June 28, 1966 A. W. KATH 3,258,115

TWO-PIECE HARD GELATIN CAPSULE

Filed May 12, 1965

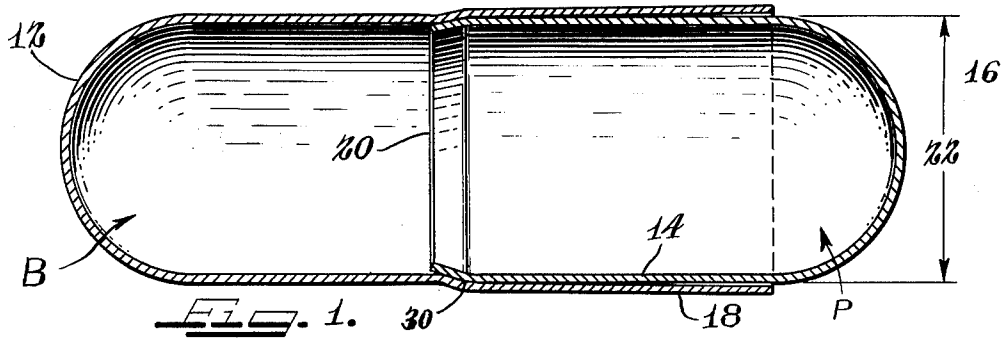


FIG. 1.

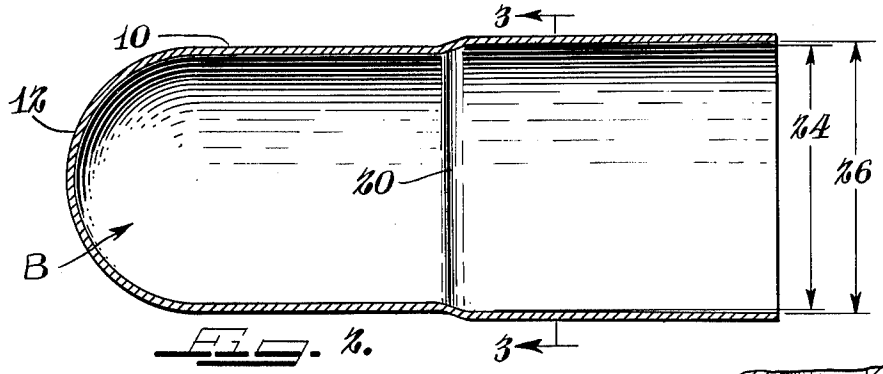


FIG. 2.

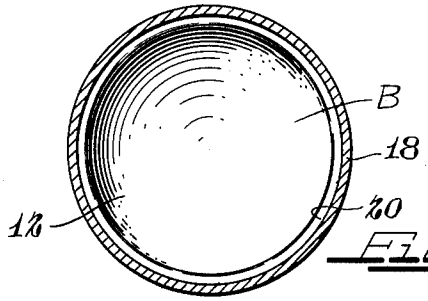


FIG. 3.

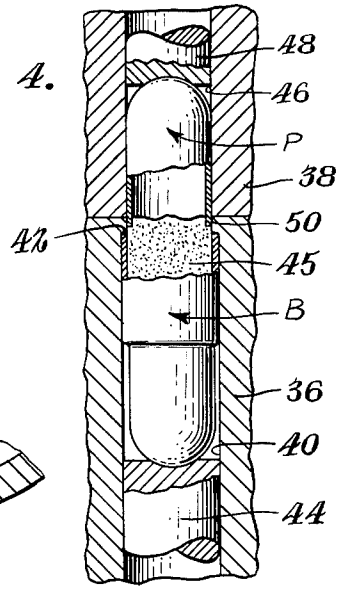


FIG. 4.

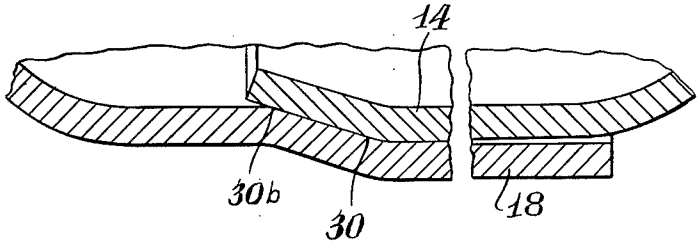


FIG. 5.

INVENTOR
ALFRED W. KATH

BY Bair, Freeman & Molinare Attys.

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TWO-PIECE HARD GELATIN CAPSULE

Alfred W. Kath, Detroit, Mich., assignor to R. P. Scherer Corporation, Detroit, Mich., a corporation of Michigan

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1 Claim. (Cl. 206—63.2)

This application is a continuation-in-part of my application Ser. No. 118,072, filed June 19, 1961, now abandoned.

