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A Review: Roller Compaction for Tablet Dosage Form Development.

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Short Communication

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ABSTRACT

Roller compaction is a unit operation in dry granulation process in which the powders containing active ingredients and excipients are agglomerated between the rollers of compactor. During roller compaction the dry powders of the active ingredients and excipients are blended in a blender and further roller compacted and milled to form granules. The resulting granules are then blended within in a blender and used for compression into tablets or for capsule filling. Compaction of powder is the term used to describe the situation in which these materials are subjected to some level of mechanical force. In pharmaceutical industries, the effects of such forces are very important in manufacturing of granule and tableting. The compaction is generally divided into two states compression and consolidation. Compression is nothing but the reduction in bulk volume of material by plastic deformation. The main purpose of roller compaction is to Improve powder flow properties, avoid wet granulation induced degradation, improve product stability, prevent segregation, reduce bulk volume hence minimizes storage volume and hence improves transport efficiencies and to reduce potential environmental hazards and ensures safety. Dis-advantages of roller compaction are densification of the powder or particle which can adversely affects the dissolution of product and the powder to be compacted must be compressible or have to add compressible excipients or additives to the formulation. Sophistications available with roller compaction system are roller cooling or heating, vacuum de aeration, Separate feed funnel for small quantities of powders and Pneumatic dry granulation.

INTRODUCTION

Roller compaction is a unit operation in dry granulation process in which the powders containing active ingredients and excipients are agglomerated between the rollers of compactor to form granules with good flow properties and stability. During roller compaction the dry powders of the active ingredients and excipients are blended in a blender and further roller compacted and milled to form granules. The resulting granules are then blended within in a blender and used for compression into tablets or for capsule filling. Compaction of powder is the term used to describe the situation in which these materials are subjected to some level of mechanical force. In pharmaceutical industries, the effects of such forces are very important in manufacturing of granule and tableting. The compaction is generally divided into two states compression and consolidation. Compression is nothing but the reduction in bulk volume of material by plastic deformation. The principle of compaction is based on the space is generally divided in three regions [1,2,3,4]:

1. Slip region (feeding zone): In this zone the powder slips from roll surface and at the same time rearrangement of particles and de aeration of powder can occur.
2. Nip region (compaction zone): In this region, the material is trapped between the rollers and is moving at the same speed of roll surface. Due to the force between rollers the particles plastically deforms. The angle

formed on the boundary of feeding zone and compaction zone is called nip angle. It is the angle between diameter of roll and the point where slip region ends or nip region starts on the roll surface. For better compaction nip angle should be sufficiently large.

3. Extrusion region (release zone): In this region the roll gap starts to increase, the compacted ribbon is released from the rolls.

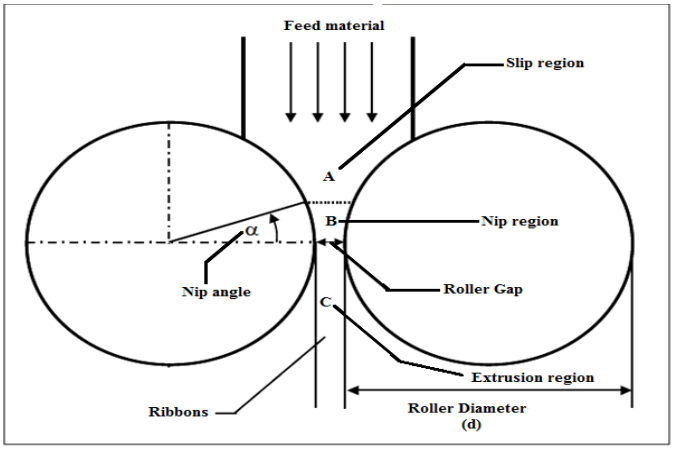

Figure No: 1 Process of roller compaction

The roller compaction processes and equipment were adapted and modified from other industries like metal, mineral and recycling industry. In early 19th century the process was utilized in mining industry to crush rocks for easy extraction of desired precious material. In mid-twentieth century the process has been used to compress pharmaceutical powders. Later on the equipment goes on improving in different aspects of parts and mechanisms to reach the need of today's 21st centurion technology [5,6,7].

The main purpose of roller compaction is to:

- Improve powder flow properties.
- To avoid wet granulation induced degradation.
- To improve product stability.
- To prevent segregation.
- To reduce bulk volume hence minimizes storage volume and hence improves transport efficiencies.
- To reduce potential environmental hazards and ensures safety.

Recently roller compaction drawn attention of Pharma industry because of some advantages of dry granulation over other granulation techniques:

- It is suitable for heat labile and moisture sensitive products.
- It improves flow properties of powders.
- It is economical process as it requires low personnel cost.
- It reproduces constant particle density.
- It is environment friendly.
- It prevents particle segregation.

