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A COMPREHENSIVE REVIEW ON COATING PANS

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ABSTRACT: The presentation of this work aims to update readers on issues associated with coating pan (CPN), having applicability in the pharmaceutical field. The coating process (CPR) is an important pharmaceutical unit operation that finds pertinence in various product areas extending from conventional (immediate) release to modified release. The CPR involves the substrate coating by spraying the coating material in liquid medium onto them, kept in motion using either CPN or fluid bed processor (FBP). The FBP is used preferably for coating of multi-particulates and powders and rarely for tablets, while CPNs are used for coating tablets and capsules, thus are in extensive use. Conventional CPNs and perforated coating pan (PPN) are the major categories of the CPNs. The PPNs are preferred for the products that call for improved drying efficiency where the drying efficiency of the drying air (DA) is highest. The perforated pan system (PPNSY) is used in the coating system based on the aqueous solvent, with preference to that based on the volatile organic solvent (VOS). Comprehensive reviews on the technical aspect of CPNs are rare, necessitating this work. Thereupon the information was studied, summarised, and attempted to be presented for convenience and enrichment of the readers. The contained information will be updating pharmaceutical professionals in this regard.

INTRODUCTION: Coating is a process in which a dry outer layer of coat is applied over a substrate (commonly solid particle or dosage form) to provide certain benefits over uncoated form, that range from protecting products (from environmental factors such as air, light, temperature, gastric acid [1, 2], moisture [2], to simplify production [3, 4], product identification [4], [5], to modify drug release [2, 3,] and many others [6, 11]. In the past process of sugar coating, was heavily borrowed from the confectionary industry [4, 5]. But now it had been replacing with film-coating (FC), as the process of sugar coating was a skilled, artful process and may last for days, even weeks [10, 12].

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In addition, the operator must be very capable of such coverage [12]. FC is therefore preferred over sugar coating [13]. Today coatings can be used for various solid orals such as tablets, capsules (soft/ hard), multi-particulates (beads or pellets), and crystals of drugs [14, 15]. The basic CPR involves the application of coating material as dispersion/ solutions in VOS or aqueous solvents, as a uniform layer, one upon other, on a moving substrate bed by simultaneous removal of the solvent by drying the previous layers with simultaneous use of hot air to facilitate solvent evaporation till a uniform coat of the desired feature has been reached [4, 5, 10, 14, 15]. Application of the coating composition onto moving substrate covers their surfaces with an adhesive polymeric film [4, 14].

Before the substrate surface dries, applied coatings change from the adhesive liquid to tacky semisolids and eventually dry non-adhesive layer [5, 15]. The process of coating is a serial process usually carried out with mechanically operated acorn-shape CPNs [16, 17] of copper, stainless steel, galvanized iron, or FBP [4, 18, 20].

The smaller FBPs and CPNs are using for the pilot plant, experimental, and developmental operations, while the larger FBPs [21, 22,] and CPNs for industrial and commercial production batches [14, 23, 24].

A few decades ago, CPNs of diverse types were used for coating of pharmaceuticals like conventional CPNs, Driacoater®, Accela Cota®, butterfly coater, and many others [14, 25]. Nowadays, a side-vented PPN-coater is the most commonly used coating device for tablets and granules, with slight modifications.

The airflow system through a PPN ensures fast and continuous drying conditions [14, 25]. Aqua-based FC process calls high drying efficiency associated with a low evaporation capacity of water [9, 14]. In addition to these, the quality of coating, thus the final product's performance is affected by spray nozzle, number of spray nozzle, pan size, etc. [9, 25].

In the coating of pharmaceuticals, the design of CPNs and embedded technology delineates the functional properties of the coated pharmaceuticals along with the film formers and excipients.

An available source that summarises information on design of CPNs and embedded technology is scarce. In this regard, the current situation warrants studying and summarising information and presenting them for convenience and enrichment of readers and pharmaceutical professionals.

The presented information will be updating professionals and the consequence is productivity and profit.

Coating Equipment

Coating Equipment Used are Categorised into Follow Categories [14]:

CPNs:

Conventional CPN:

- Standard CPN
- Modified CPN
- Immersion sword
- Immersion tube
- Baffled pan with a diffuser (Pellegrini pan)

Perforated CPN

- Pans rotating on inclined axis: Driacoater®
- Pans rotating on the horizontal axis: Glatt Coater
- Pans rotating on the vertical axis: Accela Cota®
- Hi-Coater®

FBPS (Air Suspension Processors) [14, 26, 29]:

- Top spray [14, 30]
- Bottom spray (Wurster) [14, 31]
- Tangential spray (Rotary) [14]
- Swirling [27]
- Huttlin Kugel coater [14]

Coating Processes Using Pan: The process of coating involving pan uses conventional and specialised pans [14]. The process suits substrates like tablet and particles, even for their enteric coating [25]. It is cheap and have high scale-up potentiality but difficult to master [12]. Pan coater provides usually low mechanical stress to the substrate while providing them with the required motion, during coating operation [9, 14]. The efficiency of CPNs used in experimental, developmental, and pilot plant operations and their larger sizes for industrial production actually depends on follow facts [8, 14].

- Equipments
- Parameters
- Facility and ancillary equipment
- Automation

From the beginning of the 19th century, CPNs became a part of pharmaceutical industry and operation [14]. Over time, coating methodology progressed from sugar-coating to non-aqueous FC to aqueous FC, and these gradual improvements synergized by the "Quality by Design" approach [15, 32, 38], a concept of "Process Analytical Technology" [39, 43]. These factors had been evolving CPNs to meet the increased demand of time and space. Therefore the conventional CPNs had been modified to rear- and side-vented pans for enhancing the airflow, and automated and semi-automated control systems for the process had been added [14]. In the current context, the approach of improvements, refinements, and modifications of coating technique has focused on automation and on improving automation, particle movement, spraying systems, and air and energy transport [38]. This approach consequences uniform distribution of coating material and accomplishment of increased drying efficiency and robust product [8]. The control system monitors the machine while the automation ensuing batch-to-batch quality compliance and consistency [14]. Modern coaters use computer software designed to make the process more automate and efficient (from charging to discharging) and/or to monitor the number of parameters such as the spin-rate of the drum, coating time [44], substrate surface flow velocity [17, 45], spray-rate [24], flow rate and temperature of inlet air [24], process humidity [46, 47], coating weight gain [42, 48], coating attributes [49, 52] and many more [16, 23, 53, 55]. In addition, computerization can store process instructions or recipes that produce specific results [12].

Improvements in the CPR Using Pans: Improvements in the CPR using pans are aiming for having design modifications resulting in improvements of the [9, 14, 25, 38]:

- Drying efficiency.
- Particle movement.
- Feeding, charging, and discharge.

However, other design modifications have probably resulted in improvements with more than one advantage [9, 25].

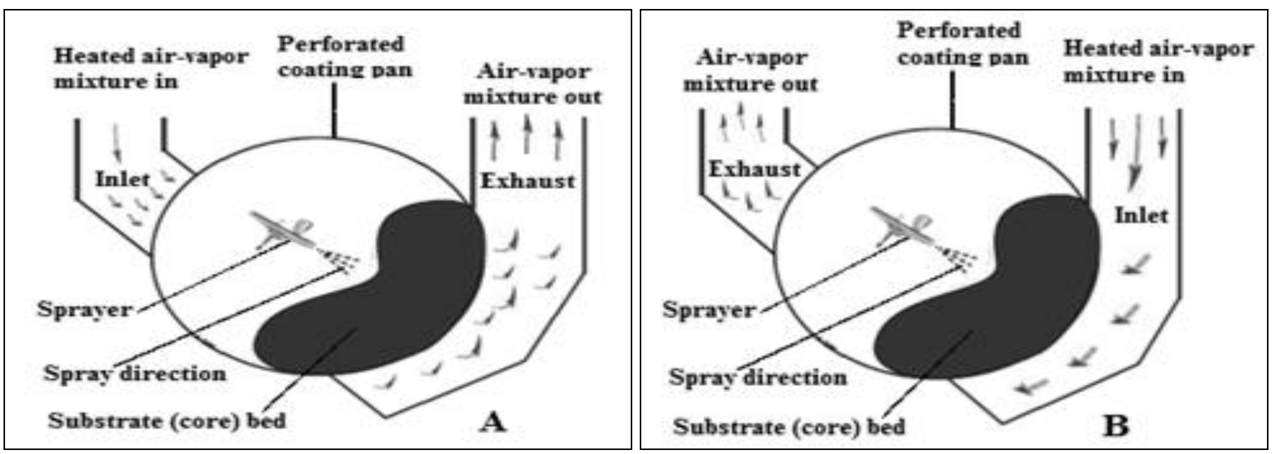


FIG. 1: FIGURE OF PPNS. A: AIR SUPPLY IS FROM ABOVE THE CORE BED. B: AIR SUPPLY IS FROM BELOW THE CORE BED [14]

