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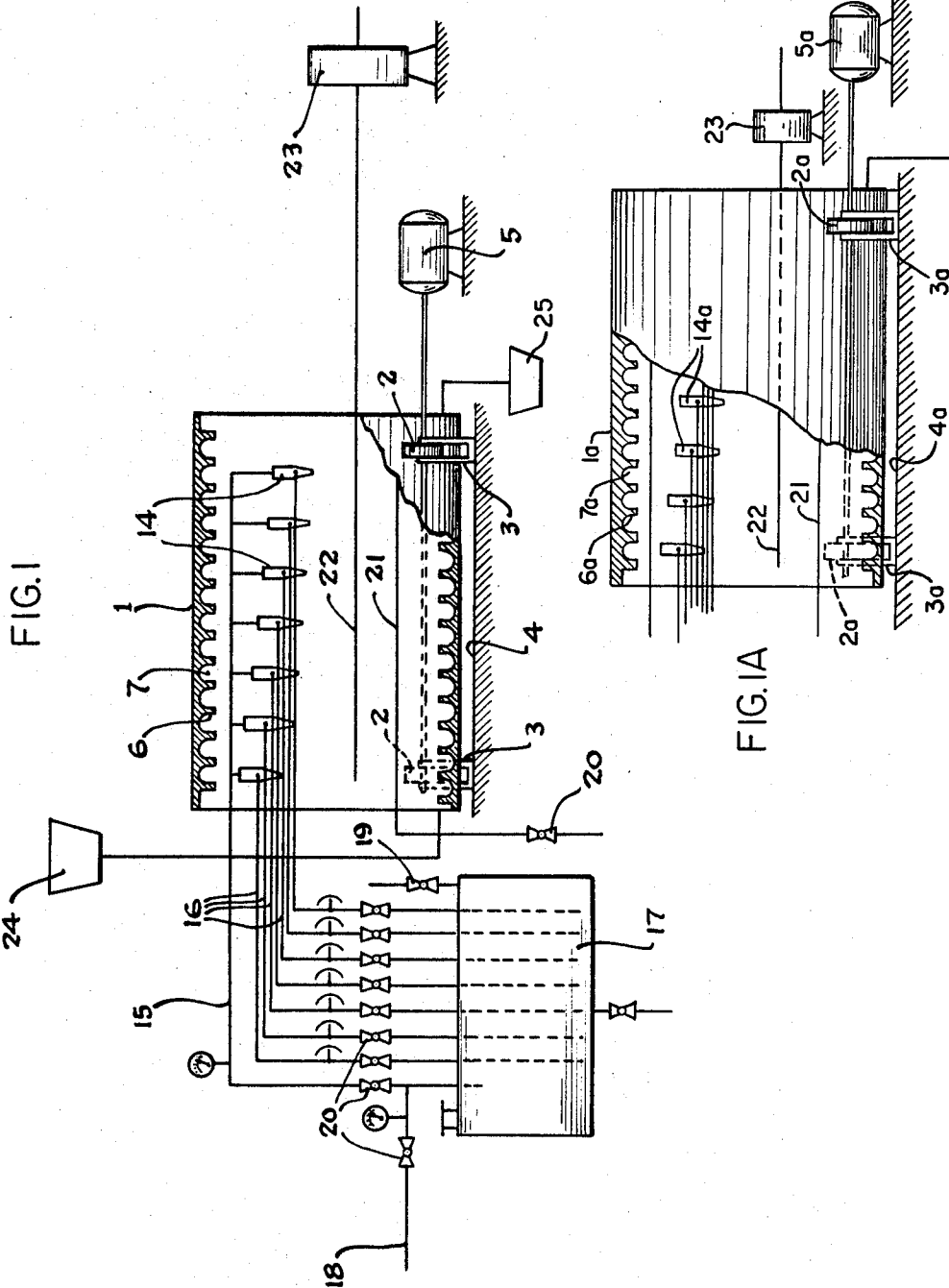
F. MARTIN

