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GLIMPSE OF PHARMACEUTICAL COATING PROCESSES

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ABSTRACT: Manuscript aims to furnish glimpse on coating processes (CoPr). The coating is the process of applying coating materials (CoMa) onto the substrate surface (S-S). With time and space dimension of CoPr, that upraised as sugar-coating (S-C) expanded to film-coating (F-C) and specialized one. Lengthy and wearisome processing and skilled operators issues inherited to S-C spring-up F-C and its improvement from non-aqueous F-C to aqueous film-coating (AF-C). Non-aqueous film-coating processes (F-CP) make use of a volatile organic solvent (VOS) while AF-C processes uses aqueous solvent (AS), as a solvent system for coating formulations (C-F). VOS is preferred over AS in F-CP, and momentum for using AS has been accelerating from past few decades. Issues from VOS's use upraised relating to safety; worker hygiene & safety; toxicity; environmental pollution; etc. These upraised issues intensified, thus, nowadays, AF-C processes are replacing VOS-based F-CP. Later on, finding the novelty of coating and CoPr thru coating of particulates became another dimension of expansion. This involves modification and/or alteration in innate properties of particulates, chemically and/or physically, thru coating, is for find their worthy attributes and functionalities. This dimensional expansion exploits the applicability of the dry-coating process (D-CP) and wet-coating process (W-CP). D-CP comprises novel and specialized CoPr based on novel technologies while W-CP comprises conventional and novel CoPr**.** Some state-of-art CoPr are AF-C process, hot-melt coating (H-MC) process, electrical-electrostatic deposition process, gas-/vapor-phase process, aerosolized CoPr, photo-curable CoPr, Resonant acoustic CoPr, thermal and mechanical process, thermo-mechanical CoPr, fluidized-bed processes, Supercell® CoPr, *etc*. CoPr and its dimensional expansion briefed for updating professionals.

INTRODUCTION: Solid dosage forms comprise a major fraction of pharmaceutical products, and their formulation ingredients, in most instances, are in particulate state [1-6]. In some instances of manufacturing processes, inevitable is a coating of themselves or component particulates [7-11]. Coating of solid dosage form or their component particulates involves deposition of CoMa, as a layer, snugly affixes on surface of said substrates [9-11].

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Said coating (layering and/or deposition) is aimed in imparting final product non-functional (protective) and/or functional attributes [6, 9, 10]. Through coating realizable attributes are alterations and improvement in aestheticism like color, odor and taste; stabilization; enhanced mechanical properties and tailored (*i.e.*, controlled/ extended/ modified/ delayed) drug release profile [1-3, 6, 9, 10].

Until 1950, S-C is the preferred CoPr, and at that time, there was much effort there to perfect its techniques & processes [1-3, 6]. Further, S-C processes have lengthy processing time and their productivity & quality mostly dependent on operator skills, are the major concern [1-3, 6]. Said concerns are chief contributors to spring-up F-CP that with time and space improved with technology improvement [4, 6, 8].

Said improvement activity made the F-CP amenable to improving aestheticism, stability, and marketability and tailing the release profile of active(s) [1, 4, 6, 12]. In F-C formulations, during the early stage of development, VOS is preferred as a solvent system over AS [1, 2, 6, 8]. Said preference in F-CP is to forefend possible debasement of active(s) and combat diverse processing problems affiliated with AS-based CoPr like over wetting, picking, sticking, and may more [6, 8]. With time and space issues/ concerns affiliated with the use of VOS like residual VOS, regulatory concerns, the safety of the operator, environmental safety & concerns, and cost providing momentum for springing-up, ameliorating, and perfecting aqueous F-CP, as alternatives [1, 2, 4, 6-8, 11, 13].

Aqueous F-CP in most instances, use aqua-dispersions as coating fluid [6, 14]. Film-former level in said dispersion is low while the quantity of AS is very high [6, 15]. Thus aqueous F-CP is energy and time consuming, affiliates from evaporating large amount of AS [6, 14-16].

Modifying surface properties/ attributes of fine & ultra-fine particles (FUFP) and particulates is inevitable in some instances [9, 10, 13, 16]. Strategies of particle engineering and/or methodology thru surface modifications involving coating were devised and ameliorated to find new and/or worthy functionalities, properties, and applications of FUFP and particulates [13, 14, 17, 18].

Most exploited techniques/ process for modification in surface attributes/ properties of them aims to alter their innate properties physically or chemically and to receive assorted advantage [10, 13, 16-18]. Amongst them, pharmaceutical applications frequently aim for protective (non-functional) and/or functional purposes [16-18].

For these purposes exploiting is chemical & physical deposition methods [13, 16]. These methods alter the innate properties of FUFP and particulates chemically or physically [10, 13, 16]. The physical method realizes physical deposition and/or embedding of coating material particles (CoMaP) at surfaces of FUFP and particulates [10, 13, 16]. Physical methods exploiting are mechanical, thermal, thermo-mechanical, electro-mechanical, thermodynamic, many others [7, 9, 13].

The chemical method realizes chemical changes at the surface of FUFP and particulates by making usage of liquid/ gaseous precursor, thereby realizing coating [6, 11, 13]. The technology of physical deposition methods involves the usage of high pressures, elevated temperatures, high-shear and/or solvents [9, 13]. Solvent-based W-CP inherits issues like cost, undesirable waste stream and regulatory limitations on VOS relating to their usage & residual solvent; and particle agglomeration reduced stability, and energy & time requirement of AS-based CoPr [1, 6, 7, 13].

These thus are preferred to a lesser extent [7, 13]. The strategy of chemical deposition methods inherits issues of relatively costlier, complex and challenging scale-up [10, 13]. Thus some physical and chemical methods are not-suits active(s) that labile to involve ambient processing conditions [9, 10, 13]. These facts spring-up specialized D-CP and techniques and their amelioration, over last-few decades [1, 5, 12, 19, 20].

D-CP are in most instances, solvent-less CoPr [16, 20]. The technology of these processes involves the usage of mechanical forces to directly attach/ fix CoMaP, as FUFP, onto a relatively larger substrate [10, 16, 20]. Applied mechanical force realizes said fixing and does not call-for binder(s) and/or solvent(s), even AS [10, 16, 18].

Methodology bears the novelty of enabling mixing powders of diverse chemical & physical properties to realize composites, a new-generation material with tailored attributes [10, 16, 18]. Resulted composites bear new functionality and/or have improved characteristics, comparing that of component materials [10, 16, 18, 20].

CoPr in present days has a diversity of type & origin; refer to Fig. 1 [1, 6, 10, 17]. The associates and inherits complex processing steps of diverse types and origins [1, 6, 13, 16, 17]. Their generalization in wider terms is wispy task [6, 13, 17].