Improvements of Drying Efficiency: The energy requirements for evaporating solvent from the coating layers that are deriving from the DA along with the efficiency of heat and mass transfer that occur during the drying phase decisively determine the duration of the CPR as well as the quality of the terminal product, thus requires improvement [9, 14, 25]. A conventional pan that uses conventional drying technique blows the DA onto the surface of the substrate bed; thus, the only surface of the substrate bed is exposed to the DA [8, 14, 25]. This limits the mass and heat transfer to the bed surface and reduces the efficiency of drying, resulting in insufficient drying of core materials in most cases while sometimes impaired spraying processes [9, 14, 25]. This calls for improved pan designs to increase the mass and heat transfers directly or indirectly [8, 14, 25]. Direct one design involves an increase in temperature and rotation speed or implementation of perforations [9, 14]. Indirect one involves improvement in the supply of the DA, the basis for developing drying gadgets like immersion sword and immersion tube, is for the conventional pans [8, 14, 25]. Based on the passage of the DA, other refinements are designs with perforations in the pan [14, 25, 38]. In a nutshell, the conventional CPN with conventional drying system has poor heat transfer; the result is inefficient CPR [14, 25, 38]. Conventional pan using drying gadgets introduce the DA from below the surface of the substrate bed, but this was only partly successful [8, 14, 25]. Thus designs based on perforated rotary CPNs developed, as are offering better heat transfer and are more efficient is coating processing [9, 25, 38]. The sizes of perforations restrict the size of the product the CPN can process, thereby limiting their applicability for coating of smaller-sized dosage forms comparing conventional CPNs [8, 14, 25].

PPNSYs: Perforation-based pan design consists of a perforated or partially PPN that rotates vertically or horizontally in an enclosed housing [14, 25]. Through the perforation of the CPN, the air is blowing into and or out of the product [8, 14, 25]. The design of the PPNSY has two broad variants for passage of DA [9, 14, 25]. One variant is designed to supply the DA from above the core bed, concurrently with the spray direction, and to exhaust it via the PPN, refer **Fig. 1A** [14, 25]. The second one is designed to supply the DA through the perforations and exhaust it from above the core bed counter-currently to the spray direction, refer to **Fig. 1B** [9, 14].

Concurrent (parallel) method of supplying the DA to the spray direction associated with the problem of unintentionally pressing the bed, as the DA forces the cores against the PPN [14, 25]. The con of the counter-current approach is the counter-current airflow affects spray pattern [9]. However, the design invented by Casey [56] overcomes these problems, as in the Accela Cota®. The progress made by Forster [57] in his design has a coating zone and drying zone. The coating zone comprises a covering that covers some portion of the PPN for reducing or even avoiding the flow of DA through this area [14]. The coating liquid is applied onto the substrate bed in this zone of reduced air transfer [25]. After that, due to the rotational motion, the coated substrates quickly pass to the drying zone [14]. As the perforations approach the drying zone, the drying process starts [9].

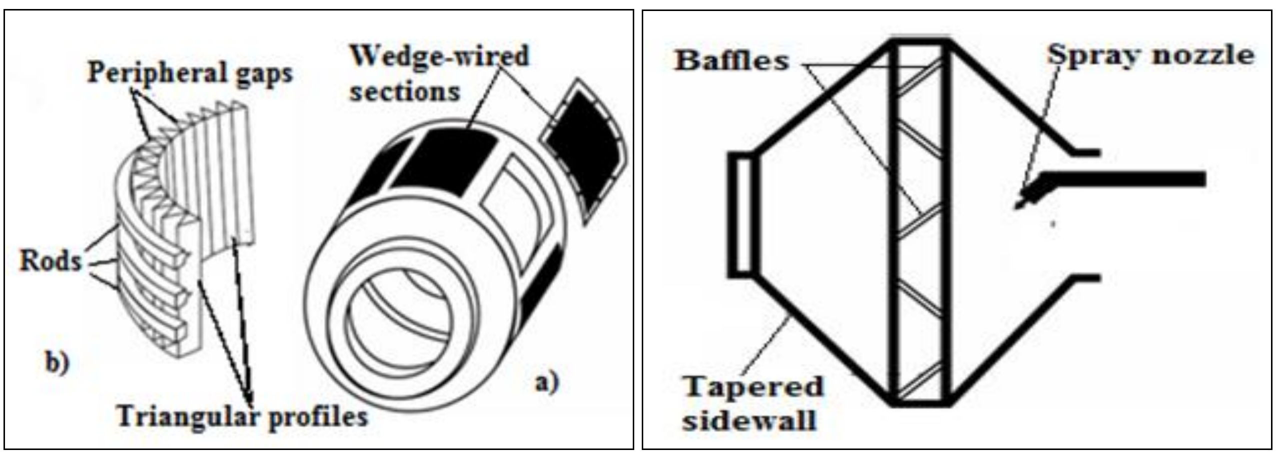


FIG. 2(A): A PAN WITH THE WALL PROVIDED OF "WEDGE-WIRED SECTIONS", B) A "WEDGE-WIRED SECTION." ADOPTED IS FROM REFERENCE [59]. FIG. 2(B): PELLEGRINI PAN, ADOPTED IS FROM REFERENCE [9, 14]

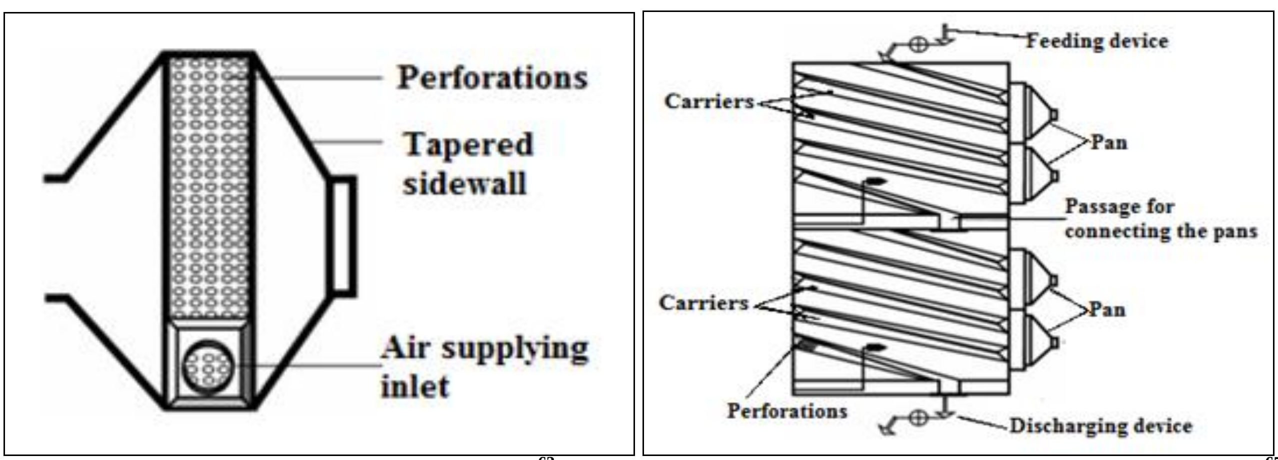
FIG. 2: FIGURE OF SIDE VENTED PAN AND PELLEGRINI PAN,

PPNSY That Suits Smaller Sized Dosage Forms: Diverse design approach made the PPNs amenable for coating small dosage forms by minimizing or preventing the passage of substrate through perforations [14]. Follows are the available design approaches [14, 25]. By providing with the throttled baffles or scoops to cover the perforated areas of the pan [58]. The wall of side-vented pans provides "wedge-wire sections" [59] consisting of triangular profiles welded onto rods, refer to **Fig. 2A.** Peripheral spaces (gaps) are placed in between these triangular profiles [14]. The width of the spaces is to be adjustable considering the size of the substrate in question [25]. This structural design offers sufficient numbers of spaces in the wall for improving air transport in the substrate bed [9]. By retrofitting the screens with spaces (openings) (~ 0.25 mm) to the existing pan of modified CPNs [60], thus making it amenable for coating of microparticles. Accordingly, McAinsh and Rowe patented a CPR in 1979 [60].