3,390,648

PROCEDURE FOR COATING PARTICLES

Filed Sept. 15, 1964

2 Sheets-Sheet 1



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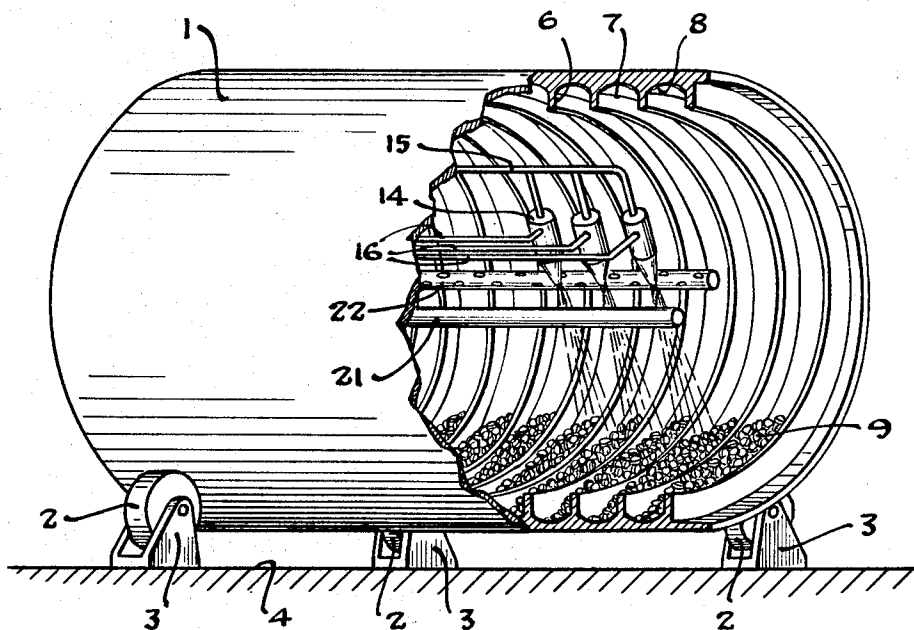


FIG. 2

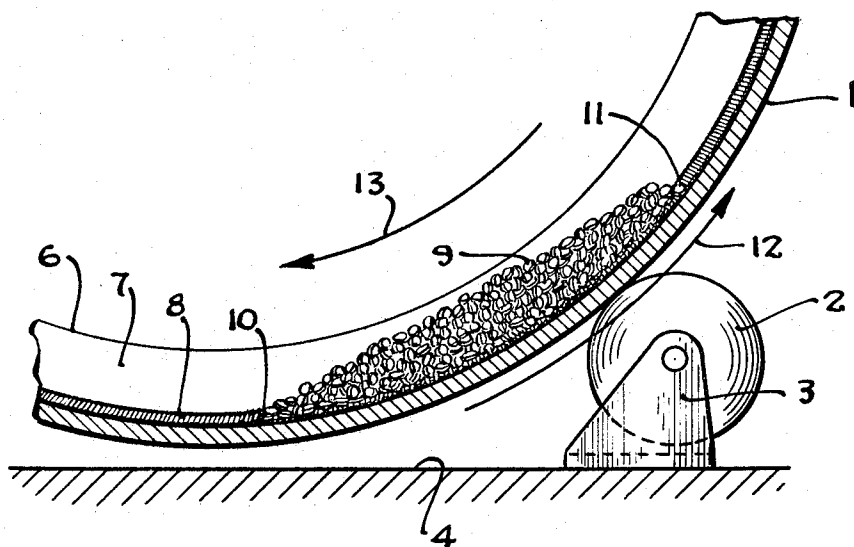


FIG. 3

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PROCEDURE FOR COATING PARTICLES

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The invention concerns a procedure for coating particles, such as tablets of, for instance, bi-convex shape, and in particular those produced by the pharmaceutical industry.

