



HU000028781T2

(19) **HU****MAGYARORSZÁG**
Szellemi Tulajdon Nemzeti Hivatala(11) Lajstromszám: **E 028 781**(13) **T2****EURÓPAI SZABADALOM**
SZÖVEGÉNEK FORDÍTÁSA(21) Magyar ügyszám: **E 09 807687**(22) A bejelentés napja: **2009. 12. 01.**(51) Int. Cl.: **B01J 2/00** (2006.01)**B01J 2/16** (2006.01)

(96) Az európai bejelentés bejelentési száma:

EP 20090807687

(86) A nemzetközi (PCT) bejelentési szám:

PCT/SI 09/000065

(97) Az európai bejelentés közzétételi adatai:

EP 2382036 A2 **2010. 06. 10.**

(87) A nemzetközi közzétételi szám:

WO 10065000

(97) Az európai szabadalom megadásának meghirdetési adatai:

EP 2382036 B1 **2016. 04. 27.**

(30) Elsőbbségi adatok:

200800295 **2008. 12. 01.** **SI**

(73) Jogosult(ak):

BRINOX, d.o.o., 1215 Medvode (SI)

(72) Feltaláló(k):

SAVIC, Slavislav, 1000 Ljubljana (SI)
GREGORKA, Matija, 1235 Radomlje (SI)
Dreu, Rok, 2380 Slovenj Gradec (SI)
SRCIC, Stanko, 1000 Ljubljana (SI)
SIBANC, Rok, Velenje 3320 (SI)
LUSTRIK, Matevz, 1215 Medvode (SI)
ZUN, Iztok, 1000 Ljubljana (SI)
Perpar, Matjaz, 1351 Dragomer (SI)

(74) Képviselő:

PINTZ ÉS TÁRSAI Szabadalmi, Védjegy és
Jogi Iroda Kft., Budapest

(54)

Feldolgozó készülék részecskék bevonására

Az európai szabadalom ellen, megadásának az Európai Szabadalmi Közlönyben való meghirdetésétől számított kilenc hónapon belül, felszólalást lehet benyújtani az Európai Szabadalmi Hivatalnál. (Európai Szabadalmi Egyezmény 99. cikk(1))

A fordítást a szabadalmas az 1995. évi XXXIII. törvény 84/H. §-a szerint nyújtotta be. A fordítás tartalmi helyességét a Szellemi Tulajdon Nemzeti Hivatala nem vizsgálta.



(11) **EP 2 382 036 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention
of the grant of the patent:
27.04.2016 Bulletin 2016/17

(21) Application number: **09807687.0**

(22) Date of filing: **01.12.2009**

(51) Int Cl.:
B01J 2/00 (2006.01) B01J 2/16 (2006.01)

(86) International application number:
PCT/SI2009/000065

(87) International publication number:
WO 2010/065000 (10.06.2010 Gazette 2010/23)

(54) **A PROCESS DEVICE FOR COATING PARTICLES**

PROZESSVORRICHTUNG ZUR BESCHICHTUNG VON PARTIKELN

DISPOSITIF DE TRAITEMENT POUR L'ENDUCTION DE PARTICULES

(84) Designated Contracting States:
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL
PT RO SE SI SK SM TR**

(30) Priority: **01.12.2008 SI 200800295**

(43) Date of publication of application:
02.11.2011 Bulletin 2011/44

(73) Proprietor: **BRINOX, d.o.o.**
1215 Medvode (SI)

(72) Inventors:

- **SAVIC, Slavislav**
1000 Ljubljana (SI)
- **GREGORKA, Matija**
1235 Radomlje (SI)
- **DREU, Rok**
2380 Slovenj Gradec (SI)
- **SRCIC, Stanko**
1000 Ljubljana (SI)
- **SIBANC, Rok**
Velenje 3320 (SI)
- **LUSTRIK, Matevz**
1215 Medvode (SI)
- **ZUN, Iztok**
1000 Ljubljana (SI)

• **Perpar, Matjaz**
1351 Dragomer (SI)

(74) Representative: **Pipan, Marjan**
Kotnikova 5
1000 Ljubljana (SI)

(56) References cited:

EP-A1- 1 295 633	EP-A1- 1 402 941
WO-A1-95/20432	GB-A- 2 187 972
US-A1- 2005 069 707	US-A1- 2006 130 748
US-B1- 6 579 365	

• **TANG ET AL: "Drying efficiency and particle movement in coating-Impact on particle agglomeration and yield", INTERNATIONAL JOURNAL OF PHARMACEUTICS, ELSEVIER BV, NL, vol. 350, no. 1-2, 28 January 2008 (2008-01-28), pages 172-180, XP022435773, ISSN: 0378-5173, DOI: DOI:10.1016/J.IJPHARM.2007.08.047**

• **HENG P W S ET AL: "Use of swirling airflow to enhance coating performance of bottom spray fluid bed coaters", INTERNATIONAL JOURNAL OF PHARMACEUTICS, ELSEVIER BV, NL, vol. 327, no. 1-2, 11 December 2006 (2006-12-11), pages 26-35, XP025113103, ISSN: 0378-5173, DOI: DOI:10.1016/J.IJPHARM.2006.07.025 [retrieved on 2006-12-11]**

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Description

[0001] The subject of the invention is a process device for coating particles that falls within the field of chemical and pharmaceutical technology. It represents an improvement on the process equipment for coating particles by spraying from the bottom and works on the principle of fluidization technology. More specifically, the invention relates to the design solutions of the essential elements of the coating device that improve the quality of the coating. The invention belongs to the A61J3/06 class of international patent classification.

[0002] The technical problem successfully addressed by the submitted invention is to effectively provide a narrow distribution of coat thickness from particle to particle even when coating small particles (50 - 300 microns). Coating particles with functional coat is a common technological process in the chemical and pharmaceutical industries. Especially in the case of pharmaceutical products, which show a prolonged release of medicinal active ingredients for which the dissolution rate of the medicinal active ingredient is defined by the diffusion through the coat, the coating thickness and the uniformity of the coating thickness from particle to particle is of crucial importance for achieving the planned active ingredient release kinetics. Providing narrow coating thickness distribution from particle to particle by exploiting the construction of the processing equipment is also important in the case where with the particle coating protects them from atmospheric, physiological, or other environments. In this case we can apply less substance to the particles in order to achieve functional coating; while at the same time reduce the time and energy consumption for the technological process. The problem is also in coating smaller particles (50 - 300 microns), which due to their low weight and inertia are more prone to the undesired agglomeration process. Independent and coated fine particles are important in the pharmaceutical and chemical technology due to the increased specific surface area as compared to larger particles. In the pharmaceutical industry, in the case of coating particles with dispersion containing a medicinal active ingredient it is particularly important to maximize the coating efficiency, which is usually the function of the position and orientation of the nozzles and volume fraction of particles around the spray nozzle.

