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F. G. ZICK ET AL

2,196,283

CAPSULE

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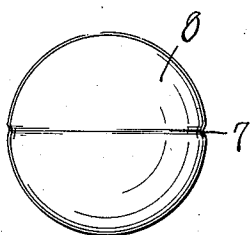


Fig. 1.

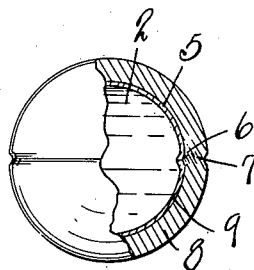


Fig. 2.

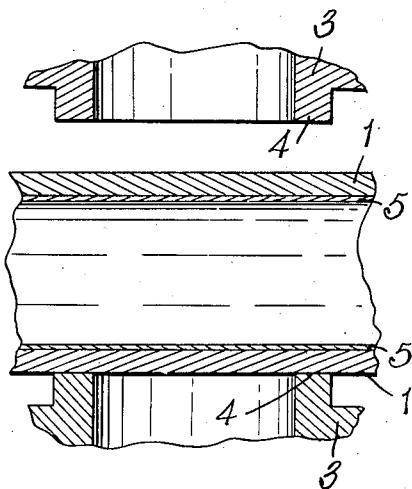


Fig. 3.

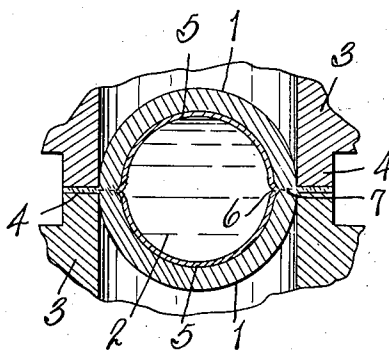


Fig. 4.

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CAPSULE

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Application April 18, 1938, Serial No. 202,657

2 Claims. (Cl. 167—83)

This application is a continuation in part of our application Serial No. 160,262, filed August 21, 1937, for capsules and method of capsulating hygroscopic substances.

5 This invention relates to gelatin capsules of the type which are commonly employed for certain therapeutic substances as well as other substances. These capsules are generally round or oval in form and consist of a gelatin coating which closely embraces the therapeutic or other substance which is capsulated. Heretofore it has not been possible to capssulate hygroscopic substances such as therapeutic substances containing yeast concentrate or the like, and it has not been possible to capssulate substances having a high water content. The wall of the capsules is formed of gelatin which is soluble in water and in the gastric juices in the stomach. The finished capsules should be soft and elastic. This is brought about by maintaining a small water content in the gelatin. If the water is completely removed from the gelatin, the capsules become hard and brittle and are unsatisfactory, developing leakage. If a hygroscopic substance is capsulated, the substance draws the moisture from the gelatin wall which results in a hardening of this wall. If a substance having considerable quantity of water is capsulated, the water will dissolve the gelatin and disintegrate the wall.

25 The objects of this invention are:

30 First, to produce a capsule of the type above referred to in which hygroscopic substances or substances having a water content which would ordinarily disintegrate the gelatin may be capsulated.

35 Second, to provide such a capsule the walls of which will dissolve in the stomach to free the capsulated material.

40 Third, to provide such a capsule which is not objectionable from a therapeutic point of view because of added material and which, if used to enclose coloring matter, or flavoring, does not add to the product made any objectionable material.

45 Fourth, to provide such a capsule with an outer wall of gelatin or the like and an inner wall of substantially inert waterproof material which may be ruptured easily after the gelatin is dissolved.

50 Fifth, to provide such a capsule in which the inner layer is composed of confectioner's lac glaze.

Sixth, to provide such a capsule which remains soft and pliable regardless of any hygroscopic properties of the fill.

Other objects and advantages pertaining to details and economies of construction will appear from the description to follow. The invention is pointed out in the claims. Preferred embodiments of our invention are illustrated in the accompanying drawing, in which:

Fig. 1 is a view of a capsule made in accordance with our invention.

Fig. 2 is a detail view partly in section showing the capsule.

Fig. 3 is a detail view showing one step in the process of producing our improved capsule.

Fig. 4 is a view showing a second step in the process of producing the capsule.

In the manufacture of capsules such as our improved capsule, two substantially flat gelatin plates or sheets 1, 1 are provided. These sheets may be formed to advantage on a metal plate and are kept heated so as to be slightly tacky for sealing. In producing capsules, these flat gelatin plates 1 are disposed between two die plates each containing a plurality of forming dies and the substance to be capsulated, here shown at 2, is inserted between the two sheets 1 of gelatin.

We have shown portions of the upper and lower die plates. The die plates are indicated at 3 and each carries a plurality of forming dies 4. We have not shown these in great detail since the die plates themselves form no part of this invention. Instead of using die plates it is possible to feed two strips of the gelatin to a machine provided with suitable dies and in which the material to be capsulated is fed between the strips prior to the meeting of the forming dies, and insofar as our invention is concerned, either method of making the capsules may be employed.

