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Advances in Roller Compaction / Dry-Granulation.

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ABSTRACT

Presented work is attempting for focusing advances in roller compaction and dry-granulation process. Roller compaction is principal step in dry granulation, an exploiting agglomeration process. Tendency of introducing lean, economical, and continuous manufacturing process to reduce expenses is attributing to advancement in forming granulate by dry-process. Advancement is achievable by recycling or reworking the wasted or refused fraction of granular material, or by process of compaction and or design of compactor. Scarce literatures are depicting poor awareness among professionals relating availability and usefulness of advance methodologies. In this regard, present work attempting a focusing. Presented information will be having wider application and be a helping hand for professionals.

Keywords: Advanced, dry-granulation, roller compaction, system.

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INTRODUCTION

Dry-granulation (DG) is the preferred granulation process inheriting to its pros not being limiting to ease and cheap. It is suitable for products labile to moisture and heat or for materials being poor compressing upon wet-granulation. Dry-agglomeration or compaction of powder is achievable applying force onto them without aid of heat and solvent. The process of compaction in general causes a considerable size enlargement. This yielding compacted mass called briquettes, flakes or ribbons. Subsequent to compaction, milling step is following to obtain the desired granules [1-4]. The process of DG is achievable in by any of following way.

1. Conventional/common methods

- Slugging or pre-compression
- Flaking or roller compaction

2. Novel/patented methods

- RC type Roller compactors
- Gerteis[®] technology (Pactor[®] and Polygran[®])
- Pneumatic dry granulation
- Moisture activated dry granulation

Slugging involves pre-compression of powder blend into large tablet or 'slug' in a heavy-duty tablet press. Roller compaction involves squeezing the continuous stream of powder blend between two pressure rollers, producing a sheet of material, called 'flake'. In conventional method, the intermediate products (tablet/slug or sheet/flake) are broken to produce granular material using suitable milling technique. In subsequent stage, the desired size fraction of granule separated out from granular material, by sieving [1-4].

Amongst conventional methods, slugging resulting granules whose properties cannot be controlling well either. However, roller compaction is advantageous inheriting to its pros and preferring with increasing importance [1, 5].

The compaction behaviour of powders in roller compaction process is influencing by several elements, as follows [6-10].

- Process conditions related factors,
- Nip angle and pressure,
- Vacuum de-aeration, and
- Factors relating powder properties.

Process conditions related factors include roll speed, roll gap, mechanisms and speed of feeding, throughput, and roll-surface texture. Difference is serration volume of rolls changes nip angle and pressure. Application of vacuum decreases normal stress with subsequent increase in gap and ribbon thickness. Factors relating powder properties are particle size, shape, moisture content, and so on [8].



All of these factors contributing to ribbon porosity of compacted mass. Changes in nip angle and pressure significantly affect ribbon thickness/porosity. Roll sets having serration volume, approximately twice, result 20-25% thicker ribbons. In addition, level of de-aeration is contributing to fluctuations in thickness/porosity of ribbon [7, 8, 11]. Ribbon porosity inversely relates ribbon thickness. Relative level of ribbon compaction is resulting ribbons with equivalent in-gap porosities [6]. In-gap ribbon porosity is contributing to optimization of the downstream granule processability. In addition, parameters of the inline granulator-mill set downstream contributing to granule properties [6, 9, 10].

Consensus is that understanding and monitoring of following parameters requisite in roller compaction/DG process to have reproducible granule properties [5, 6].

- Parameter of roller compactor: shape, size and surface texture of the rolls, gap between roll pair, throughput, and speed ratio in both first and second stages;
- Pressure and angle of nip; and
- Parameter of granulator-mill: speed and type of rotor, oscillating angle, and aperture of mesh screen.

Precise control and maintenance of discussed parameters requisites reproducible, to have granule properties reproduced. During scale up and in bench to pilot and manufacturing scale maintenance of reproducible ribbon porosity and granule properties, at each scale is thought provoking [7-11].