This invention relates to plastic capsules which are commonly made from hard gelatin compositions and used as containers for measured quantities of powders, such as pharmaceutical preparations. More particularly the invention relates to an improved capsule construction comprising a body and a plug-like closure which when filled and assembled relative to each other are not easily separated as in the case of conventional capsules.

Hard gelatin capsules conventionally are made from an elongated, cylindrical open ended body portion closed by a cap which telescopes over the open end of the body. Normally the cap is approximately one-half as long as the body. Because the cap presents an exposed end surrounding the body, it may be rather easily removed and frequently the cap becomes inadvertently displaced, thereby spilling the contents of the capsule.

Further, prior art gelatin capsules, e.g. as disclosed in U.S. Patent No. 2,936,493, are not satisfactory for use with powdered medicaments due to the problem of "boiling up" of powder contents when the end or plug portion is inserted into the body and acts like a plunger or piston to scrape the sides of the body. Such "boiling up," caused by the uncontrolled expelling of air from the capsule as the plug is inserted into the body, results in loss of powder material and necessitates cleaning with the capsules before packaging or further treatment.

A primary object of the present invention is to provide a capsule which cannot be inadvertently disconnected, thereby spilling its contents.

Another object is to provide a capsule that can be formed in the usual manner i.e., by dipping finger-like forms into fluid gelatin composition, methyl cellulose, cellulose acetate, or other suitable film-forming material.

A further object is to provide the body portion of the capsule with a shoulder for the end of the plug to engage, and beyond the shoulder a plug-enclosing cylinder of substantial length into which the plug telescopes.

Still a further object is to provide a shoulder on the body of the capsule onto which the end portion of the plug-enclosing cylinder can ride to provide a tight frictional fit between the body and plug thereby to minimize inadvertent disengagement of the plug from the body.

An additional object is to provide the plug-enclosing cylinder with a slight taper, narrowing from its end toward the shoulder, to facilitate entry of the plug thereinto, and to provide for the venting of air from the capsule as it is assembled after filling. The taper also provides a progressive frictional wedging action between the plug and the body which attains maximum strength when the plug slides under the shoulder and effectively seals the plug in relation to the body.

With these and other objects in view, my invention consists in the construction, arrangement and combination of the various parts of my capsule, whereby the objects above contemplated are attained, as hereinafter more fully set fourth, pointed out in my claim and illustrated in detail on the accompanying drawing, wherein:

FIG. 1 is an enlarged, longitudinal sectional view through a two-piece capsule embodying my invention;

FIG. 2 is a similar sectional view of the body only of the capsule;

FIG. 3 is a transverse sectional view on the line 3—3 of FIG. 2;

FIG. 4 is a sectional view through filling dies of a filling machine and shows one of my capsules being assemblied; and

FIG. 5 is an enlarged cross-sectional diagram to illustrate certain wall tapers and engagements involved in the formation of my capsule.

On the accompanying drawing I have used the reference character B to indicate in general a body and P a closure plug. The body B comprises a cylindrical wall **10** and a hemispherical closed end **12**. The plug P comprises a cylindrical wall **14** and a hemispherical closed end **16**. The walls **10** and **14** are substantially non-tapered and of substantially equal thickness throughout. The body B also has a plug-enclosing cylindrical portion **18** to receive the cylindrical wall **14** of the plug P, which portion **18** is of greater diameter than the portion **10** with the transition from one diameter to the other providing a shoulder **20** over which the inner end of the plug P slightly overlaps when assembled with relation to the body B as shown in FIG. 1.

Relative diameters of the parts described are of significance as well now be pointed out. The outside diameter of the plug P is indicated at **22** in FIG. 1, and the wall **14** is a substantially untapered cylinder. The plug-enclosing cylinder **18** has an inner-end inside diameter adjacent the shoulder **20** indicated at **24** in FIG. 2 which is substantially the same as the diameter **22**. At least the inner surface of the wall **18** is slightly tapered, such as 0.008″ per inch whereby the relationship between the walls **14** and **18** is such that the inside diameter **26** of the outer end of the cylinder **18** is enough larger than the diameter **22** to permit ready entry of the plug P into the body B, and throughout, a major portion of the length of wall **18**, the telescoping action of inserting plug P into body B permits ready escape of entrapped air. Complete circumferential contact between the leading edge of plug P and body B occurs at approximately the point **30** (FIGS. 1 and 5) where the shoulder begins thereby effecting a wedge-type sealing contact during further telescoping movement as the inner end of plug P is forced to ride up onto the shoulder **20** to full engagement as shown in FIGS. 1 and 5 for frictional surface engagement to prevent subsequent accidental dislocation of the plug P from the body B. Such engagement is with the upper portion of the shoulder at **30***b* (FIG. 5) and results in a slight deformation of the inner end of plug P to a smaller diameter thereby ensuring a tight frictional fit between plug P and body B.

