Final Diploma

Patent Examination Board

FD4 Infringement and Validity

Tuesday 29 October 2024

10:00 to 15:30 GMT

Examination time: 5 hours 30 minutes plus 10 minutes upload time

The 5 hours 30 minutes is allocated as follows:

10 minutes – Downloading and printing the question paper;
5 hours – Answering the questions;
20 minutes – Four screen breaks of 5 minutes each.

At 15.30 you MUST immediately stop answering the questions. You then have **10 minutes** in which to upload your Answer document to the PEBX system.

You MUST upload your Answer document to the PEBX system by 15.40. After 15.40 you will not be able to upload it and your examination will be void.

INSTRUCTIONS TO CANDIDATES

1. The whole assessment task is to be attempted.
2. The total number of marks available for this paper is 100.
3. You must use the Answer document for your answers.
4. Do not attempt to change the font style, font size, font colour, line spacing or any other pre-set formatting.
5. Start each part of your answer on a new page. Press the control key and the enter key simultaneously to begin a new page.
6. Do not state your name anywhere in the answers.
7. This question paper consists of **19 sheets**, including this sheet, and comprises:
   Assessment task (1 sheet)
   Client letter (1 sheet)
   Document A GB2541586B (5 sheets including one page of drawings)
   Document B TAB Inc., Product Description Sheet 7 May 2020 (3 sheets with one page of drawings)
   Document C GB2302052A (5 sheets including two pages of drawings)
   Document D Handbook of Pharmaceutical Dosage Manufacturing, 1998 (2 sheets)
   A spare set of Claims (Document A) to use in your answer if you wish (1 sheet).

AT THE END OF THE EXAMINATION

8. Save your Answer document to your hard drive and follow the instructions for uploading your document onto the PEBX system.

Assessment task

Your client sends you the letter and documents listed on the Instructions to Candidates.

Your task is to prepare advice to your client on whether the attached granted patent may be enforced and defended.

You should prepare notes on which you would base your advice in which you:

a) **provide an opinion on infringement and validity, in the UK only.**

b) **identify other patent-related legal issues pertinent to the facts presented.**

c) **outline possible actions that may be taken to strengthen your client's legal position.**

d) **summarise the opinions formed in a), b) and c) above.**

Note the following:

a) You should accept the facts given to you and base your answer on those facts.

b) You should not make use of any other special knowledge that you may have of the subject matter concerned.

Allocation of marks

Construction: 21 marks
Infringement: 20 marks
Novelty: 25 marks
Inventive Step: 21 marks
Amendment: 2 marks
Sufficiency: 1 mark
Advice: 10 marks
Total: 100 marks

Client letter

Dear Patent Attorney

Our company, CAP Technologies Ltd, is in the business of providing dosage forms for medicaments for oral administration. We take the active ingredients and process them into dosage forms having a defined amount of active ingredient in each dose. A major part of our business is the production of solid medicament dosage forms, such as tablets, caplets, and gel caps. All of our manufacturing and sales take place in the UK.

Our most profitable product is a caplet with a coating of gelatinous material, a so called ‘gel cap’. We developed a process to produce these effectively more than 10 years ago and obtained a patent on this process (copy attached). Last year, this product provided over 50% of our sales and 75% of our profit.

We have become aware of a product from our main competitor, TAB Manufacturing Inc. This product, called ‘Kwickcap’ has become popular over the past year or so and a number of our regular customers have said that they are considering moving over to this form because of its improved dissolution properties. We have also lost several contract bids which we have subsequently found have been awarded to TAB for Kwickcap products. We obtained the enclosed Product Description Sheet from one of our customers which describes the Kwickcap product. We believe that this product uses the same concept as that covered in our patent, namely, non-overlapping coatings.

TAB Inc. is based in the USA, but has a subsidiary manufacturing facility in the UK, but we also believe that some of these products are made elsewhere and imported into the UK by the same subsidiary.

We would like to look into enforcing our patent, if possible, against TAB in the UK. Please could you let us know if you think this would be possible. To help you in this task, we enclose an introduction to a chapter in one of the most common text books in this field which gives some of the background to our invention. When conducting our research, we also came across Doc C, but this seems mainly directed at forming overlapping end coatings so may not be relevant.