[0003] Known process devices for coating particles, which operate on the principle of fluidization technology, are appropriate technology for coating particles in the size range from 50 microns to 6 mm.

[0004] Process devices for coating particles acting on the principle of fluidization technology, are roughly divided into devices that spray from top, devices with tangential spraying, and devices that spray from bottom.

[0005] Process devices that spray from top are primarily intended for granulation, while in the case of coating the effect of spray drying is more strongly expressed, due to the need to obtain small droplets of dispersion for coating. If we lower the position of the nozzle, the path of the droplets to the particles does reduce, but the opposite flow of air for fluidization and the compressed air from the two-channel nozzle, results in interference to the particle flow pattern and excessive wetting of the mesh at the bottom of the device.

[0006] Process devices with tangential dispersion in combination with a rotor disc are problematic in terms of close contact of particles in the flow pattern and the relatively small heat flux through the processing chamber, resulting in facilitation of agglomeration of small particles that we want to coat.

[0007] In the case of a process device with bottom spraying, the distance between the spraying nozzle and the particles is short, and the nozzle is oriented in the direction of fluidizing airflow and flow of the particles.

[0008] The derivative of bottom spray process device is known, which contains, the so called inner or draft tube, positioned centrally above the nozzle and the distribution plate. With the inclusion of the draft tube, the processing chamber acquires the nature of a device that operates on the principle of fluidization technology with circular movement (circulating fluid bed), which is named, after its inventor, as the Wurster chamber. The advantage of this device is that the area of particle coating is separated from the drying area, furthermore, due to the pneumatic transport of particles within the draft tube and in vicinity of the nozzle, the speed of the particles is relatively large (0.7 - 2 m/s), which reduces the possibility of agglomeration of particles. The shape of the particle movement is circular and repetitive, which represents a form of controlled movement. The problems with coating using a classic Wurster chamber are reflected in the non-uniformity of the film coatings within the particle population, which is a consequence of the particle mutual shading effect of in the area of spraying of the coating dispersion, the effect of the 'dead spot' in the flow of particles, and the result of disproportionate acceleration of the smallest and largest particles in the particle population we are coating. The volume fraction of pellets in the coating area, and with it the degree of the particle mutual shading effect depends on the flow of the fluidization medium (air or inert gas), and on the set height of the draft tube. If we coat a particle population with a broader size distribution, the larger particles have a thicker coat at the end of the coating than those, which are smaller. This happens because of the nature of vertical transport of particles, since smaller particles have a better relationship between their cross-section and mass than the larger particles. Consequently, smaller particles will gain greater speed than the larger particles and rise higher after passing the draft tube, resulting in an increased time for rising and falling of smaller particles in the processing chamber as opposed to larger particles. In the overall coating time this fact expresses in the dependence of the number of particle crossings through the draft tube from the initial particle size.

[0009] Furthermore, due to the relatively high density of particles at the inner wall of the draft tube and with it, inter-particle collisions, the agglomeration of particles can be expressed in the size range of 50 to 300 microns, despite of

relatively fast drying, due to the large local flow of heated air.

[0010] Known solutions to the Wurster device problems are discussed in continuation.

[0011] It is known that the swirl flow within a tube improves the heat transfer in a two-phase flow as a result of a longer fluid path (and thus the time of contact with particles) at a distance in the axial flow direction (Algifri AH et al, Heat-transfer and turbulent decaying swirl flow in a circular pipe, International Journal of Heat and Mass Transfer, 1988, 31 (8): 1563-1568.). Due to the better heat transfer, it is expected that the problem with coating smaller particles is reduced.

[0012] The article on improving thermal efficiency in drying in a device that does not have the structure of a Wurster device, but it operates on the principle of fluidization technology and has a swirl flow generator in the form of a vane. With the inclusion of the swirl flow in this device, 5 to 25% improvement in terms of drying speed and specific drying speed was achieved, and up to 38% improvement of drying effectiveness (M. Özbey, MS Söylemez, Energy Conversion and Management, 46, (2005), 1495 - 1512).

By including the swirl flow in the Wurster chamber, the width of the coating thickness distribution is reduced in the population of coated particles with a narrow distribution size by about 43% (PWS Heng et al., International Journal of Pharmaceutics, 327, 2006, 26 -35). When compared with the conventional Wurster chamber, the occurrence of agglomeration is also substantially reduced (ESK Tang et al., International Journal of Pharmaceutics, 350, 2008, 172-180), while the coating efficiency when compared with a conventional chamber for a given derivative is somewhat poorer.

In the U.S. Patent document no. 5,718,764 (swirl flow) the solution of the Aeromatic Company is described, which used and protected the swirl flow generator within the device for coating with spraying from bottom (Wurster chamber). In their examples, the latter demonstrated a defined improvement in the uniformity of film coatings, assessed indirectly through the effect of colour dissolution from a coated core through a more or less continuous insoluble coating. Given that the effect of swirl flow on heat transfer was already known (Algifri AH et al, Heat-transfer and turbulent decaying swirl flow in a circular pipe, International Journal of Heat and Mass Transfer, 1988 , 31 (8): 1563-1568.), in the present document an own construction for achieving swirl airflow is described.

[0013] In the U.S. Patent document no. 6,492,024 B1 (granulation with swirl flow) the process of granulation in combination with a device for coating with a swirl flow generator from patent no. U.S. 5,718,764 is described.

There is a constant need for particle coating process equipment, which will when compared to the existing functional-structural solutions of the Wurster device ensure an effective particle coating process. The result of which will be a population of coated particles with a comparatively narrower distribution of film coating thickness, less agglomeration of particles, increased coating yield, and lower dependence of the coating thickness to the initial particle diameter in a population of particles with a wider initial distribution of particle sizes.

In the presented invention, we have solved the technical problem of reducing the width in distribution of film coating thickness, of reducing the agglomeration of particles, and increasing the coating yield, with an innovative construction of the swirl airflow generator (Fig. 5), which gives a different profile of air speed at entry into the bottom part of the draft tube as is the characteristic of currently known implementations of swirl flow. The reduction of the RSD of the film coating thickness is also greater in comparison with the known implementation, namely by 56 to 62% reduction against the conventional Wurster chamber, compared to 43% reduction against the conventional Wurster chamber (PWS Heng et al., International Journal of Pharmaceutics, 327, 2006, 26-35). We have also reduced the problem of the dependence of the film coating thickness to the initial particle size we are coating with an innovative design.

[0014] The invention will be further explained based on the implementation examples and appurtenant figures, each of which shows:

- Figure 1 The schematic cross section of the process device for coating particles according to the invention.
- Figure 2 A detail of the process device in the vicinity of the swirl flow generator.
- Figure 3, 4, 5 The geometry of the swirl flow generator (4).
- Figure 6, 7 A schematic implementation of a semi-industrial or industrial device for coating particles according to the invention.