Design Approach for Improving the Particle Movement: Tumbling motion of the substrate bed for mending movement of cores (individual unit) is important not only for uniform application of the coating material but also for effective drying [14, 25]. Intromission of baffles and blades in either truncated cone portions or central perforated pan is a basic approach mostly for mending the movement of the core bed in pans rotating on inclined or horizontal axes [14, 25].

A CPN with a single baffle was invented firstly by Keil in 1965 [61]. CPN rotating on horizontal axis equipped with tapered sidewalls and an integral baffle system well known as the Pellegrini pan, refer **Fig. 2B**, was introduced firstly by Pellegrini [62]. Insertion of baffles and blades inherits two important drawbacks [14]. One is it makes it difficult to clean the pan, specifically in cases where product fragments accumulate in corners and recesses, where the blades attached to the pan are difficult to see and access [14, 25]. Second is the increased risk of friction between the substrate and the pans, a potential cause for increasing amounts of dust generation during the CPR [9, 14].

For overcoming aforesaid problems focusing is on designs having PPNs to mend the airflow in the core bed and consequently for improving mixing and drying efficiency [14, 25]. Based on this, Hostetler [63] has developed a side-vented pan, refer to **Fig. 3A**, with modification. The peripheral wall is perforated, and the second is positioning an air-supplying inlet at the lower peripheral area [9, 14, 63]. In such designs, the shape of the pan, perforations in the peripheral wall, and the side positioned air-supplying inlet intended to increase substrate movement and air transfer and the contact area of the cores with the coating material [9, 25]. A design developed by Bohle [64] attempts to reduce the occurrence of dead zones, which provides perforated carriers inside the pan for having controlled movement of the substrates [25, 64]. The design permits using of CPNs, more than one, interconnected with passages for making possible a continuous coating operation [14, 25, 64]. Further refinement of the approach furnishes feeding devices in the first pan and discharging devices in the last pan [65]; refer to **Fig. 3B.**



A: SIDE-VENTED CPN OF HOSTETLER [63] **B: CPN WITH PERFORATED CARRIERS OF BOHLE [65]**

FIG. 3: DESIGNS OF SIDE-VENTED CPNS

CPNs Rotating on Inclined Axis: For example, conventional CPNs rotating on an inclined axis superimposes two basic motions; one is the tumbling motion on the horizontal axis and the second is the centrifugal motion on the vertical axis [14, 25]. This resulting motion of the substrate core bed in the pan is a combination of these two motions [9, 14, 25].

CPNs Rotating on Horizontal Axis: The pan coater designs whose pan (usually perforated one) rotates on horizontal axes are developing to increase the average contact area of the core bed with the DA [14]. The horizontal rotational motion creates a tumbling motion of the core bed inside the pan [14, 25].

Said design approach results in reduced drying time and improved process efficiency with respect to the pan's volume [14]. Yet this design approach demands further refinement in relation to substrate flow and drying efficiency [9, 25]. However, in most cases improving particle movement automatically improves the drying efficiency of the process [9, 14].

Cpns Rotating on the Vertical Axis: This design approach is to overcome the mechanical abrasion-related problem of substrate encountering horizontally rotating CPNs built-in with blades or baffles [14, 25]. Rotational motion of CPN around vertical axes causes circulation of the substrate on axis of rotation [9, 25]. The centrifugal force first pushes the substrate core outwards from the center to the periphery (that is, pan-wall) and then upward following the curve of pan-wall [9, 14]. The gravitational force acting on the substrate-core drops them down back into the middle of the CPN [14, 25]. As a usual practice, this design approach features a return device at the upper part of the CPN wall, which assists substrate to roll back into pan [14, 25]. This pattern of bed circulation intends to enable smooth and gentle movement of cores [9, 25]. More distribution homogeneity of coating material on substrates can be achievable with developing diverse designs by changing the shape of the container, air transport, and the direction of spraying [9, 14]. Based on this approach's first design, a conventional vertically driven pan was introduced by Yoshiro *et al.* in 1971 [66]. The mechanistic feature of the design is the substrate is located in a pan placed inside a vertically rotating device [14, 25].

A rotating stirrer is provided to maintain a smooth movement of the substrate close to the cylindrical wall of the pan [9, 14]. The sprayer is installed at the upper part of the pan, and the DA can flow either upwards or downwards through the substrate bed [14]. Moreover, grooves or ridges on the dish can further assist the movement of substrate bed [14, 25]. Different manufacturers have further developed the structural design of the conventional vertically driven pans was by different manufacturers, are the follows [9, 25].

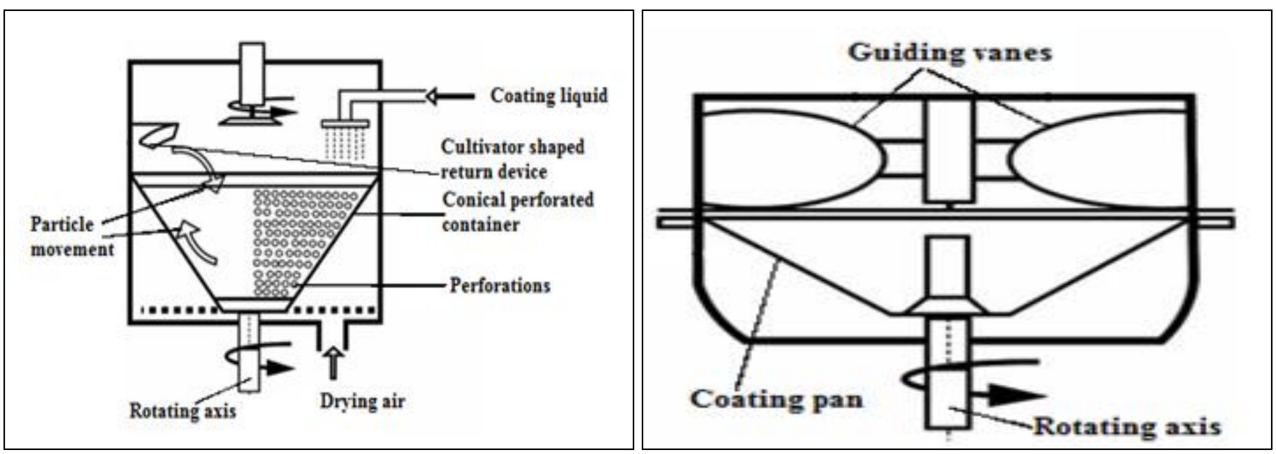


FIG. 4A: VERTICALLY DRIVEN PAN COATER WITH PERFORATED CONICAL CONTAINER AND CULTIVATOR-SHAPED RETURN DEVICE, ADAPTED FROM REFERENCE [67, 68]. FIG. 4B: VERTICAL DRIVEN PAN COATER WITH GUIDE VANES, ADOPTED FROM REFERENCE [69].