Yours sincerely
S. Waller, Director, CAP Technologies Ltd

GB2541586 Caplets with gelatinous cover and process for making same

Application Date: 6 June 2014
Date of Publication: 12 December 2015
Date of Grant: 8 August 2016

This invention relates to medicaments and processes for providing gelatinous coverings for such medicaments.

Medicaments are available in a great variety of shapes and forms, such as coated compressed hard tablets, caplets, and filled gelatinous capsules. The use of gelatinous capsules for the encapsulation of medicinal agents has been a popular method for administering drugs because many patients prefer to swallow capsules and caplets rather than tablets. Gelatinous capsules were originally formed from a hard gelatin composition but the term is now used to refer to any composition which has the same physical properties as hard gelatin capsules.

Caplets are solid, elongate, round-ended tablets (i.e. have a similar shape to a capsule). Although very popular, these have not reached the same level of consumer acceptance gelatinous capsules once had. To solve this problem, the pharmaceutical industry has sought to combine the consumer acceptance of a capsule shape with a caplet.

The invention provides a simulated capsule medicament as defined in the claims consisting of a solid core, such as a caplet, covered with two hard-shell gelatinous capsule halves.

FIG. 1 is an exploded view of a dosage form of the present invention.
FIG. 2 is a cross-sectional view along the long axis of an alternative embodiment of a dosage form of the present invention.

The basic components of the present medicament include first and second hard-shell gelatinous capsule halves. The diameter and lengths of the halves are selected to allow a medicinal caplet to fit within the capsule halves. Both capsule halves have the same

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diameter so the end of one capsule half cannot be inserted into the end of the other. Preferably the capsule halves have different colours to facilitate the simulation of a capsule medicament.

The medicinal caplet can contain any of the many medicinal ingredients presently marketed over-the-counter or on a prescription basis, such as aspirin, paracetamol, and ibuprofen.

The present invention provides a simulated gelatinous capsule medicament 10. As shown in FIGS. 1 and 2, the medicament 10 comprises a caplet-shaped core 12 covered with a pair of hard-shell gelatin capsule halves 14 and 16. The cavity formed by the capsule halves 14 and 16 has a length of no more than the length of core 12, such that when capsule halves 14 and 16 are slipped onto core 12, their ends may touch, but will not overlap. Overlapping of the ends is also prevented since capsule halves 14 and 16 are of the same internal diameter. In a preferred embodiment, hard-shell capsule halves 14 and 16 each having the same length are placed onto core 12 so that the annular ends of capsule halves 14 and 16 contact each other at a point about midway 11 along the core 12.

In the manufacturing process, a first end 13 of the core 12 is inserted into a holder (not shown) leaving a second end 15 exposed. A dot of liquid gelatin 19 is then placed on exposed second end 15. A hard-shell gelatin capsule half 16 is then placed over the second end 15 and into contact with gelatin dot 19 so that the shell is held in place on the core 12 to form a first half-shell/core combination. The first combination is dipped into a tank (not shown) of hot water up to the edge of the capsule half 16 for a period sufficient to allow the hard gelatin shell to hydrate and plasticize. The first combination is removed from the tank and the hard-shell gelatin capsule half 16 is dried to cause the hard-shell gelatin capsule half 16 to shrink to fit the form of second end 15 to form a first shrink-wrap gelatin hard-shell covering/core combination. The first end 13 of the core 12 is then displaced from the holder and the covered second end of the first covering/core combination is inserted into the holder and a dot of liquid gelatin 18 is placed onto the exposed first end 13. A hard-shell gelatin capsule

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half 14 is then placed over the first end 13 and into contact with gelatin dot 18 so that the shell is held in place on the core 12 to form a second half-shell/core combination. The second combination is then dipped into the hot water bath to allow it to hydrate and plasticize and dried to shrink fit the form of first end 13 to form a second shrink-wrap gelatin hard-shell covering/core combination.

Gelatin dots 18, 19 have a melting point of greater than the temperature of the water so that capsule halves 14, 16 will remain in place on the ends 13, 15.

The covering/core combination is then displaced from the holder.