Available literature summarizing information on CoPr, an area of such diversity, as a glimpse, is scarce. Thus it seemed requisite to work in this regard for the convenience & enrichment of professionals.

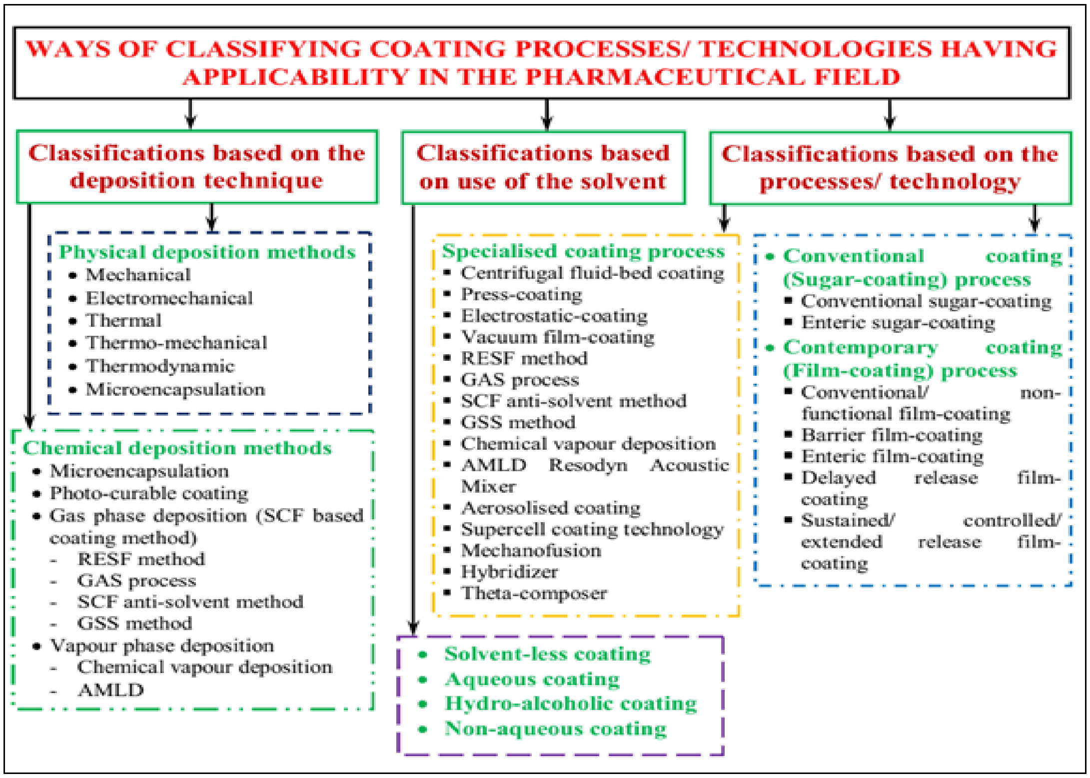

FIG. 1: DIVERSE COATING PROCESS WITH PHARMACEUTICAL APPLICABILITY, AS ADAPTED FROM [2, 11, 17]

Recent developments in the area of CoPr having pertinence in the pharmaceutical field are at this moment, attempted for outlining and briefing. This presentation hoped to provide a glimpse on CoPr, an effort that will enable to find CoPr suiting candidate pharmaceutical and their improved/ new industrial applications. The consequence is improved productivity & profit, ultimately welfares of mankind.

Basic Principle of Coating/ Deposition Process: In the present scenario, available CoPr is of diverse types & origins [1-3, 17]. Generalizing their basic principle in broader terms is a wispy attempt [4, 5, 17].

However, in general, a principle is deposition that involves applying CoMa onto a moving substrate-bed (S-B) with the involvement of concurrent processing step facilitating fixing of CoMa on the S-S [4, 6, 7, 9-11, 17]. The CoPr and equipment is must have proviso for [7, 9-11]:

1. Application & distribution of CoMa: for evenly distributing formulation of CoMa over the whole of the available S-S [9, 11],

2. Rotation of the S-B: for continuous renewal of S-S to facilitate deposition of CoMa, uniformly [7, 9, 10],

3. Fixing/curing: to fix CoMa on S-S for realizing even and firm coat [9, 11] and

4. Removal of the process waste: generated process waste call-for their removal to facilitate the realization of a uniform and smooth coat and eliminate impurities from products [7, 9, 10].

Sugar-Coating: S-C, a multi-step process, involves treating the substrate cores successively with coating-medium of sucrose in AS [1-3, 6]. The coating-medium may contain other functional ingredients like fillers, colors, *etc.* [1-3, 6]. Inclusion of other functional ingredients in coating-medium is done depending on stages of coating reached [1, 3, 6]. The duration of S-C processes ranges from a few hours to a few days [1-3, 6]. The S-C process usually out comes in elegant, highly glossed finished products 1, 3, and [6]. The substrate with a deeply convex core and minimal edges, usual tablets, is ideal for suiting the S-C process [1-3, 6]. The process increases substrate weight usually by 50-100 % [1, 3, 6]. In fact, the quality of S-C depends upon operator's skill [1-3, 6]. S-C comprises of sealing, sub-coating, grossing/ smoothing, coloring, polishing and printing steps [1-3, 6]. The build-up of coat in S-C is due to the transference of coating-medium from one substrate to another [1, 3, 6]. Typically, a single-liquid C-F application is be made, basing upon the stages of coating, refer **Table 1** for major components of C-F [1-3, 6]. Applied C-F allows spreading on entire S-B utilizing the mingling capability of candidate equipment [1, 3, 6]. At this time-point drying, operation is usually performed with hot-air for, drying applied C-F [1-3, 6]. The entire cycle then is repeated successively [1, 3, 6].

TABLE 1: COMPOSITION OF C-F USED IN DIFFERENT STEPS OF S-C [1-3, 6]

Seal-coating	Syrup-coating	Sub-coating	Polishing
Methylene chloride	Calcium carbonate	Acacia	Bees wax (white)
Oleic acid	Cane sugar powder	Corn syrup	Carnauba wax (yellow)
Polyethylene glycol	Colorant	Gelatin	Paraffin wax
Propylene glycol	Corn starch	Sugar cane powder	Naphtha
Shellac / Zein	Sub coating powder	Syrup	
Alcohol	Syrup	Purified water	
	Purified water		

Enteric Sugar-coating: Enteric S-C sealcoat is modified to comprise one of the enteric polymers [1-3, 6]. Applied seal coat be in sufficient quantity to pass the enteric test for disintegration [1, 3, 6]. Herein, the subsequent coating steps, as in the conventional S-C process, should be followed, including sub-coating [1-3, 6].

