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ROLLER COMPACTION: IMPERATIVE PROCESS FOR TABLET MANUFACTURING: A REVIEW

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ABSTRACT
Roller compaction is widely used granulation technique for a solid dosage form which contains moisture sensitive material. Granulation is any process of size enlargement, whereby small particles are gathered together into larger permanent agglomerates. Dry granulation is a method where no moisture and heat is used to process powders into granules. Slugging and roller compaction are the processes followed during roller compaction. At last material is subjected to milling to achieve the desired size particles. Roller compaction is less expensive and more precise method as compare to other granulation methods.

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INTRODUCTION

In recent years the concern about environmental effects was increased, there is a high interest for methodologies which are environmentally friendly[1]. Due to the fact that roller compaction is a technology where no organic solvents are used, it became widely accepted in pharmaceutical technology. Although, it has been used since more than 50 years, it has recently drawing increasing attention.

Roller compaction is conceptually a very simple process: the feed powder is passed between two counter rotating rolls where the flow being induced by the friction acting at the surface of the rolls[2]. Even though, it looks very simple at the first sight compaction in a roll press is a complex process and not yet fully understood. A lot of parameters are involved in the process and a lack of understanding of the compaction mechanisms can lead to undesirable results.

Direct compaction requires a very good flowability and compressibility of the materials. Those parameters become even more critical if the formulation contains large amount of active substance. To overcome these problems, several alternatives have been used. Roller compaction is a very attractive technology in the pharmaceutical industry. It is a fast and efficient way of producing granules, especially suitable for moisture sensitive materials.

After roller compaction a material tend to loose mechanical strength. This phenomenon is affected by deformation behavior of the materials exposed to roller compaction. Plastic deformable materials are particularly sensitive because of the limiting binding potential which may be consumed in the first compression step by increasing particle size and decreasing specific surface area. However, materials which undergo fragmentation under pressure showed less or even no loss of tabletability after roller compaction. The loosing of mechanical strength is called loss of reworkability or loss of tabletability. To diminish or even eliminate loss of reworkability the crucial moment is the development of a correct and robust formulation. If excipients with adequate properties, regarding an active material, are chosen it is possible to hold mechanical strength of the tablets. Another problem that could take place during roller compaction is disruption of crystal lattice and changing of polymorphic form of the material. Polymorphic transformation may occur as a result of applied pressure during roller compaction or even due to double compaction after tableting.

Tablet Dosage Form

The tablet is the most commonly used dosage form for pharmaceutical preparations. For manufacturing of tablets certain qualities of the powder are required: low segregation tendency, good flowability and compactibility [3]. Therefore, granulation becomes an integral part of pharmaceutical processes that attempts to improve powder characteristics.

Granulation is any process of size enlargement, whereby small particles are gathered together into larger permanent agglomerates in which the original particles can still be identified. Pharmaceutical granules typically have a size range between 0.1 and
2.0mm.

Dry Granulation

As all granulates in this work were made by a dry granulation, a special accent is given to this process.

Dry granulation is a method where no moisture and heat is used to process powders into granules. Although, dry granulation has been used in pharmaceutical industry since more than 50 years, it has recently drawn increasing attention[7].

There are two types of dry granulation: **slugging** – where a powder is compressed into large tablets or slugs, and **roller compaction** - process in which uniformly mixed powders are compressed between two counter rotating rolls to form a compact ribbons (see figure 2.1). In both cases these intermediate products, slugs and ribbons are broken using suitable milling technique to produce granular material which is then sieved to separate desired particle size.

In the pharmaceutical industry, dry granulation process in the 1950s – 1970s favored a slugging. Slugging involves the use of circulating dies to produce a large compact, often 25 mm or larger in diameter, for granulation. In this process, round, flat – faced punches should be used in order to avoid trapped air within the slug, which may be trapped with concave punches. To get better feeding and high production rate the maximum diameter should be used[8]. Slugging tends to be more limiting in terms of uniformity and capacity than roller compaction system.

The advances of roller compaction over slugging are: greater production capacity, more control over operating parameters, simplifier and continuous processing.

The bonding mechanisms which occur during dry granulation process are described as a mixture of van der Waals forces, mechanical interlocking, and recombination of bonds established between created surfaces and solid bridges, which are created as a result of partial melting and solidification during compression[4].

Formation of granule bond usually occurs in the following orde[8]:

1. Particle rearrangement – when powder is filled in void space air begins to leave the powder blend's interstitial spaces and particles move closer. Spherical particles will tend to move less than particles of the other shape because of their packing.

