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Various Extrusion Technique and Its Effect on Bulk Density of Pellets

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ABSTRACT: Pharmaceutical industry defines pellets as small, spherical and free-flowing particulates made from the agglomeration of the fine powders or granules using suitable equipment. Extrusion spheronization is the most commonly used pelletization techniques amongst all. In this study, we are performing research on different types of extruders namely - single screw cone type, radial type extruder, axial type extruder etc. The main objective of this study is to make pellets from excipient . This includes estimation estimating several parameters such as the bulk density, batch yield are explained with reference to extrusion,spheronization is included. This is a multistep process that involves dry mixing, extrusion, wet granulation, screening. Each technique has their own pros and cons , hence a thorough understanding of the process variables is important so that an appropriate pelletization method can be chosen..

KEYWORDS:Pelletization ,Extrusion–spheronization , Pellets , Process parameter, Excipients, Quality Parameters, Physical Characterization

I. INTRODUCTION :

Pelletizaton is a process that changes small minute particles of bulk drugs in small, sperical, free-flowing unit called as pellets.The size typically range from 400 to 2000 micron. Pellets are also present in multiparticulate forms. These are preferrable over single unit of dosage because of their benefits like uniformity, predictable gastric emptying, preventing formation of dust and less inter and intra-subject variability. In an usual event, pellets are commonly filled into hard gelatin capsules but they can also be compressed into tablets. The most commonly used strategy for formulating pellets is through Extrusion Spheronization. Pellets were previously used as multiparticulate delivery systems during 1970, but in recent years this has gained more popularity in view of several technological advantages over traditional forms. To produce uniformly sized pellets, extrusion spheronization is used. This technique is useful for making dense granules which can be used in controlled release solid oral dosage forms of pelletes that contain very less amount of excipient. The pellets that are produces using this method have an intrinsic tendency towards slow release of ingredients that are active. This depends on several factors such as -shape, nature of the liquid use din granulation, quantity and importantly the excipients used to perform extrusion-spheronization. The most commonly used base excipient for formulations of pellet is MCC + LACTOSE. The reason for its popularity is its powder masses provides mixtures with rheological properties for extrusion-spheronization. In recent years, we have been working mainly on improving the performance of MCC + LACTOSE pellets. Attempts have been made to develop more effective techniques for morphological characterization of pellets. The objective of the current study, is to evaluate alternative materials that can be used to improvise the properties and quality of pellets that are produced by extrusion-spheronization.Density of the pellets is affected by the modification in the formulations or process. This also affects several processes and factors. Such as many pellets are filled in hard gelatin capsules by using automated capsule-filling machines. For any reason, if the density is different for each pellets from various batches , then this will

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also impact the finished capsule.Variations in the pellets density affects the size of the batch.[1][2][3]

EQUIPMENT PARAMETERS :

MIXER:

The first step is preparing the wet mass. There are many types of granulators , for ex. rapid mixer granulator that are used to perform the mixing of the blend from powder along with granulation liquid. However, we need to understand that high shear mixers will cause plenty of heat in the mass during the granulation process, which can eventually lead to evaporation of the granulation liquid. This will thus have an impact on the extrusionbehavior of the mass.To avoid this situation, we should cool the granulation bowl.[3][4]

EXTRUSION:

The next process is Extrusion. This step comprises of shaping the wet mass in longer rods. These are referred as 'extrudate'. In addition to the pharmaceutical industry, this process is widely used in food, polymer, and ceramic industries. As of today, this process is used as a substitute for the creation of tables which are water-soluble in nature. There are four main classes in which extrusion device typescan be grouped - Single screw cone type extruder, axial extruder, radial extruder, die roller extruder and dome extruder.[3][4]

DIFFERENT TYPES OF EXTRUDER:

SINGLE SCREW CONE TYPE EXTRUDER (USSE-60) :

