May 19, 1953 F. E. STIRN ET AL 2,638,686

DRYING GELATIN CAPSULES

Filed Nov. 21, 1950

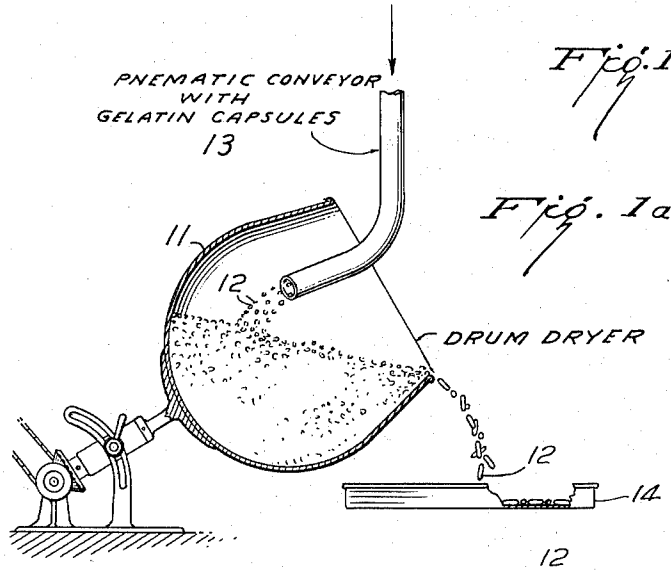


Fig. 1a.

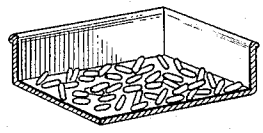


Fig. 1d.

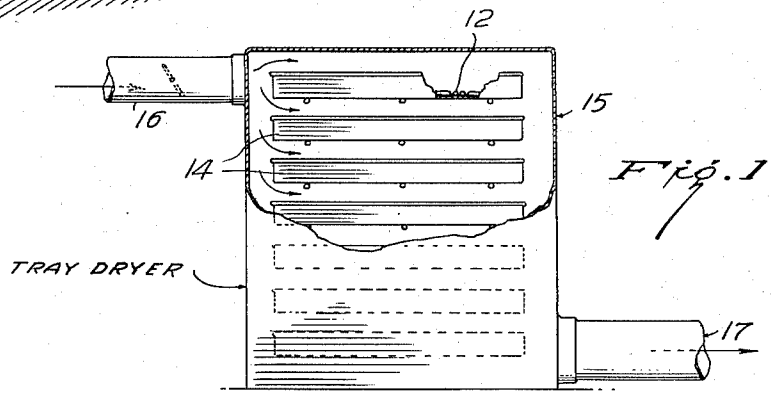


Fig. 1b.

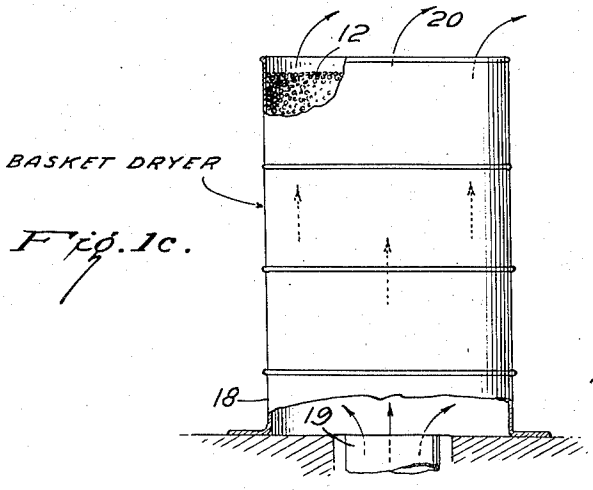


Fig. 1c.

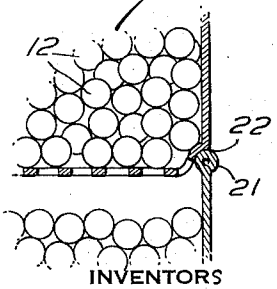


Fig. 2.

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Patented May 19, 1953 2,638,686

UNITED STATES PATENT OFFICE

2,638,686

DRYING GELATIN CAPSULES

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Application November 21, 1950, Serial No. 196,746

7 Claims. (Cl. 34—17)

1

This invention has for its object a method for the drying of soft gelatin capsules in a particularly expeditious and economical manner and, at the same time provides a method of insuring that they are evenly formed and fault-free.

In the past, gelatin capsules of the so-called soft variety have been made by symmetrically assembling two mold shells together, at the same time filling them with a liquid, pressing them firmly together with cutting-out rims to cut the gelatin sheets and simultaneously unite to form a homogeneous, symmetrical, liquid-filled soft gelatin capsule. These capsules were placed on trays in a single layer and permitted to air-dry, after which they were packed in vials, bottles, or otherwise counted, sorted, inspected, shipped, or disposed of.

