Patented June 15, 1943 2,321,694

UNITED STATES PATENT OFFICE

2,321,694

SUPPOSITORY OR BOUGIE

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No Drawing. Application October 30, 1939, Serial No. 301,952

7 Claims. (Cl. 167—64)

This invention relates to suppositories or medicinal bougies, balls and the like, and more particularly to a base for such articles which may be adapted to carry, support and release the desired medicament when and as desired in application.

Suppositories or bougies are commonly made of easily fusible material so that under the body temperature they will fuse and will release any medicament incorporated in or carried by the said fusible base.

The bases of such suppositories and bougies are commonly and easily fusible cones or cylinders of cocoa butter, soap, or glycerinated gelatin. Because of this easily fusible character of the bases of which these articles are made, tremendous losses are incurred annually by both manufacturer, seller and user. In the more temperate localities, and particularly in the warmer climates wherein the temperatures often reach above the body temperatures, the bases of these articles fuse, with consequent destruction. For a great many years this difficulty has been recognized, both my manufacturers, wholesalers, retailers and users. Most users hesitate to place such articles in private refrigerators, and many losses have occurred because of sudden temperature increases and the failure of handlers of such articles to have available adequate refrigeration facilities. Patients endeavor to avoid the use of such articles where they can only be properly handled in refrigerators, and therefore they lose the beneficial applications possible through this method of application. There has to my knowledge been no adequate solution heretofore found for this problem.

I have discovered a base composition for such articles which is practically unaffected by heat changes but which may be made to fuse easily and equally effectively in the presence of moisture. I have found further that this base material may carry any desired or required medicament and may be caused to fuse and release the medicament as desired by the control of the constituents of the composition of which the base is formed.

I have further discovered that by incorporation in the base of my invention of suitable quantities of hygroscopic substances such as glycerine that I am able to control the moisture present to cause the effective fused disintegration or expanding as the case may be of the base of these articles to release the medicaments as desired or to produce a desired dilative suppository where medication is not desired.

It is therefore an object of my invention to provide a base for suppository, bougie, or the like which is substantially unaffected by heat changes but which will readily fuse in the presence of moisture.

It is another object of my invention to provide a base composition for a suppository or bougie which will readily fuse under the influence of moisture and which is so combined with a substance of hygroscopic character as to control the moisture to enable the control of the fusing, disintegration or dilative characteristics of the suppository or bougie.

It is another object of my invention to provide a base for a suppository or bougie which includes a material which, under the influence of moisture will cause the said bougie to fuse or disintegrate so as to release any medicament as carried in said base.

Another object of my invention is to provide a base material for the holding of the desired medicaments for the formation of suppositories or like substances and which suppositories or like substances as formed will be substantially heat resistant and unaffected by ordinary or drastic temperature changes.

Other objects and advantages of this invention it is believed will be apparent from the hereinafter set forth detailed explanation thereof as applied to the several modifications thereof.

In accordance with my invention, the base for a suppository is formed which is resistant to fusing under temperature changes but which will readily fuse in the presence of moisture or will expand or disintegrate under the said influence, depending upon the particular composition of the product and its desired applicability, that is, substances of this character are manufactured both for their dilative effect and for delivering desired medicaments over a period of time. Thus the particular type of product utilized would determine the particular application, whether of an expansible character or one which disintegrates or fuses in its application.

As an example of the coating embodying my invention wherein the base is of the disintegrating character, I form the base in the proportions of:

	Parts
Stearic acid	2
Agar, powdered	1
Glycerin	2½

In this combination the stearic acid and agar proportions are determinative of the rate of ab-

sorption of water, as is the degree of subdivision to which the agar is powdered. The availability of water for absorption by the agar is controlled by the quantity of the water abstracting substance which here is set forth as glycerin. Any other suitable water abstracting substance may be utilized and the proportions as herein set forth are not critical but are determinative of the rate at which the substance will disintegrate to release the medicament. It will be obvious that these proportions may be varied over wide ranges and that the varying of the proportions of one substance permits a like variation of the proportions of the others.

While we have in this example and in the other examples set forth stearic acid as one of the principal base materials, any other similar material may be utilized in the preparations which will with the disintegrating element, i. e., agar, be determinative of the rate at which the water will be taken up by the agar. Other oils, waxes or similar substances may be utilized.