After completion of the shrink-wrapping process, the two hard-shell gelatin capsule halves 14 and 16 are substantially in intimate contact with the core 12, i.e. capsule halves 14 and 16 have been shrink-wrapped onto the core 12. As shown in FIG. 2, the shrink-wrapped capsule halves 14 and 16 sometimes are not in contact at a point about midway along the core. Capsule halves 14 and 16 shrink upon completion of treatment, which may cause them to pull back from each other at the middle of the core 12. This may be acceptable. If not, a gelatin ‘belly’ band 17 can be added to core 12 to cover the gap between capsule halves 14 and 16 to facilitate the simulation of a gelatin capsule medicament.

The gelatin hard-shell capsules halves 14 and 16 can include different pigments such that the final product will look like a conventional two-colour capsule. Typical colours are red, white, yellow and blue.

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Claims

1. A medicament comprising:
(a) a solid generally cylindrical caplet with first and second ends;
(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet;
(c) a second hard-shell gelatinous capsule half secured on said first end of said caplet, wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half, and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.

2. A medicament as claimed in claim 1, wherein
the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and
the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.

3. A medicament as claimed in claim 1 or 2, wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.

4. A medicament as claimed in claim 3, wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.

5. A medicament as claimed in any preceding claim, wherein the first hard-shell gelatinous capsule half has a first colour, and the second hard-shell gelatinous capsule half has a second colour different from the first colour.

6. A medicament as claimed in any preceding claim, further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.

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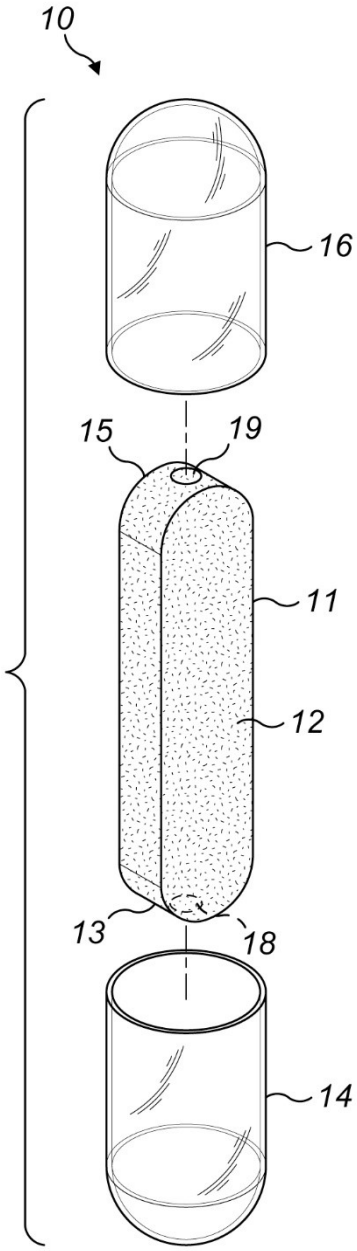

FIG. 1

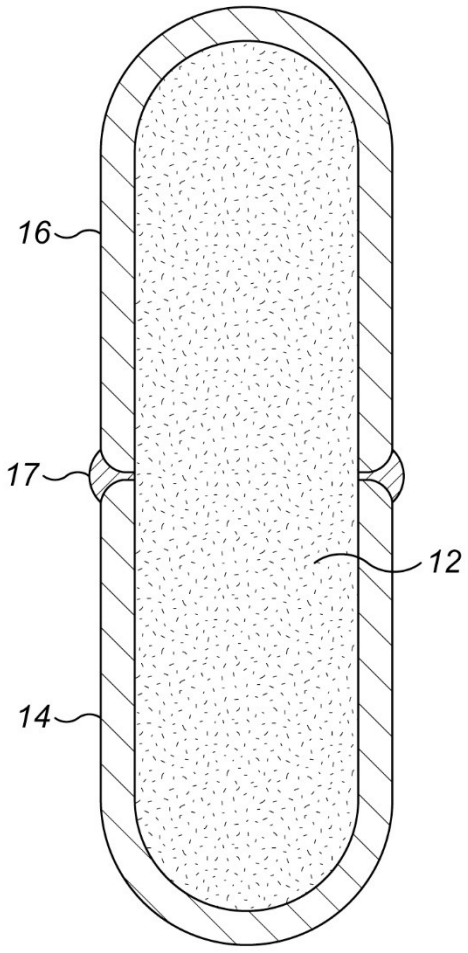

FIG. 2

Kwikcap: Rapidly disintegrating gelatinous-coated tablet

Kwickcap is a gelcap dosage form comprising a tablet core including gelatinous coatings over both ends. Gelatinous endcaps on opposing ends of the tablet core do not meet and form a circumferential gap or band through which the core is visible.