FIG. 4: VARIANTS OF VERTICALLY ROTATING PPNS

Design Approach To Improve Drying Process: Following this approach, an equipment design was invented by Bretschneider *et al.* [67]. The design consists of a vertically rotating perforated conical container with a planar bottom that is removable [14, 25]. Besides this, cultivator-shaped return devices and a sprayer installed at the top of the container [67, 68], refer **Fig. 4A.** The distribution of upwardly moving DA, through the perforated wall into the substrate bed results in an intensive and homogeneous drying of them, while removable container eases handling [14]. The rotational speed of the container and temperature of the DA can be conditioned to suit substrate properties [9, 14]. As an improved design, the cultivator-shaped return devices are replaced by guide vanes to enhance particle movement with avoidance of abrasion of substrate [9, 14, 69], refer to **Fig. 4B.**

Designs To Improve Particle Movement: The design approach of Hüttlin is for addressing the aforesaid issue, has modified bottom and air supplying devices [70, 71], refer **Fig. 5** and the rotating container with a bottom fixed with several concentric rings in a fashion that adjacent rings overlap each other forming a series of concentric slots [14, 25]. DA passes through the concentric slits and through a gap between the bottom and the container wall [9, 25]. Additional featuring is bottom, and the container wall can be uncoupled [9, 14]. This feature allows the driving of the bottom and container at an independent rotary speed [25]. The upper part of the container is installed with a conventional return device, while the spraying nozzle is mounted between the lower end of the return device and the bottom [14, 25]. Described mechanistic features aim at moving the particles less compactly while allowing more efficient drying [9, 25].

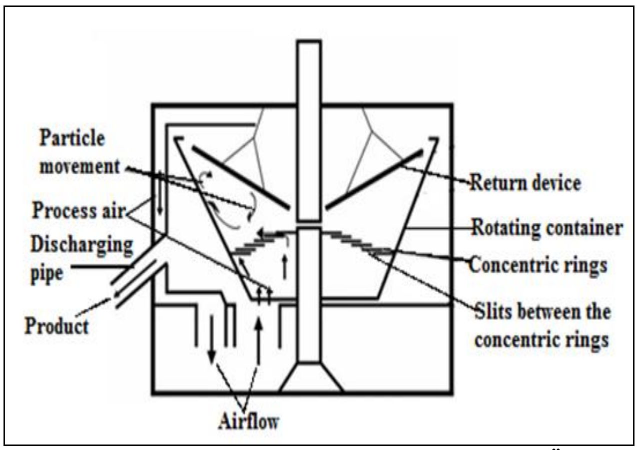


FIG. 5: VERTICALLY ROTATING PPN OF HÜTTLIN [70, 71]

In his later invention, the upper part of the wall (intimate to the return device) is equipped with at least one slit for airflow [14, 25]. Further, the static bottom of the container provided with air slits in order to allow the DA to flow tangentially through these slits towards the container wall [9, 14]. These features provide an air bearing feature that prevents the friction between the material and the return device and the drying effect [9, 14, 72].

In his subsequent invention, the concentric arrangement of overlying rings modified to provide a breaking-up zone is forming by the collision of two air streams [73]. One air stream is flowing from the concentric gaps near the center towards the container wall, while the other flows from the concentric gaps near the container wall towards the center [14, 25]. This mechanistic feature forces the material into a vertical movement along the breaking-up zone [25]. However, after a certain distance, the material drops down on both sides of zone [14]. The sprayer is positioned directly in the breaking-up zone, where the feed material is in intensively fluidized state [9, 25], refers to **Fig. 6.**

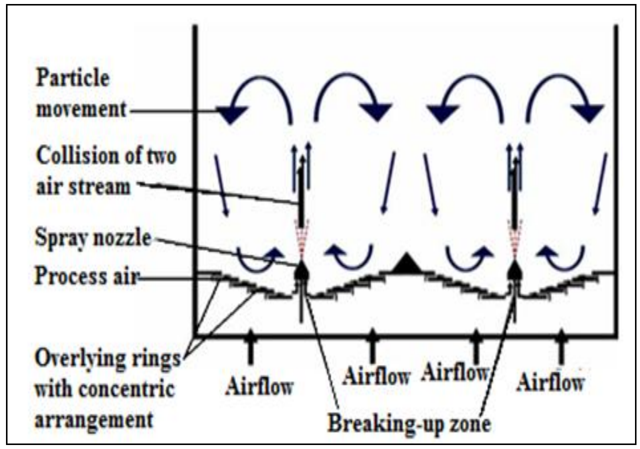


FIG. 6: CROSS-SECTION OF THE COATING APPARATUS WITH BREAKING-UP ZONE OF HÜTTLIN [73]

Improvement in the Feeding and Discharge: The feeding and discharging of the pans during the CPR were also attempting for improvement [9, 14]. Accordingly, Trebbi 74 has designed a pan with separate and independent feeding and discharging openings to avoid the potential risk of contamination between incoming and out-going products [14]. Scipioni [75] has invented a design of lid for closing the CPN [14].

The lid allows feeding and discharging operations to be performing without having to remove drying and spraying devices usually attached to the lid [9, 75]. Grabowski [76] has designed a drum with a perforated periphery and is providing with adjustable inserts [14, 25]. This insert divides the drum into coating zone and inactive zone [14].

Thus is permitting coating of relatively a small amount of substrate, under conditions identical to those used for coating the bed of substrate is wholly loaded drum [14, 76]. Later on, Morrow and Westcott [77] designed CPN for optimizing the efficiency of the CPR for different amounts of tablets [9. 14]. The mechanistic feature of the pan allows the drum's volumetric capacity to achieve the desired substrate depth for the quantity of substrate in questions [14, 77].

CONVENTIONAL (STANDARD) CPNs: Standard CPNs are 8-60 inches in diameter, mounted angularly at an angle around 40 º and are rotated on their horizontal axis using a motor [8, 9, 14]. Other shapes of conventional CPN systems consist of hexagonal or pear-shaped [8, 14, 25].

The rotational motion of the pan causes substrates to tumble, thus makes multiple passes through the coating application zone [8, 9, 14]. DA directed into the pan and onto substrate bed surface via a duct and exit out through other duct positioned over substrate, in front of pan [8, 14]. The coating liquid is applied either through ladling or spraying [9, 14]. The use of conventional CPN in film CPR is associated with three major drawbacks [8, 14];

Low Drying Efficiency: AS much of drying takes place on the surface of substrate bed [14].

Poor Mixing Efficiency: Results in dead spots (regions of low product movement) in the substrate bed [14].Health hazards for the operator and increased risk of Explosion; in case of VOS-based FC due to improper balance between inlet & exhaust air which causes solvent vapors to leak into the general coating area [14].

Modified-conventional CPNs: Conventional pan has initially formed the basis for the film CPR [14, 25]. The lack of drying efficiency of these pans is being offset by the use of highly VOSs [9, 14]. Numerous modifications were done to the design of DA handling device to accommodate it with the aqueous process [8, 14]. Example of such modification includes designing of the conventional CPNs with:

- Immersion tube systems [8, 25]
- Immersion sword systems [9, 14]
- Baffled pan and diffuser systems (Pellegrini pan) [8, 9]

Immersion Tube Systems: In this system, refer to **Fig. 7A.** a tube is immersed in substrate bed [8, 25]. The tube delivers the heated air and coating composition [11, 14]. A spray nozzle is constructed at the tip of the tube for providing coating compositions [11, 25]. Hot air is passed into the substrate bed, and air flows in upward direction [8, 9]. Exhaust air removed by exhaust vent or duct [14]. The DA and coating liquid introduced simultaneously [8, 11].

Immersion Sword Systems: In such systems, refer to **Fig. 7B,** the DA is introduced via a metal sword device with perforations which is immersed in substrate bed [8, 11, 14]. The DA flows upward from the metal sword through the substrate bed, thereby drying wetted substrate [14]. Exhaust air removed by exhaust vent or duct [8, 9, 11].