Film Coating: Wearisome and lengthy processing along with skilled-operator's issues are chief amongst the reasons inherited to S-C, refer to **Table 2**, spring-up F-CP [1, 2, 5, 6, 8, 11]. Further, F-C enables substrate's protection from light, temperature and humidity thus improves stability; enables masking the obnoxious taste and/or odor, improving the appearance and facilitating swallowing, thereby improving aestheticism; enables product identity and can tailor release profile of active(s) [4, 6, 8, 12]. The F-C realizing modifications in release profile are modified release F-C, whilst that achieves conventional release are conventional release F-C [1, 6, 12]. Conventional release F-C is for immediate release [4, 12]. The modified release F-C is ether for delayed/ enteric release or extended/ controlled release [4, 8]. Herein film-coat membrane is a barrier controlling/ tailoring drug release, thereby tailors release [4, 6, 8].

TABLE 2: DIFFERENCES BETWEEN F-C AND S-C [2, 6, 11]

Area	Features	F-C	S-C
Tablet	Appearance	- Retain counter of core - Usually dull comparing sugar-coated one	Rounded with high degree of polish - Usually highly shiny
	Logo or break lines	Possible	Not possible
	Other solid dosage form	Coating of multi-particulates is very important in modified release form	Coating feasible with little industrial applicability
	Weight increase (in %)	2-3	30-50
Process	Compliance to Good Manufacturing Practice	High degree of compliance.	Difficulty may arise
	Functional coatings	Easily adaptable for delayed/ sustained/ controlled release	Not usually possible apart from entering coating
	Operator training	Requires easy training	Requires special training
	Process automation	Tends itself to automation	Not possible
	Process stages	Multistage process	Usually multi stage process
	Typical batch coating time	1.5 to 2.0 hours	8 hours, but usually longer

F-CP spraying of film-forming polymer (F-FP) onto the S-S realizes thin coat layer [6, 8]. The C-F comprising F-FP, in liquid state, is sprayed onto portion of moving S-B using one or more spray-gun [4, 6]. Substrates in the S-B are kept moving by their rotation or by fluidization using panning equipment that is conventional, sophisticated, or fluid-bed processor (F-BP); to accomplish automation and efficient drying, to reduce CoPr time, to improve efficiency and accomplish reproducibility of CoPr [4, 6, 8]. Herein CoPr makes usage of C-F comprising film-former, plasticizers, and other excipients (like pigments) in an aqueous or non-aqueous solvent system [1, 6, 8]. The C-F is formulated as a solution or dispersion in either aqueous or non-aqueous solvent [6, 8, 12].

The type of C-F is in turn call-for changes in overall CoPr and processing requirements [1, 2, 6]. In broader term the F-CP can be [2, 6]:

- AF-C process: CoPr that make usage of water as a solvent system for preparing C-F.
- Non-aqueous F-CP: CoPr wherein VOS is the solvent system for preparing C-F.

Non-aqueous F-CP is preferred over the AF-C process in earlier days due to various issues, as discussed in sections 1, 6, and [8]. Latter, on the usage of VOS invoked concerns; following are major one [4, 8]:

1. **Restriction on Venting of Untreated VOS:** Regulatory authorities imposed restrictions on venting VOS vapors into the atmosphere, which it is ecologically detrimental [1, 6]. Further, treatment of gaseous effluent as regulation-mandate is an add-on cost and a costly affair [1, 2, 6].
2. **Compliance of Hazard Proof (Fire and Safety):** VOS are flammable, toxic, and explosive; thus, their usage call-for infrastructure facilitated with hazard proof facilities for fire, explosion, and chemical and hygiene [1, 2, 6].
3. ***Cost***: VOS are relatively costly, and in the future, they are likely to be costlier [1, 6]. They have a higher storage cost [6]. Insurance premium now-day is much higher for facilities using and storing VOS [1, 6].
4. **Residual Solvent:** Quantifying the residual VOS for products of F-C are must [1, 6].

Aforesaid concerns restricted VOS's use to CoPr demanding rapid drying characteristics, especially when [1, 6]:

- CoPr is unable to accommodate the use of AS; for instance, causes like poor drying rate, attained adhesion is unacceptable, instability, and many other [1, 2, 6] and
- CoPr cannot avoid the use of aqua-insoluble F-FP, which is unavailable as a pseudo-latex/ latex system [1, 2, 6].

Process Basis: CoPr involves spraying liquid C-F, using a liquid atomizing/ spraying system, onto the moving S-B [1, 6]. Atomizing/ spraying system is here to atomize the bulk coating fluid as fine droplets and deliver them onto the S-B, kept in moving [6, 11]. Said droplet's delivery is in a state that they retain sufficient fluidity [1, 2, 11]. Their fluidity is sufficient enough to wet S-S, spread out, and coalesces to form film-coat [6, 11]. Drying conditions must enable solvent removal from realized film-coat [1, 11]. From there, the deposition of CoMa, as a thin film of 20-200 µm, around each substrate-cores/ particles (S-C/P) [1, 6]. An excellent and efficient film coat is smooth and uniform, ensures the product's physicochemical stability, and adheres satisfactorily to S-S [1, 6].

Aqueous Film Coating: Increasing level of understandings relating pernicious-nesses of VOS with concomitant worldwide tightening-up of rules on Foods & Drugs, worker's exposal to VOS, and industrial hygiene; is confining their usage [1, 2, 5, 6, 8, 21]. These issues are added with concerns like increasing cost of VOS, today's environment of competitive business, searching for cost-cutting means to improve product's market viability and success, *etc.* [4, 6, 21]. As a substitute & combat said untoward situations, last few decades manifested wide exploitation of AF-C systems based CoPr [4, 6, 21].

Earlier days AF-C processes were seen with skepticism [4, 6, 21]. This is attributed to facts of lengthy-time of CoPr, dull appearance, possible decomposition of active, and troubles during coating [4, 6, 21]. Research conjoined industrial experience has revealed issues of skepticism are of low concerns during practical application [4, 6]. These troubles/ issues/ problems can be addressed thru evaluating reasons scientifically and making substantial advancements in equipment design and process technology [6, 8, 21].

Most troubles/ issues/ problems could be categorized as related to material, process, instrument, and equipment [2, 4, 6, 21]. Following the innovation of latex & pseudo-latex systems, conjoined development and launching of improved equipment designs have been continuously seen broadening the spectrum of AF-C 1, 6, 21 always. In present-day, said innovation and improvement and perfect processing conditions have made it feasible to realize AF-C of fine particulates free from agglomeration and of tablets carrying superdisintegrants without their surface-erosion and core penetration [1, 6, 8]. Advancement in AF-C formulations is aqua enteric-coating systems [1, 6, 21]. Said systems eliminate separate inclusions of pigments, plasticizers, detackifiers, other process additives, and process aids [4, 6, 21].