Umang's cone type of extruder is extensively used for the formation of different size of pellets starting from 400 microns to maximum of 2000 microns. This extruder includes Hopper for loading wet mass. Hopper is connected to gear to push and rotate material in an orderly manner into the feed hopper of the extruder chamber. This chamber consist of twin screws. These are used to transfer the material directed to pressing cam and out from the perforation of the desired dia.[4]

AXIAL EXTRUDER (USSE-60) :

Axial extruder at umangpharmatech is extensively used for making pellets.The size of the pellets range between 400 microns to the maximum of 2000 micron .this extruder provides mild compaction and hence suitable for the formulation which is related to extrusionprocess .It has ahopper which is used to load wet mass,this acts as internal blades which is connected to gear that rotates and pushes the material into the feed hopper of the extruder chamber in a systematic manner. This chamber is jacketed from the exterior so that cold water can be circulated to maintain the temperature of the product .This is helpful if the product is of sensitive nature.[4]

RADIAL EXTRUDER (USSE-60) :

This extruder is built on the proven umang technology and is the new extrusion range with many benefits. This is placed around the screw, that discharges the extrudate in a perpendicular angle to the axis of the screw. The size ranges between 400 microns to 1500 microns. This ensures low pressure extrusion for the products.[4]

DIE ROLLER EXTRUDER (UDRE-65) :

Umang's Die Roller Extruder is specially designed for pharmaceutical and chemical industry, where it is used to produce granules of a defined diameter from moist or pasty raw materials. Granulation cylinders with minimum gap of 0.3 mm & bores between 1.0 mm and 3.0 mm are available to achieve different granule diameters along with better compaction The counter-rotating perforated cylinder and knurled,which improves the drawing behavior. Furthermore, the modular design allows changing and cleaning of all work tools and thus fullls the requirements for flexible work resulting in efficient output & performance as well. This size ranges from 1000 micros to maximum 3000 microns.[4]

DOME EXTRUDER (USSE-60) :

This extruder is built on umang's proven technology of pellets range equipment's and is of screw extruder range.It uses a dome or half sphere shaped screen as the die. This is a screw extruder range that is used to build pellet range equipment's. The unique feature of this extruder is that it is optimized and has a compact design. Cabling, connections, supplies are covered, integrated and sealed so the exterior is easy to clean and smooth. These reasons makes the machine flexible, we can change the product quickly , hence it increases productivity and cost efficiency. The range is between 300 microns to 1200 microns.[5]

SPHERONIZATION (USPH-250) :

Spheronizer at umang is a simple equipment .this is a very important step of granulation from extrusion .this machine is designed to produce spherical pellets at faster rates .the size of the machine is compact in nature.It is a process where the preformed Vermicellli once dropped in the bowl & exposed to rotating Chequered Plate, are fragmented into pieces - equal

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length of diameter of Extruders, because of the tangential & centrifugal force, they collide with the cylindrical walls of the Spheronizer. Finally the rope type movement of the extrudes at the outer border give a rolling action on the fragmented extrudes & convert them into spheres. [5]

DRYING (MINI DRYER -1) :

Fluid bed drying is an efficient method to remove residual moisture. During the process, the moist Spheres are fluidized, dried and carried through each section of the fluid bed using hot air blown through specially designed bottom perforated plate. Umang's Bench Top Mini Dryer is perfectly designed to acquire limited amount of bench space. It consists of an Inlet chamber, Product 13 / 27 chamber & filter bag. The material is charged into the product chamber & cartridge heated Air current is induced inside the chamber by means of a blower. The hot air stream passes through the bed of the material and fluidizes the product particles by creating the turbulence in the chamber This turbulence inside the bed helps in the movement of the material across the area of the dryer .Due to fluidization, the particles get surrounded by hot air, which leads to quick & uniform heating and drying.[5]

SCREENING:

To achieve desired size distribution, screening should be done for each pellet.Sieves should be used for this purpose. If the pellets are made by extrusion spheronization, screening has tobe done after it gets manufactured. This is essential to avoid pellets with that has high size polydispersity index.[5][6]

II. MATERIALS AND METHODS :

Excipient and Granulation liquid were used for the preparation of binary mixture.The mixture of required concentrations were prepared by suitable dilution of the stock solutions. After desired mixture was prepared, the mixture were taken and was tested in batch process in different type of extruder ,spheronizer, drying and then screening .