Capsules have long been recognized as a preferred dosage form for the oral delivery of active ingredients, which may be in the form of powder, liquid, or granules. One type of commonly used capsule is a two-piece hard-shell capsule, typically made from gelatin. The hard-shell capsule typically comprises a longer body and a relatively shorter cap having an inside diameter that will just fit over the outside diameter of the body. The cap fits snugly over the body, creating an overlapping portion of the capsule.

In view of the tamperability of old-fashioned capsules, which can be taken apart, steps have been taken since the 1980s to manufacture capsule shells which, once assembled, cannot be disassembled without their destruction.

Kwickcap provides an improved gelcap having faster disintegration and/or dissolution times relative to the commercially available gelatinous-coated products.

FIG. 1 is a view of a gelcap core.
FIG. 2 is a view of a Kwickcap dosage form.

Tablets are solid forms prepared by compaction of powders on a tablet press. Tablets can be made in a variety of shapes. A ‘gelcap core’ is one type of elongated, capsule-shaped tablet having straight or slightly bowed sides, and a generally circular cross-section, and having a length to diameter ratio from about 2 to about 5.

FIG. 1 shows a gelcap core 10 in the shape of an elongated tablet having two ends 12a, 12b at opposing sides of a longitudinal axis. A bellyband 14 occurs along the longitudinal circumference where the core comes into contact with the walls of the press during compaction.

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The core 10 can contain active ingredients, such as pharmaceuticals.

FIG. 2 illustrates a Kwickcap dosage form 20 having ends 12a, 12b with gelatinous coatings 24a, 24b that do not contact or overlap one another. The gelatinous coatings 24a, 24b are separated from one another and create a gap 26. The opposing ends 12a, 12b of the Kwickcap dosage form 20 are covered with coloured gelatinous materials having a different colour to that of the core 10. The colours on each end may be the same or different from one another, such as red and white, or blue and yellow.

The gelatinous coatings 24a, 24b are provided by inserting one end 12a of the core 10 into a holder, immersing the other, exposed, end 12b into a selected gelatinous material, and then reversing the core 10 in the holder and repeating the steps with respect to the opposing end 12a of core 10. The gelatinous coatings 24a, 24b are provided in such a way that gelatinous coatings 24a, 24b do not meet, and in fact, form a gap or band 26 around the circumference of the core 10 through which the outer surface 22 of the core 10 can be seen.

The Kwickcap dosage form has a gap width in the range of about 0.6 mm to 4.0 mm. Research has shown that the slipperiness of the dosage form is not effected, and most people cannot detect a height transition, i.e. ‘step-up’ from the core to the dipped ends.

The gap or band region 26 can be off-centre or centred on final dosage form 20. The optimal gap 26 for a gelcap core of 19.0 mm in length has a width of about 2 mm to 3 mm. If the gap becomes too small, the level of improved dissolution diminishes.

Depending on the size of the gap, the Kwickcap dosage form dissolves up to 6 minutes faster than a fully coated gelcap with no gap.

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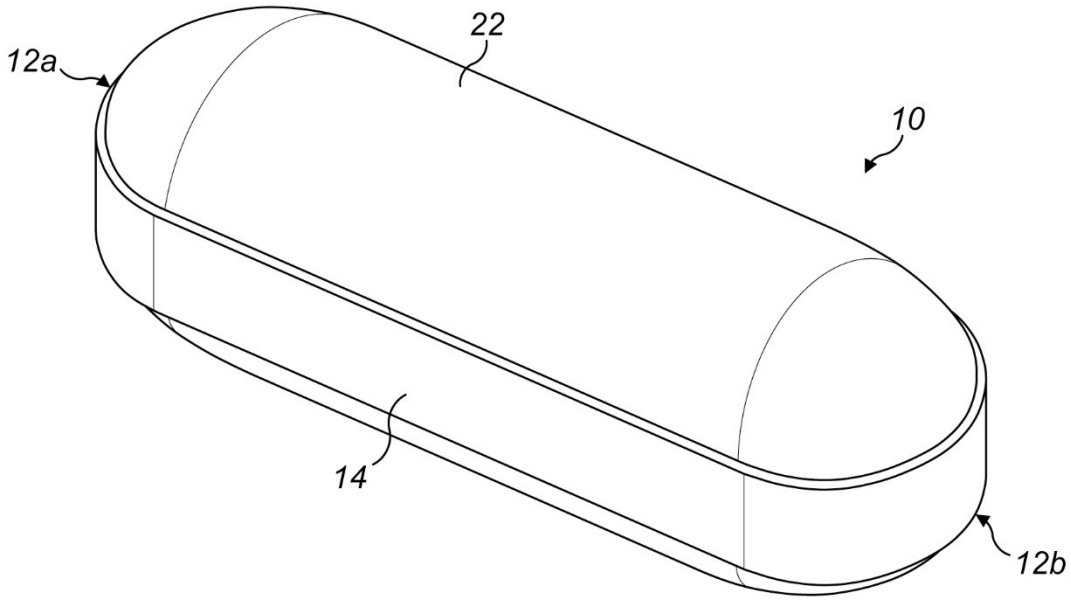

