

1

3,043,747

## TABLETS COATED WITH CARBOXYMETHYLCELLULOSE SHELLAC COMPOSITION

Stuart Long, Kalamazoo, Mich., assignor to The Upjohn Company, Kalamazoo, Mich., a corporation of Delaware

No Drawing. Continuation of applications Ser. No. 768,852, Oct. 22, 1958, now Patent No. 2,997,784, dated Aug. 29, 1961, Ser. No. 768,854, and Ser. No. 768,855, Oct. 22, 1958. This application Feb. 20, 1961, Ser. No. 90,223

20 Claims. (Cl. 167-82)

This invention relates to an improved coating for solid medicinal dosage forms, and more particularly to an improved coating composition of a water-soluble cellulose derivative and solid medicinal dosage forms which have been coated therewith.

This application is a continuation of applications Serial No. 768,552, now U.S. Patent 2,997,784; 768,854; and 768,855; all filed on even date of October 22, 1958.

The coating of medicinal tablets for oral use is an old and often practiced process of the pharmaceutical art. Many advantages are obtained by a coating such as protection from chipping or breaking during handling and protection from the atmosphere during storage. Other advantages from the standpoint of the person who must take the medicament, are a pleasing appearance, masking of disagreeable taste or odor and ease of swallowing.

Many coating materials have been used, with coatings consisting essentially of sugar being the most popular. The use of sugar coatings requires a time consuming multiplicity of steps in the process of application.

In recent years a new group of materials has been made available and is finding acceptance and use in the coating art. This group consists of cellulose derivatives, e.g., methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, ethyl cellulose, cellulose acetate phthalate, and others, and forms what is called a film coating. The members of this group are of two types, the water soluble and water insoluble.

For coatings that are to disintegrate and release the medicament in the stomach, the water soluble types are preferred. The coating procedures used in the past have consisted of the following sequence of steps: first, the application of a sealing coat of shellac and then the coating solution containing a particular cellulose derivative is applied. A characteristic inherent in these compositions and their use is the tendency for the cellulose derivative to be deposited over the surface in a film of uneven thickness, leaving the edges with a lesser amount of covering material. Another characteristic of the coating is that, with the passage of time or on ageing, the disintegration time increases and the medication is not released as quickly. Both of the preceding characteristics are disadvantages for a coating which is intended to disintegrate in the stomach.

It is therefore an object of the present invention to provide a composition suitable for the coating of solid medicinal dosage forms. Another object is to provide a coating composition which will adhere and form a coating of uniform thickness when applied by the usual methods. Still another object is to provide a coating composition which forms a coating that will rapidly disintegrate in the stomach and which will not materially lengthen its disintegration time on ageing. A further object is to provide a solid medicinal dosage form with such a coating material. A still further object is to provide a solid medicinal dosage form with a coating which is uniform in thickness. A still further object is to provide a solid medicinal dosage form with a coating which allows rapid disintegration and release of medicament in the stomach

2

unaffected by ageing. Other objects will be apparent to one skilled in the art to which this invention pertains.

The foregoing and additional objects have been accomplished by the provision of a composition for coating solid medicinal dosage forms comprising a hydro-alcoholic solution containing dissolved therein a member selected from the group of water-soluble cellulose derivatives consisting of methylcellulose, hydroxyethyl cellulose and sodium carboxymethylcellulose and suspended particles of purified, arsenic-free shellac. According to this invention it has been discovered that the presence of shellac particles suspended in a hydro-alcoholic solution of cellulose derivative form an improved coating composition for solid medicinal dosage forms, especially tablets. When the composition is applied to the surface of a tablet, the shellac apparently has the ability to keep the cellulose derivative from slipping upon evaporation of the solvent and thereby leaves the tablet edges covered with the same thickness of coating as the rest of the coating. The composition when applied by the usual methods forms a coating of uniform thickness. Because of such adherence to the edges, and even deposition of material, fewer applications and a lesser amount of coating composition is required, resulting in the following advantages: a solid medicinal dosage form which is smaller than that coated by other means with attendant savings in material, packing and shipping costs, and ease of swallowing; a savings of time and labor; a coating that will rapidly disintegrate. The application of shellac and cellulose derivative as a single composition results in a coating which can rapidly disintegrate in the stomach, even after ageing. Furthermore, the composition is compatible with the addition of one or more or any combination of the following types of coating adjuvants: coloring agents, opacifiers, plasticizers, flavoring agents, and sweetening agents. Also, dusting materials can be applied between applications of the composition in the coating process and waxes applied to polish the coating.

An unexpected advantage of the compositions of the present invention is the ability to provide coatings which can be readily polished to an elegant lustre by conventional means.