Technical progress reached in this field is described in a paper by K. Münzel entitled, "Neuerungen auf dem Gebiet der pharmazeutischen Dragierung" ("Innovations in the Field of Pharmaceutical Coated Tablet Manufacturing"). This appeared in the journal "Pharmaceutica Acta Helvetica," Nos 2 and 3, of 1963. The disadvantages of the traditional method of sugar-coating cores in a pan have prompted suggestions for improvement, both as regards the coating substance used and the process and equipment respectively. These disadvantages relate to the time required—anywhere from a few hours to several days—for the coating process and the need of a skilled staff to supervise and direct it; the insufficient theoretical command of the process, making quality variations and ruined batches inevitable; and the considerable increase in the weight of the tablets with need of correspondingly larger packages and transportation costs, among other things. Besides the so-called rapid coating procedures and the sugarless coating procedures with substances soluble in water, the lacquering method has recently acquired practical importance. This involves applying to the core a solution preferably film-forming, dissolved in an organic solvent.

In the well-known lacquering techniques, the lacquer solution is poured or preferably sprayed on to the mass which is revolved in the conventional pan, whereby volatilization of the solvent can be aided by introducing heat—for instance, by radiation or the blowing on of hot air—and sucking off the solvent vapours.

The unavoidable abrasion when a pan is used, batches of from 20 to 50 kg. and more being rolled around for hours, is far more disadvantageous in the lacquering procedure, in which the coating is very thin. In the sugar-coating method this abrasion is to some extent desirable (in the initial stage because of the rounding-off of the edges of the cores, giving the coating a uniform thickness, and later because of the polishing effect), and there is no disadvantage, since because of the long duration of the process and the considerable thickness of the coating, the outer layers of the coating contain hardly any substance rubbed off the cores. Furthermore, when using the lacquering technique, the danger of the film already formed being damaged increases with the weight of the load. When applying the lacquer solution by the spray process, assisted by heat, there is the additional factor that the film is formed essentially on the free surface of the mass of tablets. The larger this mass, the more unfavourable (in a potentiated ratio) for the individual tablets the ratio between the travel-time in which they are exposed to the coating processes, and the time during which the negative influences (abrasion of core substance and its incorporation into the covering layer, impairing of the coating already formed) prevail; in addition, the bigger will be the deviations from the statistical means of the travel-time in which the individual tablets are on the free surface. This again results in greater variation in the attained thickness of the film.

To compensate for these disturbing factors and to guarantee sufficient probability that the coating will never drop below a certain minimum thickness, when using the lacquering process in a pan, one must still reckon with a comparatively lengthy processing time (with correspondingly high abrasion) and a sizable average thickness of the coating. In the case of largish pans some 15 sprayings will be needed, requiring about four hours' working time. The abrasion resistance must then be even higher than with the sugar-coating process. On the other hand, leaving out economic considerations, there is a lower limit for the mass of tablets (batch) being made in one operation through the fact that with given dimensions of the pan the required revolution of the cores can only be guaranteed with a certain minimum loading. Should this critical limit not be reached, the mass as a whole begins to slide, causing it merely to oscillate.

If one uses for the lacquering process drums rotating around their horizontal axis, instead of pans, as already proposed for the conventional sugar-coating (see French Patent No. 1,288,469), the problems are basically the same as when using a pan.

By changing over to the fluidized bed process, as described for instance in the British Patent No. 899,900, it was possible to reduce considerably the processing time (to about half an hour to one hour). However, the abrasion of the cores against each other is no less than in the pan. In addition, a good deal more equipment is needed than for the conventional coating process, so that the fluidized bed method has not so far gained any extensive practical importance.

The invention presented here is based on the perception that both in lacquering in the pan or in the drum, as well as in the fluidized bed equipment, far too large batches of tablets are, or have to be handled. In my own experiments I observed the movements of marked tablets in batches and—in part specially equipped—pans of various sizes, and in particular I determined the ratio of the travel-time of the tablets between appearing on the surface and disappearing into the mass, and vice-versa, as well as the incidence of this ratio. In addition, I examined under varying working conditions the abrasion of core substance and the damage done to partially formed films. This showed that the inherent advantages of lacquering—such as shortening of the operation period, reduction of the thickness of the coating and better control of the process itself—could only be partially utilized when employing the usual equipment, for the reasons already mentioned, and that these and other factors can be greatly improved by adopting the process of my invention.

