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A REVIEW ARTICLE ON ROLLER COMPACTION

[1]Sonia.M.Goyal, [2]Yogeeta.S.Agrawal, [3]Rajshri.R.Dusane, [4]Monika.S.Jadhav

[1]R.C.Patel Institute of Pharmaceutical Education And Research Shirpur Dist-Dhule 425405.

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Abstract:

In pharmaceutical oral solid dosage forms we have been widely used for decades which are mainly depend on their convenience of administration with suitability drug delivery for its systemic effects. Granules, pellets, tablets and capsules are commonly used in pharmaceutical solid dosage forms. As the solid pharmaceutical dosage forms which mainly containing the drug substances with or without suitable diluents were prepared by either compression or molding methods that is define as tablet. Direct compression, wet granulation and dry granulation are the three basic tableting methods. If the materials have sufficient inherent binding or cohesive properties to form granules dry granulation may be used. The process of granulating without the use of liquids it may refer as a dry granulation. Slugging and roll compaction are the two dry granulation methods which are used in the pharmaceutical industry. Particles which are consolidated and dignified by passing the material between two high pressure rollers are in the roll compactor. Reduced form to the uniform granule size by milling is used by the dignified material from roller compactor. Chemically moisture or physically moisture sensitive drugs are processing for choice of method with (RC/DG) Roll compaction/dry granulation and which has no liquid binder required in the granulation. This literature review illustrates the progress and the use of RCDG in the production of directly compressible excipients, the compaction of drugs and drug formulations.

Keywords: *Roll compaction, Dry granulation, Tablets, Excipients, Herbal dry extracts, immediate release, Controlled release.*

Corresponding author:

Sonia.M.Goyal,

R.C.Patel Institute of Pharmaceutical Education And Research Shirpur Dist, Dhule 425405.Email Id- soniagoyalfeb95@gmail.com

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INTRODUCTION:

Dry granulators are also called as roller compactors. Compaction of powder is the term used to describe the situation in which these materials are subjected to some level of mechanical force. Compression is nothing but the reduction in bulk volume of material by plastic deformation. 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 compaction is generally divided into two states compression and consolidation. The resulting granules are then blended within in a blender and used for compression into tablets or for capsule filling. The force required to fine powder between two counter rotating rolls and press the raw materials into a solid compact (flakes, sheets, strips) is a roller compactors. In dry granulation process roller compaction is a unit operation in which the powders containing active ingredients and excipients are agglomerated between the rollers of compactor to form granules with flow properties and stability is good. In pharmaceutical industries, the effects of such forces are very important in manufacturing of granule and tableting.

Figure No.1. Roller Compaction

Basic principle:

A roller compactor generally consists of three major units

1. Feeding system- which converts the powder to the compaction area between the rolls.

2. A compaction unit- where powder is compacted between the two counters rotating rolls to a ribbon by applying force.

3. A size reduction unit- for milling the ribbon to the desired particle size.

The force which is applied is expressed in KN/cm, being the force per cm roll width. The force which had applied on the powder compacted between two rolls and the most important parameter in the dry granulation process is force applied.

Roller compaction theory:

As the powder is compacted, it passes through three different regions. Mixture powder which is to be compacted reaches to roller from screw feeder with different mechanisms. Roll compaction is an agglomeration process in which powder is dignified by passing through two equal diameter counter rotating rollers.