[0015] Figure 1 presents a schematic cross section of process device for coating particles consisting of the outer wall (1), which at the bottom of the device has the shape of a cylinder, or truncated cone. At the bottom of process device, where the particles we are coating dwell during the process, is the swirl flow generator (4) with the perforated plate (3) in the outer area, by the wall (1) of the device. The perforated plate (3), which from the floor plan is ring shaped, can be straight or curved in the cross section. Just above the perforated plate (3) and the swirl flow generator (4) is woven metal mesh with row gaps of 20 to 40 microns. The coating dispersion spraying nozzle (6), which can be a single or multiphase type, is introduced centrally through swirl flow generator (4). According to figure 1, the two-channel nozzle (6) for spraying has conduit (7) for coating dispersion, and conduit (8) for compressed air. Due to the acceleration of compressed air at the end of nozzle (6) for spraying and consequently the resulting shear stresses, a cloud (10) of dispersion droplets for coating is formed in the form of a full or hollow cone, which represents a narrower area of particle coating. Below the perforated plate (3) and swirl flow generator (4), the wall (2) of the process device forms space in which we supply

medium (9) (usually air) for fluidization and it is in this part of the device that is in positive pressure with regard to the area of the process device above the swirl flow generator (4) and perforated plate (3). The draft tube (5) is clamped centrally in the processing chamber in the form of a tube at such a height that it forms a gap (usually from 5 to 25 mm in size) with the swirl flow generator (4) with the perforated plate (3). Particles are in the serial implementation of the process device positioned in the form of a layer around the draft tube (5) above the flat or curved perforated plate (3). It depends on the number of and arrangement of orifices in the outer perforated plate (3), the flow of medium (9) for fluidization, the size and density of particles whether that layer is in the form of a static, loose bed or fluidized state. The centrally located swirl flow generator (4) for medium (air) forms in the area of draft tube (5) horizontal cross-section a swirling flow (17) of air with an axial and tangential component. The swirling flow (17) of air creates a negative pressure in the area of the gap between the draft tube (5) and the outer perforated plate (3) due to the large local variations in the air speed, which results in horizontal suction of particles (11) in the area of the gap. Because of the sufficiently large axial and tangential air velocity, the particles from the swirl flow generator (4) level rise vertically in the direction of the arrow (12) along the draft tube (5) in which they partially follow the movement of air in the form of a swirl due to the tangential component of airflow. During the vertical movement of particles upwards, they fly through the area (10) of coating dispersion spray around the nozzle. In this area (10) random collisions of particles and droplets occur, at which a drop after the collision distributes along the surface of particle in accordance with the contact angle with a given solid. Part of the drop can penetrate to the interior of the particles, which occurs particularly at the beginning of the process of coating. If the number of collisions of particles and drops are sufficient, the droplets can coalesce in the form of a film. As the air stream (17) for fluidization is heated (usually at 40 to 80 ° C) before entering the processing chamber, and is in good contact with the solid particles, there is an effective evaporation of the solvent of the coating dispersions from the surface of particles (water or an acceptable organic solvent). The surface wetted particle dries quickly enough that on accidental collision with other particle the formation of a liquid bridge and potential agglomerate is avoided. If the density of particles around the nozzle (6) is too small, the effect of spray drying or the coating of the inner wall of the draft tube (5) can occur, both of which reduce the coating process yield. Particles along the entire tube (5) accelerate, but when leaving the tube (5), their speed begins to reduce, as the local air velocity quickly falls due to the rapid increase of this section of the process device, as well as the particle drag force in the air stream. After reaching their maximum height in the expansion part (13) of the process devices, the particles fall back between the outer wall of the draft tube (5) and the wall (1) of the process device until they reach the level of the particle bed at the bottom of the device. During the upward and downward movement of the particles, the process of drying is continuously in operation so that when the particle gets in contact with particle bed it is practically dried. With the balance of the coating dispersion spray rate, managing the droplet size through the spraying pressure, and size of the heat flow controlled through the flow and temperature of the medium for fluidization, we create conditions during the process of coating that favour the process of coating and not the agglomeration of particles. During coating, the particles depict repeating circular movement in the chamber and so pass the coating area many times. Thus, with time the coating at first forms a continuous film over the surface of the particle, whose thickness increases during further coating.

[0016] Figure 2 shows a detail of the process device in the vicinity of the swirl flow generator (4) and spraying nozzle (6) for distribution and the shape of the local flows (15), (16), (17) of medium (air) for fluidization. The typical layout of an orifice density and cross-section on the outer perforated plate (3) is also shown. In the area of the perforated plate (3) along the wall (1) of the process device, a band of orifices of larger cross-section is located, which generates greater local air flow (16) than is the case for air flow (15) of the remaining orifices of the perforated plate (3). In this way, the effect of particles dwelling in the corner between the perforated plate (3) and the wall (1) of the process device is reduced.

[0017] In Figures 3, 4 and 5 the geometry of the swirl flow generator (4) is shown. The swirl flow generator (4) diverts air into a vortex, which is the result of the inclination of the grooves (18) (most often, the grooves (18) form an angle of 30° to the vertical line or in interval between 10 and 45°) in the generator (4). The total floor area of the grooves (18) of the swirl flow generator (4) is from 20 to 50% of the horizontal cross section of draft tube (5) surface area. The diameter of the swirl flow generator (4) is from 65 to 100% of the diameter of the draft tube (5). The fact that the grooves (18) of the generator (4) are open to the outside (they have no walls at the periphery of the generator (4)) is of key importance, since this causes the distribution of airflow with an increased flow centrally along the side of the spraying nozzle (6) and a reduced airflow externally to the radius, which corresponds to the radius of the draft tube (5). If the airflow in the lower transverse cross-section of the draft tube (5) has the distribution of speed as described above, then this distribution homogenises on the upper transverse cross-section of the draft tube (5). Due to the generated shape and characteristics of the swirl flow of air through the draft tube, there is less opportunity for the recirculation of particles in the lower part of the draft tube (5) and gap, resulting in lower potential for particle agglomeration because of over-wetting and the reduced variability in thickness of film coatings.

During a potential instalment of a peripheral wall of grooves (18), the generated swirl would due to its initial homogeneity in the distribution of air velocity along the radius of the generator through centrifugal air force and the immediate expansion of the air vortex after passing through the generator (4), push aside particles from the gap between the draft tube (5) and distribution plate (3), and thus disrupt the suction of particles into the area of horizontal traction (11).