The manner of combining the ingredients is merely the manner of suitable mixing to obtain a homogeneous mass. Thus the powdered substances, i. e., the powdered agar and powdered stearic acid, are placed in a mass mixing machine and mixed together, at which time the medicament may be added, particularly if a powdered medicament is used. After the dry ingredients have been mixed, the wet ingredients such as the glycerin may be added and mixing continued until the same is all complete and homogeneously mixed together. If a liquid medicament is utilized, it may be most conveniently added with the glycerin to the dry mixed substances.

In this preparation the disintegration or fusing of the base of the suppository or bougie is caused by the water as absorbed by the agar. The water is made available to the agar for absorption by the ability of the water abstracting substance glycerin to take water from its surroundings. Thus, the quantity, of agar, the quantity of glycerin, and the protection offered to the agar by the stearic acid determines the rate at which the base material will disintegrate under the influence of the moisture to release the medicament carried thereby.

In this type of preparation a water abstracting substance of the character of glycerin appears to be essential in order to bring into contact with the base material a sufficient amount of water to cause the rapid fusing of the base material to liberate the medicament as rapidly as is desired. This, however, depends to a considerable degree upon the rate at which the medicament is desired and the time within which it is desired to release the medicament. It will be obvious from the foregoing that many substances other than agar are utilizable. Thus any substance which has the property of expanding rather rapidly under the influence of water absorbed may be substituted for agar. Such substances, to enumerate a few of them, are powdered: elm, cinnamon bark, cornmeal, thyme, kaolin, psyllium seeds, bentonite clay, okra and pectin. These substances are what I desire to term here as water-absorbing agents as differentiated from the substances of water abstracting character such as glycerin, which have the property of drawing or abstracting water from surrounding tissue and not merely taking up water by absorption when in contact with water.

The third element of this composition in this example set forth as stearic acid is the water retarding agent of the composition and acts to protect the water-absorbing agent from immediate absorption of water with consequent and immediate disintegration of the base material. Thus many types of this material may be utilized among which are carnauba wax, stearic acid, petroleum jelly, either mixed as desired or separately, depending upon the control desired of the water absorption. With the ingredients properly mixed, they are then preferably subjected to suitable pressure in suitable molds in order to form the same into the desired cylinders or cones or balls of such shape as may be desired in the particular application.

In some cases it is found advantageous to glaze the surface of the cylinders, cones or balls. Such glazing may be accomplished in a number of ways, for example, by mixing into the product an alcoholic solution of candy glaze, white shellac, or the like, prior to, or during, pressure-forming of the said articles.

As a separate and further example, and particularly as an example of the expanding type of suppository or bougie which does not readily disintegrate, the following is given:

3 parts of powdered stearic acid are mixed with one part of powdered okra. After these substances have been thoroughly mixed, or during their mixing, glycerin to the extent of approximately 2% of the total mixture is added. The base material thus formed is handled in substantially the same manner as herein set forth with the medicament being added in the manner as indicated.

After the suppository or bougie is formulated under the pressure of this composition, it will be found that the same gradually expands as water is absorbed by the powdered okra without substantial disintegration. Thus an expanding or dilative type of suppository or bougie is provided from which the medicament is released during the period of expansion.

A further example of my invention is found in the use of powdered elm in place of powdered agar, the first example given. In this type of structure the base material will be partially of the expanding and partially of the disintegrating type. In this case 15 parts of powdered stearic acid are mixed with 10 parts of powdered elm and 3 parts of glycerin. The mixing, the forming and medication of the base material may be the same as set forth in connection with the first example above set forth. In this case it is advisable to glaze the formed material with an alcoholic solution of a candy glaze, white shellac, or the like, in order to cause the particles under pressure to more closely adhere. When this base material is utilized, it will be found that it has characteristics of both the disintegrating and expansible types in that it fuses both through expansion and disintegration as the water is absorbed.

As a further example of this invention, powdered stearic acid in two parts may be mixed with one part powdered pectin and 2 parts of glycerin. This mixture may be handled in substantially the same manner as hereinabove set forth, both as to mixing, medication and forming. This particular preparation has one added advantage not present to such a marked degree in the other preparations set forth, and that is, of providing a mucilaginous substance as the water is absorbed and the pectin swells to cause disintegration of the base material with consequent liberation of the medicament.