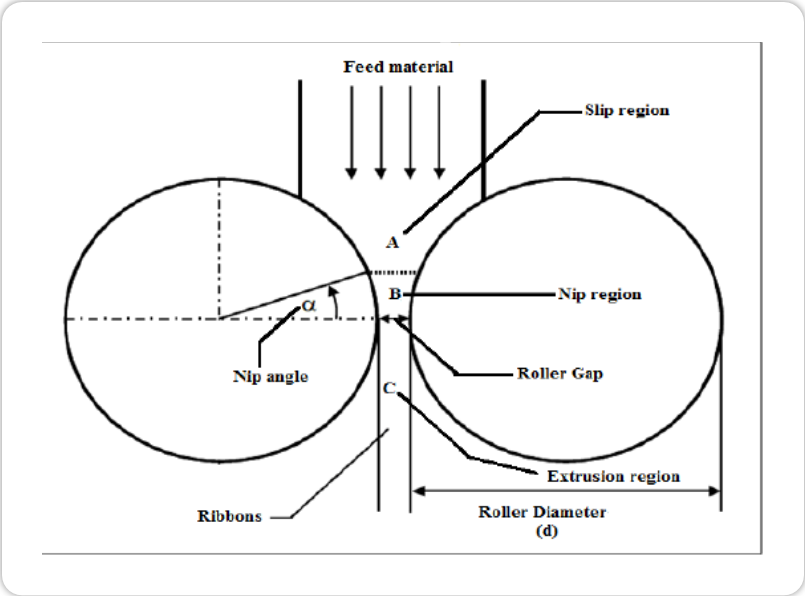


Figure No.2. Roller Compaction Process

1) Slip region (feeding zone): The slip region is the zone close to the feeding of the powders. The slip region is effectively related to wall friction and antiparticle friction of the feed. Material starts to move downward at a rate less than the surface speed causing the formulation "slips". In this region Particle rearrangement and de-aeration may occur, but the pressure exerted on the powder is relatively small in this region as compared to nip region

2) Nip region (compaction zone): In the nip region, the material is subjected to maximum stresses between two rolls leading to the formation of solid compact or sheet. In this region powder moves at the same speed as that of roll surface. To achieve acceptable compaction, the nip angle must be sufficiently large. Densification occurs due to the decrease in the gap and results in a significant increase in the roll pressure.

3) Extrusion region (The release region): In release region there is great decrease in pressure as roll gap starts to increase again as the compact is ejected and can expand due to elasticity. The compacted ribbon exhibits relaxation as pressure is released from the rolls. The beginning of the ejection region is sometimes referred to as a neutral point because it sets the boundary between the region where the material moves at the same speed as wall surface it comes in contact with and the region where the material moves faster than the roll.

Design of Roller Compactor:
Design of roller compaction consists of roll design, feeder system design, design of mills and other accessories. Quality of granule depends upon optimization of process parameter.

1. Roller Unit:
Rollers create pressure on powder material and converts into compacted ribbon. In fixed gap system powder feed is controlled by screw feeder and in variable gap system powder feed is controlled by width between rolls and screw feeder. Those two types are roller compactor with a fixed gap system and roller compactor with variable gap system. Roller unit consist of two equal diameter counter rotating roller through which powder is passed and get compacted. Two types of roller compactors are available according the nature of the gap between two rollers. Rollers are oriented on the machines in different ways and the design of roller orientation varies from manufacturer to manufacturer.

I) Roller orientation:
Three types of roller orientation are commercially available.

a) Horizontal orientation:

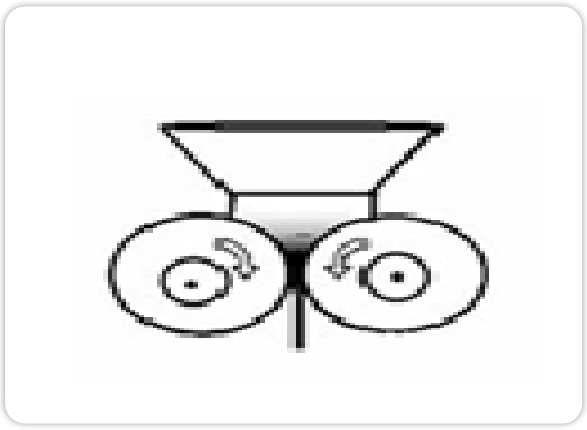


Figure No.3. Horizontal orientation

Hosokawa Bepex GmbH, the Fitzpatrick Chilsonator™ Company, Freund Industrial is an example. Bypass occurs because material may remain in nip region for certain and which is uncontrolled time period. Vertical or inclined feeders are used for horizontally aligned rolls. Also it should be noted that the roller orientation defines feeder orientation as well. Usually in Horizontal orientation of rolls material loss is high from bypass. This is most commonly used orientation design. In these design rollers are arranged horizontally. Incorporation of side seal in compacter design reduce material bypass. This also negatively affects ribbon density as well.