2. Particle deformation – as compression force is increased particle fragmentation occurs. This deformation increases the point of contact between particles where bonding occurs and is described as plastic deformation.

3. Particle fragmentation – the next bonding stage which occurs at increased force level.

4. Particle bonding – with created of particle deformation and fragmentation particle bonding occurs. In general, it is accepted that bonding take place at molecular level, and that is due to the effect of van der Waals forces.

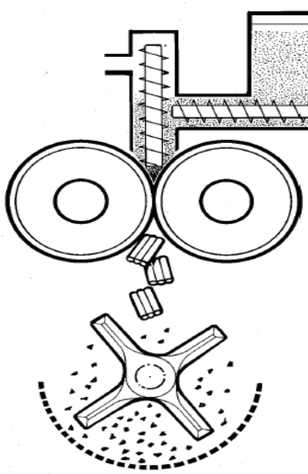

Figure 2.1.: A typical roll compaction process

Mechanisms of Roll Compaction

The principle of compaction is based on equipment design and operating parameters that influence the starting material in a manner to produce an optimum compact[10]. The space between two rolls, where different mechanisms occurs, is generally divided in three regions (see figures 2.2)[11]:

1. Slip region (feeding zone) – this zone is characterized with particles slipping at the roll surface and at the same time rearrangement and de-aeration can occur. The effectiveness of the slip region is related to wall friction and interparticle friction of the feed[10]. The speed of the material is lower than the peripheral speed of the rolls.

2. Nip region (compaction zone) – in the nip region, the material is trapped between two rolls and is moving at the same speed as the roll surface. This forces the material through the region of the maximum pressure where the particles deform plastically and/or break. The limit between feeding and compaction zones is the nip angle α. This angle is directly affected by the roll diameter and established in a line through the rolls' centers to a point on both roll where the powder starts to move at the same speed as the roll (see figure 2.2). To achieve acceptable compaction, the nip angle should be sufficiently large. It is about 12° and material characteristics, as particle size and density, can have influence on this value.

3. Extrusion region (release zone) – when the roll gap starts to increase, the compacted ribbon exhibits relaxation as it is released from the rolls.

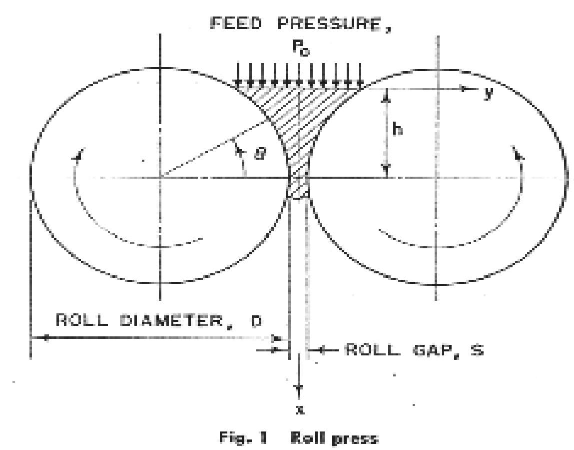

Figure 2.2.: Schematic diagram of the roll compaction process[12]

Equipment

The successful roll compaction of a powder depends on the matching powder properties, especially its compressibility and flowability, and to both the design and operating conditions of the compactor[13]. In the pharmaceutical field only a few producer of roll compactors are established. Although the general layout of the machines looks alike, there are some features that differ from compactor to compactor. These lead to a type classification:

Roll assembly: rolls can be mounted in a horizontal, inclined and vertical position(see figure 2.3)[2].

Horizontal position of rolls is a characteristic for Fitzpatrick Company, Bepex, Komarek (A), inclined for Gerteis (B) and Vertical for Alexanderwerk (C)[11].

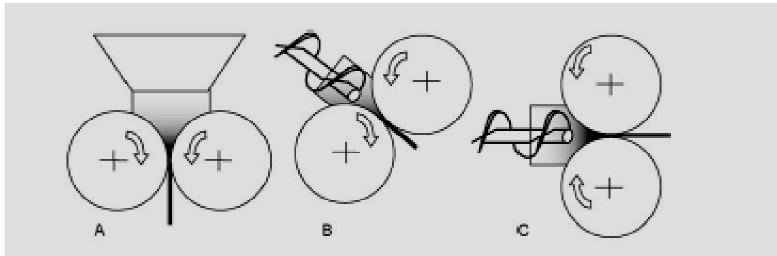

Figure 2.3.: Configuration of roll compactor

The position of the rolls is mainly a manner of design and therefore it only plays minor role. However, the vertical assembly might induce that the nip angles in upper and lower roll differ. This can happen because the direction of force by friction and force of gravity is completely different for the two rolls. If nip angle is quite small the powder might stay in place, showing an increase in temperature, giving reason for concerning a thermal degradation of the material. When vertically assembled rolls are used differences in nip angles should be taken in to account[2].