In my invention the lacquering is done in a drum rotating round its horizontal axis. By contrast with conventional methods, this drum contains such a small batch of tablets that with the usual smooth nature of the inner surface of the drum there would be no revolving motion. With such a smooth inner surface it is generally necessary to fill the drum to a minimum of about 10% of its volume to assure a revolving motion, whereas with the procedure invented by me the volume of the drum filling is considerably inferior to 10%. Notwithstanding this, so that the batch of tablets will revolve, in my invention the inner surface of the drum must be such that the tablets slide much less well against it than among themselves. In my invention, the layer of the revolved tablet batch—hereafter called the revolving layer—must in addition have a maximum height which lies between three times the smallest and ten times the largest diameter of the tablets.

These conditions are found to be advantageous not only for the lacquering of tablets but also for other procedures intended to provide particles with a covering coat-

ing, in which there are similar governing criteria as in the lacquering of tablets. The invention thus is concerned with a new procedure for coating particles, such as tablets of, for instance, bi-convex shape, and in particular those produced by the pharmaceutical industry, especially by spraying on a lacquer solution, which comprises revolving the particles while being coated in the interior of a drum rotating round its horizontal axis, the inner surface of the drum being of such a nature that the particles slide considerably better among themselves than against it, said particles forming a revolving layer occupying considerably less than 10% of the internal volume of the drum, the maximum height of the revolving layer being between three times the smallest and ten times the largest diameter of the particles.

The particles constituting the revolving layer resulting from the arrangement described must necessarily follow a movement which is characterized by two turning points with two accelerating stretches in between. From the lower turning point, roughly corresponding to the lowest point of the drum, the particles are conveyed in forward motion according to the rotating speed of the drum's surface in a circular path to the upper turning point. From here, under the influence of gravity, they drop back to the lower point, sliding more or less straight over the particles conveyed upwards. Since the acceleration in the field of gravity is independent of weight, the dynamics of the revolving layer is largely independent of the size and weight of the particles.

The adhesion of the particles to the inner surface of the drum, which is necessary in the new procedure, can be achieved, for instance, by cladding the surface with a profiled rubber lining or something similar. The essential point is that the particles resting on the surface and those immediately next to them are drawn along by the ascending drum wall, so that the desired revolving motion can actually develop and that the load in its entirety does not slide down along the ascending drum surface, as would be the case with the thin layer of our invention, if not special measures were taken to increase adhesion.

While the particles slide back from the upper to the lower turning point, the lacquer solution is sprayed on, and this can be accompanied by direct heating by means of radiation or adduction of hot air. Because all the particles must of necessity pass regularly under the spray, the coating is extremely regular, with minimum deviations from the standard value and without being affected by abrasion of the cores or damage to the coating, because the revolving layer is not very high. As the thickness of the coating depends very closely on both the apparatus factors and the duration of the operation, films of a thickness of, if desired, about 10^{-2} cm. can be formed with a high degree of accuracy and without any danger of bare spots. The coating operation is completed within a few minutes because of this and also as a result of the extremely favourable ratio, for every single particle, between spraying time and idle time, i.e. the time during which no spraying is done. This is why, with a comparable amount of equipment, and despite relatively small batches, production is much greater with the device developed by me than with the traditional pans, drums or fluidized equipments.

Simultaneous coating of larger quantities of particles, with the other dimensions remaining identical, requires a correspondingly longer drum. In this case, the inner surface of the drum is suitably sub-divided by means of circular ribs or lamellae into channels, the width of which is from three to ten times the maximum diameter of the particles. It is even more advantageous if these ribs are inter-connected to form a helical track, so that the particles being coated are moved axially on this track through the rotating drum.