The swirl flow generator (4) reduces the RSD of coating thickness (implementation example 1) in such a way that the circular movement of particles that follow the stream of air reduces the effect of particle mutual shading. The particles are also more evenly distributed throughout the volume of the inner tube. Due to the higher overall air speed (axial and tangential component), the swirl flow of air is more effective at sucking particles and thus reduces the 'dead spot' effect, which also reduces the RSD of coating thickness. Due to previously described forms of particle movement in the draft tube as a result of swirl airflow the coating yield is increased. Due to the improvement of heat transfer (as a result of the longer path of particle movement on the journey through the draft tube and the expansion area of the device), and the reduction of local density and inter-particle collisions at the wall of the draft tube (5), when compared to the conventional Wurster chamber, we observed in the case of the process device with a swirl flow generator (4) substantially lower agglomeration of particles against the conventional Wurster chamber (implementation examples 2 and 3). Due to the centrifugal component of particle movement smaller particles after passing through the draft tube (5) collide against the wall of the device (1) and fall towards the bottom of the device sooner, which reduces the problem of coating thickness dependence on the initial particle size, which is characteristic for a conventional Wurster chamber (implementation example 4).

Figures 6 and 7 indicate the schematic implementation of semi-industrial or industrial device for coating particles with swirl flow generators (4), where the capacity increase of the process device is made by increasing the number of swirl flow generators (4), spraying nozzles (6), and draft tubes (5) within one process device with filters (19).

IMPLEMENTATION EXAMPLE 1

[0018] For the implementation example 1 we coated 1 kg of pellets with the dye tartrazine, and during the coating experiment we sprayed 915g 8% (m/m) of aqueous dispersion HPMC with 10.9% (m/m) part of the colouring agent. At the end of the coating, we sampled 30 samples of pellets, each containing 10 pellets and dissolved them in a phosphate buffer with pH = 6.5 and measured spectrophotometrically the concentration of dye at a wavelength of 425 nm. From the population of dye concentration measurements we have calculated the relative standard deviation of the film coating thickness, as with a narrow and defined distribution of round shaped pellets the variation of concentration of dissolved dye is above all a function of the film coating thickness of pellets before dissolving. In calculating the RSD of the film coating thickness between individual pellets, we have used the methods and equations given in Cheng XX, Turton R, The Prediction of Variability occurring in Fluidized Bed Coating Equipment. II. The Role of Particle Nonuniform Coverage Rates and a Bottom-Spray Fluidized Bed Coater. Pharm Dev. Tech., 5, 2000, 323 - 332.

[0019] We carried out three coating experiments of 1000g of pellets, with a fraction size from 710 to 800 microns according to the procedural scheme set out in Table 1. We performed the coating in a conventional Wurster chamber and in a Wurster chamber with a swirl flow generator (4).

Table 1: Process variables of the film coating procedure

process	temperature		spraying		
	inlet [°C]	product [°C]	pressure [bar]	pump [RPM]	rate [g/min]
preheating	55	/	/	/	/
tempering	55	45	/	/	/
spraying	55	40 - 46	2.0	8	~10.5
drying	70	40 - 54	/	/	/
sampling	70	55	/	/	/
stop		61-63			

[0020] Fluidizing airflow was set to 130.4 m³/h.

Table 2: Results of determining the RSD film coating thickness per coating experiment

Device type	Draft tube height [mm]	RSD of coating thickness [%]
conventional Wurster chamber	20	21.1
Wurster with swirl flow generator	10	8.05
Wurster with swirl flow generator	20	9.28

It is clear from the results that by using a process device with a swirl flow generator we achieved 56 to 62% reduction of the RSD film coating thickness with regard to the conventional Wurster chamber.

IMPLEMENTATION EXAMPLE 2

[0021] The fraction of agglomerated phases after experiments of coating pellets with an initial size of 800 to 1000 microns has been determined by sifting the pellets through a sieve 1.200 mm, in which the clusters of agglomerated pellets were left behind on the used sieve, while individual coated pellets passed through the sieve unimpeded. We divided the mass of the remaining agglomerated pellets on the sieve by the mass of the entire series of coated pellets before sifting. In this way we calculated the fraction of the agglomerated phase of the coating procedure, which we expressed in percentage terms.

[0022] We calculated the coating yield by dividing the actual increment in mass of the pellets during coating by a theoretically calculated mass of dispersion dry material, which was sprayed during the coating.

[0023] We performed the pellet coating experiment with 8% (m/m) of aqueous solution HPMC with the addition of dye where we used the process parameters listed in Table 3. We coated 1000g of pellets (800 to 1000 microns) with 986g of coating dispersion.

[0024] Fluidizing airflow was set to 130.4 m³/h at relative humidity of inlet air at 38 to 39% (humidity measured at 18 °C). The height of the draft tube (5) (the size of the gap between the draft tube and the distribution plate) was set to 20mm.

[0025] From the results in Table 4 it is clear that the use of the swirl flow generator (4) reduces the fraction of agglomerated phase by 57.5% against the fraction of agglomerated phase obtained by a conventional Wurster chamber. It is also shown in Table 4 that using a swirl flow generator (4) improves coating yield.

Table 3. Process variables of the film coating procedure

process	temperature		spraying		
	inlet [°C]	product [°C]	pressure [bar]	pump [RPM]	rate [g/min]
preheating	56	/	/	/	/
tempering	56	45	/	/	/
spraying	56	40 - 46	2.0	14	~13.3
drying	70	40 - 54	/	/	/

Table 4: Results of determining the fraction of agglomerated phase and coating yield

device type	agglomeration fraction [%]	coating yield [%]
conventional Wurster chamber	27.8	76.91
Wurster with swirl flow generator (4)	11.8	80.25

IMPLEMENTATION EXAMPLE 3

[0026] The coating of pellets sized from 200 to 355 microns was performed in a conventional Wurster chamber and the chamber with a swirl flow generator (4). The fraction of agglomerated phases following pellet coating experiments was determined by sifting the coated pellets through a sieve 0.500 mm, in which the clusters of agglomerated pellets were left behind on the used sieve, while individual coated pellets passed through the sieve unimpeded. We divided the mass of the remaining agglomerated pellets in the sieve by the mass of the entire series of coated pellets before sifting. We calculated the coating yield in the same way as in implementation example 2.

[0027] We performed the pellet coating experiment with 8% (m/m) of aqueous solution HPMC with the addition of dye where we used the process parameters listed in Table 5. We coated 1000g of pellets (200 to 355 microns) with 986g of coating dispersion. Fluidizing airflow was set to 105 m³/h at relative humidity of inlet air at 39% (humidity measured at 18 °C). The height of the draft tube (5) (the size of the gap between the draft tube and the distribution plate) was set to 10mm.