Aqueous Polymeric Dispersion: These enable aqua-processing of water-insoluble polymers, an important pro [1, 6, 8, 21]. Specialized commercial products of water-insoluble polymers are ammonium methacrylate copolymers and ethyl-cellulose [1, 6, 21]. Their applicability is often encountered in F-C of granules & beads and in modified-release products [1, 2, 4, 6, 8, 21]. However performance of aqua-dispersion depends significantly on conditions set during CoPr [6, 8, 21]. Variable results, like ultimate drug-release feature(s), may often attributing significantly from choice of wrong processing parameters, an incompatible one, and/or from lack of controls on processing parameters; instead from any variableness in aqua-dispersion used [6, 8, 21].

Dry and Wet Coating Processes: Application of coating on the S-S is achievable by a method based on either W-CP or D-CP [2, 6, 7, 9-11, 16, 17]. W-CP is useful primarily to realize a barrier-coat between S-C/P and surrounding environment [6, 10, 16]. Realized barrier-film modify release [10, 16]; overcomes incompatibilities; improves stability and/or aestheticism; and many others [6, 17]. Enhancement of aestheticism is thru odor/ taste/ color masking [6, 10]. Improved stability and shelf-life is thru product's protection from incompatible ingredients, light, atmospheric oxygen, water vapor, *etc* [6, 16]. While modifying release profile, barrier-film controls/ extends/ sustains/ delays the same [6, 17].

The D-CP can achieve tailored surface properties apart from forming a barrier-film [16, 18]. Said tailoring surface attributes of S-C/P is to diverse degree [17, 18]. Amongst tailored attributes of diverse degree, attributes of pharmaceutical interest are solubility, wettability, dispersibility, hydrophilic & hydrophobic properties, sphericity, particle shape, flowability [10, 16, 18, 22], solid phase reactivity, optical activity, electrostatic & magnetic property, sinterability, odor, flavor, color, taste and many others [2, 10, 22].

Wet-coating Processes: The process typically involves spraying C-F as solution or dispersion of CoMa onto S-S, kept in either motion or fluidized state [7, 10, 11, 16,]. After that S-S are wrapped by the film of C-F, in individual-level [6, 10, 11]. Upon evaporation of solvent from the coating-fluid film, a new solid layer is formed [6, 10]. Thereby realizing coating of individual substrate [2, 7, 16].

From a processing point of view, W-CP comprises sequential steps that usually include droplet formation, wetting, spreading, evaporation, and drying [6, 16]. However, there may be variations in processing steps [6, 17]. Said variation depends on nature of CoMa and substrate, processing conditions, and apparatus [6, 16].

W-CP-based coating methods are fluidized-bed coating, pan coating, wet-chemistry-based techniques (interfacial polymerization, coacervation, formaldehyde/ urea deposition, *etc*.), and many more [6, 7, 11, 16, 23].

CoPr following W-CP becomes less preferable as it might leave residual VOS [7], can reason reduced stability [7, 11] and particle agglomeration [6], and may arouse environmental concerns [2, 6, 17]. The fact that environmental concerns are arousing may be from the generation of unwanted waste streams and emissions of VOS [6, 16].

Dry-coating processes: Methodology of D-CP involves directly fixing/ attaching CoMa (as FUFP) onto S-C/P that are relatively larger than CoMaP [10, 16]. Herein the CoMaP, as FUFP, is brought in close proximity with S-C/P thru the involvement of chemical and/or electrical interactions or by thermo-mechanical interactions [10, 13]. Said interaction realizes coating thru the deposition process [10, 16]. Involved deposition processes are mechanical, thermo-mechanical, electrical-electrostatic, or chemical one [13, 17]. The chemical deposition process is gas-phase or vapor-phase one [16, 17]. Thermo-mechanical one realizes embedding & layering of CoMaP thru strong force of mechanical and/or impaction type accompanied by generated heat [2, 10, 13-15, 18]. In some instances, D-CP might ether CoMaP or causes them to get embedded onto surfaces of substrate-particle [10, 16]. Said embedding and/or deformation realize firm coating side-by-side alters surface morphology and topography [6, 10]. Thereby reducing adhesive forces of substrate particle [10, 17]. The D-CP thereby creates engineered particulates are value-added composite particulates with tailored surface attributes [10, 16]. Thereby creating composite particles are with new & exciting applications [6, 17]. Comparing W-CP the D-CP does not call for any binder(s), solvent(s), or even AS [10, 16, 17]. Further, D-CP does not produce effluents like any organic gas, liquid waste stream, *etc* [10, 17]. However, D-CP is a potential alternate to W-CP, environmentally benign, and cost-effective [10, 16]. Over the past few decades, D-CP steadfastly established itself as viable method to realize composite particulates [2, 10, 22].

Particulate Coating Processes: Manufacturing processes of solid dosage forms, in some instances, most inevitable is handling of particulate active(s) that are difficult to formulate [2, 10, 13, 16]. They call for modification of their surface and surface attributes and are made achievable by coating their surfaces with suitable CoMa [10, 13]. Most of CoPr, suiting surface modifications of particulates is W-CP or D-CP that alters their innate properties, physically or chemically [9, 16, 17]. CoPr suiting particulates are also exploited for finding particulate's new and/or worthy functionalities/ properties, as drug carriers/ delivery systems [2, 9, 10, 16, 17].

Hot-Melt Coating Process: This process involves depositing meltable CoMa, in a molten state, onto the S-C/P [10, 13, 16]. When the product is subjected to cooling, solidification is of meltable CoMa realizes coating [17, 24]. Usually, lipid, glycerides, fatty acid, wax with low melting point suit as meltable CoMa [25, 26]. CoPr, herein, involves simple technique and don't require complicated and sophisticated equipment [10, 13, 17]. The CoPr can be performed with spheronizer, conventional pan coater, F-BP, and spouted-bed processor [1, 10, 13, 16]. The CoPr suits moisture labile drugs also for enhancing dissolution rate and aqua-solubility of poorly aqua-soluble drugs [27-29]. Said CoPr finds applicability for a wider range of substrates with diverse particle sizes and for realizing coating in multiple layers [13, 16]. The absence of solvent evaporation phase in this CoPr realizes nonporous & strong particles [10, 24, 27-29].

Spray Congealing: A highly versatile CoPr follows the H-MC method suiting for particles [10, 16]. The CoPr realizes particles having a diameter within the range of 10-3000 μm [16, 17]. Processing of said CoPr involves spraying/ atomizing a hot-melt product containing substrate and CoMa into the air-chamber [10, 13]. The chamber's temperature is to be maintained below the melting point of meltable material(s) or at the cryogenic temperature [13, 16]. Granular particles are realized upon cooling of sprayed/ atomized droplets [6, 16].