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Fixed vs. movable rolls: according to gap system two type of roller compactors exist.One in which the distance between the rolls is constant during the process of powder densification and one in which this distance can be changed[2]. In the first case gap size cannot be varied during the process of compaction. Ribbons which are produced have the same geometrical dimensions, but porosity can be changed with the fluctuating mass flow[11]. Compactors with variable gap system have one fixed and one moveable roll. The consolidating force on the material between two rolls is supplied by hydraulic units. This unit acts upon the floating roll which can move horizontally depending on feeding rate and applied pressure[9].

Roll surface: Roll surface has an effect on the efficiency and production rate in the powder compaction. According to powder properties different roll surface can be used: smooth, knurled and pocket design (see figure 2.4).

Figure 2.4.: Various roll surfaces for compaction[9]

Feeding system: three different ways of feeding material into to the compactor exist, gravity transport, single screw feeder and double screw feeder (see figure 2.5). It must achieve a uniform and continuous flow of material in order to fill the nip between the rolls correctly and sufficiently, so that the formed compacts are not heterogeneous[2] . When powder is dense and free flowing gravity feeder can be used, but for most powders, which are lightweight and do not fly freely single or double screw feeder is required. During feeding, vacuum deaeration can be applied toremove air from a powder with low bulk density[9,15].

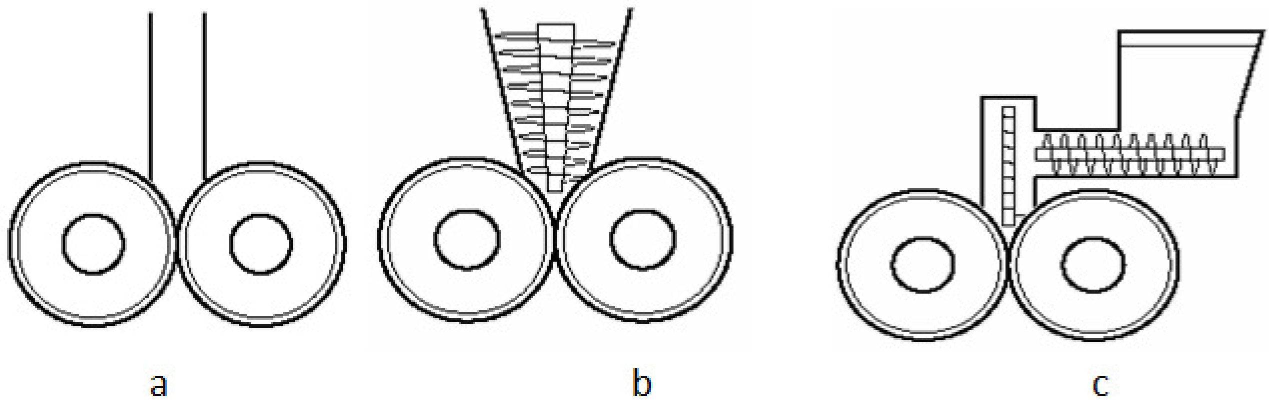


Figure 2.5.: Different feeding system: a) gravity feeder, b) single screw feeder, c) double screw feeder[16]

Process Parameters

Compaction in a roll press is more complicated than it looks at the first sight.

Efficiency of roller compaction is based on the equipment design and operating parameters. The main process variables which can affect compaction are:

Compaction pressure: if pressure is too low there is no compaction, but in the same time if it is too high over compaction will occur.

Speed of feeding screw (vertical vs. horizontal): speed of vertical and horizontal screw should be optimized otherwise feeding is not continuous and compaction is not homogeneous. Roll speed affects the compaction by determining the dwell time that material should spend in the nip region which has an impact on the ability of the product to deaereate prior to passing between two rolls.Roll gap is the distance between the rolls at their closest point. This is the critical parameter of compaction and one that needs to be stabilized by the process parameters mentioned above. It is in a function of pressure applied to the rolls and the amount of material that is passed between them[9].