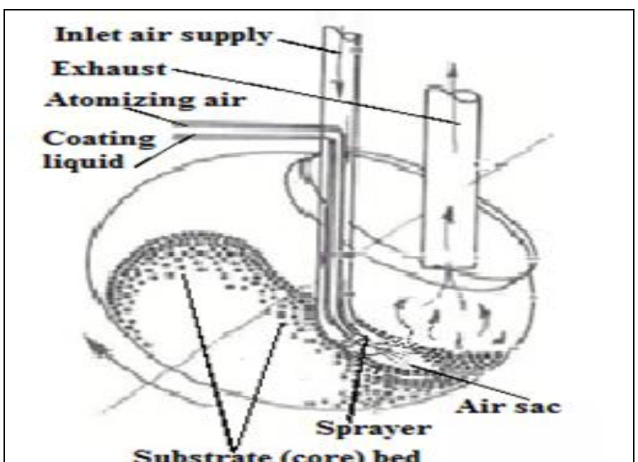


FIG. 7A: FIGURE OF IMMERSION TUBE PAN

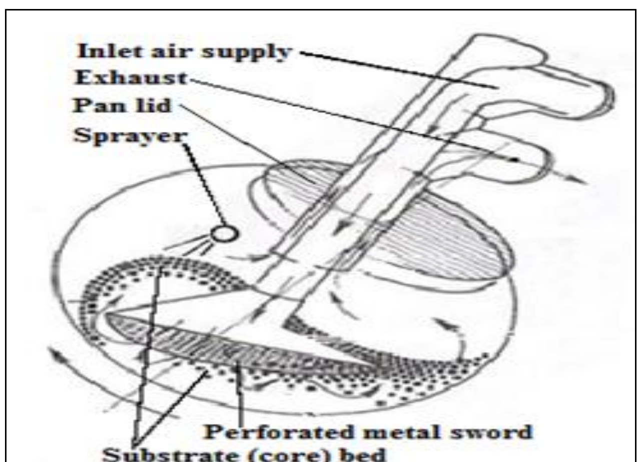


FIG. 7B: FIGURE OF IMMERSION SWORD PAN

FIG. 7: MODIFIED CONVENTIONAL CPNS [9, 14]

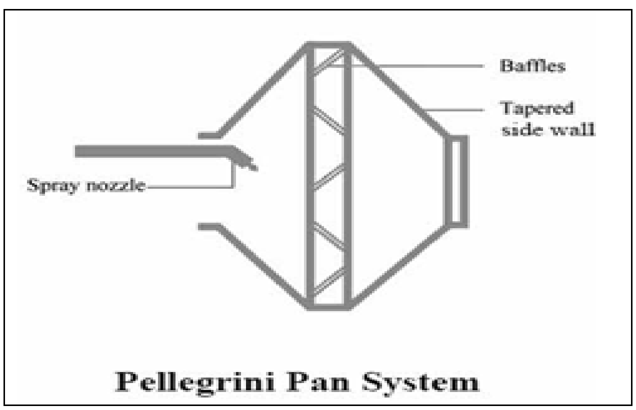
Pellegrini Pan: Pan of Pellegrini system, refer **Fig. 8A**, has baffled pan and a diffuser [9, 14]. Diffuser distributes the DA over the surface of the substrate bed [8, 25]. It can distribute DA uniformly on the coated substrates [9, 11]. The coater is available in the range of 10-1000 kg batch sizes [8, 14]. It is only suitable for sugar coating due to the limited drying capability; a limitation was overcome by installing a Glatt immersion sword air handling system to improve drying efficiency [14, 25].

Perforated Coating Pans: This system, refer to **Fig. 8B**, uses a perforated or partially perforated drum (pan) that rotates on its horizontal axis in an enclosed housing [14]. Coating system of this type is more efficient in drying comparing a conventional one [11, 25]. The equipment based on PPNSY was developed to maximize the interaction between the substrate bed and the DA [8, 14].

This is achieved by drawing DA through the tumbling substrate bed as contrarily to supplying DA to the bed surface only [9, 14]. This is a chief contributor to the development of aqueous FC. Due to relative high latent heat of vaporization of water (539 kcal/kg) is much greater comparing to that of popular VOSs (200 kcal/kg) ethanol) [8, 25]. With such a system marked decrease in coating time can be achieved, thus it has surfaced as the design of choice in most FC applications with major exception being for the FC of particles (like beads, pellets, and powders) unless modified with a mesh insert [14, 25]. Mixing efficiency is achieved by use of appropriately designed baffles on the pan surface [9, 14]. These come in various designs, depending on the vendor, with the intention to maximize the machine's drying capability to minimize core penetration at high spray rates [8, 14]. Follows are the available equipment based on perforated CPNs [8, 14]:

- Accela Cota®: from Thomas Engineering (Manesty), USA [14].
- Hi-Coater®: from Freund-Vector, Japan and USA [14].
- Driacoater®: from Driam Metallprodukt GmbH, Germany [14].
- Glatt Coater: from Glatt, Switzerland, Germany, and USA [14].
- Huttlin Butterfly Pan: from G S, Italy [14].
- IDA Coating equipment: from Dumoulin, France [14].

In all of these PPNSYs, the spray nozzle atomizes coating fluid [14]. The only difference is how the machine supplies and removes the DA [9, 14].



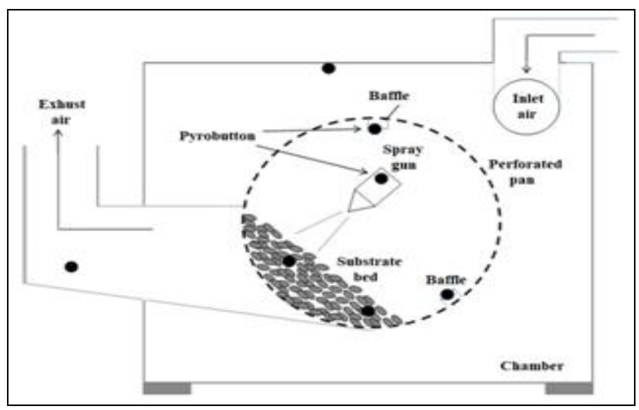
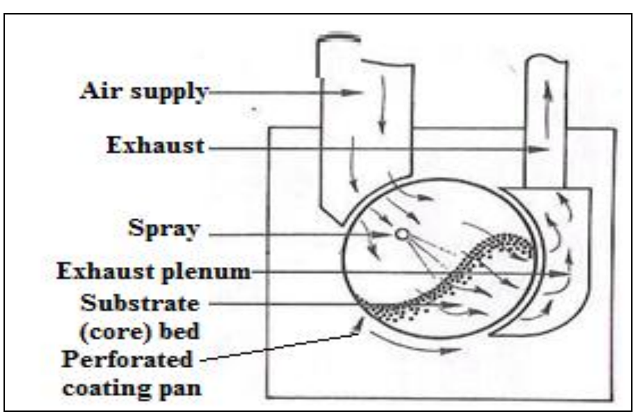


FIG. 8A: FIGURE OF PELLEGRINI COATER **FIG. 8B: FIGURE OF PERFORATED CPNS**

FIG. 8: FIGURE OF MODIFIED PPNS [8, 14]



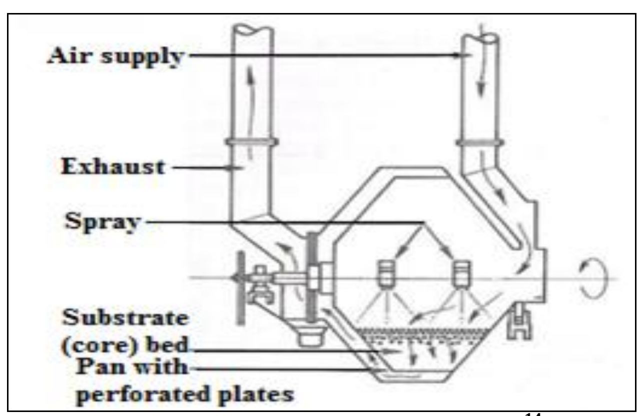


FIG. 9A: FIGURE OF ACCELA COTA® 14 **FIG. 9B: FIGURE OF HI-COATER® [14]**

FIG. 9: FIGURE OF MODIFIED PPNS

Accela Cota®: DA is passed in to perforated cylindrical pan and air is drawn into substrate bed. Application of coating solution is on substrate bed by spraying [14]. Exhausted air is passed through a duct located at the bottom of the pan [8, 14]; refer **Fig. 9A.**

Hi-Coater®: The function of Hi-Coater® is the same as Accela Cota® [14]. DA is passed into a perforated cylindrical pan through an inlet [14]. The coating solution is applied by spraying nozzles [14]. Exhaust air is passed through perforated plates present at the bottom of the pan [9, 14]; refer **Fig. 9B.**

Driacoater®: Inside periphery of Driacoater® is attached with perforated ribs which are hollow one [8]. It provides multidirectional airflow as follows [14, 38]; refer **Fig. 10.**

Direct Air Flow: Air is passed through the ribs (baffles) located top of the pan and exhausted through the ribs located below the substrate bed [8, 10].