Advancement in methods being contributing to combat said and allied technical issues. Advance and novel methods are employing basic principle of conventional flaking method but with add-on features. Add-on features involve recycling or reworking the wasted or refused fraction of granular material, and or modifying the process of compaction and or design of compactor [1-4].

Consequence of facts and for introducing lean, economical, and continuous process a Swiss manufacturer, Gerteis®, developed and patented roller compaction system, 'Gerteis®' [12-17]. While Powtec Maschinen und Engineering Gmbh, Germany developed and introduced ranges of RC type Roller compactors [18], 'Pneumatic dry granulation' by Atacama Labs [19, 20], and advanced model of Chilsonator® roll compactors by Fitzpatrick [21, 22].

However, rare literatures describing technological aspect and usefulness of advanced method. In setting of above, associated technical matters and usefulness had being focusing with present work. Presented information will be a helping hand for researchers and has usefulness in dry-granulating wider formulations.

Advancement in Roller Compaction/Wet-Granulation

RC type Roller compactors

RC type Roller compactors are developing by Powtec Maschinen und Engineering Gmbh. These are high-performance roller compactors developed for press-agglomerating



powder and dust. For meeting demands from laboratory to production scale these offering a wide range of various roller compactors (Table-1). Laboratory machine is being processing a few hundred grams while production machine throughout more than 4,000 kg/h. Area of their application covering pharmaceuticals to chemical materials or metal powders right up to flavours for food production [18].

Table 1: Features of model range of RC type roller-compactor machines [18].

Machine-Model	Typical throughput (kg/h)	Press-Force	Electrical power	Weight (kg)
		absolute (kN)	(kW)	
RC 100	15	49	2	300
RC 120	60	60	4	600
RC 150	120	76	6	900
RC 170	200	116	8	1.100
RC 210	350	186	12	1.700
RC 250	600	269	20	2.400
RC 290	900	402	25	3.300
RC 370	1.600	637	40	5.400
RC 500	4.500	1.127	80	9.900

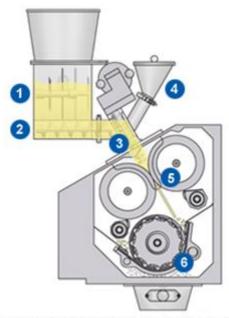
Table 2: Options and features of Pactor® and Polygran® model range.

Options and Features	Mini-Pactor® [12]	Macro-Pactor® [13]	Ultra-Pactor® [14]	Polygran® [15]	Mini- Polygran® [16]	Mini-Polygran® Plus [17]
Fully instrumentation	Available	Available				
Full machine calibration	Available	Available		Available		
Occupational exposure limit level	< 3μg/m³	< 3μg/m³	< 0.1μg/m³			< 5μg/m³
Gap between rollers (in mm)	1-6	1-6	2-6	2-5	1-4	1-4
Press force (in N/cm)	1 – 20	1-20	1 – 20	1 – 15	1 – 15	1 – 15
Roller speed (in rpm)	1-30	1-30	1 – 30	2 – 15	0.5 – 5	0.5 – 5
Throughput (in kg to kg/h)	0.1 to 400	0.1 to 400	0.1 to 400	0.5 to 300	10 to 20	10 to 40
Suitable for						
Research and	Yes	Yes	Yes	Yes	Yes	Yes
Development	Yes	Yes	Yes	Yes	Yes	Yes
Bench and small-scale	Yes	Yes	Yes	Yes	No	No
Development and pilot	No	No	No	No	Yes	Yes
scale	No	No	No	Yes	Yes	Yes
Mobile frame	No	No	No	Yes	Yes	Yes
Quick and fast						
maintenance Inter-batch						
changeover						
Gross weight (in kg)	1200	1700	2500	1200	400	500

Table 3: Specifications of Chilsonator® machine with model range [22].