b) Vertical orientation:

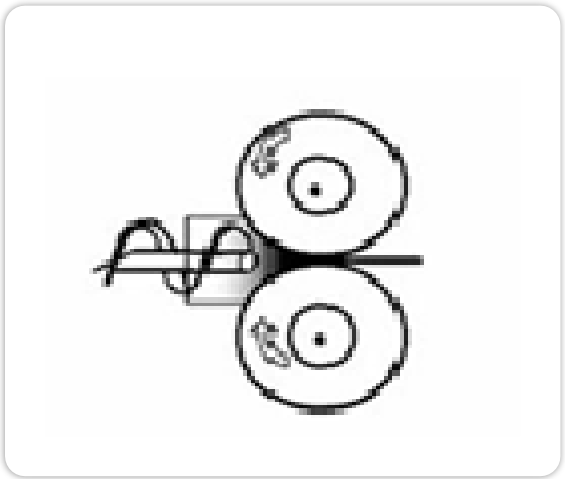


Figure No.4. Vertical orientation

The advantage of less bypass of material, to the vertical design is preferred for low dose product. Due to the vertical orientation direct bypass through rolls is minimized because of the material movement is not governed by gravity feeding system.

c) In-cline orientation (position between horizontal and vertical):

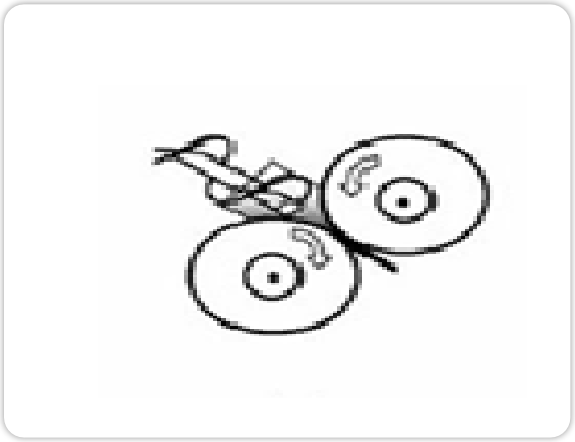


Figure No.4. In-cline orientation

Such type of design reduces bypass of material up to 10- 15 %. E.g. Gerteis Machine.

II) Roll Surface: Smooth and corrugated rolls are the most commonly used in pharmaceutical industry. Types of roll surfaces are smooth, corrugated and fluted rolls. Corrugated rolls are therefore particularly suitable for increasing bulk density is of light, fluffy, aerated materials. Roll surface is also important in maintaining flow of powder material through nip region. Smooth rolls can minimize sticking problems. Rough roller surface reduce the by-pass material. When the roll speed is fast, back pressure is created on the powder leading to the improper flow of material through nip region

2) Feeder design: Vertical feeders take advantage of the head pressure in the hopper above the horizontally aligned rolls. The feed screw could be either straight or slightly tapered. In case of light, fluffy and aerated powder tapered screws are better. For some equipment the inclined screw feeders are used as they utilize gravity to feed powder but have less powder leakage. Screw feeding continuously dignified and which deaerates the blend. Feeding system is critical for achieving a good compacted product. Feeder designs play vital role in creating positive pressure that regulates powder flow towards roller. It is very important to maintain uniform and continuous flow of material in order to fill the nip between the rolls correctly and sufficiently. Such design of powder reduces volume of powder, enhances the deaeration and also gives pre-densification effect. . Feeder orientation could be vertical, horizontal, or inclined. Compared to vertical screw feeders, horizontal screw feeders are advantageous in minimizing leakage and improving press capacity. When the powder is dense and free flowing gravity feed system can be used. In a force feeder, a rotating screw is installed in the center of the hopper. There are two types of feeders, single screw feeder and double screw feeder. The compacts are formed homogenously. Feeder orientation depends upon the selection of equipment design considered and character of the blend which is used for compaction. In a gravity feeder, the feed flow control is by use of hopper without an external driving force to compaction zone. The feeder is classified in to gravity feeder and force feeder.