Figure no 1:MCC Excipient

Figure no2 : LACTOSE Excipient

PREPARATION OF MIXTURE FOR EXTRUSION PROCESS :

MCC is the principle excipient in the pellets prepared by extrusion process . Water is an appropriate liquid forpreparation of binary mixtures of MCC+ lactose. Take 60 % MCC: 40 % lactose mixture.Add water inRapid mixer granulator for 10 min .After proper mixing in rapid mixer granulator desired mixture was found,then transfer this into different type of extruder and set all parameter like extruder ,spheronizer ,drying and screening .

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Figure no 3:Single Screw Cone Extruder

Figure no 4 :Axial Extruder

Figure no 5: Radial Extruder

Figure no 6: Die Roller Extruder

Figure no 6 :Dome extruder

Figure no 7 : Spheronizer

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Figure no 8: Final pellet produc

CHARACTERIZATION

The instruments used for Physicalanalysis were for Bulk density apparatus:

III. RESULTS AND DISCUSSION:

Table no 1: The Physical Characterization of excipient

Type of extruder	Single screw cone type extruder	Axial extruder	Radial extruder	Die Roller extruder	Dome extruder
Water used in rapid mixer granulator	100 ml	100 ml	100 ml	100 ml	100 ml
Extruder speed	100 rpm	100 rpm	100 rpm	100 rpm	100 rpm
Extrusion time	3 min	3min	3 min	3 min	3 min
Size of extrusion screen	1 mm	1 mm	1 mm	1 mm	1 mm
Spheronizer process					
Spheronizer speed	1000 rpm 500 rpm 800 rpm	1000 rpm 500 rpm 800 rpm	1000 rpm 500 rpm 800 rpm	1000 rpm 500 rpm 800 rpm	1000 rpm 500 rpm 800 rpm
Checker plate size	2 mm	2 mm	2 mm	2 mm	2 mm
Water used	20 ml	20 ml	20 ml	20 ml	20 ml
Spheronision time	6 min	6 min	6 min	6 min	6 min
Weight before drying	265.6 gm	309 gm	239 gm	212 gm	294 gm
Drying process (Fluidized bed dryer)					
Time taken for drying	1 hr	1 hr	1 hr	1 hr	1 hr
Temperature	50° C	50° C	50° C	50° C	50° C
Weight after drying	175gm	230 gm	161 gm	185 gm	200 gm
Screening					
OK material	151.3 gm	221.6 gm	150gm	175gm	149 gm
Over/under size	91 gm	11 gm	75 gm	20 gm	54 gm
Bulk density	0.67 gm/cc	0.71 gm/cc	1.05 gm/cc	0.68 gm/cc	0.68gm/cc
Batch yield	60.52 %	88.64 %	60 %	70 %	60 %

IV. CONCLUSION:

Extrusion is an effective technique for producing pellets. The success of this methods highly depends on its advantages over the others. This method has proved itself to produce pellets with uniform size and density.When mixture of excipient was being tested across all extruders and spheronizer , it showed that in single screw cone extruder the bulk density found 0.67 gm/cc . In axial extruder the bulk density found 0.71 gm/cc .In radial extruder the bulk density found 1.05 gm/cc .In die roller extruder the bulk density found 0.68 gm/cc .In dome extruder the bulk density found 0.68 gm/cc.To conclude, we can say that this process is capable of high throughput, easy-to-perform operations and minimal wastage. Our research shows that different kinds of materials can be passed through several types of extruders, spheronizer with a good physical characterization to produce pellets. Hence, depending on the material, the bulk density that is targeted, commercialization of the above extruders,spheronizer should be done at a faster rate.

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