My process can be carried out either by feeding one batch at a time, or continuously. In the former case, one or several circular tracks on the inner surface of the

drum will suffice. One way of taking the particles out is by inserting after the coating is finished specially-fitting collectors in the tracks ahead of the lower turning point and allowing these to be taken up to the upper point. In this way, the particles are caught by the container instead of returning to the lower turning point. New particles can be loaded by inserting similar containers holding the desired batch, which can be dropped into the rotating track by inserting containers holding the desired batch with said containers being open at the back side thereof with respect to the direction of rotation of the drum, and by allowing the containers to be moved within the drum from the lowest point therein to the upper turning point. Both operations can be carried out without stopping the drum, in one single operation which can be made automatic. Other methods of loading and unloading will be evident to the specialist—for instance through openings in the drum surface which can be closed by sliders, by conveyor belts, silo-like storage containers, and similar devices.

If the track of the revolving layer on the inner wall of the drum is of the helical type, loading need only be done at the beginning of the helical track, and this can be done either batchwise (one per revolution of the drum), or continuously. In continuous loading, the first helical revolution collects the batch, which is conveyed axially through the drum; in order to prevent disparities, spraying should in this case be done only from the second turn of the helix onwards. At the end of the helical track batches of coated particles need only be collected. With this continuous method, the operating time is determined by the characteristics of the apparatus. This time can however be varied by loading the particles in a later turn instead of in the first one.

In the process described here the rotary speed of the drum and the intensity of the spraying are variable within certain limits. These values have however certain optima which can be determined empirically and depend on the particles and coating solutions used, and there should be no great deviations from these optima. There is also an optimum for the quantity of particles which can be treated in one turn of the track on the interior surface of the drum. Obviously, revolving layers which are too large and particularly too high would partially cancel out the advantages sought by my process.

Therefore, the maximum height of the revolving layer must be inferior to ten times the largest diameter of the particles; however it may not be inferior to three times the smallest diameter of the particles because otherwise an actual revolution of the layer would no longer be assured. In the case of bi-convex pharmaceutical tablets of usual size, batches of from 100 to 1000 grams are preferred in the lacquering technique in accordance with the invention.

For spraying, the well-known mixing jets can advantageously be used, it being possible to vary the air pressure and the supply of solution. The airstream conveying the solution possesses a remarkable jet pressure which, though as with nearly all spraying systems (except for electrostatic ones) causes substance to be lost, offers considerable advantages. The air streaming in with particles of solution at the same time removes any dust which may be adhering to the tablets, so that no foreign substances can penetrate the film. In addition, there is a physical-mechanical film formation, which also produces adherent films on apparently smooth non-porous tablet surfaces. The paper mentioned earlier and certain references quoted in it contain many suggestions as to the composition of the spray solutions. In addition to lacquer solutions in the proper sense, for the application of which my process is particularly suited, consideration can also be given to aqueous solutions as well as aqueous and non-aqueous suspensions of substances which are preferably film-forming.

(c) spraying a coating solution on the revolving layer of tablets.

2. A process as in claim 1, characterized by introducing said tablets into said drum provided with an internal frictional lining.

3. A process as in claim 1, characterized by said tablets in contact with said drum adhering to said internal friction surface more readily than to each other when said drum is rotated, whereby said tablets in contact with said surface are carried upwardly from the lower part of said drum before being moved away from said surface and moved downwardly to the lowest part of said drum under the force of gravity.

4. Procedure according to claim 1, characterized by the fact that the interior surface of the drum is sub-divided by ribs or lamellae into circular tracks, the width of which corresponds to from three times to ten times the largest diameter of the particles.

5. Procedure according to claim 1, characterized by the

fact that the interior surface of the drum is sub-divided by ribs or lamellae into helical tracks, the width of which corresponds to from three times to ten times the largest diameter of the particles, the particles to be coated being fed into one of the revolutions of the helical track, either continuously or according to the rhythm of the rotation of the drum.

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