Model	Roller width X Diameter	Roll pressure (lbs/ linear	Roll speed (rpm)	Throughout
	(inches)	inches)		(lbs/h)
IR220	0.75 X 8.0	0 - 15,000	4.0 - 14.0	0.1 - 22
IR520	2.0 X 8.0	0 - 15,000	6.0 - 24.0	22 - 220
IR4LX10D	4.0 X 10.0	0 - 10,000	6.0 - 24.0	220 - 2,200
4B4LX10D	4.0 X 10.0	0 - 19,650	6.0 - 24.0	220 - 2,200
7LX10D	7.0 X 10.0	0 - 11,900	6.0 - 24.0	440 - 4,400
12LX12D	12.0 X 12.0	0 - 10,300	6.0 - 24.0	770 - 7,260
12LX16D	12.0 X 16.0	0 - 16,800	6.0 - 24.0	990 - 9,680
12LX20D	12.0 X 20.0	0 - 19,625	6.0 - 24.0	1210 - 12,100
16LX20D	16.0 X 20.0	0 - 19,625	6.0 - 24.0	1760 - 19,360





Hopper 2. Feed auger 3. Tamp auger 4. Hopper for small quantity material
 5. Press rollers 6. Milling section

Figure 1: Basic design of roller compactors by Gerteis® [12-17].

These RC compactors suitable for powder that does not flow, cannot be dosing accurately, contain higher proportion of dust, segregates, or bulkier. Their advantages, standard options and special features are followings [18].

Advantages

- Economical: Large variety of models and comprehensive standard variations is ensuring considerable reduction in costs. Each machine tailored to individual need and application.
- Space saving and high-grade: All machines are featuring compact design and built-up from high-grade stainless steel.
- Easy to clean: Featuring unique patented roll exchange system conferring easy and quick cleaning of machine components and machine. In addition, machine components are easily accessible for inspections.
- Variability and reliability: Achieving wishing and adjustable granule properties like size, bulk density, flowability and solubility. The models are suitable for batch as well as continuous process.
- Environment friendly: Minimise dust burden and product loss and avoid cross taints.

Special features

- Innovative and latest state-of-the-art features assuring maximum throughput capacity, process stability, reproducibility and product quality.
- A specially constructed pre-compression feeder screw is enabling efficient processing, even of light, bulkier and fluidising powders. In addition, feeder screw has de-aerating effect on the raw material.
- Improved accuracy of dosing assuring even product feed across entire roll width.



- Various shapes of roller surfaces improving the product feed behaviour and maximize yield.
- Constant roll force distribution contributing for yielding flakes with consistent ribbon porosity and granules with consistent properties.
- Inbuilt novel roll-seal-system for optimising compacting process, increases yield and reduces requirement for separation and recycling of fines.
- Drives with adjustable speed and hydraulic pressure are ensuring high process flexibility.
- The hydraulic unit keeps the set roll pressure constant for assuring homogeneous flake while scrapers keep the rolls clean.
- Compaction zone and mechanical drive area being enclosed individually and can be kept isolated from one another.
- The process results can be scaling up and down.

Standard options

- Options for executing chemical, food, or pharmaceutical (in cGMP- design) is available.
- Feature with control system having touch-sensitive panel.
- Recipe administration is doable.
- Exhibition of Design Qualification/ Installation Qualification/ Operational Qualification/ Performance Qualification including Factory Acceptance Tests and Site Acceptance Tests, is optional feature.
- Various screw feeders and stirrers complying individual need and requirement.
- Water-cooling of rolls feature is suiting thermolabile products.
- Pneumatically operated lifting device aids simple and fast cleaning of screw feeder
- Rolls built from various materials with diverse surfaces featuring for wider usefulness.
- Gentle, high-performance, low dusting, and size reduction in one-stage or twostage design is doable.
- Roll gap control is doable.
- Optional integrated sieving machine and pneumatic system (to re-feed under and over size particle).
- Special designs suit in handling abrasive products like metal or diamond powder.
- Designs suit for operation in hazardous and explosive areas complying ATEX guidelines.
- Complete turnkey DG systems.

Gerteis® Roller Compaction System

Consequence of introducing lean, economical, and continuous process is Gerteis® roller compaction systems. Basis of invention is discussing in following paragraphs [12-17].