H-MC using F-BP: Herein mix of powdered non-meltable materials & meltable CoMa is applied onto starting seeds (starting particles or powdered particulate cores) in an F-BP for realizing coating [2, 30-32]. The meltable CoMa (binder) can apply onto seeds as either molten liquid or solid particles [33]. Procedure wherein particulate meltable CoMa is used that melts during the process to realize coating is termed *melt-in procedure* [13, 30]. CoPr wherein meltable CoMa sprayed on starting seeds, as a molten liquid, is termed *spray-on procedure* [16, 31]. From an industrial application angle, the procedure of melt-in process is simpler one comparing spray-on process, is favored over spray-on process [30, 32].

Hot-melt Granulation and Hot-melt Pelletization: These CoPr calls-for meltable CoMa with high viscosity and small particle size [34, 35]. High viscosity grade meltable CoMa is required for improving the mechanical strength of coating [13, 36]. Smaller particle-sized meltable CoMa are required to prevent the realization of coating with rough surface [16, 36].

Solid Dispersion Hot-melt Fluid-bed Coating: Said CoPr is termed *Tumbling H-MC*, a modified version of H-MC [16]. It is F-BP based system that eliminates the spraying step but realizes coating by solid dispersion [10, 31, 37]. Thus the CoPr does not demand a steam jacket, heating assembly and/or nozzle [2, 10, 13, 16].

Herein the nonpareils (powdered substrate particles) and powder of polyethylene glycol (size 1.41–3.36 mm) were fluidized together [10, 31, 32, 37]. During processing inlet-air temperature is increased [10, 37]. Thus the polyethylene glycol melts and thereby get transferred onto nonpareils [10, 37]. Then typical steps of H-MC are followed, like cooling & congealing [10, 37]. Following this method, multiple coatings can be realized by applying coatings as multiple layers [10, 37]. For this, CoMa with descending rank order of these's melting point be using [10, 37]. Thus is to realizing additive coating layers, is resulting multiple layers of coatings [10, 37].

Turbo-jet Coating Process (Modified): A modified version of Turbo-jet CoPr adapts methodology to coat FUFP and particulates [2, 10]. Alteration is, suspending S-C/P in the spiral of ascending-air [10]. Said spiral air-flow provisos homogeneous distribution of S-C/P as individual particle [10]. The molten CoMa is lipidic one [10]. The same is be dispersing from the bottom of the tank & tangentially to particle-flow [2, 10]. The lipid crystallization inside the nozzle expansion is prevented thru the use of microenvironment surrounding the nozzle outlet [2, 10].

Aerosolized Coating Process: A one-step D-CP involves the principle of co-aerosolization under ambient temperature to realize the coating of particulates [2, 9, 10]. Said aerosolized state realizes clouds of individual particles [10]. Realized cloudy state commences the intimate contact of individual particle clouds [9]. Commencing interactions facilitate attachment of CoMaP (as FUFP) onto S-S, usually a coarse particle [9, 10]. Further, commencing interaction, in some instances, confers engineered attributes to S-S, without any untoward Physico-chemical modification, even of super sensitive active(s) [2, 9, 10].

Herein coating happens in an aerosolized state thru particle-particle interactio; therefore, during processing, there is no exposure of substrate and C-F to heat, mechanical attrition, and solvent [2, 9, 10]. Precise control of processing parameters, herein this CoPr, can realize consistent product performance even from commercial-grade excipients [9].

Mechanical Deposition Processes: A simple D-CP, wherein realizing direct deposition of CoMa onto substrate thru compaction/ compression [2, 10, 22]. It involves compacting/ compressing CoMa around a substrate-core, usually a tablet, using the specialized machine designed/ devised specifically for said purpose [1, 9, 16, 22]. The process is well-suited for labile components to heat, VOS, and moisture; but calls functional or non-functional coating [1, 5, 16, 22]. This CoPr suits tablet substrate-cores for moisture-proofing or for separating incompatible ingredients [2, 5, 12, 16, 22].

Resulted tablets are two/ three-component systems [5, 12]. Two-component systems are tablet-within-a-tablet [1, 16]. Three-component systems are tablet-within-a-tablet-within-a-tablet [5, 16]. Said CoPr may result non-uniform coating due to off-centre positioning of core tablet [5, 16]. The issue is short-out with "one-step dry-coated tablet manufacturing method" design approach [2, 5, 16].

Vacuum Film Coating Process: A novel W-CP based CoPr is designed for coating the tablet substrates using non-aqueous C-F and a specially designed coating pan, a jacketed one inbuilt with baffle [5, 12]. There, an airless spraying nozzle is suitably positioned in the pan for spraying C-F [2, 5]. The pan is jacketed for its heating & cooling operation and also has the facility to get sealed to create vacuum [2, 5]. During processing, the contented air of the pan displaces thru purging of nitrogen until realizing the desired vacuum level [2, 5]. The inbuilt vacuum system is for removing evaporated solvent vapors [2, 5]. Major pros of equipment & process are its design featured with environment safety of highest degree [5, 12].

Photo-Curable Coating Process: Photo-curable coating or photo-curing process is the chemical approach of CoPr devised to coat substrates rapidly at/or below room temperature, very quickly [2, 6, 17]. The CoPr was devised to rapidly convert solvent-less compositions (pre-polymers or monomer in liquid form, specifically formulated one) into solid film through the photo-curing process [13, 17]. The photo-curing process involves irradiating the product with ultraviolet or visible light [2, 6, 13, 17].

The radiant energy of irradiated light generates free radical that initiate polymerization reaction, which realizes polymerization of functionalized liquid monomers or pre-polymers [2, 13, 17]. The initiated polymerization reaction of liquid monomers or pre-polymers realizes their polymerization that causes their transition to solid film [6, 17]. Ultraviolet light is much energetic thus is more effective to rupture chemical bonds and initiate & realizing polymerization, comparing visible light [13, 17]. Thus, ultraviolet light-mediated photo-curing is preferred one [6, 17]. Contrary visible light-mediated photo-curing process is safe, easy to handle attractive features for receive attention [2, 13, 17].

Heat Dry Coating Process: Inclusion of plasticizer commonly practiced in D-CP [2, 10, 17]. Said practice un-suits F-FP having low glass transition temperature (*Tg*) [10, 17]. A high level of plasticizer in C-F causes pre-plasticization [10, 17]. Combating said issues done with devised heat-dry CoPr that uses heat only to realize coating while abandons plasticizer usage [2, 10, 17].