It has some disadvantages as well:

1. Roller compaction densifies the powder or particle which can adversely affects the dissolution of product.
2. The powder to be compacted must be compressible or have to add compressible excipients or additives to the formulation.
3. The various process parameters involved in roller compaction process and its interrelation are given in figure.

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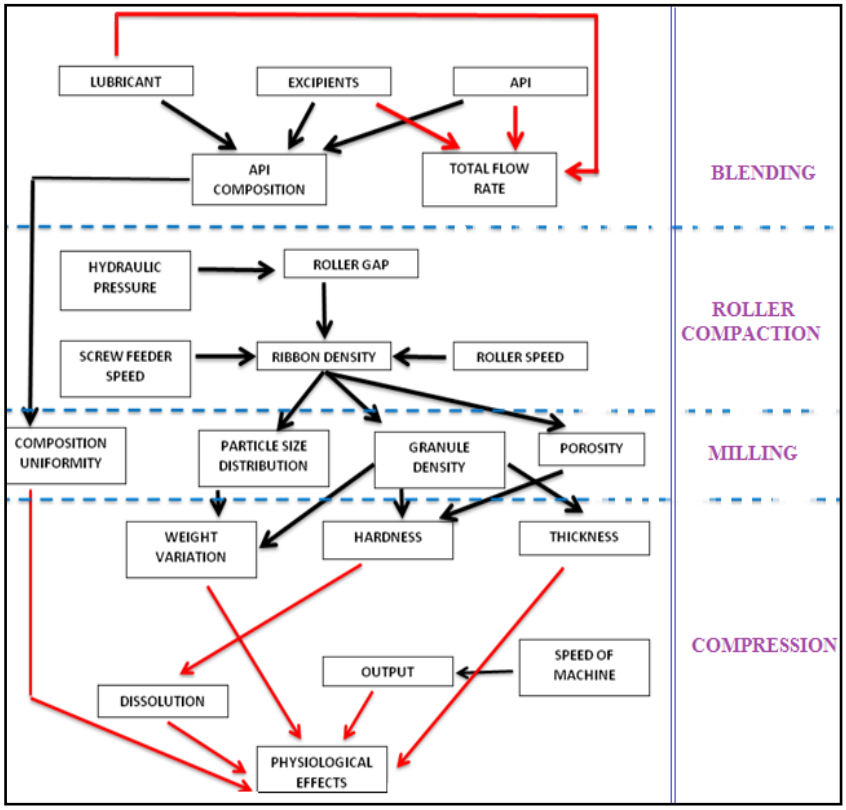

Figure No 2: An interrelation of process parameters

Equipment of roller compaction [8,9,10]

The roller compactor used for roller compaction having major components is:

1. Feed hopper
2. Screw feeder
3. Rollers
4. Flake crusher
5. Pre and fine granulator

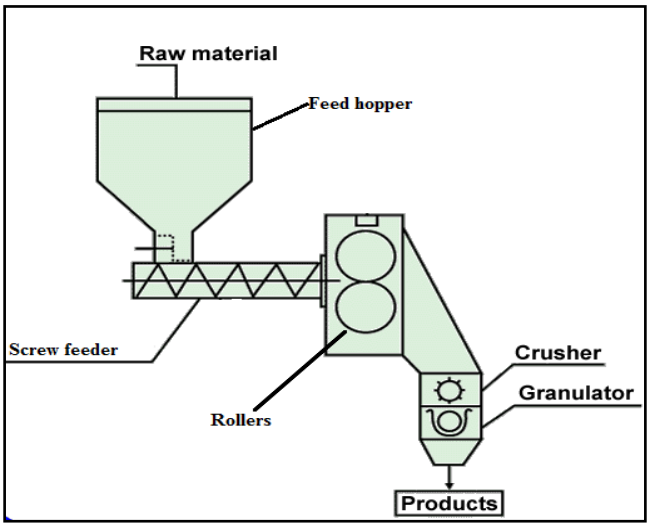

Figure No 3: General diagram of roller compactor

Feed hopper

Material is filled into feed hopper through the opening at the top which falls down in the direction of rotating chopper of the feed hopper. The rotor arms transport the material evenly downwards through the hopper in the direction of screw feeder.

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Screw feeder

Functions- it helps to carry material to the rollers and it somewhat de aerates the material. Generally three types of screw feeder used in industrial practice.