[0028] From the results in Table 6 it is clear that the use of the swirl flow generator (4) reduces the fraction of agglomerated phase when compared with a conventional Wurster chamber, also in the case of coating small particles (200 - 300 microns), which indicates better thermal efficiency of the new device. The coating yield for both processing chambers is comparable.

Table 5. Process variables of the film coating procedure

process	temperature		spraying		
	inlet [°C]	product [°C]	pressure [bar]	pump [RPM]	rate [g/min]
preheating	56	/	/	/	/
tempering	56	45	/	/	/
spraying	56	40 - 46	2,0	10	~ 9.5
drying	70	40 - 54	/	/	/

Table 6: Results of determining the fraction of agglomerated phase and coating yield

device type	agglomeration fraction [%]	coating yield [%]
conventional Wurster chamber	70.7	56.3
Wurster with swirl flow generator (4)	43.6	57.7

IMPLEMENTATION EXAMPLE 4

[0029] Fraction pellet interval size from 500 to 700 microns and interval size from 800 to 1000 microns were mixed in weight ratio 1:1. We performed two experiments of coating pellets using a polymer solution HPMC, which contains 10.9% of tartrazine dye. The coating process was carried out with a conventional Wurster chamber and a chamber with a swirl flow generator (4).

[0030] We performed the pellet coating experiment with 8% (m/m) of aqueous solution HPMC with the addition of dye where we used the process parameters listed in Table 7. We coated 1000g of pellets of the above-mentioned mixture with 975g of coating dispersion.

[0031] Fluidizing airflow was set to 130.4 m³/h at relative humidity of inlet air at 38% (humidity measured at 18 ° C). The height of the draft tube (5) (the size of the gap between the draft tube and the distribution plate) was set to 20mm.

[0032] After completing both coatings, we used a 0.800mm sieve to sift the coated pellets into two basic size fractions. From each size fraction, we randomly sampled 12 samples of 10 pellets each and spectrophotometrically determined the concentration of dye for the samples of both size fractions. We calculated the average value of dye concentration for both size fractions. With the correction factor, based on the area ratio of the initial size of the pellets of both size fractions, we multiplied the average concentration of dye measured for the smaller size fraction of pellets, and so achieved that the concentration of dye represents a comparable average coat thickness in individual size fractions of pellets. We compared the difference between the average values of dye concentrations for both fractions of pellets after coating, for both coating with a conventional Wurster chamber and a chamber with a swirl flow generator (4).

Table 7. Process variables of the film coating procedure

process	temperature		spraying		
	inlet [°C]	product [°C]	pressure [bar]	pump [RPM]	rate [g/min]
preheating	55	/	/	/	/
tempering	55	45	/	/	/
spraying	55	41	2.0	10	~ 9.3
drying	60	48 - 49	/	/	/

Table 8. Results of determining the average concentration of dye with corrections in respect to the surface area of each pellet sample

Fraction size of pellet	conventional Wurster chamber	Wurster with swirl flow generator
	Dye concentration [g/mL]	Dye concentration [g/mL]
500 - 800 microns	$(3.18 \times 10^{-6} \times 2.21) = 7.03 \times 10^{-6}$	$(3.39 \times 10^{-6} \times 2.21) = 7.49 \times 10^{-6}$
800 - 1000 microns	9.40×10^{-6}	7.77×10^{-6}
Dye concentration difference between fractions	2.37×10^{-6}	0.28×10^{-6}

[0033] From table 8 it is clear that in the case of a conventional Wurster device, there actually exists a dependence of the thickness of the applied coating to the initial size of the pellet, which is reflected in the difference between the, on the surface normalised average concentrations of dye for each size fraction of pellets. By using a process device with a swirl flow generator (4), the difference between dye concentrations of the larger and smaller size fraction of pellets is significantly reduced. The reduced differences of the dye concentration shows that with the use of the process device with a swirl flow generator (4), the difference in the applied coating for pellets of smaller and larger size fractions has also reduced.

Claims

1. A process device for coating particles in which on the inside wall (1), there are one or more units installed, in which each unit consists of swirl flow generator (4) around which is located in cross-section a straight or curved perforated plate (3) and draft tube (5), where centrally through the swirl flow generator (4) a single or multi-phase spraying nozzle (6) is installed with a conduit (7) for dispersion for coating and a conduit (8) of compressed air, **characterized in that**, the swirl flow generator (4) has grooves that form an angle to the vertical line, and the grooves (18) are open to the outside.
2. A process device for coating particles according to the claim 1 **characterized in that**, the angle of grooves (18) to the vertical line are between 10 and 45°.
3. A process device for coating particles according to the claim 1 and 2, **characterized in that**, the total floor area of grooves (18) of swirl flow generator (4) is from 20 to 50% of the horizontal cross section cut of the draft tube (5) and the diameter of the swirl flow generator (4) is from 65 to 100% of the diameter of the draft tube (5).

Patentansprüche

1. Prozessvorrichtung zur Beschichtung von Partikeln, an deren Innenwand (1) eine oder mehrere Einheiten angeordnet sind, jede Einheit bestehend aus einem Drallströmungsgenerator (4), um welchen eine im Querschnitt gerade oder gekrümmte Lochplatte (3) sowie ein Saugrohr (5) angeordnet sind, wobei mittig durch den Drallströmungsgenerator (4) eine Ein- oder Mehrsprühdüse (6) mit einer Leitung (7) zur Dispersion und Beschichtung sowie einer Druckluftleitung (8) angeordnet ist, **dadurch gekennzeichnet, dass** der Drallströmungsgenerator (4) Nuten aufweist, die einen Winkel zur Vertikalen bilden und die Nuten (18) nach außen geöffnet sind.
2. Prozessvorrichtung zur Beschichtung von Partikeln nach Anspruch 1, **dadurch gekennzeichnet, dass** der Winkel der Nuten (18) zur Vertikalen zwischen 10 ° und 45 ° beträgt.
3. Prozessvorrichtung zur Beschichtung von Partikeln nach Ansprüchen 1 und 2, **dadurch gekennzeichnet, dass** die gesamte Oberfläche der Nuten (18) des Drallströmungsgenerators (4) zwischen 20 % und 50 % des horizontalen Querschnitts des Saugrohrs (5) beträgt und dass der Durchmesser des Drallströmungsgenerators (4) zwischen 65

% und 100 % des Durchmessers des Saugrohrs (5) beträgt.

Revendications

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1. Un dispositif de traitement pour l'enduction de particules, dans lequel une ou plusieurs unités sont installées sur la paroi interne (1), chaque unité étant constituée d'un générateur de tourbillons (4), autour duquel, en coupe transversale, sont disposés une plaque perforée plate ou incurvée (3) et un tube d'aspiration (5), une buse de pulvérisation mono- ou multiphasique (6) munie d'une conduite (7) pour la dispersion de revêtement et d'une conduite (8) pour air comprimé étant installée au centre du générateur de tourbillons (4), **caractérisé en ce que** le générateur de tourbillons (4) comporte des rainures inclinées selon un angle par rapport à la verticale et que les rainures (18) sont ouvertes vers l'extérieur.

