Drug Dev Ind Pharm / 1990 / 16: 2409–2429.
- 35. Dawoodbhai S et al / Optimization of tablet formulations containing tale / Drug Dev Ind Pharm / 1991 / 17: 1343–1371.
- 36. Wang DP et al. / Formulation development of oral controlled release pellets of diclofenac sodium /Drug Dev Ind Pharm / 1997 / 23: 1013–1017.
- 37. Fassihi RA et al / Potential use of magnesium stearate and talc as dissolution retardants in the development of controlled release drug delivery systems / Pharm Ind / 1994 / 56: 579–583.
- Fassihi R et al. / Application of response surface methodology to design optimization in formulation of a typical controlled release system / Drugs Made Ger / 1996 / 39(Oct–Dec): 122–126.
- 39. Schultz P et al. / New multiparticulate delayed release system. Part 2. Coating formulation and properties of free films / J Control Release / 1997 / 47: 191–199.
- 40. Oetari RA et al. / Formulation of PGV-O a new antiinflammatory agent as a tablet dosage form / Indonesian J Pharm / 2003 / 14(4): 160–168.
- 41. Pearnchob N, Bodmeier R. / Dry powder coating of pellets with micronized Eudragil (R) RS for extended drug release / Pharm Res / 2003 / 20(12): 1970–1976.
- Mani N et al. / Microencapsulation of a hydrophilic drug into a hydrophobic matrix using a saltingout procedure: II. Effects of adsorbents on microsphere properties / Drug Dev Ind Pharm / 2004 / 30(1): 83–93.
- 43. Lin K, Peck GE./ Development of agglomerated talc. Part 1. Evaluation of fluidized bed granulation parameters on the physical properties of agglomerated talc / Drug Dev Ind Pharm / 1995 / 21: 447–460.
- 44. Lin K, Peck GE. / Development of agglomerated talc. Part 2. Optimization of the processing parameters for the preparation of granulated talc / Drug Dev Ind Pharm / 1995 / 21: 159–173.

- 45. Lin K, Peck GE. / Development of agglomerated talc. Part 3. Comparisons of the physical properties of the agglomerated talc prepared by three different processing methods / Drug Dev Ind Pharm / 1996 / 22: 383–392.
- 46. Bubik JS. / Preparation of sterile talc for treatment of pleural effusion [letter] / Am J Hosp Pharm / 1992 / 49: 562-563
- 47. Waghmare J.S / Glidants on the flow property of floating tablet / International journal of chemical and physical sciences / 2014 / vol 3 / ISSN:2319-6602
- 48. Gerald Gold, Ronald N. Duvall, Blaze T. Palermo, James G. Slater / " Powder Flow Studies II: Effect of Glidants on Flow Rate and Angle of Repose / Journal of Pharmaceutical Sciences / Volume 55, Issue 11 November 1966/ Pages 1291-1295
- 49. Ashika Advankar 1, Rahul Maheshwari 1 2, Vishakha Tambe 1, Pooja Todke 1, Nidhi Raval 1, Devesh Kapoor 3, Rakesh K. Tekade 1 4/ Chapter 13 Specialized tablets: ancient history to modern developmentsDrug Delivery Systems Advances in Pharmaceutical Product Development and Research 2019 / Pages 615-664.
- 50. Apeji YE, Olowosulu AK / Quantifying the effect of glidant on the compaction and tableting properties of paracetamol granules / J Res Pharm / 2020 / 24(1): 44-55.
- 51. https://www.pharmainform.com/2022/10/glidants.html

International Research Journal International Research Journal Research Through Innovation