3) Flake crusher: The Flake Crusher is designed for dust free processing Flake crusher improves material flow by crushing of compacted ribbon.. Flake crusher is located between roll and granulator. Compacted Ribbon or flake which comes out from roller is crushed by flake crusher and converts in to smaller size pieces.

4) Milling or size reduction: Size reduction equipment is based on according to the way in which forces are applied, impact, shear, attrition and compression. Milling is process in which the ribbons formed during compaction and which is crushed by flake crusher to form different size compacted pieces. Milling improves flow ability, particle size distribution, and content uniformity and reduces segregation. Screen located directly under the blade or scraper, prevents particles to leave the chamber which are larger than screen orifice size. .These different size pieces is required make uniform particle size by using appropriate size screen. Different mill screen orifice size used may be varying with blend to blend for size reduction.

5) Deaeration: To remove entrapped air deaeration system is sometimes used in the machines. Selection of proper feeder screw helps to eliminate air entrapment issue to certain extent. The section consists of a sintered metal or screen that permits air to be removed via a vacuum device Air entrapped during feeding of blend to the rollers can make the ribbon weaker or brittle.

6) Feeder vibrator: Installation of a feeder vibrator can be an easy and effective way to improve the flow. A simple gravity feeder and force feeder may not work to be good enough. By providing a constant driving force, feeder vibrators can break the stagnant powder bed, drive the powder toward the rolls, and help densification and deaeration. To maintain proper uniform continuous flow of feed material powder especially in case of a poor flow powder.

7) Temperature control: In this case, special flight with a cooling jacket can be used to improve processibility. The screw flight can generate a lot of heat when rotating in the powder bed. Which cause the powder to be partially melted and stuck to the flight in a highly packed powder bed, excessive heat may elevate the local temperature. This may even cause batch failure.

Impact of process parameters:

Roller compaction process parameters have very significant effects on the process feasibility, ribbon quality, granule flow ability and blend uniformity. Efficiency of roller compaction is based on the equipment design and operating parameters. Compaction force, roll speed, screen size, feeder screw speed, and roll gap are the critical parameters needed to be optimized to improve product quality.

1) Compaction force: For most pharmaceutical formulations, the powder mixtures usually contain both plastic and brittle materials. Also During over compaction force there may be chance of rise in temperature. Sufficient Compaction force is required to compact the loose powder. Optimum compaction force which gives good quality granule may vary with mixture of material. Under pressure the powder gets dignified and bonded to form Ribbon. Increasing roller pressure at certain limit increases ribbon density, granules mean particle size, granule flow ability. Over compaction force may break the ribbon which results in poor quality granule that may create tablet compression problem such as low hardness, capping, and high friability.

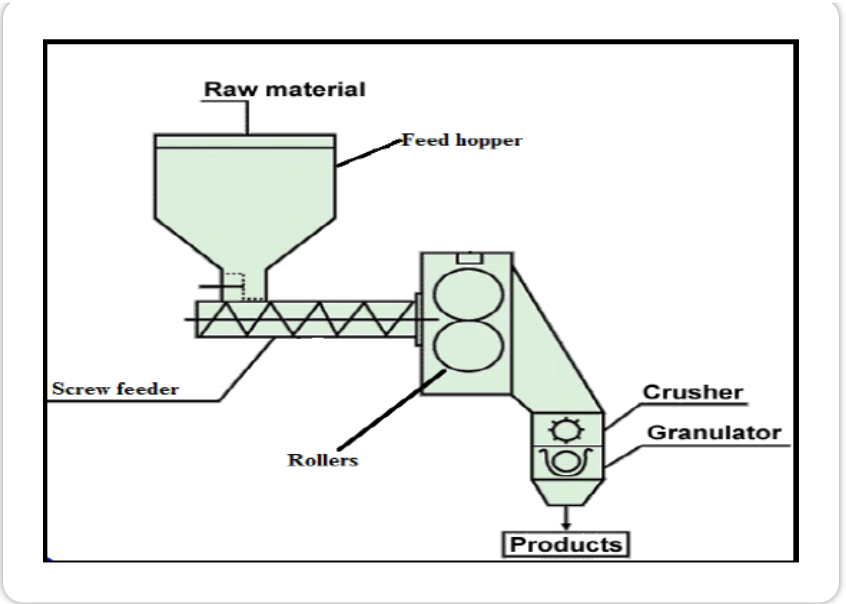
2) Roll gap: Roller gap exhibited a significant impact on ribbon density, granule flow ability, ribbon hardness and granules content uniformity. It is in a function of pressure applied to the rolls and the amount of material that is passed between them. Roller compaction force increases with decrease of roller gap. Roll gap is the distance between the rolls at their nearest point. This is the critical parameter of compaction and one that needs to be stabilized by the process parameters mentioned above.