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2. Le dispositif de traitement pour l'enduction de particules selon la revendication 1, **caractérisé en ce que** l'angle des rainures (18) est compris entre 10° et 45° par rapport à la verticale.

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3. Le dispositif de traitement pour l'enduction de particules selon les revendications 1 et 2, **caractérisé en ce que** la surface au sol totale des rainures (18) du générateur de tourbillons (4) est comprise entre 20 % et 50 % de la section transversale horizontale du tube d'aspiration (5) et que le diamètre du générateur de tourbillons (4) est compris entre 65 % et 100 % du diamètre du tube d'aspiration (5).

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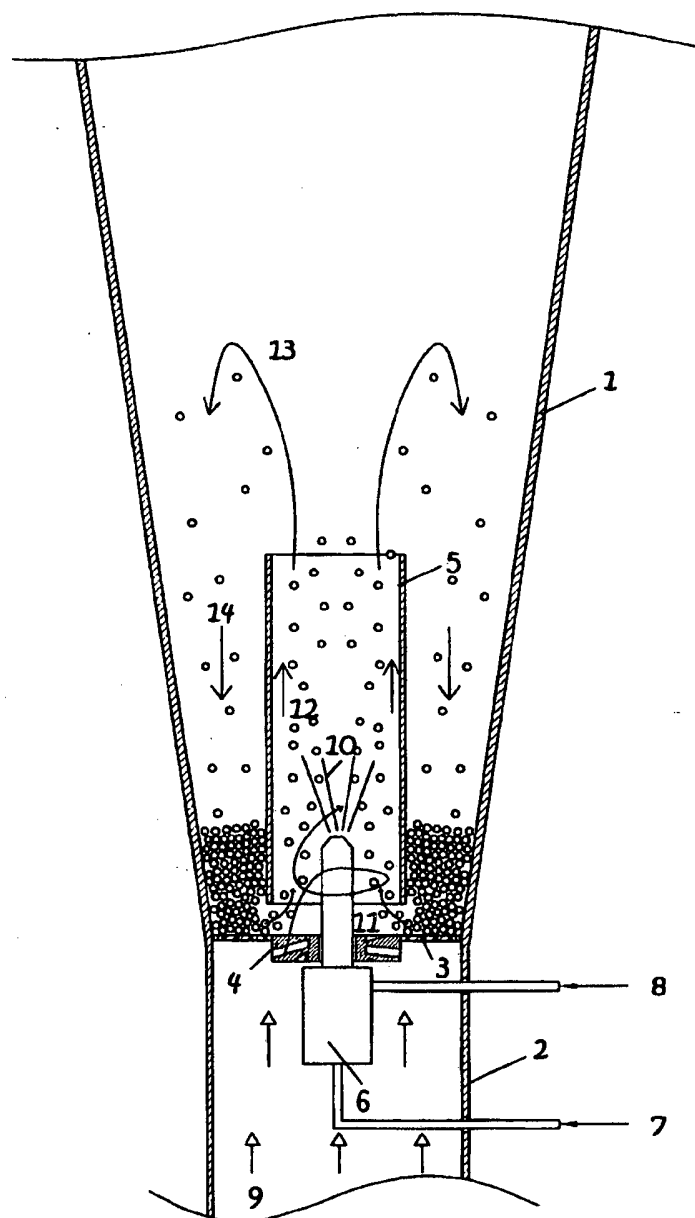