Roller compaction is achieving either with floating/variable-gap rollers or with fixed-gap rollers. Maintaining analogous normal stress applied by the rolls on ribbon for a given gap



between rollers, is troublesome. Consequently, these contribute to large fluctuations in the properties of ribbon and granule [7, 8, 11].

Gerteis® roller compaction system is capable in measuring and controlling all product quality relevant parameters, on-line. Said system employs floating type roller minimises fluctuations in the properties of ribbon and granulates. Thus, allowing DG of wider ranges of formulation comparing fixed-gap roller compactor [12-17].

Gerteis® system based machines from Gerteis® calibrate and validate all the product quality relevant parameters and deliver a well-documented and assured manufacturing process. Managing inter-batch variations, said machines built with control systems allowing equal granule properties during manufacturing, according to 'process analytical tool'. Option is available providing solutions to Title 21 Code of Federal Regulations Part 11. Gerteis® system built with following unique features [12-17].

Unique features of Gerteis® roller compaction system

- It built in logical feeding system with torque control of screw feeder and tamp auger. This is ensuring precision dosing of powder to rollers.
- Reinforced angled compaction rollers with free-floating gap design and in process force control. These features allowing feed consistency, constant ribbon density and minimise temperature gain.
- Built larger diameter of rollers provides a longer dwell time in the nip area.
- Reinforcing superior punch and die roller design to provide a constant density over the ribbon width. Compaction system is employing interchangeable press roller with different surface like knurled, smooth, toothed or custom design. These features virtually eliminate fines minimizing demand for their recirculation or reworking.
- Built three-stage flake-milling process includes granulating oscillating mill and adjustable screen clearance. Granulator is open star rotor, closed pocket type integrated with bulk-breaking and pre-crushing featuring optimum results. Features ensuing consistent and controllable particle size distribution.
- Inbuilt perfect sealing system is reducing dusting of fines.
- High containment solution ensuing standard containment performance level $< 3 \,\mu g/m^3$.
- Complete harmonized designs makes scale-up simple, straightforward, and fast.

Roller compactors from Gerteis® featuring Gerteis® roller compaction system

The flagship of Gerteis® had designed and engineered roller compactors comprising a Gerteis® roller compaction system and a gentle milling (granulation) system. Inline coexistences of these two systems minimize generation of too many fines [12-17].

They comprise generally a feeding system, a compaction unit and a size reduction unit (Figure-1). Pactor® range include Mini-Pactor®, Macro-Pactor®, and Ultra-Pactor® while Polygran® range include Polygran®, Mini-Polygran®, and Mini-Polygran® Plus. However, model ranges are for meeting demands of development and pilot projects, and up to full-scale production batches (Table-2). Said model ranges differ by several options or features,



add-on or optional (Table-2). The add-on or optional options and or features are for assuring to receive the optimal solution for needs of DG formulation, case-to-case basis.

Pactor® and Polygran® range has complete harmonized designs, being assuring with use of identical roller diameters. Complete harmonization makes scale-up simple, straightforward, and fast, avoiding common problems and risks. Said harmonization is breezing scale-up to full size production. In addition, is reducing cost of material and active and saving time by quickening market launching.

Advantages of Gerteis® roller compactors over conventional roller compactor.

Gerteis® roller compactors ensuing several advantages over conventional, as follows [12-17].

- No temperature issue, heating up of material throughout whole process is only 2-4
 °C.
- Roller cooling option is featuring handling of material with melting point < 30 °C.
- Consistent material feeding system ensue consistent product characteristics and quality.
- Reinforcing unique combinations of inclined roller arrangement, movable press roller with rims and gap control minimizing amount of un-compacted fines.
- Unique milling system ensue granules with optimal particle size distribution and minimise amount of fines.
- Featuring improved containment safety and ultra high containment options.
 Features are avoiding contamination of manufacturing areas and personal by high potent actives.
- Ranges of occupational exposure limit options with multiple cleaning options.
- Energy efficient, requiring no air conditioning, and low running costs.
- Integrated air handling system, integrated nitrogen adding and oxygen monitoring option is available.
- Reproducible results are accomplishable along with real data calibration and calibration of the whole system is doable.