FIG. 1

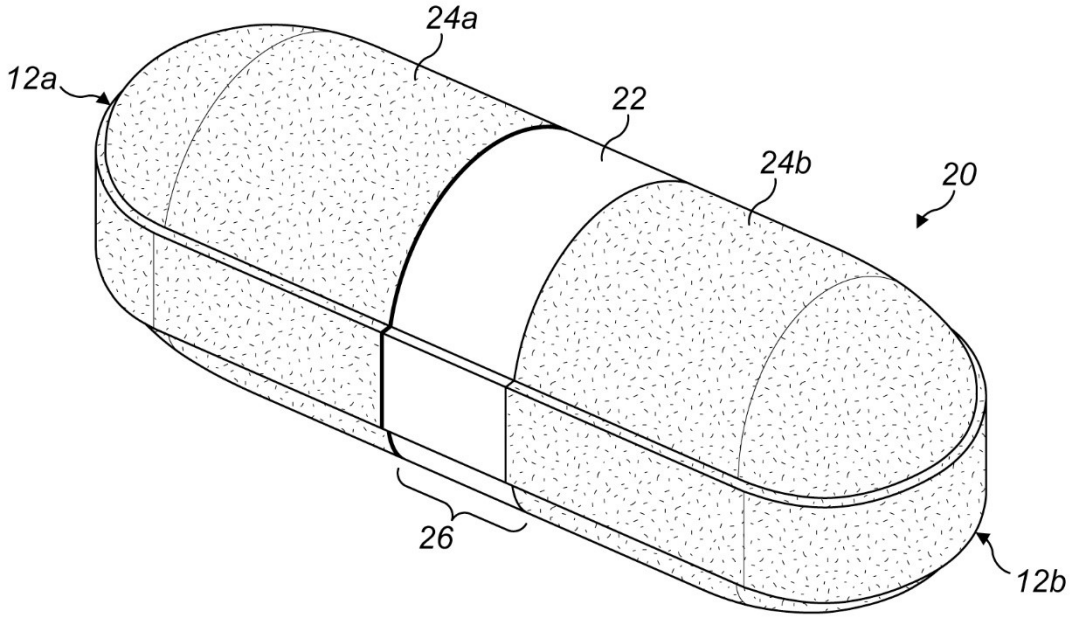

FIG. 2

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GB2302052A Gelatin-coated caplets and process for making same

Date of Publication: 3 September 2009

This invention relates to coated medicaments and processes for providing gelatinous coverings for such medicaments.

Many patients find it easier to swallow capsules than tablets. This preference has prompted pharmaceutical manufacturers to market certain products in capsule form even though they are also available in tablet form. However, capsules are vulnerable to tampering by separating the capsule halves and then replacing or adding to the powdered contents.

Although gelatin-coated medicaments and processes have achieved some commercial success in the marketplace, a need remains for a coated medicament which is at least as tamper-resistant as a solid caplet while providing the ease of swallowability of a capsule. There is also a need for a less expensive medicament coating method capable of producing a multi-coloured, capsule-like coating which is perceived to be more effective.

The present invention provides a method for coating solid cores, such as caplets, with gelatinous coatings to produce simulated capsule-like medicaments. Such capsule-like medicaments are achieved by individually dipping first one end and then the other end of each caplet to provide a medicament which appears similar to a regular capsule.