A further example of my invention is found in the mixing of stearic acid, carnauba wax, petroleum jelly, with powdered agar and sufficient alcohol to form a paste. In this modification the stearic acid, carnauba wax and petroleum jelly are melted, cooled, pulverized, and then mixed in a suitable mixing machine with the powdered agar and alcohol and mixing is continued until the mass is a homogeneous paste. During this mixing glycerin is added in sufficient quantity to draw the moisture out of the tissue so that it may be absorbed by the agar. This mixture tends to give a more water impervious base material by more thoroughly protecting the agar from water and may act to slow up the rate of water absorption by the powdered agar.

As heretofore set forth, any other suitable substance may be used in the place of glycerin, as the water abstracting agent and which product or substance has the property of drawing moisture from the surrounding tissue so that the suppository or bougie will fuse or disintegrate in the proper period of time. As an example of such other substances which may be used in place of glycerin, there is potassium acetate and other deliquescent products. An example of the preparation utilizing potassium acetate in the place of glycerin is prepared from two parts of powdered stearic acid, two parts of powdered agar, two parts of potassium acetate, and one part of alcohol, mixed together to produce a moist powder which is then compressed into the shape desired in the ordinary suppository-preparing machines.

Having fully described my invention, it is to be understood that I do not wish to be limited to the details herein set forth, but my invention is of the full scope of the appended claims.

I claim:

1. A solid base material for suppositories, bougies or the like, which is substantially unaffected by heat at body temperature but which will abstract moisture from surrounding tissue and release a medicament in the presence of said abstracted moisture at a desired rate, consisting of a water absorbing agent selected from the group consisting of powdered agar, elm, cinnamon bark, cornmeal, thyme, kaolin, psyllium seeds, bentonite clay, okra and pectin; a water absorption retarding agent selected from the group consisting of petroleum jelly, carnauba wax, and powdered stearic acid; and a water abstracting agent selected from the group consisting of glycerine and potassium acetate.

2. A base material for suppositories, bougies or the like, which is substantially unaffected by heat at body temperature but which will abstract moisture from surrounding tissue and fuse in the presence of said abstracted moisture and release a medicament at a desired rate, consisting of the following materials in about the proportions specified: 2 parts of powdered stearic acid; 1 part of powdered agar; and 2½ parts of glycerin.

3. A base material for suppositories, bougies or the like, which is substantially unaffected by heat at body temperature but which will abstract moisture from surrounding tissue and fuse in the presence of said abstracted moisture and release a medicament at a desired rate, consisting of the following materials in about the proportions specified: 2 parts of powdered stearic acid; 1 part of powdered pectin; and 2 parts of glycerin.

4. A base material for a dilative type suppository, bougie or the like, which is substantially unaffected by heat at body temperature but which will abstract moisture from surrounding tissue and expand in the presence of said abstracted moisture and release a medicament at a desired rate, consisting of the following materials in about the proportions specified: 3 parts of powdered stearic acid; 1 part of okra; and glycerin in the ratio of about 2% of the total mixture of stearic acid and okra.

5. As an article of commerce, a suppository, bougie or the like, consisting of a medicament, stearic acid, dry agar, and glycerin in such relative proportions that the mixture is substantially unaffected by heat at body temperature but is capable of abstracting moisture from surrounding tissue and releasing the medicament at a desired rate in the presence of said abstracted moisture.

6. As an article of commerce, a suppository, bougie or the like, consisting of a medicament, stearic acid, dry agar, and glycerin in such relative proportions that the mixture is substantially unaffected by heat at body temperature but is capable of abstracting moisture from surrounding tissue and fusing and releasing the medicament at a desired rate in the presence of said abstracted moisture.

7. As an article of commerce, a suppository, bougie or the like, consisting of a medicament, powdered stearic acid, powdered okra, and glycerin in such relative proportions that the mixture is substantially unaffected by heat at body temperature but is capable of abstracting moisture from surrounding tissue and expanding and releasing the medicament at a desired rate in the presence of said abstracted moisture during the period of expansion.

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