Important options and features of Pactor® and Polygran range are follows [12-17].

- Featuring is with full machine calibration, and instrumentation with critical quality process parameter and data-acquisition.
- Option is for vacuum de-aeration, and press-roller cooling and or heating.
- Separate feeding system for feeding materials of small quantity.
- Option features operator interface for industrial PC solution.
- Ranges of occupational exposure limit options.
- Multiple cleaning options like manual, Wash-in-Place (WiP), and Clean-in-Place (CiP).
- Integrated air-handling system ensues for containment safety, optional.
- Integrated nitrogen adding and oxygen monitoring is optional feature, for reducing product oxygen exposure and explosion risks.
- Easy and fast dismantling of components allows manual cleaning in Polygran® range.
- Models can additionally be featuring with a pneumatic system.



WiP option is for removing air borne dust during dismantling reducing cleaning cycle time. CiP option ensue complete automated cleaning without dismantling. Occupational exposure limit level designs of < 3 $\mu g/m^3$, < 1 $\mu g/m^3$, and < 0.1 $\mu g/m^3$. CiP feature and limits level design of < 0.1 $\mu g/m^3$ eliminates contact of operator with potent and hazardous products.

Mini-Pactor®

The Mini-Pactor® designed for laboratory development and small to medium scale, and for production runs but is ideal for laboratory development. Pilot projects and small-scale production batches be handling easily [12].

Macro-Pactor®

Macro-Pactor® is the premium roller compactor. It having throughout capacity up to 400 kg/h, however can handle amounts from as little of 100 g. Have suitability for development and pilot scale environments [13].

Ultra-Pactor®

The Ultra-Pactor® is the most technologically advanced one and advanced design of Macro-Pactor® being classing as 'high containment roller compactor'. It designed within an ergonomic containment isolator having throughput capacities from 100 g up to 400 kg/h. This feature allows processing of potent products where high containment is required. Compliance to high containment good practice Ultra-Pactor® is being designing with full CiP feature [14].

The Ultra-Pactor® is ensuing optimal protection of the operator from potent and hazardous substances. It is having ability to purge N_2 into the process area and designed with ATEX-compliancy. Said features truly push the boundaries in containment installations for DG applications [14].

Options of Mini-Pactor® and Macro-Pactor®

Available options with Mini-Pactor® and Macro-Pactor® are follows [12, 13].

- Options are of WiP / CiP cleaning.
- Featuring enhanced containment performance.
- Build in 'process analytical tool' control systems.
- Optional feature is of press roller cooling and or heating.
- Option is for vacuum de-aeration.
- Interchangeable different roller surface designs.
- Option is for separate feed funnel for small quantities.
- Build in industrial PC solutions.



Novel features of Ultra-Pactor® comparing Mini-Pactor® and Macro-Pactor®

Novel features Ultra-Pactor® over Mini-Pactor® and Macro-Pactor® are follows [12-14].

- Built ergonomically designed high containment isolator delivering highest safety to the operator.
- Inbuilt RTP ports for optimised operator handling.
- Filter designs are push-push.
- Online pressure monitoring of all seals and pressure zones is doing with inbuilt permanent online pressure monitoring system.
- Delivering containment performance < 0.1 μg/m³.
- Inbuilt feature completely automated cleaning, CiP and WiP.

Polygran®

The Polygran® is unique and entry-level roller compactor. It offers outstanding value for money in the similar class while suitable for both development and medium production quantities. Polygran® has throughput capacity between 500 g to 300 kg/h. It includes many of the features of Pactor®, including Gerteis® roller compaction system. Setup of Polygran® featuring simplified handling and controls for easier and convenient accessibility [15].

Polygran® - setup

This attributes smart engineered parts assembly contributing to effortless machine maintenance. **S**mart and sophisticated engineering of Polygran® setup is attributing in delivering excellent DG results. Valuing superior features of Polygran® setup over Pactor® are following [12-17].