Reverse Flow A: Air enters through baffles located beneath substrate bed and is exhausted via baffles at the top of pan [8, 14].

Reverse Flow B: Air entry is via baffles located beneath substrate bed, and exit of air is through plenum connected to the opening at the back of the pan [8, 9].

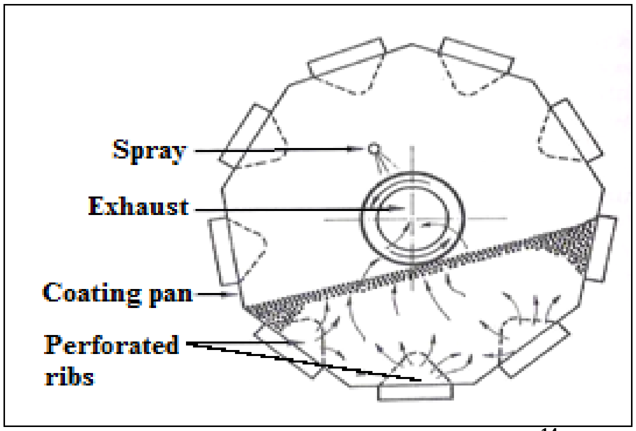


FIG. 10A: FIGURE OF DRIACOATER® [14] M

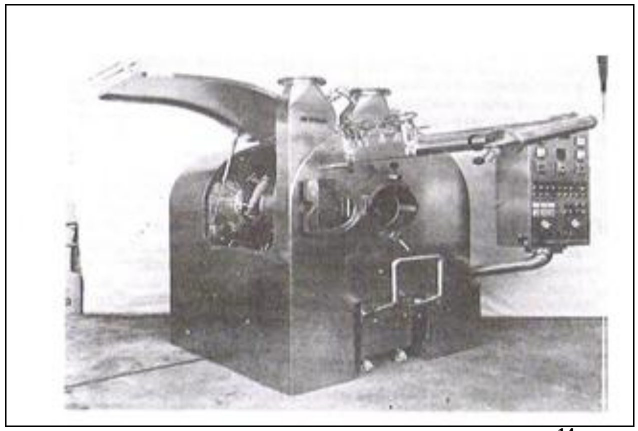


FIG. 10B: FIGURE OF GLATT COATER [14]

FIG. 10: FIGURE OF MODIFIED PPNS [9, 14]

Glatt Coater: The Glatt coating machine's design resembles that of the Accela Cota® [8, 14], refer **Fig. 10B.** It is one amongst of those latest PPN tablet coater that ensures accurate and consistent coating [8, 11].

Their drums have a unique geometrical shape with baffles on the periphery, which ensures effectual mixing of substrates while simultaneously protects the product from damage [8, 9]. DA passed through substrate bed from the inner side of drum and exhaust through exhaust duct [8, 25].

While it's unique design minimizes turbulence that may happen around spray nozzle [8, 14]. This ensures an even distribution of coating solution on substrates [8, 9]. The optional split chambered plenum is used to pass the DA in a reverse manner through the perforations for the partial fluidization of tablet bed [8, 10]. The equipment has high spray rates and extremely short processing time [8, 11].

Huttlin Butterfly Pan: This comprises a series of large, angled, and slotted openings in pan wall at the junction of cylindrical portion with each of the back or front panels [8, 9]. These opening permit is exhausting of the air from pan [9, 25]. The back and front of the pan can be disconnected from the cylindrical central section and can be hinged down [10, 11]. DA is applied onto the surface of the substrate bed through a slotted tube [8, 14].

Dumoulin IDA: The equipment has a perforated cylindrical central section with two air plenums [8, 14]. Air plenums function as both exhaust or inlet air systems and are located near the outside of the pan, and a third plenum [8, 11]. The third plenum is connected to a slotted tube positioned inside the pan and above cascading substrate bed [8, 13]. This allows inlet air only to be routed onto the surface of the substrate being coated [14, 25]. The airflow patterns are as follows [8, 14].

- Single flow
- Reversed single flow
- Double flow
- Direct double flow

Facility & Ancillary Equipment: Facilities require should meet the requirements of cGMP [14]. Adequate space is required for equipment, solution preparation, and in-process storage [14, 25].

Safety requirements depend on the solvent's nature like specialized ventilation, electrical explosion proofing, and many others [11]. Exhaust air treatment to recover solvent or to prevent entry to atmosphere [14].

Spraying Application Systems (Spray Gun): The success of film CPR rests on the availability of coating equipment with a spray atomization system that allows coating liquids to be applied in a much more controlled and reproducible manner [8, 11, 14]. Spray-atomization systems available suiting coating compositions are [14]:

- High-pressure airless system [14].
- Low-pressure air atomized system [14].

Both these systems vary in atomization of liquid [14]. The selection of a spray system depends upon composition of coating fluid and on a process developed for the particular products [9, 14].

High-Pressure Airless Systems: In these systems, the liquid is pumped at high pressure (250-3000 psig) through a narrow orifice (0.009-0.20 inch) in fluid nozzle [8, 14].

Atomization of the liquid occurs as it expands rapidly on emerging from the nozzle [8, 14]. The spray rate and degree of atomization are controlled by the orifice size, fluid pressure, and liquid viscosity [14].

Because of high delivery rates, these systems are typically used in large-scale FC operations that are VOS-based coating [8, 14].

Disadvantage: May block due to small orifice, thus coating suspension be filtered or finely milled [14]. Do not provide independent control for the degree of atomization, rate of suspension application, and width of the spray fan [8, 14].

Low-Pressure Air Atomised System: In this system, liquid is pumped through a larger orifice (0.020 - 0.06 inch) at relatively low pressure (5 - 50 psig) to nozzle [8, 14]. Subsequently, a blast of compressed air (of about 10 - 100 psig) contacts the liquid stream at tip of the nozzle to atomize and disperse it into fine spray [8, 14]. In this system, atomization can be controlled independently of the operating pressure; also fan width can also be controlled [8, 14].

The degree of atomization depends upon fluid pressure, fluid cap orifice, the viscosity of the liquid, air pressure, and air cap design [8, 14]. The system is typically more effective in small-scale CPR and all those involving aqueous- FC operations [8, 14].

Disadvantage: The atomizing air can give rise to premature spray drying of atomized droplets outcoming in the non-glossy porous film being formed [8, 14].

Validation of CPN: Major elements of a validation protocol for a CPN are [38]:

- Installation qualification.
- Operational qualification.
- Performance qualification.
- Installation qualification

The Main Objectives of Installation Qualification Are [38]:

- To establish confidence that equipment is installed properly [38].
- Installation must meet manufacturer's fixed guidelines and design challenges at installation [14, 38].

Also, supporting electrical utilities should satisfy all electrical codes [38].

Follows are the information necessary for evaluation of.

Installation Qualification [14, 38]:

- Equipment identification,
- Required documentation,
- Major component specifications,

- Equipment utility requirements,
- Component material,
- Equipment safety features, and
- Lubricants.

Equipment identification

Record the Equipment ID Number in a Table with Follow Information [14, 38]:

- Equipment's manufacturer's,
- Purchase order number.
- Model number.
- Serial number.
- Company assigned equipment number.

The Location of Equipment:

Required Documentation: Record the equipment and manufacturer's maintenance and operation manual and drawings in **Table 1** and standard operating procedures (SOPs), which cover setup, operation, and cleaning of CPN in **Table 2** [14, 38].

TABLE 1: LIST OF EQUIPMENT AND MANUFACTURER'S MAINTENANCE AND OPERATION MANUAL AND DRAWINGS [14, 38]

Number	Description	Date
A46-031	CPN instruction, operational and maintenance manual.	-----
A46-032	Electrical diagram drawing.	-----

TABLE 2: LIST OF SOPS THAT COVER SETUP, OPERATION, AND CLEANING OF CPN [14, 38]

Number	Description	Release date
COA059	Setup and operation of the CPN.	09/08/2020
COA060	Coating dept equipment cleaning procedure.	19/07/2020

Equipment Utility Requirement: Record the location of the power supply source [38]. Compare manufacturer's specified voltage, amps and compressed air pressure needed to their as found out conditions at the time of qualification testing and record results in **Table 3** [14, 38.] Record the instruments used to measure the volts, amps, and compressed air as per the format of **Table 4** [14, 38].