Methodology, herein, make usage of spheronizer built with screw powder feeder and infrared lamp positioned at top, a heating source [2, 10, 17]. The powder feeder is to spread CoMaP continuously onto S-S, during processing [10, 17]. Spheronization conjoined with heat realizes the melting of CoMaP and their spreading on S-S [10, 17]. Herein heat-based adhesion realizes curing of spread coat [2, 10, 17].

Eudragit® E PO is a CoMa that suits this process [10, 17]. The major challenge overcome in this CoPr are getting a smooth, uniform, and thick coating, only thru heat-based adhesion [2, 10, 17].

Plasticizer Dry Coating Process: These are the CoPr based on D-CP that makes use of plasticizer(s) for realizing coating [6, 10]. Said CoPr are suitable for instances that call for F-FP of low Tg or where protecting actives from getting damaged during their processing at high temperature is essential [2, 6].

Upon spreading powdered CoMa onto S-S, the plasticizer is sprayed simultaneously from a separate spraying nozzle [6, 10]. Thus then, sprayed plasticizer wets S-S and CoMaP [10]. This in-turn promotes adhesion of CoMaP onto S-S [2, 6]. Then the realized coated substrates were cured for a preset time above *Tg* of F-FP, to realize continuous film [6, 10]. The substrates suiting said CoPr are particles, tablets, FUFP, and many others [2, 6, 10].

Electrical-Electrostatic Coating Processes: Involved technology in these CoPr ensue electrostatic deposition of charged CoMaP onto surfaces of charged S-C/P [2, 17, 38]. Processing involves applying a strong electrostatic charge onto the S-C/P, to make their surfaces electrically conductive [5, 16]. Then CoMaP, which comprises oppositely-charged conductive ions, is sprayed [5, 17]. Following this product is subjected to curing thru heating it suitably until applied CoMaP fuses to form film-coat [1, 2, 38].

An optimized CoPr can realize coated substrate having excellent coating uniformity [6, 16, 17]. Resulted in coating is smooth-surfaced continuous film [2, 6, 17]. Realized F-C releases drug significantly similar to that of S-C/P [12, 38]. Applicability of said CoPr finds to realize coating of powders, capsules, tablets and living cells [1, 2, 12].

Plasticizer electrostatic coating: Feature of these CoPr is herein coating is realized by companioned use of plasticizer, heat, and electrostatic-field [10, 16]. In said CoPr, including a suitable liquid plasticizer in enough quantity reduces *Tg* of polymeric CoMa and increases substrate's electrical conductivity [17, 38]. Herein this CoPr plasticizer's inclusion promotes adhesion of CoMaP, encourages film formation, lowers-down curing temperature, and shortens processing time [38, 39]. This CoPr is called-upon when processing under lower curing temperature is warranted [2, 5, 12, 38].

Electrostatic Fluidized-bed Coating: Herein, this CoPr, coating is realized in F-BP using electrostatic-field [17, 40]. During processing, the powder blend comprising CoMaP and S-C/P is kept in a fluidized state by passing fluidizing dry air through the porous base-plate of F-BP [10, 16]. The fluidized powder particles were subjected to electrostatic field [16, 17]. Fluidization companioned with repulsive effects of charged particulates creates clouds of charged particles above the S-B [16, 17]. Unheated and/or heated charged particulates make several passes through said charged-particle cloud, thus realizing coating [17, 40]. Said CoPr does not suit substrates that are elongated or pass axially or vertically across through S-B and/or charged-powder cloud [2, 16, 17].

Thermo-Mechanical Deposition Processes: This CoPr comprises a group of processes that realizes coating thru the use of thermal energy and/or impaction force or by application of ambient shearing stress [1, 10, 13, 17]. Herein these CoPr applied ambient mechanical/ impaction force companioned with generated heat realizes embedding & layering of CoMaP onto S-S [10, 14, 15]. In some exempla, coating of S-C/P realizes thru deformation of

CoMaP along with embedding of them onto S-S [10, 16]. In several instances, said embedding and/or deformation realize much stronger coating [10, 16]. Thereby these CoPr realizes an engineered particle with complete dissimilar functionality & surface attributes [2, 16]. These CoPr are resulting value-added composite particulates with tailored properties [10, 16]. Thus these are value-addition CoPr, as confer composite new & exciting applications to S-C/P [10, 16]. These CoPr are exploited thus in instances requiring significant changes in functionality and/or properties of S-C/P [10, 16].

Mechanical Dry Coating Process: These are the group of D-CP involving high-shear & high-energy interactions amongst the particle-device wall and/or particle-particle for realizing coating [9, 10, 16, 17, 22]. These interactions aims in realize coating thru fixing of CoMaP on surfaces of S-C/P [16, 41]. In some instances of these CoPr physico-chemical binding and mechano-chemical interaction might contributes fixing/ adhesion [10, 16, 42]. Thereby these processes modify S-S attributes [9, 16]. These CoPr are safer, faster, simpler, straight forward, single-stepped, potentially cheaper, and environment-friendly [2, 9, 10, 16].

Important CoPr of this group are Hybridization, Magnetically assisted impaction coating, Mechanofusion, Theta composing, and many more [10, 13, 16, 17, 42]. These are single-stepped straight forward process wherein load powdered blend of S-C/P and CoMaP into processing vessel of machine, then turns it ON [10, 16]. Operate the machine for preset time and speed, and then turn it OFF [16]. Then unload coated powders [2, 10].

Operator's skill is of minimal concern in these groups of CoPr [10, 16]. Further, these CoPr bears ability for designing them to have continuous processing [10, 16].

Mechanofusion®: Herein embedding is realizing thru mechano-chemical-reaction that merges CoMaP on substrate particles by inputting mechanical energy of high degree [10, 13, 16, 17, 18, 43]. During processing, materials in a mechanofusion reactor are subjected to compression & simultaneous stress by intense shear [10, 16]. Thus, composite particulates with differing properties and controlled particle size & shape [16, 18, 41, 42, 44, 45]. The process is arguably grabbing much attention, specifically in the pharmaceutical-field [41, 44, 45].

Hybridization®: A batch-operated D-CP makes use of a Hybridizer® machine for realizing particulate coating [16, 42]. It enables the embedding of the CoMaP onto S-S very fast, within 1-5 minutes [10, 16]. The Jacketing facility facilitates control of local build-up temperature [2, 10, 17].

Herein employed high impaction force induces particles of CoMaP and substrates to undergo legion collisions and build-up temperature [13, 16, 17]. Said collisions realize breaking-up of fine agglomerate(s) and coating thru embedding concomitant filming of CoMa onto S-S [2, 10, 16]. The embedding and filming are aided by the built-up temperature that aids in curing the coat [13, 16, 17].