FIG. 1

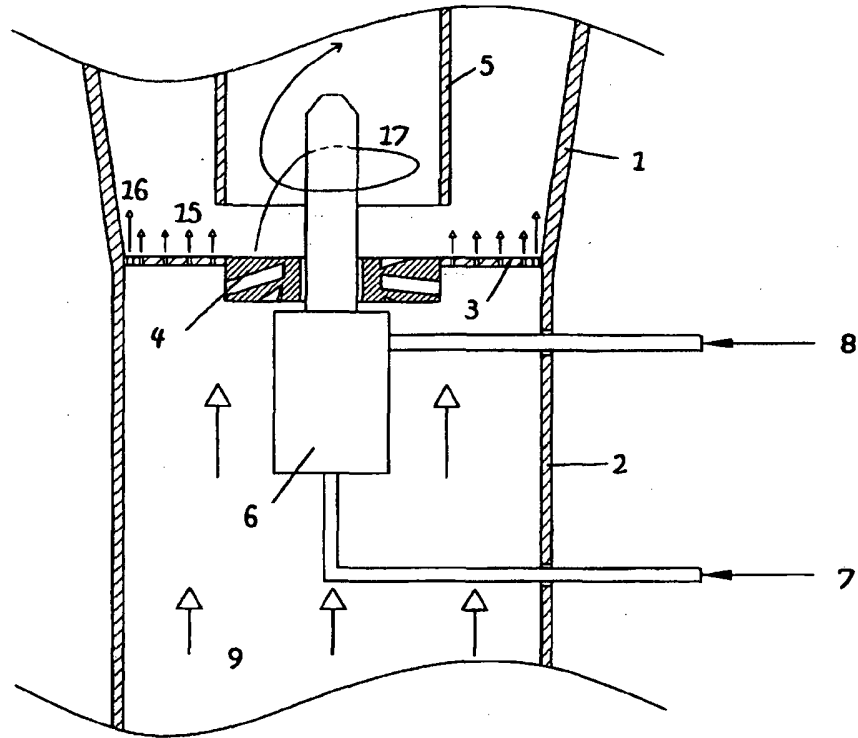


FIG. 2

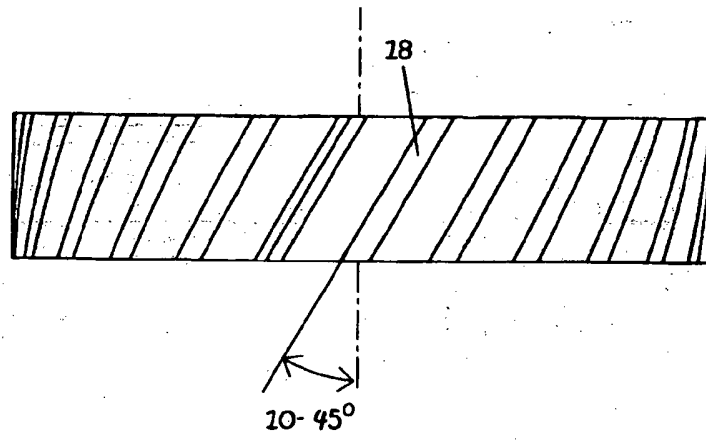


FIG. 3

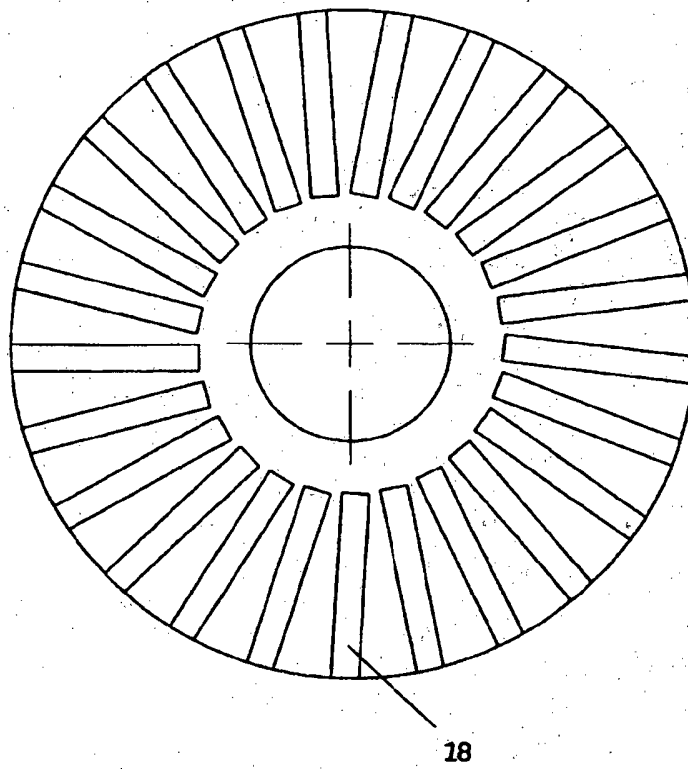


FIG. 4

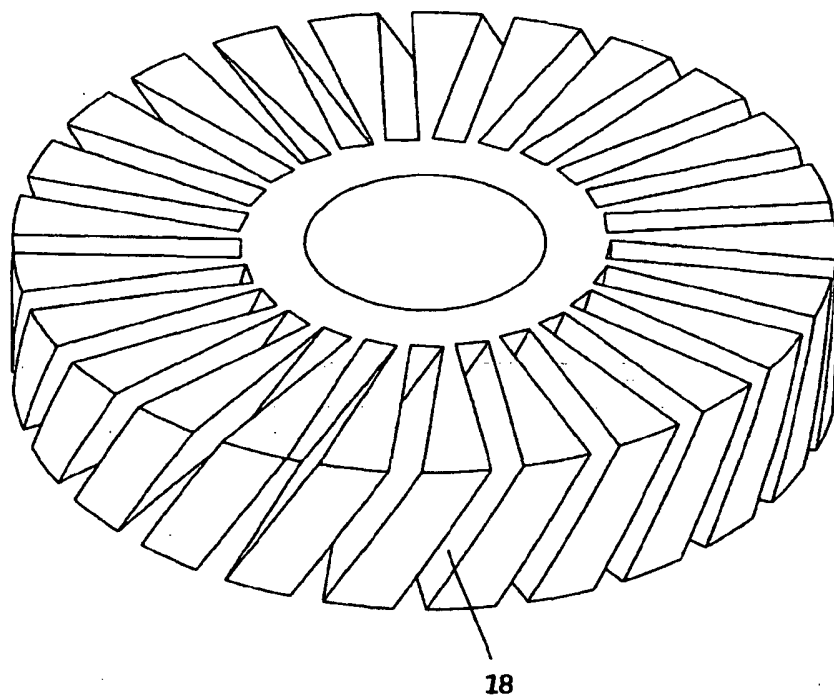


FIG. 5

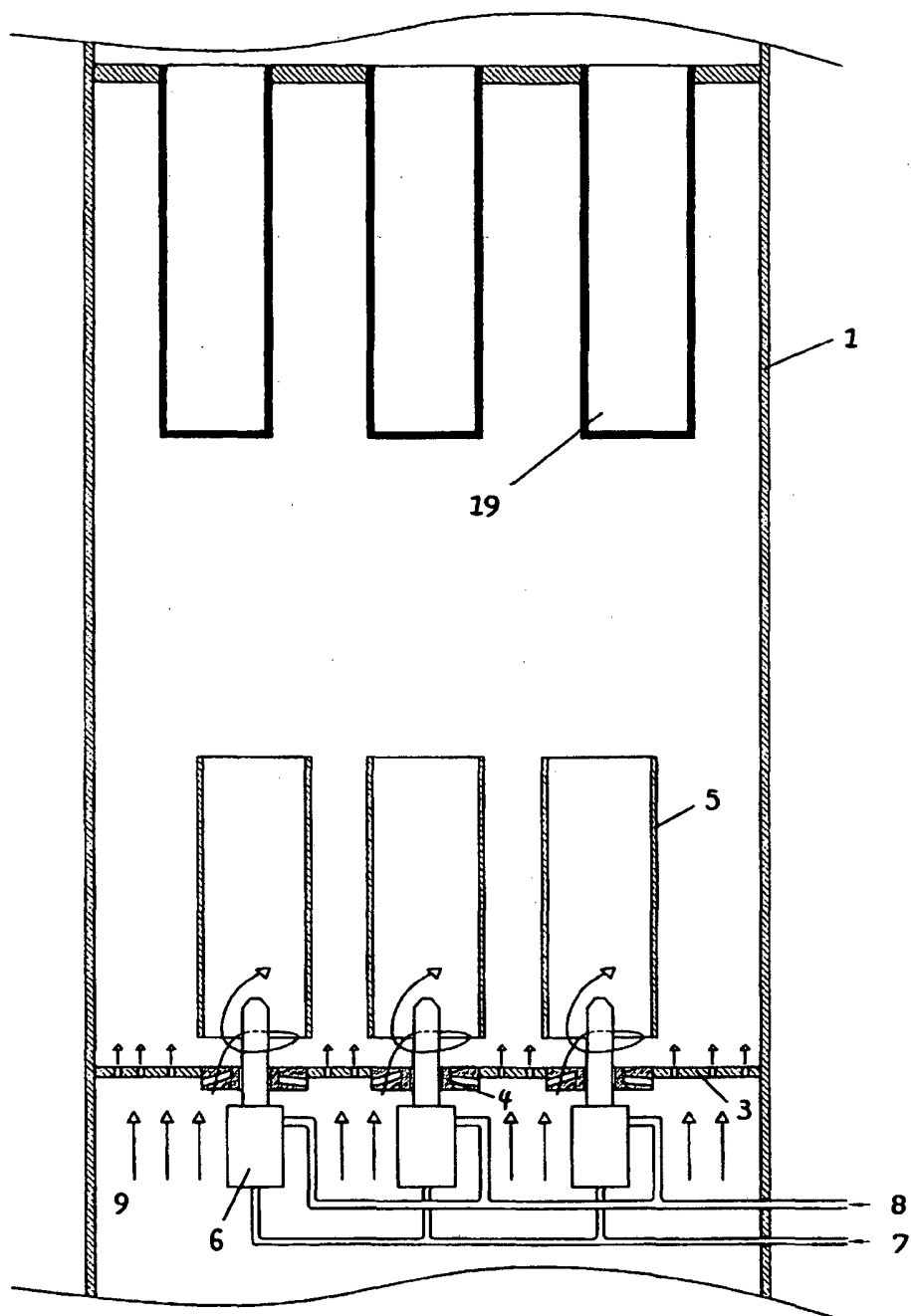


FIG. 6

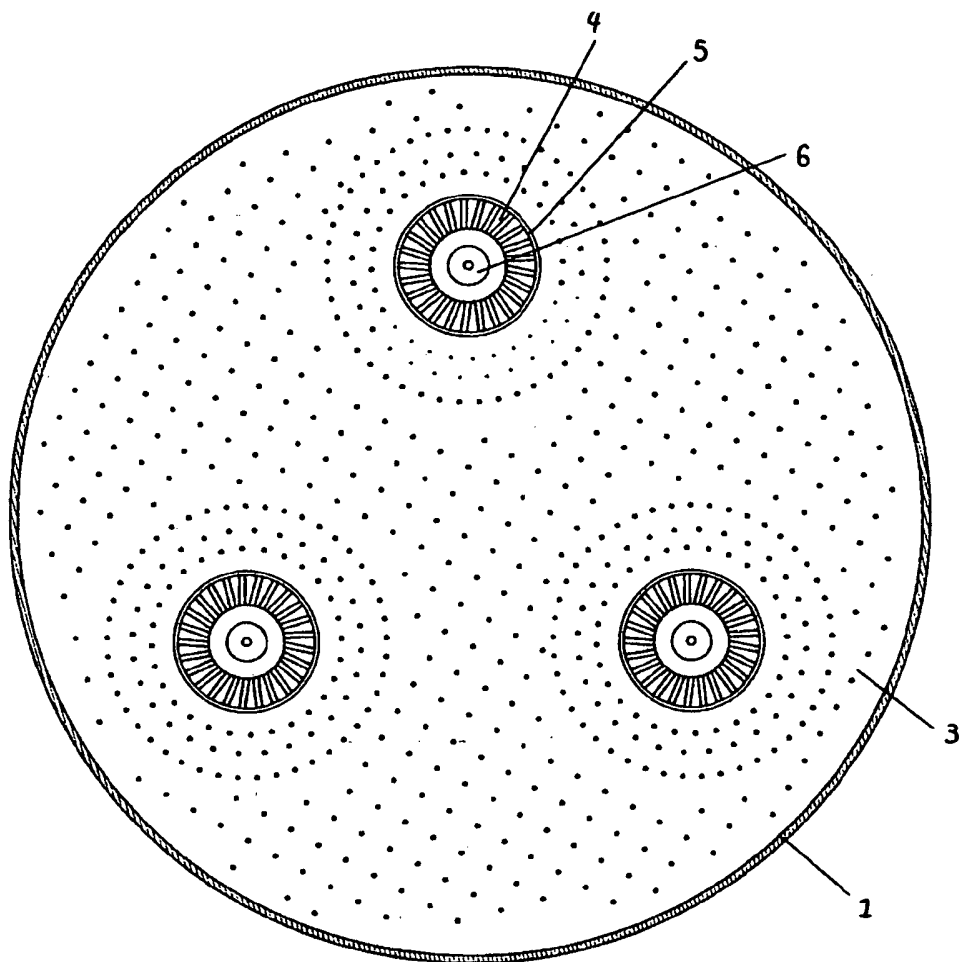


FIG. 7

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5718764 A [0012] [0013]
- US 6492024 B1 [0013]

Non-patent literature cited in the description

- **ALGIFRI AH et al.** Heat -transfer and turbulent decaying swirl flow in a circular pipe. *International Journal of Heat and Mass Transfer*, 1988, vol. 31 (8), 1563-1568 [0011]
- **M. ÖZBEY.** MS Söylemez, *Energy Conversion and Management*, 2005, vol. 46, 1495-1512 [0012]
- **PWS HENG et al.** *International Journal of Pharmaceutics*, 2006, vol. 327, 26-35 [0012]
- **ESK TANG et al.** *International Journal of Pharmaceutics*, 2008, vol. 350, 172-180 [0012]
- **ALGIFRI AH et al.** Heat-transfer and turbulent decaying swirl flow in a circular pipe. *International Journal of Heat and Mass Transfer*, 1988, vol. 31 (8), 1563-1568 [0012]
- **PWS HENG et al.** *International Journal of Pharmaceutics*, 2006, vol. 327, 26-35 [0013]
- *Pharm Dev. Tech.*, 2000, vol. 5, 323-332 [0018]

**FELDOLGOZÓ KÉSZÜLÉK RÉSZECSKÉK BEVONÁSÁRA
SZABADALMI IGÉNYPONTOK**