3) Screw speed: In case of vertical and horizontal screw needs to maintain optimum screw speed for homogeneous compaction. Generally the feed rate should be equal to the rate of discharge. High screw speed may cause a highly dignified zone in the nip area, and cause melting or caking of particles on the flight. High screw speed is not solution for poor flow materials. Optimum range of screw speed depends upon powder material flow, roller speed and roller gap. When screw speed is low, material reaches in nip region in insufficient quantity resulting in to formation of ribbons with low strength. Screw speed is a critical process parameter in the roller compaction.

4) Roll speed: Roller speed needs to be adjusted in accordance to feeder screw speed and flow of powder. Roll speed is inversely related to dwell time for particle compaction which affect ribbon density. When roller speed is high material passing through rollers is being inadequately compacted ultimately result blend segregation and consequently loss of content uniformity.

5) Milling: The mill screen orifice size directly impacts particle size distribution which can potentially impact granule uniformity and flow ability. If excessive fines are generated in the milling process, it dignifies the blend and thus affects flow ability. Ribbons size reduction can be done by applying force which result desired size granules. Desired granule size required for uniform particle size distribution, good flow ability, compressibility. Excessive quantity of fine subsequently effect on content uniformity, tablet hardness in tablet compression. Milling screen orifice size and milling speed which shows significant impact on granules flow ability, granules uniformity, and particle size distribution.

Roller compaction diagram:



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Equipment of roller compaction:-

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

1. Feed hopper: - The rotor arms transport the material evenly downwards through the hopper in the direction of screw feeder. 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.

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

2. 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.

i) Flat rollers: These are suitable for powders tend to stick or cling to roll surface.

ii) Punch shaped rollers: These are suitable for highly voluminous, light, and fluidizing material.

iii) Pocketed rollers: Suitable for products which can release cleanly from rolls.

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

4. Pre and fine granulator

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

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.

Advantage of roller compaction:

• 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.

Disadvantage of roller compaction:

- Roller compaction defines the powder or particle which can adversely affects the dissolution of product.
- The powder to be compacted must be compressible or have to add compressible excipients or additives to the formulation.
- The various process parameters involved in roller compaction process and its interrelation.

Applications:

For many years pharmaceutical companies as well as specialized providers all over the world have been using solutions supplied by Alexanderwerk to produce tablets, capsules, life science products, flavours, instant powders, intense sweeteners and many more.

CONCLUSION:

Roller compression affects particles size distribution, flow ability, homogeneity, compressibility, compatibility of active pharmaceutical ingredients, and such parameters can in turn affect dissolution profile, disintegration time, hardness and other post compression parameter of tablets. Roll compaction is a method of choice for processing of physically or chemically moisture sensitive drugs, as no liquid binder is required in the granulation With technological advances in drug development, dry granulation by roller compaction is more advantageous than wet granulation process with simple manufacturing process, low operational cost, no use of liquid solvent, large scale production and suitability for heat and moisture sensitive drug. Selection of drug and excipient for roller compaction is based on their physical and chemical attributes. Selection of formulation design and process parameter play vital role in roller compaction. Optimization of process parameters such as compression force, roll speed, roll gap, screw speed, milling speed, and milling screen orifice size is essential and critical in roller compaction. 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 compatibility. This review indicates the effect of multiple variables of roll compactor e.g. hydraulic pressure, roller speed, roller gap, roll surface, granulator speed and screw feeder speed on the granule deliverable properties of product. The granule deliverable properties studied are flow ability Technical process improvements can solve these problems and provide solutions to these issues, bulk and tapped densities, particle size distribution.