This entails the use of many individual trays, which trays of course were very convenient for the inspection, counting, sorting and processing of small numbers of individual pharmaceutical capsules. When a large number of capsules were to be filled, the use of a large number of trays became economically inefficient, but nonetheless were used.

With "powder-filled" soft gelatin capsules, in which a powder charge is packed into a soft gelatin shell, over which is placed a soft gelatin cover and the two cut out to form a powder-filled capsule, such a process is not satisfactory.

Because the powder is not capable of transferring hydrostatic pressure, it is found that the capsules as formed are apt to be misshapen with the powder unevely spaced, and the gelatin shell also distorted. We have found that if the powder-filled capsules are tumbled, or agitated, the powder is shaken and then becomes more free-flowing and by continual pounding action, any irregularities are reduced so that a smooth, rounded, even capsule may be obtained. At the same time, the seal line may shift until it is symmetrically on the capsule, if the film temperatures and tensions are correct, and there are obtained smooth, evenly formed, perfectly shaped soft gelatin capsules.

These moist capsules are extremely tender and are easily deformed or pressed out of shape. We have found that it is particularly convenient and economical to agitate the capsules in a rotating drum, a standard pharmaceutical pan-coater being satisfactory for this purpose.

As the capsules are formed, they may be transferred by an air blast from the capsule filling machine to the rotating drum or pan. The tumbling they receive during the transfer partially aids in shaping them, and causes them to become slightly air-dried, sufficiently so that they do not as readily stick to each other. Frequently at least part of the capsule is coated with an oil, and this also aids in preventing the capsules from sticking to each other.

2

The air blast from the conveyor keeps a constant current of cool, dry air flowing through the drum. An additional blast of dry air may be used but is normally unnecessary. The conveying blast can be directed so as to cause the capsules to be carried to the bottom of the pan. As the pan rotates, and as they are tumbled, they progress towards the mouth of the pan, from which they may be permitted to freely fall into single layer trays. By the time they fall into the trays, the capsules have a symmetrical shape, have a thin oil film, and are sufficiently air dry that they will not deform from their own weight or the few inches fall into a tray and may be permitted to fall into the tray in which they are spread by hand until a single layer covering substantially the entire tray is obtained. The filled tray may then be replaced by an empty tray and the filled tray allowed to dry. We prefer to stack the trays, with air circulation spaces between, in a tray drier.

In the tray drier, dry air is circulated over the trays of capsules. Because of the drying characteristics of the capsules, the amount of moisture that is lost in the rotating pan is comparatively high for the time involved. The rate of moisture removal in the tray drier is slower; but it is found that in a matter of approximately 12 to 24 hours, the capsules will have been sufficiently dried to become firm, in which form they may be moved, if handled gently.

If permitted to dry sufficiently for packing and handling, it is found that the capsules must be permitted to remain in the tray drier at a temperature of approximately 65° F.–80° F. and a relative humidity of less than about 40%, for not less than 3–5 days. For small scale production, this is satisfactory, but with large scale production the space occupied by the tray driers is costly. The amount of moisture removed in the last few days is only a small proportion of the total, but nonetheless it must be removed to provide satisfactory capsules.

We have found that after approximately 12 to 24 hours in the tray drier, the capsules are sufficiently rigid that they will not deform if placed in baskets to a depth of twelve inches or more.

The capsules may be dumped from the tray into the basket and permitted to stand in the basket, which is perforated to permit dry air to circulate, for a period of about 3 to 5 days. In this manner, the duration of the expensive stage of tray drying is cut to a minimum and the capsules are stored in baskets, in which they do not occupy such large spaces in the air-conditioned rooms and in which they may be kept after they are dried for periods of weeks, or until used in the final packaging or finishing operations. The use of the three-stage drying procedure in which each stage is modified according to the characteristics of the capsules at that particular time, provides a very efficient and economical method of drying our capsules. The process is shown diagrammatically in the drawings. Figure 1 shows the three stages of drying at (*a*) drum drying, at (*b*) tray drying, at (*c*) basket drying, at (*d*) a single layer of capsules in a tray. Figure 2 shows a detail of the basket nesting.

In the drawings, the pan-coater **11** is rotated as the capsules **12** are introduced by an air conveyor **13** and tumbled from the conveyor into the single layer tray **14**. As the second phase is shown in Figure 1, *b*, a tray drier **15**. The dry air supply **16** and exit air **17** are diagrammatically illustrated. As the third phase is shown in Figure 1, *c*, a basket drier **18** showing how the baskets may be stacked to conserve space. Dry air flows in through an inlet **19**, through the stack of baskets and out the top **20**.