- Vertical
- Inclined
- Horizontal

Table No1: The advantages and disadvantages in short

Vertical SF	Inclined SF	Horizontal SF
	Advantages:	
Enhances pre-compaction and de aerates powder within the hopper	Feeder can be adjusted during operation to handle a powders with variable flow properties	Good mixing ability
Suitable for dense and free flowing powders	-	Suitable for light, voluminous and fluidizing powders
-	-	Even powder distribution onto compacting rollers
	Disadvantages:	
Uneven distribution of powder	Unable to pre-compaction and de aeration of powders	Leakage of powder between rollers during compaction
Not suitable for fine and fluffy powders having poor flow properties	-	-

Rollers

It compacts to the material in the gap area of the compacting rollers. The various types of rollers are, flat, punch and pocketed shaped and many more available in market.

- Flat rollers: These are suitable for powders tend to stick or cling to roll surface.
- Punch shaped rollers: These are suitable for highly voluminous, light, and fluidizing material.
- Pocketed rollers: Suitable for products which can release cleanly from rolls.

Flake crusher

It serves for the coarse crushing of compacted flakes. It is having six blades to break or cut the flakes coming from rollers into small pieces. The speed of flake crusher is very important parameter to optimize which may affect the ratio of granules to fines.

Pre and fine granulator

Function: To take up the flake pieces falling down from the hopper and generate a finer granulates. Granule size is determined or maintained by choice of suitable mesh size.

Sophistications in the Roller Compaction Techniques [11,12].

Sophistications available in the roller compaction processes and equipment are as follows.

1. System for roller cooling or heating: The material with low melting point melts in rollers because of friction between rollers some amount of heat generated. To cool or re heat the rollers the water is circulated through the rollers which helps to maintain the temperature of rollers.
2. Vacuum de aeration: It consists of vacuum pump, a vacuum regulating valve, suction pipes, vacuum gauge and filter. It builds up a vacuum and absorbs the material to be compacted from screw feeder on to the filter. It helps to transport highly voluminous and fluidizing materials.
3. Separate feed funnel for small quantities of powders.
4. Pneumatic dry granulation: It extends application of dry granulation, because flowability material can also achieved at low ribbon density thus improving recompactibility of the resulting dry granulate. In this method in which the finer granulated material from a Roller compactor is pneumatically fractionated using controlled conditions of circulating gas in a rotating perforated cylindrical drum; recirculated and recomapcted in to rollers hence method is economical as the loss of material minimized.

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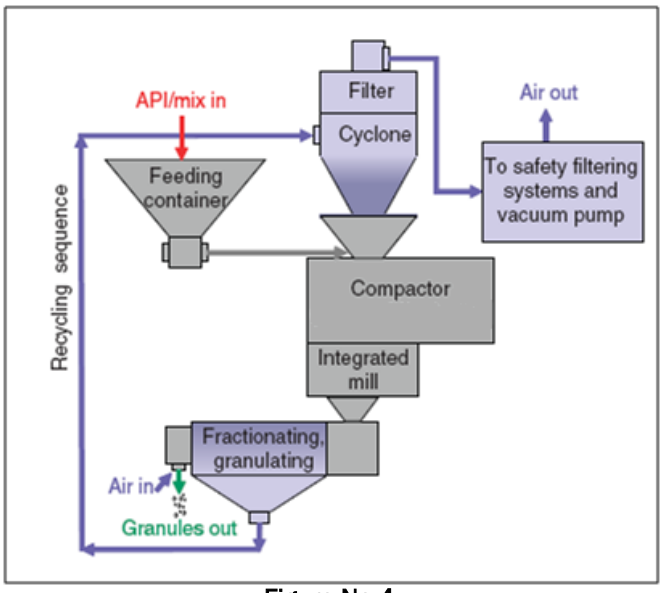

Figure No 4

Troubleshooting in roller compaction

Table No 2: Problems of roller compaction and its troubleshooting

Problem	Possible cause	Remedies
Sticking to compaction rolls	Insufficient lubricant level	Add lubricant
	Excessive moisture	Reduce moisture content and dehumidify environment
	Excessive force	Decrease roll force
	Melting of product	Cool rolls to decrease temperature; use water or nitrogen
Excessive fines	Compaction force too low	Increase compaction force
	Compaction (dwell) time too short	Decrease roll speed
	Air entrapment	Use deaeration system
	Poor powder compressibility	Increase compressible binder. Screen/sieve product to desired particle size
	Low compaction force	Increase roll force
	Particle size too large	Use finer screen/plate to mill the compacts
	"challenging material"	May need to pass material through roller compactor several times

CONCLUSION

The use of dry granulation, that is, RC, has increased recently in the development and manufacturing of pharmaceutical dosage forms. There are still potential problems with RC such as adequate powder flow and material compactability. Technical process improvements can solve these problems and provide solutions to these issues.

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