REFERENCE:

1. YueTeng, ZhihuiQiu, Hong Wen; Systematical approach of formulation and process development using roller compaction; European Journal of Pharmaceutics and Biopharmaceutics, 2009,Page No.219–229.
2. Gurpreet Kaur1, Manoj Gera1, Pallavi Bassi1, Ashok K Tiwary; Review roller compaction /dry granulation(Rcdg):Technologies and their applications in drug delivery and Development;International Journal of Drug Delivery, 2011,Page No.397-414.
3. AjayS. Chougule, Amrita Dikpati,TusharTrimbake;Formulation Development Techniques of Coprocessed Excipients; Journal of Advanced Pharmaceutical Sciences,2012, Page No.231-249.
4. Chialu Kevin Changet al.; Roller Compaction, Granulation and Capsule Product Dissolution of Drug Formulations Containing a Lactose or Mannitol Filler, Starch, and Talc; AAPS PharmSciTech,2008, Vol. 9,Page No.No.2.
5. Sabine Inghelbrecht, Jean Paul Remon; The roller compaction of different types of lactose; International Journal of Pharmaceutics; 1998, Page No.135–144.
6. Johanson JR. A Rolling Theory for Granular Solids.ASME. J App Mech. 1965;32(4):842-848.
7. Kristensen H, Schaefer T Swarbrick J, Boylan B. Granulations, Encyclopedia of Pharmaceutical technology, Marcel Dekker, Volume 7, 1992, Page No. 60-121.
8. Operation and instruction manual of roller compactor, Kevin process technologies Pvt. Ltd. Page No. 12 - 19.
9. P Guigon, O Simon. Roll press design: influence of force feed system on compaction. Powder Technol. 2003; 130:41–48.
10. Ravendra Singh, MarianthiIerapetritou, RohitRamachandran. An engineering study on the enhanced control and operation of continuous manufacturing of pharmaceutical tablets via roller compaction.Int J Pharm. 2012; 438:307–326.

11. Alexanderwerk AG. Germany. URL: http://www.alexanderwerk.com, accessed on February 2011.
12. Horisawa E, Danjo K. Sunada H. Influence of granulating method on physical and mechanical properties, compression behavior, and compactibility of lactose and microcrystalline cellulose granules. Drug Dev Ind Pharm 2000; 26: 583-593.
13. Bultmann JM. Multiple compaction of microcrystalline cellulose in a roller compactor. Eur J Pharm Biopharm 2002; 54: 59-64.
14. Rambali B, Baert L, Jans E, Massart DL. Influence of the roll compactor parameter settings and the compression pressure on the buccal bio-adhesive tablet properties. Int J Pharm 2001; 220: 129-140.
15. Ende M, Blackwood DO, Gierer DS, Neu CP. Challenges in development and scale-up of low-dose drug products by dry granulation: a case study. In: Formulation and analytical development for low-dose oral drug products, J Zheng (Ed.) John Wiley & Sons, Inc., New Jersey, 2009: 117-155.
16. Farrenkopf J. Relevant aspects of roller compaction covering the impact of excipients, milling devices, fines and feasibility prediction Ph. D. Dissertation University of Heidelberg, 2010: 1, 235.
17. Ravendra Singh, Marianthi Ierapetritou, Rohit Ramachandran. An engineering study on the enhanced control and operation of continuous manufacturing of pharmaceutical tablets via roller compaction. Int J Pharm. 2012; 438:307–326.
18. Miller R, Sheskey PJ. Roller compaction technology for the pharmaceutical industry. In: Parikh DM, editor, Handbook of pharmaceutical granulation technology. Marcel Dekker, New York, 2006. Page No. 3159-76.
19. Timothy J. Smith, Gary Sackett, Paul Sheskey and Lirong Liu, Developing solid oral dosage forms “Pharmaceutical theory and practice”, Elsevier Inc. 2009, Page No. 715- 722.