As a result, novel capsule-like medicaments are provided having smooth, relatively thick, shiny, multi-coloured gelatinous coatings thereon. These medicaments are easier to swallow and more effective than prior art caplet medicaments, while providing much greater tamper resistance than conventional capsules.

It is, therefore, an object of this invention to provide a simulated, capsule-like medicament having a gelatinous coating capable of being provided in two or more colours.

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FIG. 1 is a cross-sectional view of a holder with a caplet being dipped in a gelatinous material.

FIG. 2 is a top view of an uncoated caplet.

FIG. 3 is an end view of the caplet of FIG. 2.

FIGS. 4a–c are side views of caplets illustrating various coating patterns.

The process of the invention comprises the steps of providing a holder 26 for a caplet (FIGS. 2 & 3) and inserting a first end of a caplet into the holder while leaving the second end of the caplet exposed. The holder is then moved relative to a bath of gelatinous coating to dip the second exposed end of each caplet. The resulting gelatinous coating on the second exposed end of the caplet is then allowed to dry to form a coated end. Once dry, the coated (second) end of the caplet is then displaced through the holder to expose its uncoated first end. A gelatinous coating is then applied to the uncoated first end of said caplet. The coating applied to the first end of the caplet is then allowed to dry. In accordance with the preferred embodiment method, the baths of gelatinous coating into which the caplet ends are dipped may be of different colours, to thereby create a simulated 2-piece capsule look to the finished caplets.

FIG. 1 illustrates apparatus for dipping solid caplets into a gelatinous material embodying the teachings of this invention. A holder 26 with a caplet channel 106 receives a caplet 16 having a first and second end, 110 and 104, leaving the second end of the caplet 104 exposed. Next, a gelatinous coating, is applied by lowering the exposed end of the caplet 104 into a bath of liquid gelatinous coating material 28. The extent to which the second end 104 can be coated is dependent upon the desired colour configuration and ‘seam’ requirements. The half-coated caplet is then dried using a dryer (not shown), which permits the gelatinous coating on the second end 104 to dry, forming a coated second end. The caplet 16 is then repositioned in the caplet channel 106 to expose the first end 110. The caplet 16 is then coated with a gelatinous material on its first end 110 and dried in the same manner as described above, resulting in a dry caplet substantially covered in gelatin.

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As indicated in FIGS. 4a–c, the colour scheme can be bifurcated as depicted by caplet coatings 304 and 306, and a seam 302 or 300 can be provided by overlapping the gelatinous coatings on the first and second ends 110 and 104.

Colouring can be added to the coatings to produce colours such as red, white, pink, green, reddish brown, blue, yellow and black. Coloured medicaments are necessary to give a specialty product a distinctive appearance.

As indicated in FIGS. 4b–c, a seam 300 or 302 can now be provided by overlapping the dried coating on the second end 104. Through careful selection of gelatin colour schemes, the seam can exhibit a different colour than the ends of the caplet, e.g., green and yellow coatings on the ends can be overlapped to form a blue seam.

Gelatin-coated caplets have been produced using the above method, wherein the second applied gelatinous coating partially overlaps the first applied gelatinous coating forming a capsule-like seam circumscribing the medicament at about a midway point of a longitudinal access of the medicament.

(Claims omitted)