As shown in FIG. 5, when plug P is in engaged relation with body B the end portion of wall **14** rides atop shoulder **20** at point **30***b*. Depending upon the hardness of the gelatin material and the dimensions and configuration of shoulder **20**, wall **14** will contact wall **18** at point **30***b* and also at intermediate points along the shoulder down to a point **30** as shown in FIG. 5 where the shoulder begins, i.e., if the gelatin is relatively soft and the shoulder angle obtuse, wall **14** will deform at its inner end as plug P is forced onto the shoulder so as to conform in its outer periphery to the contour of the shoulder. On the other hand, if the gelatin is relatively hard and the shoulder angle less obtuse, the end of wall **14** will contact the upper portion of the shoulder at **30***b* and will not conform to the shoulder contour between points **30***b* and **30**. In the latter case, there may be a slight gap between walls **14** and **18** between points **30***b* and **30** but such will not materially affect the extent of frictional engagement holding plug P in body B.

Also illustrated in FIG. 5 is the fact that there is a loose fit between walls **14** and **18** toward the outer end of body B and the closed end of plug P. This is because diameter **26** of body B is slightly greater than diameter **22** of plug P as hereinabove described.

My disclosed capsule construction has a number of advantages not readily obvious and which make it superior to conventional capsules as will now be pointed out. The different diameters of the wall **10** and the plug-enclosing cylinder **18** together with the shoulder **20** reinforce the capsule body, making it less susceptible to breakage. Capsules are usually made of a composition which upon hardening may be fragile and subject to fracture. The "hard" gelatin composition from which these capsules are made is usually prepared from a high Bloom strength gelatin containing very little or no plasticizer and in these respects differs from what is known in the trade as "soft" gelatin. The shells that constitute the bodies and plugs are prepared separately in pairs and are later brought together to form the complete capsule. The film is deposited on finger-like forms and permitted to harden. In the case of gelatin this is accomplished by evaporating water from the composition using heat and/or conditioned air. The fragile hardened deposit which may comprise a shell for the body or one for the plug of the finished capsule is then stripped from the form. The shells may then be trimmed in accordance with the disclosure of Scherer Patent 2,936,493 of May 17, 1960.

After the body and plug have been trimmed to desired lengths, the powder or other content for the capsule may be charged into the body B from a suitable die cavity and subsequently enclosed by telescoping the plug P into the body B. When the plug is in its final seated position it rides on and slightly overlaps the shoulder **20** as shown in FIG. 1 and described hereinabove. The final size of all assembled capsules are substantially the same inasmuch as this shoulder aids in controlling the distance that the plug can be inserted, i.e., when the plug P is assembled in the manner as shown in FIGS. 1 and 5 it frictionally engages the shoulder portion and a press interference fit is effected. Such fit when coupled with the small smooth exposed end **16** is sufficient to hold the plug in place even when the capsules are roughly handled during subsequent packaging and other operations.

In the filling of conventional capsules there is always spillage of 5% to 10% of the charge from the capsule as the cap is placed on the body because the upper particles of the fill are subject to disturbance by escaping air and the powder "boils" over, spilling on the outside of the body. The filled capsules must then be cleaned. On the other hand my capsules can be cleanly filled due to their design.

To explain this difference, reference is made to FIG. 4 wherein is shown parts of a filling die **36** to receive the body B and a die **38** to receive the plug P. The die **36** has a bore **40** receiving the body B and the body is engaged with a shoulder **42** by means of a plunger **44**.

The die **38** has a bore **46** for the plug P backed by a plunger **48**. Initially the die **38** is spaced from the die **36** and the body B is filled with powder or other material **45** to the level of the top of the die **36**. The die may be slightly over-filled and the surplus scraped off. This level predetermines the quantity of the charge **45** which in most instances is rather critical. Therefore by having the body B definitely located (against the shoulder **42**) and the powder **45** scraped off to the level of the top surface of the die **36** accurate measurement is possible.

While only a single cavity or bore **40** is illustrated, the die **36** would have many of these bores for simultaneous filling of a considerable quantity of bodies B for economy of production.