- Validated gap and force measurement is achievable.
- Operator interface is touch screen.
- Reduced number of interchangeable parts ensue their easy disassembly and reassembly.
- Maintenance and changeover from batch to batch can be doing in simple, quick and fast way, even from scale-up to production batch size achievable instantly and hassle-free.

Polygran® - setup based compactor for Research and Development

Said setup based compactor suiting laboratory scale is Mini-Polygran® and Mini-Polygran® Plus. These tabletop models are small-scale roller compactor suit Research & Development while Mini-Polygran® is compact. They are striking perfect balance between performance and flexibility [16, 17].

Mini-Polygran®

Mini-Polygran® is most compact roller compactor from Gerteis®, in their product range. It belongs to Research and Development class however suiting for bench and small-



scale with throughput capacity range of 10 g to 20 kg/h. Its intelligent design and engineering allowing interchange of the lower compression roller with the unique Gerteis® granulating mill, simply and quickly. Inbuilt offline granulation setup is achieving milling within the same housing. Followings are the features of Mini-Polygran® [16].

- Featuring optional small quantity feed system.
- Have longer dwell-times comparing other roller compactors, in same class or range.
- A range of different roller surfaces is available featuring for optimising process, in hand.
- Virtual no heat gain with the Gerteis® patented angled roller design.
- Easily scale-up to the Polygran® and Pactor® lines.
- Reduced number of parts is featuring simple cleaning procedures and quick changeover.

Mini-Polygran® Plus

The Mini-Polygran® Plus is advanced design of Mini-Polygran®, with a fully integrated Gerteis® granulation-mill. This offering an outstanding opportunity for successful development of DG formulas with assured excellent results. Have throughput capacity between 10 g to 40 kg/h suiting DG development programme. Its add-on option for integrating assembly like Buck® Valve split butterfly valves or HicoflexÒ flexible containment. Said add-on option, an advanced sealing design, suits processing potent products without worry of operator exposure. Superior features of Mini-Polygran® Plus over Mini-Polygran® are follows [16, 17].

- Inbuilt is on-line and integrated two-step granulation system.
- Optional advanced sealing system suiting higher product containment.
- Featuring is optional WiP design.
- For facilitating flexible placement, it built with mobile frame with a fitting of fourwheels.

Pneumatic dry granulation

Pneumatic dry granulation, a technology from Atacama Labs traded as PDG Technology™. An innovative DG process built with additional pneumatic classification feature, for recycling excess fines. It is featuring with automatic or semi-automatic production of porous granules with excellent compressibility and flowability, and flexible high drug loading (70-95%). It is having several superiorities over conventional roller compaction process, as follows [19, 20].

- Process is economical, efficient and reliable, high throughput, and continuous production.
- Fast and simple development process (within weeks), even with difficult material.
- Suitable for lowering production costs, managing life cycle, and extending market, of new galenic forms.
- Can achieve high drug loading, even with materials known to be historically difficult to handle, taste masking, excellent stability, and so on.



- Enables flexible modification of drug load, disintegration time and tablet hardness.
- Achieves good granulation results even at high drug loading,
- A closed system offering safety even with toxic materials,
- Little or no waste of material, and
- Scale-up is straightforward.

Followings are the important building components [19, 20].

- Roller compactor (Mini-Pactor®): It is featuring with lowest possible compaction force to confer maximum binding capacity of the granules.
- Classinator (Atacama): New gas-flow based fractionating device lowers level of fines ensuring excellent flowability.
- Pneumatic recycling of fractionated fines improves process efficiency. Blend to be granulated recycled powder feed hopper integrated mill PDG-0260 in cGMP environment
- Closed-loop system minimizes leakage of dust.

Advanced model of Chilsonator®

Fitzpatrick designed advanced model of Chilsonator® to provide the ultimate process flexibility for a wide variety of products (Table-3), model IR520 unique one. Its design features for quick dismantling and cleaning to meet sanitary and cGMP requirements, with accurate repeatable results suiting critical applications. Follows are the important features and options [21, 22].