The bottom die plate in the method first referred to is formed with a marginal flange and one of the gelatin sheets 1 is laid over this die plate. The material 2 to be capsulated is then poured on the sheet 1 and the top sheet 1 is rolled over the material to eliminate any air so that in the final product the gelatin covering closely embraces the capsulated material. The die plates are then brought together and the gelatin is extended into the forming dies 4, as shown in Fig. 4, and the edges are sealed together.

In making our capsules or perles, we prefer to employ a gelatin sheet of about .025 inch thickness. This sheet is kept warm. Prior to placing the material to be capsulated on the bottom sheet 1, we apply a coating of an inert waterproof material to the side of the sheet which

engages the material to be capsulated. We apply a similar coating to the bottom side of the top sheet 1 before it is rolled in place on the material to be capsulated. This material may be applied with a soft brush very satisfactorily and we prefer to apply a coating of from .002 to .004 inch in thickness. The material which we use preferably is an arsenic and rosin free shellac manufactured from East Indian lac which is an exudate from an organism known as the lac insect (*Tachardia lacca*). Prior to our use of this material it is thoroughly purified, bleached and refined to eliminate all rosin and arsenic. This material is substantially inert and is not objectionable therapeutically and is not classed as objectionable by the United States Food and Drug Administration.

We employ a solution of this material for coating the gelatin sheets 1. Three to four pounds of the glaze are dissolved in one gallon of approved alcohol solvent. This solvent consists of one hundred parts ethyl alcohol and five parts ethyl acetate. The solution is applied to the surface of the warm gelatin and sufficient time elapses to permit the solvent to evaporate before the capsulating process is completed. This solvent evaporates promptly and leaves a continuous tacky coating 5 of the confectioner's lac glaze on the surface of the gelatin. If the capsulating is carried out while the coating 5 is still tacky, a satisfactory sealing of the inner layer is obtained. The sealing is then carried out in the conventional manner and when the dies come together, the layers 5 of the lac join together as is indicated at 6 in Fig. 4, and the gelatin sheets 1 join together as indicated at 7 in Fig. 4, forming a capsule which closely confines the capsulated material 2 in two layers.

Referring to Fig. 2, the outer layer 8 is of the gelatin and is soft and elastic. The inner layer 9 is of the lac glaze. The inner layer 9 is preferably from .002 to .004 inch thick and in a capsule of the ordinary size which is of a diameter of about one-quarter of an inch, this layer will not alone support the contents or capsulated material 3 sufficiently to permit handling. If the gelatin coating 8, which is in intimate contact with the inner wall 9, is removed by dissolution in water the inner wall 9 will rupture easily, in most instances from its own weight, freeing the contents of the capsule. The inner layer 9 serves to protect the gelatin from the contents of the capsule and if the contents happens to contain some hygroscopic material such as yeast concentrate, there will not be a dehydration of the gelatin causing it to stiffen. The average gelatin of the finished capsule wall contains about 2% to 3% moisture which is not ordinarily lost at room conditions but which would be lost if hygroscopic material were capsulated.

If an inner layer thicker than the above is employed, it is not necessarily objectionable because in therapeutic use the digestive juices of

the user of the capsule may tend to weaken the layer after the gelatin has been dissolved and the manipulation of the capsule by the normal physiological movements of the digestive tract will rupture the inner layer, freeing the contents.

If a substance containing considerable water such as a fruit flavor is capsulated, the waterproof layer 9 which is thin enough to be pliable will protect the gelatin from the water so that the gelatin will not be dissolved by the water in the contents of the capsule.

Regardless of what is capsulated, if the capsule is taken into the stomach or is dropped into some substance to which fruit flavor is to be added, the gelatin will dissolve and thereafter the inner wall 9 will rupture either by its own weight or by mechanical action on the substance and the contents of the capsule will be released.

In the completed capsule, the inner layer 9 of confectioner's glaze is in intimate contact with the gelatin wall. It is joined thereto and apparently a small amount of the glaze penetrates the gelatin slightly. In the finished capsule, however, it is possible to break any bond between the inner and outer walls by rolling the capsule between the fingers and the inner wall does not rupture when this is done because the inner wall is sufficiently thin to be pliable.

In capsules made according to our invention, we have found it is possible to store hygroscopic materials for a considerable length of time without dehydration of the gelatin and we have for the first time made possible the capsulating of hygroscopic material or material containing water sufficient to disintegrate the gelatin wall and to use for such capsulating a soft elastic gelatin.

Having thus described our invention, what we claim as new and desire to secure by Letters Patent is:

1. In a perle the combination of a continuous pliable inner wall consisting of a continuous integral layer of waterproof confectioner's lac glaze of a thickness incapable of alone supporting the contents of the capsule without rupture, and a continuous soft elastic gelatin outer wall in intimate contact throughout with said inner wall and supporting it and the contents of the capsule, whereby said outer wall is protected by said inner wall from the contents of the capsule and on dissolution of the outer wall the inner wall will rupture to release the contents of the capsule.

2. In a perle, the combination of a continuous inner wall consisting of a continuous integral larger of waterproof confectioner's glaze, and a continuous soft elastic gelatin outer wall in intimate contact throughout with said inner wall and supporting it and the contents of the capsule, whereby said outer wall is protected by said inner wall from the contents of the capsule.

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