At Figure 2 is shown a detail of basket construction in which a bead **21** fits into a groove **22** in the bottom of a basket to support the upper baskets, and lock the stack. Other modifications may be used. The one shown is neat, clean and economical.

The coating pan, tray drier and basket drier are all well known items of equipment, and various modifications and equivalents may be used. Our invention lies not in the individual components but in their combination and the method of use.

A powder-filled capsule was manufactured, containing an anemia preparation, from a gelatin film approximately $^{30}/_{1000}$'' thick. The capsules were approximately $^{5}/_{16}$'' in diameter and ½'' long. These capsules were tumbled in an 18'' diameter pan-coater into which the air conveyor introduced a large quantity of air at a temperature of approximately 65° F. and a relative humidity of about 20–30%. The capsules as they were delivered therefrom fell into a single layer tray on which they were spaced so as to provide a single layer in which the capsules were adjacent to or touching each other without resting on or deforming the adjacent capsules. A tray 24'' x 32'' held approximately 1500 capsules. The trays were stacked in a tray drier, sufficient space being allowed to permit air to circulate between the adjacent trays. After 12 to 24 hours, the capsules were transferred to the drying baskets. Baskets about 17'' x 24'' and 9'' deep held approximately 15,000 capsules. They were stacked as the air was circulated through the bottom of the baskets to evenly dry the capsules. With the capsules thus stacked in baskets, the space requirement was cut to aproximately 10% of that required for tray driers, and the capsules dried satisfactorily.

Because of the compactness of the baskets, it is convenient that the capsules be kept in such baskets until ready for coating or shipping, The residual moisture came off over a period of about three days, after which time the capsules were in their finished, hard, and dry condition.

The exact amount of drying in each of the stages may be varied over reasonable limits, depending upon the initial composition and the exact temperatures being used; the gelatin is harder at lower temperatures and will resist more handling, but a longer time is required for the drying.

Having thus described our invention in a manner to render it clear to those skilled in the art, we claim:

1. The method of drying soft gelatin capsules which comprises tumbling soft gelatin capsules until evenly formed and partially dried, transferring to single layer trays, spreading the capsules in a single layer therein, drying until sufficiently firm so as not to deform when packed in multi-layer packing, transferring to multi-layer baskets, and drying until hard.

2. The method of drying soft gelatin capsules which comprises the steps of subjecting the soft gelatin capsules to cool, dry air while simultaneously tumbling the capsules for a sufficient period to prevent their sticking to each other, and to cause them to assume an even, rounded symmetrical configuration, transferring them to single layer trays, spreading the capsules in a single layer therein, subjecting them to dry air until sufficiently firm that they may be handled, transferring them to multi-layer baskets, and subjecting them to dry air until commercially dry.

3. The method of drying soft gelatin capsules which comprises tumbling powder-filled soft gelatin capsules while simultaneously subjecting them to cool dry air until the capsules are sufficiently firm not to stick to each other and are symmetrically shaped, transferring them to flat single layer trays, spreading the capsules in a single layer therein, subjecting to dry air until sufficiently firm that they may be handled, and transferring them to multi-layer baskets, and subjecting them to dry air until commercially dry.

4. In a method for drying powder-containing soft gelatin capsules, the steps which comprise tumbling powder-containing soft gelatin capsules in the presence of dry air until evenly formed and partially dried, transferring to a single layer tray, spreading the capsules in a single layer therein, and subjecting the capsules to dry air until at least sufficiently firm that the capsules may be conveniently handled.

5. The method of drying and shaping soft gelatin capsules which comprises tumbling soft gelatin capsules in a dry atmosphere until evenly formed and partially dried, transferring to single layer trays, spreading the capsules in a single layer therein, drying until sufficiently firm so as not to deform when packed in multi-layer baskets, transferring to multi-layer baskets, and drying in said baskets until commercially dry.

6. The method of drying and shaping soft gelatin capsules which comprises tumbling soft gelatin capsules in a dry atmosphere until evenly formed and partially dried, spreading the capsules in a single layer, contacting them with a dry atmosphere until sufficiently firm so as not to deform when packed in multi-layer containers, transferring to multi-layer containers, and drying in said containers until commercially dry.

7. In a method for drying soft gelatin cap-

sules, the steps which comprise tumbling soft gelatin capsules in the presence of a dry atmosphere until evenly formed and partially dried, subsequently spreading the capsules in a single layer and contacting the capsules with a dry atmosphere until at least sufficiently firm that the capsules may be conveniently handled.

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