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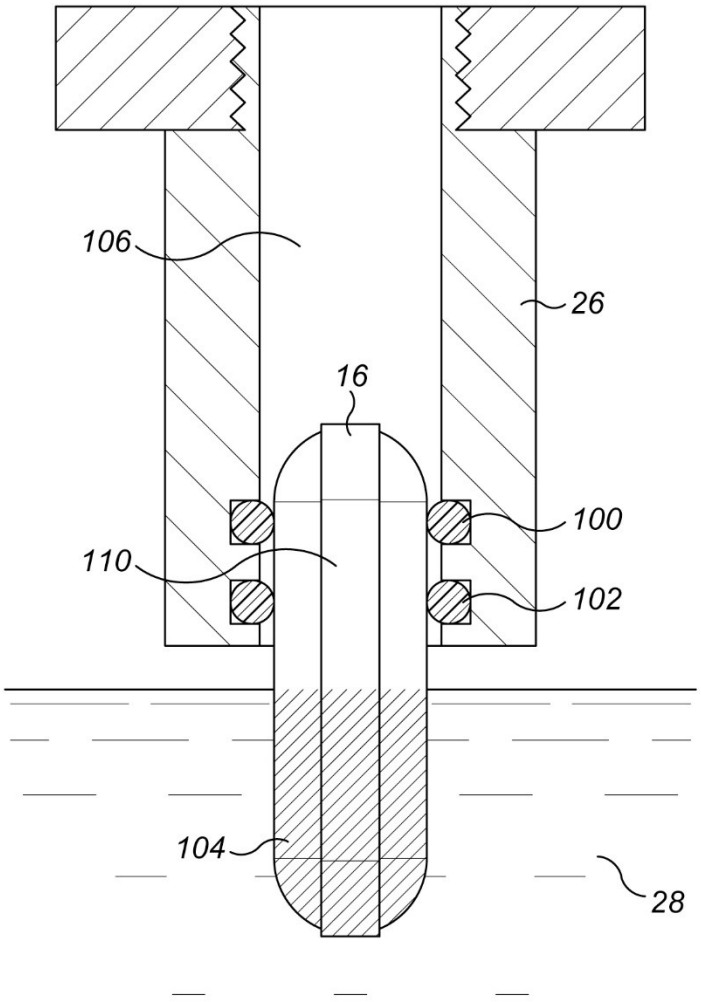