Theta-composing: A novel D-CP to coat particulate substrate using Theta-composer® [13, 17, 42]. Herein this CoPr, the powder blend comprising CoMaP and the particulate substrate, is subjected to strong shear stress with concomitant compaction force while their pushing up through a narrow gap within the processing chamber of the machine [2, 42]. The sequential formation of the narrow gap with concurrent attrition results in peculiar rotation of the inner elliptical rotor and rotating outer elliptical vessel [16, 42]. The inner rotor rotates very fast in an anti-clockwise direction inside the slowly rotating vessel in clockwise direction [16, 17, 42].

Magnetically Assisted Impaction CoPr: A D-CP-based soft CoPr wherein coating is realized thru mechanical impaction of oscillating magnetic beads [10, 13, 16, 17]. The process warranted for handling thermo-labile, easily deformable, and relatively soft CoMa and substrate [1, 5, 42]. The coating is realized with miser degradation of components and miser deformation in particle shape & size [1, 2, 5]. Herein this CoPr, generated oscillating magnetic field, surrounding processing vessel, agitates magnetic particles [10, 16]. Magnetic particles while agitating causes collisions among magnetic particles & CoMa/ substrate particles, CoMaP & substrate particles, and substrate particles/ CoMa & vessel wall [10, 17]. Concomitant occurrence of said collisions causes peening of CoMaP onto S-S, thus realizing coating [2, 16, 42].

F-Bp Based Processes: The F-BP-based CoPr improved and novel processes, alternative to pan-CoPr [2, 17]. These CoPr bear potential pros being able to effectuate the most effectual drying of diverse products compared to any other existing CoPr [2, 17]. Thus, these CoPr are particularly popular for coating multi-particulates, pellets, fine particles, and microencapsulation [2, 17]. The use of these CoPr is uncommon for coating of tablets, especially in large scale, as associated high process attrition causes tablets to break, chip, and abrade out [2, 17].

F-BP based CoPr having applicability in pharmaceutical fields are [2, 17]:

1. Top-spray CoPr,
2. Bottom-spray (Wurster) CoPr,
3. Tangential-spray (Rotary) CoPr,
4. Rotating (centrifugal) fluidized-bed CoPr,
5. Supercell® coating process and
6. Huttlin Kugel coater-based CoPr.

The C-F, as liquid, is continuously applied through spray nozzle(s) located at the top of the chamber (in top-spray CoPr), the bottom of the chamber (in Wurster CoPr), or tangentially (in Rotary CoPr) onto the fluidized S-B [2, 17]. Amongst the said CoPr selection of suitable/ efficient one is often decided by nature & intended functionality to be realized from the coating (refer **Table 3**) for example [17]:

a) Films produced by CoPr using top-spray F-BP are not of uniform thickness [2, 17]. Thus favored in instances where critical control of drug release rate is not desirous, like taste masking and barrier films [17]. However, suit in hot-melt CoPr [17].

b) CoPr using Wurster F-BP is for conferring sustained/ controlled/ extended/ enteric/ delayed release property to a wide variety of multi-particulates and pellets [17]. Said CoPr also suits drug layering with dose in low-to-medium range [2, 17].

c) CoPr that use Rotary F-BP has applicability in modified-release (controlled/ sustained/ extended/ enteric/ delayed-release) and F-C of wide-ranged multi-particulate products [17]. These CoPr are ideally suited for drug layering having dose in the medium-to-high range [17]. It finds usefulness also in the extrusion & spheronizing process to get pellets with modified-release attributes [2, 17].

Rotating (Centrifugal) Fluidized-bed Process: W-CP-based soft CoPr employs F-BP operating with rotating fluidization principle [2, 17]. They find applicability for delicate and soft particulate substrates [2, 17]. High rotational speed mediated centrifugal force conjoined inwardly directed radial-air-flow fluidizes the revolving S-B [2, 17]. Onto the fluidized S-B, a binary-fluid sprayer sprays C-F fluid onto them to realize coating [2, 17]. Excellent mixing is add-on pro of the CoPr thus achieving nice coating and operating in a continuous mode [2, 17].

TABLE 3: DISADVANTAGES, ADVANTAGES AND APPLICATIONS OF F-BP BASED COPR [2, 17]

Processing method	Disadvantages	Advantages	Applications
Top spray CoPr	Limited applications	Simple setup Large batch size Easy access to the nozzle	For aesthetic and enteric coating Not recommended for tablet coating or sustained-release products
Wurster CoPr	Tedious setup Impossible to access the nozzle during the process Tallest fluid-bed machine for particle coating	Moderate batch size Uniform and reproducible film characteristics Wider application range	Sustained-release, enteric coating, aesthetic coating, and layering Not recommended for tablet coating
Rotary CoPr	Mechanical stress on the product.	Simple setup Nozzle access during the process High spray rate Shorter machine	Very suitable for sustained release, enteric coating, layering Not recommended for tablets and friable products.

Supercell® Coating Process: Using conventional coaters in CoPr, in most instances, outcomes inaccurate/ non-homogenous coat [1, 2]. CoPr based on said coaters while coating tablet substrates causes their grounding off and filling in of their integration [2, 5]. Further, said methodologies of CoPr are unsuitable for tablets with flat & other odd shapes, as they fail to consistently coat their corners/ edges/ faces [1, 2]. Thus, in a nutshell, said methodologies are unsuitable for modified release coating, friable, extremely hygroscopic, and flat & other odd-shaped tablets [2, 5]. Solutions to talk over issues are made with devised "Supercell coating technology®" [1, 2]. It's a novel and gentle F-BP (Wurster type) based W-CP to realize coating of hygroscopic/ friable/ flat & other odd-shaped tablets [1, 2, 5].

Gas-Phase Deposition/ Coating Process: These comprise a group of D-CP that are based on Supercritical fluid (SCF) and aerosol flow reactor [2, 10, 16, 46-48]. CoPr of this group suits FUFP and particulate substrates [10, 16]. Herein C-F is prepared using SCF as solvent/ medium for carrying CoMa [9, 10, 46]. Basically, strategies of CoPr following gas-phase deposition are complex, relatively expensive, and challenging during scale-up [10, 47, 48]. SCF-based CoPr with applicability in pharmaceutical fields are based on [16, 17].

- **a.** Rapid expansion of SCF [49].
- **b.** SCF anti-solvent [49].
- **c.** Gas anti-solvent [50].
- **d.** Gas-saturated solution [49, 50, 51].

Rapid Expansion of SCF Based CoPr: Rapid expansion of SCF companioned rapid supersaturation is the underlying principle of this approach [2, 10, 46, 47]. Rapid expansion of SCF consequences a rapid change in density along with solvent power of SCF [9, 10, 48, 49]. This thus translates into rapid crystallization rates, resulting in fast precipitation of CoMa thereby realizing coating [10, 48].