Table 2.1.: Advantages and disadvantages of roller compaction

Advantages	Disadvantages
-Binder-less agglomeration	-Weakening or disruption of the
-Suitable for heat and moisture liquid and drying) -Production fines	crystal lattice -sensitive material (no
-Use less equipment and time (cheap)	Loss of reworkability
-Continuous process	

Since granulating solvent is not used during dry granulation, solution or solution- mediated phase transformations are eliminated, thus the probability of phase transitions with this granulation unit operation is reduced. However, the applied mechanical stresses during processing may lead to phase transformation via the
solid-state or melt mechanisms[17].

Milling

The final product of the roller compaction – ribbons, must be subsequently broken to the required particle size. In general, the milling or size reduction is the mechanical process of reducing of the size of particles or aggregates. To initiate reduction of particle size external forces should be applied[18].

The milling is affected by a variety of factors and has a direct influence on the quality of the final product. The selection of equipment which should be used for this process is determined by the properties of feed material and specification of the product.

Classification of Mills

The most convenient classification of size reduction equipment is according to the way in which forces are applied; impact, shear attrition and shear-compression[19].

Table 2.2.: Characteristic of Different Types of Mill[19]

Mechanism of Acting	Example	Particle size
Impact	Hammer mill	Medium to fine
Shear	Extruder and hand screen	Coarse
Attrition	Oscillating granulator	Coarse to medium
Shear-compression	Comil	[illegible]

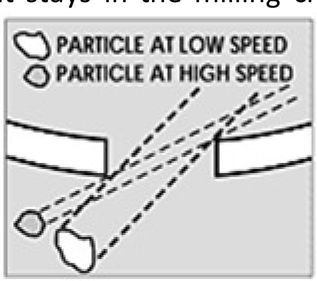
The type of mill can affect the shape of the granules and throughput, and shape of the granules affect the flow properties. An impact mill produces sharp and irregular granule where flowability sometimes may be a problem, whereas granules produced by attrition mill are more spherical.

Process Parameters

Besides the type and design of mill, the most important factors which can affect the quality of particles are: feed rate, screen size and rotor speed.

Feed rate controls amount of material that enter to the mill and can control overfeeding or underfeeding. Although, either phenomenon should be avoided, overfeeding is relatively more harmful. When amount of material which is fed is bigger than amount which is discharged it stays in the milling chamber and it leads to greater size reduction, over loads the motor and reduced capacity of the mill[19]. In general, the feed rate should be equal to the rate of discharge.

Screen, located directly under the blade, prevents particles to leave the chamber until they are at least the same size as the screen holes. The screen size doesn't necessarily define the particle size of the final product. Depending on rotor speed, particles find various dimension and shape of angle at which they approach the screen. The higher rotor speed will influence the smaller angle under which particles hits the screen. This means that particles will pass through the smaller hole in the screen (see figure 2.6), leading to smaller particle size of the final product. The thickness of the screen has influence on the particle size as well. The thicker the screen, the smaller particle can pass the screen (see figure 2.7)[19].



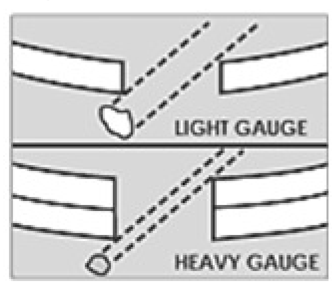


Figure 2.6.: Influence of the rotor speed Figure 2.7.: Influence of the to particle size[19]
screen thickness to particle size[19]

Rotor speed directly affects the particle size range. If all the other variables are the constant, faster rotor speed induces the smaller particle size. As all processes, milling has some advantages and disadvantages, which should be considered before starting with size reduction of the material (see table 2.3.).

Table 2.3.: Advantages and disadvantages of milling

Advantages	Disadvantages
- Increase of surface area	- Change in polymorphic form
(increase dissolution and bioavailability)	- Possible degradation of the drug
- Enhance content uniformity	
(increase number of particles per unit weight)	
- Improve flowability	
(irregular shape of the material)	
- Control particle size distribution	

CONCLUSION:

The process of roller compaction mainly depends on the nature of material used. No solvent used in the entire process which helps the formulator to keep away from the problems of moisture sensitive ingredients. various compactors available in the market make the process easier because of technology innovation.Milling is an essential process soon after compacton which gives the desired size particles.

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