FIG. 1

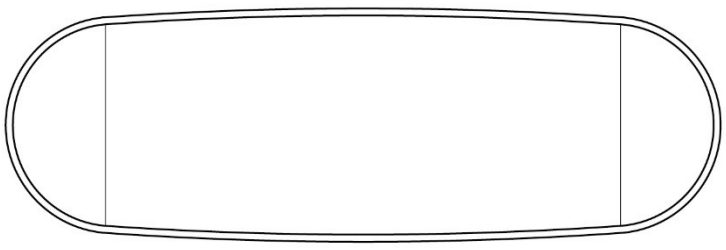

FIG. 2

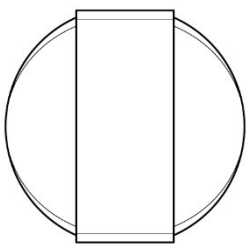

FIG. 3

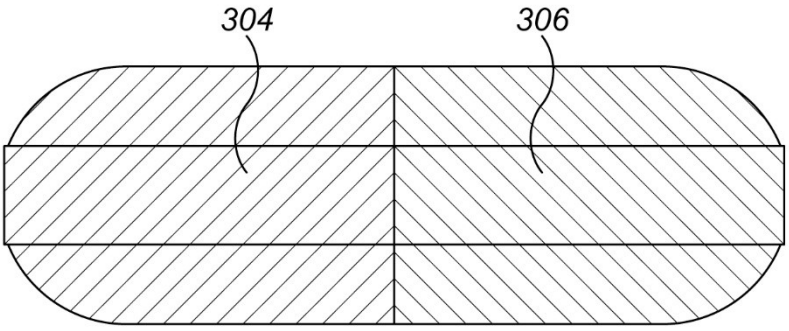

FIG. 4a

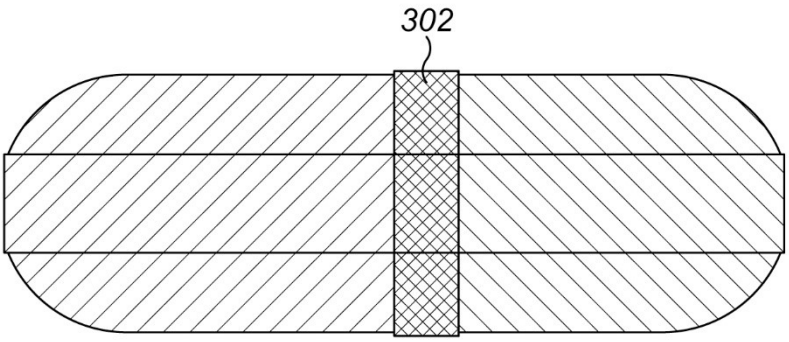

FIG. 4b

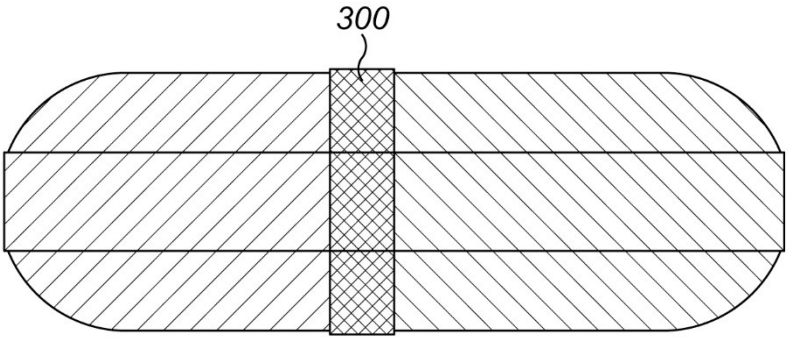

FIG. 4c

Handbook of Pharmaceutical Dosage Manufacturing, pub 1998

Capsules, caplets, and gel caps

Introduction

The use of hard gelatin capsules for the containment of pharmaceuticals in dosage forms has been known for years. As opposed to tablets, in which the medicament is compressed into a solid cylinder, gelatin capsules have been used to administer pharmaceuticals in different forms, such as powders and liquids. As opposed to tablets, capsules completely envelop the drug until it reaches the stomach, where the gelatin coating is dissolved, thereby releasing the medicament. This provides an additional benefit of not only masking the bitter taste of certain pharmaceuticals, but also providing a smooth texture to the surface of the medicament for easier swallowing and passage into the digestive system.

Standard capsules known in the art are prepared by dipping rows of stainless steel pins into solutions of gelatin coating material. The dipped portions are then dried and stripped off the pin. Both capsule halves are formed in this manner. One-half or first portion is generally referred to as the capsule 'body', while the half that fits over the open end of the first portion is referred to as the 'cap'. The cap is mated with the body by fitting its open end over the respective open end of the body. This is possible because the inner diameter of the cap is no smaller than the outside diameter of the body. The capsules are generally sold in this assembled manner and the drug or medicament filled later.

One of the concerns in the use of such hard gelatin capsules in the over-the-counter (OTC) market became evident several years ago when tampering incidents took place. The problem with standard capsule technology is that the two halves of a capsule can be easily pulled apart and the medicament exposed.

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Anything can be added to the composition at this point and the halves then compressed together to again form one whole capsule. Moreover, there is generally nothing that would indicate that the composition inside the gelatin capsule had been changed, i.e. there is no tamper-evident indication incorporated into most commercially available gelatin capsules.

The tampering incidents forced pharmaceutical manufacturers to take additional packaging steps to ensure that such tampering could not occur without it at least being noticeable prior to consumption.

Some capsule products were replaced by 'caplets', solid oblong tablets comprised of the medicament and coated with a material such as cellulose. The solid caplet form of the drug not only protected against further tampering, since the caplet would have to be broken apart get to the ingredients, but the coating also provides a certain amount of ease in swallowing.

Consumer surveys suggest that the shiny, familiar capsule shape has a special appeal to patients as being easy to swallow. There exists then, a need for tamper resistant capsule or capsule-like encapsulating materials for pharmaceuticals.

There is also a strong preference for bicoloured or two-tone coloured capsules. Specific colours or colour combinations can be used to identify particular medicaments. These two-colour capsule dosage forms are preferred since they assure the consumer that they are getting a specific medication by a brief, visual examination.

There are a number of known methods for the preparation of coated pills or tablets, for example by dipping them into gelatin solutions of one type or another. These typically involve immersing half of the pill body into the gelatin. The pill is then inverted so that the other half can be coated.

Spare Set of Claims

1. A medicament comprising:
(a) a solid generally cylindrical caplet with first and second ends;
(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet;
(c) a second hard-shell gelatinous capsule half secured on said first end of said caplet, wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half, and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.

2. A medicament as claimed in claim 1, wherein
the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and;
the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.

3. A medicament as claimed in claim 1 or 2, wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.

4. A medicament as claimed in claim 3, wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.

5. A medicament as claimed in any preceding claim, wherein the first hard-shell gelatinous capsule half has a first colour, and the second hard-shell gelatinous capsule half has a second colour different from the first colour.

6. A medicament as claimed in any preceding claim, further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.