TABLE 3: COMPARING VOLTAGE, AMPS, AND COMPRESSED AIR PRESSURE NEEDED FOR THE CPN, AS SPECIFIED BY THE MANUFACTURER [14, 38]

Utility	Specifications	Measured results	Acceptable (yes or no)
Voltage	Spray systems: 115	112	Yes
	CPN: 460	458	Yes
Amps	CPN motor: 4.8	4.8	Yes
	Supply blower: 4.8	4.7	Yes
	Exhaust blower: 4.8	4.8	Yes
Compressed air	90 ± 10% psig		

TABLE 4: LIST OF THE INSTRUMENTS USED TO MEASURE VOLTAGE, AMPS, AND COMPRESSED AIR [38]

Test instrument	ID number	Calibration date	Operation date	Operation time
Multimeter	ME-025	04/21/21	--/--/----	--/-- to --/--
Air pressure gauge	P-102	02/19/21	--/--/----	--/-- to --/--

The manufacturer, model number, serial number and other utilities required should be specified. The major components include [14, 38]:

- CPN motor
- Supply blower motor
- Exhaust blower motor
- Spray systems
- The material of construction of different components should be specified as in Table-[5, 14, 38].

TABLE 5: THE MATERIAL OF CONSTRUCTION OF DIFFERENT COMPONENTS [14, 38]

Component	Material
CPN	304 SS
Spray system	Stainless steel

Lubricants: Record the lubricant used to operate CPN and indicate if they make contact with the product [14, 38].

Equipment Safety Features: Record the safety features of the equipment [14, 38].

Operational Qualification:

The Objectives of Operational Qualification Are As Follows [14, 38]:

- An operational qualification evaluation should establish that the equipment can operate within specified tolerances and limits [14, 38].
- The CPN will be validated for its operating ability [14, 38].

Information required for the operational qualification evaluation is the calibration of the instruments used to control the pan, equipment control functions (switches and push buttons), and equipment operation (CPN rotation, pan speed, pan supply temperature, spray system operation) [14, 38].

Calibration requirements: Verify that all critical instruments on the equipment have been logged into the calibration systems, have calibration procedures in place, and are in calibration at the time of qualification testing [14, 38]. Record all the information for the calibrated instruments used to control the CPN [14, 38].

Equipment Control Functions: The objective of the testing equipment control functions is to verify that the push buttons on the CPN operate per manufacturer's specifications [38].

The pan will be operated with the pan empty [14, 38]. Operate each control listed in **Table 6** and verify its proper operation [14, 38].

CPN Rotation Direction Test: The objective of this test is to verify that CPN rotates in the proper direction [38].

The pan will be operated empty [14, 38.] Press the start push button and observe the direction of rotation of the CPN as viewed from the front and record the results [14, 38].

TABLE 6: VERIFICATION RECORD OF PROPER FUNCTIONING OF THE CONTROLS [14, 38]

Test operation	Expected results	Acceptable (Yes/ No)
Power start/stop push-button	When the pan start/stop push button is pressed, the pan starts and rotates continuously [14, 38]	Yes
	When the pan start/stop push button is pressed again, the pan stops rotating [14, 38]	Yes
Pan jog push button	When the pan jog button is pressed, the pan rotates clockwise; then, it stops rotating when the pan jog push button is released [14, 38]	Yes
Heater on/off push button	When the heater is on, the push-button is pressed, the fan heater starts [14, 38]	Yes
	When the heater is off, the push-button is pressed, the fan heater stops [14, 38].	Yes
Fan on/off push button	When the fan start push-button pressed, the fan starts and rotates continuously [14, 38]	Yes
	When the fan stop push button is pressed, the fan stops [14, 38]	Yes
Exhaust plenum clamp switch	When the exhaust plenum clamp switch is rotated counter-clockwise, the plenum is clamped into place [14, 38]	Yes
Speed control knob	When the pan speed control knob is rotated counter-clockwise, the pan speed decrease [14, 38]	Yes
	When the pan speed control knob is rotated clockwise, the pan speed increases [14, 38]	Yes

CPN Speed Test: The objective is to document the speed of the tablet CPN with the pan empty [38]. A tachometer will be required for this test [14, 38].

Measure the speed of the CPN with a calibrated tachometer and record the results in **Table 7** [38]. Verify that the measured speed is within 10% of the variable speed of 12-36 rpm [14, 38].

Record the instruments used to measure the speed, following the format of **Table 4** [14, 38].

TABLE 7: CPN SPEED TEST REPORT [14, 38]

Set Speed (in RPM)	Measured results	Acceptable (Yes/ No)
12	11	Yes
24	23	Yes
36	37	Yes

CPN Supply Temperature Control Test: The objective is to verify that the pan supply temperature controller operates according to the manufacturer's specifications [14, 38].

CPN Operation Test: The operation of the CPN is tested to document its performance using placebo tablets but without spray systems, placebo will be used for maximum loading conditions [14, 38]. Fill the pan with the placebo tablet to the appropriate level and record the test material used [14, 38]. Set the pan speed to 12 rpm and run 5 tests for 5 min each after the steady-state is achieved [38]. Enter the setpoints and conduct the tests and record the results [14, 38].

Spray System Operation Test: The test is to verify that it operates according to the manufacturer's specifications [38]. Water will be used as a spray medium [38]. A graduated cylinder and a stopwatch will be required [14, 38]. Start the spray systems and select a low flow rate [38].

Capture the water from the spray systems with a graduated cylinder for 1 minute [38]. Repeat this test for medium and high flow rates and record the results in **Table 8** [38]. Record the instruments used to measure the volume of the water and operating time following the format of **Table 4** [14, 38].

TABLE 8: SPRAY SYSTEM FUNCTION TEST REPORT [14, 38]

Flow rate	Selected delivery flow rate	Measured delivery flow rate	Acceptable (Yes/ No)
Low	50	50	Yes
Medium	100	109	Yes
High	200	220	Yes

Qualification: Once it has been established that the equipment is properly installed and functioning within specified operating parameters, it must be shown that the CPN can operate reliably under routine, minimum, and maximum operating conditions [14, 38].

CPN Operation: The pan operation is tested to document the performance and speed of the tablet CPN using placebo tablets and Opadry (orange) coating medium; a tachometer will be required [14, 38].

Procedure: Fill the CPN with placebo tablets and record the placebo and spraying materials used in the format of **Table 9** [14, 38]. Enter the setpoints and start spraying the tablets after the steady-state is achieved and record the results in **Table 9** [14, 38]. Measure the speed of the CPN with a calibrated tachometer and record the results in **Table 9** [14, 38].

Verify that the measured speed is within 10% of the variable speed from 12 to 36 rpm [14, 38]. Get the performance report of the spray system in accordance with **Table 8** and record the result in the format of **Table 9** [38].

Record the instrument used to test the CPN and spray system speed following the format of **Table 4** [14, 38].

TABLE 9: CPN OPERATION AND PERFORMANCE TEST REPORT [14, 38]

Parameter	Placebo used	Specifications	Measured result	Acceptable (Yes/ No)
Speed of the CPN loaded with placebo.	Paracetamol	12 RPM	12	Yes
	Paracetamol	24 RPM	23	Yes
	Paracetamol	36 RPM	37	Yes
Flow rate of coating liquid.	Opadry (orange)	Low	52	Yes
	Opadry (orange)	Medium	108	Yes
	Opadry (orange)	High	219	Yes

Coating Parameters: During coating, the substrate moves through an application zone in which a small portion of substrates receives some coating [24].

Most of the time, substrates are in drying mode as are moving off from the application zone whilst repeatedly subjected for recycling through application zone [38]. Throughout coating operation (in continuous mode), equilibrium is maintained between the application rate of coating composition and the rate of solvent evaporation [38], *i.e.*, rate of application of the coating composition = rate of solvent evaporation. Mathematical model for aqueous system based automated CPR is: inlet A (T1, H1) + C1 (S) + pSA1 → A (T2, H2) + C2 + pSA2 exhaust [8]. Where, A (T, H) is the Air capacity a function of T (Temperature) and H (humidity) of the air, C(S) is the coating composition, and SA is the Substr surface area [8].