SCF Anti-solvent Based CoPr: CoPr has synonym 'Aerosol solvent extraction systems' [9, 10]. 'Solution-enhanced dispersion by supercritical fluids' is its reported variant [10, 48, 49]. The design approach of the CoPr is for handling CoMa and substrate that are soluble in VOS; whilst they are insoluble in SCF and solution of VOS and SCF [9, 10, 17]. However, the SCF is miscible with VOS [2, 10, 16].

Gas Anti-solvent Based CoPr: The design approach of the CoPr is to handle substrate and CoMa that are soluble in SCF but insoluble in inert gas [16, 17]. The process basis herein is an interacting solution of substrate and CoMa in SCF with an inert-gas [10, 50]. Used inert gas should be non-solvent for substrate and CoMa but miscible with SCF [10, 50]. Rapid mixing of SCF solution with inert gas during the interaction phase lowers SCF's solvent power and causes substrate and CoMa to precipitate [10, 16]. Said rapid precipitation realizes deposition of CoMa on S-S [10, 17]. During processing, the inert gas may be kept at a pressure that is elevated or par to the pressure of SCF solution [2, 16, 17].

Gas-saturated Solution Based CoPr: Basis of CoPr, herein, involves mixing of polymeric CoMa in SCF and substrate particles at elevated pressure [10, 49, 51]. During processing, penetration is of SCF into polymeric CoMa, causing swelling of CoMa [51, 52]. The ensued mix is then heated at a temperature higher than *Tg* of polymeric CoMa, for liquefying polymer [10, 16]. Then the pressure is released [10, 17]. As when pressure is released CoMa gets deposited on S-S [9, 10]. The CoPr suits substrate and CoMa that may be insoluble in SCF of choice [2, 16, 17].

Vapor-Phase Deposition/ Coating Process: These comprise a group of CoPr; up-roused novel D-CP for FUFP, particulates, and solid dosage forms; wherein electro-deposition is the underlying principle for realizing coating [2, 10, 53, 54]. Said electro-deposition involves generating vapor of desired CoMa thru electro-dispersion and then permeating generated vapor onto S-S, for realizing deposition of CoMa on S-S [55, 56]. The CoMa, used herein, in most cases is powder but the liquid is in minor instances [16, 17]. CoPr can realize uniform and durable coating of controlled thickness on particulates at the individual level, which is slow-dissolving [10, 20]. The terminal product has orchestrated functionalities and surface and surface-topography [10, 53, 55-58]. Major cons associated with CoPr based on this strategy are involvement of vacuum creation that requires huge investments arising from immense overhead costs, in process equipment [2, 10, 16]. CoPr, herein, comprises of dispersal-phase & maintenance-phase [10, 16]. Dispersal-phase realizes electro-dispersion, which is the process of dispersing powder or liquid with thru application of electrostatic-field [20, 53, 57, 58]. The electro-dispersion makes usage of an intense electric-field that realizes dispersal of a part of the static-bed, comprising substrate & CoMa, into a stable cloud [9, 57]. Said cloud is of fast-moving particles herein termed dispersed phase [53, 57]. A dynamic equilibrium is maintained between static and dispersed-phase during the maintenance phase; herein, electro-deposition effected [2, 10, 16, 57, 58].

The involved methodology of these CoPr is as follows [16, 17].

Chemical vapor deposition (CVD) [10].

- ❖ Plasma enhanced CVD [10].
- ❖ Initiated CVD [10, 54].
- ❖ Fluidized-bed CVD [10]

Atomic/ molecular layer deposition (AMLD) [10, 58, 59]. Both AMLD and CVD realize F-C using gaseous reagents [2, 46, 57-60]. Even though AMLD is relatively expensive which often requires toxic precursors but can realize effective fine coating with a fineness of a few atomic layers only [16, 61].

Fluidized-bed CVD CoPr: The state-of-art technology combines CVD and fluidized-bed process for realizing coating [60]. CVD on fluidized S-B is an efficient technique to functionalize & to deposit CoMa on individual substrate particles [60]. CoPr herein involves two steps [60]. One process step aims to deposit CoMa on substrate by itself while the other aims to suspend CoMaP in deposition zone [60]. The suspending step is resulted most often by upwardly flowing fluidizing gas through powder-bed [2, 60].

Resodyn Acoustic Coating Process: D-CP realizes particulate coating following "Resonant Acoustic Technology®" using "Resodyn Acoustic Mixer®" [2, 16, 17, 62-64]. Said mixer is a sophisticated benchtop mixer [16, 62]. Embedded state-of-art technology creates a low-frequency, high-intensity shear field within the mixer's processing vessel [16, 17, 63]. During processing, generated acoustic energy realizes the coating of particulate substrates as they collide with each other [16, 62, 64]. The coating is ensured in very short time span [16, 17].

CONCLUSION: W-CP and D-CP can be realized by modifying the surface, surface topography, and surface attributes of solid dosage form and FUFP thru coating. In major instances, W-CP suits CoMa that is liquid or solid, whilst D-CP suits solid CoMa. The D-CP fits for coating of FUFP, whereas W-CP is unfit for coating of FUFP. Residual VOS and handling of environmental issues along with unwanted waste streams are major concerns of VOS-based W-CP. In this regard, D-CP is novel alternatives.

D-CP is a one-step straightforward CoPr, that bears minimal concern to process deviations invoking from operator skills. Further, some of them can be designed for continuous operation. Most of D-CP inherit scale-up potentiality of a higher-degree. CoPr based on D-CP can realize composite products having novel/ new functionality and/or surface attributes.

Realization and reproduction of coating uniformity in D-CP, particle size of CoMa, and substrate play crucially. Mechanical compaction-based D-CP is unfit for elastic CoMa and substrates. The possible realization of composite products from plastic CoMa and substrates is possible through their mechanical interlocking of them.

Specialized W-CP and D-CP involve technologies that make use of ambient conditions like elevated temperature, high pressures, high shear and/or solvents. Vapor-phase and gas-phase deposition processes involve vacuum creation and/or pressure generation. CoPr based on these processes mostly requires immense capital investment & huge overhead costs, in-process equipment. Strategies like CVD, plasma-enhanced CVD, AMLD, and SCF-based CoPr are complex, expensive, and challenging scale-ups. Among the W-CP aqueous F-CP be considering the first option for realizing coating of the solid orals, regardless of conventional release and modified-release applications. It's hoped that D-CP will become robust upon optimization & validation. These CoPr thus may have a high degree of potentiality suiting to manufacturing line-up. Finally, for finding the pharmaceutical applicability of W-CP and D-CP, their scalability potential for larger and pilot manufacturing-scale batches calls for an immense and robust investigation.

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