1. Feldolgozó készülék (process device) részecskék bevonására, amelyben a belső falon (1) van egy vagy több beiktatott (installed) egység, ahol minden egység egy örvény áramlási generátorból (swirl flow generator) (4) áll, amely körül keresztmetszetben egy egyenes vagy görbített perforált lemez (3) és egy szívócső (draft tube) (5) helyezkedik el, ahol az örvény áramlási generátor (4) révén központosítva egy egy- vagy többfázisú permetező fúvóka (spraying nozzle) (6) van beiktatva egy vezetékekkel (conduit) (7) a bevonásra szolgáló diszperzióhoz és egy vezetékekkel (8) a sűrített levegőhöz, **azzal jellemezve, hogy** az örvény áramlási generátorok (4) barázdái (groove) vannak, amelyek szöglet képeznek a vízszintes vonallal, és a barázdák (18) kifelé nyitva vannak.

2. Az 1. igénypont szerinti feldolgozó készülék részecskék bevonására, **azzal jellemezve, hogy** a barázdák (18) szöge a vízszintes vonalhoz 10° és 45° között van.

3. Az 1. vagy 2. igénypont szerinti feldolgozó készülék részecskék bevonására, **azzal jellemezve, hogy** az örvény áramlási generátor (4) barázdáinak (18) teljes alapterülete (floor area) a szívócső (5) vízszintes keresztmetszeti vágatának (cross section cut) 20%-a és 50%-a között van, és az örvény áramlási generátor (4) átmérője a szívócső (5) átmérőjének 65%-a és 100%-a közötti tartományban van.