- Versatile installation: Feature have self-contained freestanding or portable installation of machine. Feature is contributing from easy dismantling and reassembling characteristic for all operation units enclosing technical components.
- 'In-wall' design: The feature separates the product contact parts from the mechanical components.
- Easy to clean: Robust stainless steel parts quick disassembles for aggressive cleaning.
 In addition, components are designing with smooth accessible corners and without product catching ledges. These features are facilitating thorough inspection and easy reassembly. Optional WiP system is available.
- Feeding system: Optional Fitzpatrick feeding system built in horizontal feed screw for metering material, and a vertical pre-compression screw for pre-compression, deaeration, and feeding material to compaction rolls. Additional de-aeration can be achievable with optional 'vacuum de-aeration system' assisting in drawing the entrained air of product.
- Low capacity feed system: This optional system is allowing processing as little as 50 g, and up to 2 kg, with minimal loss, suiting research and development requirements. This makes scale up to the standard IR520 or larger Chilsonator®(s), easy and convenient.
- Precise size reduction of compacted products: The granulating mill (FitzMill®) operating parameter be selecting and configuring to get the desired particle distribution. Selectable options of operating parameters include rotor type, screen type and operating speeds.



- Various roll surfaces: Its cantilever design allowing easy changing and installation of a variety of roll designs.
- Pneumatic feeding system: This charges material into the feed hopper of Chilsonator® from ground level utilizing pneumatic conveyor, manually with a wand, or automatically dumped from a bin into a pneumatic conveyor pick-up hopper. This confers simple and cleanable method of charging.
- Recycling system: Recycling system removes all fines and overs from the product.
 Recycling system typical includes compactor, granulator, screener, initial feeder, level sensors, and mechanical or pneumatic conveyor.
- Product containment system and N₂ inert processing: Product containment system, an add-on option of Chilsonator® system suits high containment processing. This minimise product exposure to operator and environment, and prevents product contamination and product loss. For reducing product oxygen exposure and explosion risks, product containment system can be combining with system for N₂ inert processing.
- Bin-to-Bin processing: Typical Chilsonator® installation designs feeds material from an initial product bin, through the Chilsonator® and FitzMill®, and into a product receiver bin. This is featuring convenient and unattended processing with simple connection and retrieval of product bins, totally in enclosed system.
- Chilsonator® automated control system: Optional feature, 'automated control system' providing optimum process control with excellent operator interface and data monitoring. Operator interface facilitates pictorial viewing of instrument measurements and machine status information. Controls system be designing for qualifying 'user requirement specifications' for meeting customer specified classifications and standards like execution of ATEX guidelines, special voltage requirements, and in-wall or portable electrical enclosure. Universal features of Chilsonator® automated control system are following.
 - On-line help and diagnostic functions,
 - Restricted access of various functions,
 - Maintenance and calibration procedures,
 - Roll gap control,
 - Historical trending,
 - Report generation,
 - Alarm management, and
 - Title 21 Code of Federal Regulations Part 11 solutions.

Model IR520 Chilsonator® can be configuring with numerous features and options suiting variety of applications. These customized featuring components are easy to disassembling and installing, with hand fasteners. These convenient features make it amenable for laboratory and small production installations.

CONCLUSION

Novel and advanced machines will bring solutions to dry-granulate wider range of formulations. They will be operating within regulations, subject to use of appropriate machine and add-on features. Basing on the performance and convenience use of Gertix

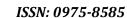


roller compactor will be wise option, for pharmaceutical and food. The novel feature is its harmonized design, facilitating scale-up through simple, cost effective, straightforward, and fast way. As an alternative RC roller compactors preferring but requires multiple models from development to production scale. Advanced model of Chilsonator® be using for their mobility and convenient dismantling and reassembling feature. These are suitable for robust processing design. Pneumatic dry granulator has least flexibility for throughout feature but uses patented granule fractionating device, aiding efficiency.

Awareness among professionals relating utility of advanced roller compactor will revolutionise DG process. Besides, on-line monitoring and controlling all product quality relevant parameter and complete automation will improve efficiency and applicability. Effort had to be allowing dry-granulate wider range of formulations within regulations. Future will proclaim application by gifting enormous product in field of pharmaceutical, food and chemical.

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