Deviation from said equilibrium will result in a serious coating problem [8]. These parameters may be adjusted by adjusting [8]:

- The pan load.
- Spray gun position.
- Coating composition.
- Air temperature and volume,

Pan Load: Underloading of the CPN will bring a situation where substrate does not fully cover exhaust plenum, and the majority of DA stream will bypass substrate bed and efficiency of drying will be poor [8, 38].

Spray Gun Position:

Gun-to-wall Distance: Accurate positioning up, saves cleaning work [8, 38].

Gun-to-bed Distance: Spray gun position should be 6-18 cm from the substrate bed, 45º angles to the substrate bed [8, 38, 78]. Production scale: approx. 15-20 cm, Lab scale: approx 10 cm [38].

Gun-to-gun Distance: Fan width is not overlapping or too far (if the number of gun is ≥ 2) [8, 38]. Place periodically, not too close together to avoid the possible over wetting resulting from overlapping [38].

Coating Composition: The solvent of coating composition carries ingredients intended for applied onto the surface of substrates, thus acting as the carrier only [8, 38]. These solvents, however, are not needed in the final product thus be removed [8, 38]. The balance must be established between the flow rate of the coating composition and drying variables (temperature and quantity of the DA, and quantity of exhaust air) [8, 38].

Air Temperature and Volume: Drying efficiency affects the uniformity of coatings, is a function of process temperatures that are controlled by quantity and temperature of DA (hot inlet air), and the quantity of exhaust air [24, 38, 78].

A high temperature of the inlet air increases the drying efficiency of film CPR based on the aqueous system, decreases water penetration into substrate and residual moisture content of the coated substrate, and decreases tensile strength and porosity of coating [14, 24, 38].

Too much inlet air temperature increases the premature drying of the spray during the application, decreasing the coating efficiency [14, 38]. The exhaust temperature functions inlet air temperature, spray rate, process air volume, and atomizing air pressure [14, 24, 38]. It's important to balance exhaust and inlet airflow rates to slight negative air pressure in chambers [14, 24, 38]. Also, the temperature difference between exhaust and inlet air must be within 20-30 ºC 3[8]. Thus it's important to monitor the following three temperatures [14, 24, 38].

- Intake
- Exhaust.
- Substrate bed.

Substrate bed surface temperature is most critical of all temperatures, as exactly here happening is most important process detail [14, 24, 38]. Temperature distribution within the substrate bed is also played a role [14, 24, 38]. Measuring the pan air temperature helps to manage the optimum conditions during the CPR, enabling predicting possible drying or over wetting problems which may result in the poor appearance of film or may have unfavourable effects on moisture and heat sensitive substrate cores [14, 24 38].

Air Capacity: Air capacity monitors the quantity of water or solvent removed during CPR that depends on [14, 24, 38]:

- Quantity of airflow through substrate bed [38].
- Temperature of inlet air [38].
- Water content of inlet air [38].
- Substrate bed temperature (most critical) [38].
- Exhaust air temperature [38].

Excessive air temperature increases premature drying of the sprayed droplet during application and afterward decreases coating efficiency [14, 24, 38].

Spraying/Atomising Air Pressure: The pressure of spraying air disperses coating fluid into droplets and results in droplet size distribution and spreading of the droplet and their penetration on substrate surface [8, 14, 38, 78].

For the formation of adhesive and adequate film coat, the atomized droplets have to spread completely over the surface of the substrates [8, 14, 38]. An increase in The air pressure of spray decreases the surface roughness of coated substrate and produces thinner and denser films [8, 14, 38]. If The air pressure of spray is excessive, spray loss is higher, as droplets formed are very fine and could spray dry before reaching substrate bed, resulting in inadequate spreading of droplet and coalescence [8, 14, 38]. The Air pressure of spray is insufficient, the film thickness is low, and variation in thickness is greater, perhaps due to change in the film density and loss of smaller droplets [8, 14]. Low atomizing air pressure results in larger droplets that could locally over the wet surface of the substrate and cause them to stick one another [38]. Adjusting the pressure of spray gun are required as atomizing air creates fumigation, fan air sometimes termed “control air” creates a form of the pattern (oval or round), needle air results lose in liquid line [8, 14, 38] and many other.

Flow Rate of the Coating Liquid: Aqueous CPR will be successful if the flow rate of coating liquid equals water evaporation rate from coated substrate surface [14, 24]. The flow rate of the coating liquid is an important parameter as it impacts moisture content and the uniformity and quality of the film, as follows [8, 14, 38]. Increasing flow rate allows a higher number of droplets to spread onto the substrate bed per unit of time and increases droplet size [14, 38]. Lower flow rate causes coalescence of the polymer incomplete due to the insufficient wetting, ensuing brittle films [14, 38]. A higher flow rate of coating liquid may result in over wetting of the substrate surface and later problems like sticking and picking [14, 38]. If the spray rate is high and the temperature of the substrate surface is low, then films are not formed during spraying but post-drying phase [38]. Furthermore, rapid drying often results in cracks in films [14, 38].

Spray Rate and Batch Size: Higher the spray rate [78] and larger the batch size, the more efficient is the CPR [14, 24, 38].

Possible Spray Rate Should Be Function of Follows [38]:

- Drying efficiency of the equipment.
- Core properties.
- Film properties.
- Quality of machine set up.

Correlate between required process time and batch size is needed to apply 3% w/w weight gain [14, 38].

Rotating Speed of the Pan: The pan speed influences the time a substrate spends within the spraying zone and afterward homogenous distribution of coating liquid on each substrate surface throughout batch [38, 78]. Increasing the rotational speed of CPN improves substrate mixing while decreasing the residence time of substrate under spraying zone [14, 38].

Factors governing residence time of substrate are pan speed, pan diameter, number and type of baffles, pan load (batch size), and tumbling behavior of the core substrate [14, 38]. An increase in the CPN speed decreases variation in the thickness and improves coating uniformity [38]. The too-high rotating speed of CPN causes the substrate to undergo excessive breakage and attrition [14, 38].

Effect of Residual Moisture: The use of VOSs may arouse the possibility of the residual solvent issue in finished product [38]. The fact is growingly a concern to regulatory authorities due to their untoward effects on health [14, 38, 46, 47.] Water has low volatility comparing VOSs. Thus, it will require better drying capacity and contributing a higher cost of energy to the CPR [14, 38, 46, 47].

Optimized formulations of FC are there, with a very low affinity for aqua, which can be run at higher spray rates and lower temperatures [14]. Few of such products available from Ideal Cures Pvt. Ltd. (under Instacoat range of products) that dries faster and entire CPR can be finished at the same time or sometimes little less compared to that based on VOSs [38, 46, 47].

Practical Hints:

- Pre-heat with jog mode (or even gentler manually) [14].
- At starting of process the pan speed should be as low as possible, but substrates must flow constantly [14, 38].
- Increase pan speed gradually over the complete process time [38].

- Cooldown under slow permanent rotation [14].
- Excipients should be compatible with the process and ingredients of formulation [14, 79].

CONCLUSION: In the coating of pharmaceuticals along with the physico-chemical properties of film formers and excipients the design of CPNs and embedded technology delineates the functional attributes of the coated pharmaceuticals. Furthermore the quality of coating thus the performance of final product is affected by spray nozzle and their number, pan size and many more.

Nowadays, aqueous solvent-based CPR and coating systems are preferred and are rapidly replacing organic solvent-based systems, irrespective of the purpose and applications of a conventional release for immediate release profile and modified-release for enteric/ delayed/ extended release profile. These systems call highly efficient drying systems associated with water's low evaporation capacity. The airflow pattern through a PPN ensures continuous and fast-drying conditions. Present-day witnessing major improvements made in CPR, CPN, and coating machines and their ancillaries for amenable them to aqueous coating. The continued popularity of CPRs based on CPN is mainly for their cheapness and high scale-up potentiality. It eases in validation of the equipment and CPR; however, they are difficult to master. Selection of proper CPN and CPR combination should be based on their suitability, amenability, and compliance to the prevailing relevant regulatory requirements in the intended marketing area.

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