After the fill has been scraped off as just described, the die **38** with the plug P therein is lowered, and its bore **46** matches the bore **50** of the die **36** above the shoulder **42**. Accordingly, when the plunger **48** is moved downwardly relative to the die **38** it will move the plug P into the bore **50** as shown and guide it accurately into the body B. It is desirable that the diameter of the bore **50** be slightly less than the outside diameter of the plug P so that the advancing edge of the plug will scrape the powder clean from the bore **50**. Of course when the plug enters the body B, no powder can escape past the shoulder **42**. Consequently, spillage of the powder is reduced to a minimum and accuracy of fill within very close limits results.

During the filling operation, entrapped air escapes through spaces between the capsule parts and the bores **40**, **46** and **50**, and through the space between the dies **36** and **38**. These spaces are minute enough however, to effectively prevent escape of the powder **45**. Actually this accuracy when using my type of capsule is within 0.5% by volume as compared to conventional capsules which may lose as much as 5% to 10% of the fill during the filling operation.

In the printing of contents, trademarks or source etc., on the capsules, there is assurance that all parts of the printing will remain in proper alignment as the printing is applied to the body B only. On conventional capsules on the other hand the printing must be restricted in size or part of it printed on the body and part on the cap. Subsequently, when the cap rotates relative to the body the printing is out of alignment, an undesirable condition entirely eliminated with my capsule construction.

Conventional capsules when filled present two different diameters which make is possible to rectify or properly orient the opposite ends thereof for packaging purposes, printing or other operations. My filled capsule has the same advantage due to the two different diameters **10** and **18** of the body B. Additionally, the unfilled bodies and plugs can be similarly rectified for orienting them with respect to the dies of the filling or assembling machine.

When the capsules are assembled and shipped empty, they do not come apart as do conventional capsules. Also during transit many of the conventional capsule caps will find their way over the round ends of the conventional capsule bodies and are difficult to remove. This nesting condition is even more prevalent when the conventional capsules are shipped unassembled. If my capsules are shipped unassembled there is no possibility of the plug fitting over the round end of the body as the round ends of both are substantially the same size and diameter. Comparative tumbling tests have been conducted which bear out this contention.

Also conventional capsules, when one is reversed relative to the next one, present opposed cap edges that readily result in the caps being pulled from the bodies due to jostling action in transit. On the other hand it will be noted that the hemispherical end **16** of the plug P starts at approximately the terminal end of the body B so that beyond this end there are no cylindrical sides that tend to align adjacent capsules in such manner that pull-apart thereof results. Accordingly, all empty capsules in a shipment are useable whereas conventional capsules that have become disoriented so that the cap is nested with the round end of the body are automatically rejected by the filling machine. Thus the invention produces greater economies than the conventional capsule construction.

While I have described the walls **10** and **14** as substantially non-tapered and of equal thickness throughout, and only the inner surface of the cylinder **18** tapered, in actual practice all walls of dipped gelatin capsules inherently are slightly tapered in thickness. The open ends have thinner walls due to the downward flow of the liquid gelatin on the form after dipping and before setting. Therefore if the inner surface of the wall **14** is not tapered (due to being deposited on a form of con-

stant diameter), the outer surface would be slightly tapered and the taper would be in the same direction as the inner surface of the wall 18.

Some changes may be made in the construction and arrangement of the parts of my capsule without departing from the real spirit and purpose of my invention, and it is my intention to cover by my claims any modified forms of structure or use of mechanical equivalents which may reasonably be included within their scope.

I claim:

A two-piece hard gelatin capsule comprising an elongated, smooth-surfaced cylindrical body having one end open, a smooth-surfaced plug received in said open end, said cylindrical body and said plug being of such size and shape as to contain a pharmaceutical preparation for swallowing and being capable of dissolving within the body after being swallowed, the walls of said body and plug being substantially equal in thickness throughout, the portion of said body surrounding said plug being of greater diameter than the rest of said body, the transition from one diameter to the other forming both internal and external rounded shoulders, the inner surface of said portion of greater diameter and the outer surface of said plug being reversibly tapered relative to each other so as to facilitate entry of said plug into said body portion of greater diameter and said portion adjacent said internal shoulder being of substantially the same internal diameter as the external diameter of the inner end of said plug, said plug being telescoped within said body with the inner end of said plug overlapping and in tight frictional engagement with said internal shoulder, said inner end being deformed by said frictional engagement and conforming in external contour to the internal contour of said internal shoulder, the portion of the body toward its open end being in spaced relationship to said plug thereby forming a loose fit between said plug and body outwardly of said adjacent portion.

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LOUIS G. MANCENE *Primary Examiner.*