Additional advantages furnished by a coating obtained from the composition of the present invention are protection from atmospheric moisture, covering any disagreeable taste or odor, and protection from chipping or breaking during handling. The coating also provides a suitable base for further applications of other material, such as other medicaments or other types of coating material.

The present invention finds its principal use in the coating of medicinal tablets and is particularly advantageous for coating irregularly shaped tablets, i.e., whose shape is other than the usual round type, having an increased number of edges. However, other medicinal forms can be coated and for this reason the term "solid medicinal dosage forms" is used. The term "solid medicinal dosage form" is used in the generic sense to mean those objects with a shaped form that are intended to serve as a carrier for a dosage unit of medication. For example, the term would include such pharmaceutical forms as tablets, pills, pillules, wafers, and granules.

The present invention permits flexibility in the concentration of the various ingredients. The preferred concentrations given represent the range wherein the maximum advantage of the invention is obtained. Outside the preferred concentration the advantages are obtained, although to a lesser degree, and diminish as the concentration is varied away from the preferred range.

Each of the water-soluble cellulose derivatives, e.g., methylcellulose, hydroxyethyl cellulose and sodium carboxymethylcellulose are available in a variety of forms

3

which differ in the degree of viscosity imparted to aqueous solutions of identical concentration. The forms may be described as being low viscosity (less than 100 cps.), medium viscosity, and high viscosity (greater than 1500 cps.). Satisfactory coating compositions can be prepared using any of the various forms in a concentration, dependent upon the particular form used, of from about 2% to about 10%. For example, it is possible to prepare solutions with higher solids content from the low viscosity forms than from the high viscosity forms and still maintain the required fluidity for coating purposes. The preferred concentrations for the various forms are: low viscosity methylcellulose, from about 5 to about 10%; medium viscosity methylcellulose, from about 3 to about 5%; high viscosity methylcellulose, from about 2 to about 3%. Mixtures of the several forms can be used and the concentration would then depend upon the particular forms and their proportional relationship.

A low viscosity form of the cellulose derivative is preferred as the solutions with higher solids content permit the formation of a coating in a lesser number of applications than is needed by solutions containing a low solids content. For example, one application of 200 cc. of a 10% solution would be equivalent, in terms of coating deposited, to 5 applications (1000 cc.) of a 2% solution.

Expressed in general terms, the maximum concentration of the cellulose derivative is that amount (a) which will dissolve in the hydro-alcoholic solvent and (b) which when dissolved will form a solution that is of such viscosity as to have the fluidity necessary for application. Whether (a) or (b) limits the maximum concentration is dependent upon the alcohol-water proportions. For example, with a high alcohol and low water relationship, the maximum concentration would depend upon solubility of (a). Conversely, with a low alcohol and high water relationship the concentration would depend upon viscosity or (b).

The minimum concentration of the cellulose derivative can be very low; however, practical considerations require a concentration which will furnish sufficient cellulose derivative to deposit a coating in a reasonable number of applications.

The shellac used in the composition of the present invention is the refined, arsenic-free grade which is non-toxic and suitable for medicinal purposes. This type of shellac is also known as confectioner's glaze. The shellac can be used in the dry flake form; however, it is more convenient to use the commercially available solution of shellac, 30% w./w. in ethyl alcohol. The amount of shellac to be present in the composition is dependent upon the amount of cellulose derivative present and is expressed in terms of percent by weight of the cellulose. The preferred concentration is from about 40 to about 100% by weight of the cellulose.

Coating compositions can be prepared using a greater or lesser concentration than that given as the preferred; however, disadvantages occur as a result of such variation. For example, a lesser concentration results in a loss of the advantages of an even deposition of cellulose, with such loss being gradual and in proportion to the decreasing concentration of shellac. An increase in concentration results in disadvantages which are observable as characteristics of the composition's stability and the finished coat. The stability of the composition is altered by increasing the shellac concentration for reason of increased solid particles and the tendency of the particles to conglomerate and settle out of the composition as an amorphous mass which cannot be resuspended, thereby ruining the composition for coating purposes. Increasing the shellac concentration of the composition results in an increased shellac concentration in the coating; the coating takes on the characteristics of a shellac coating and loses the characteristics of a cellulose coating and results in an increase in disintegration time on aging.

4

The remainder of the composition is an alcohol. Ethyl alcohol is preferred, although other alcohols can be used, for example, methanol or isopropanol. The other alcohols which can be used are those which dissolve the shellac and when mixed with water will precipitate the shellac in very fine particles.

A preferred adjuvant for the coating composition is a plasticizer, such as propylene glycol, glycerin, or polyethylene glycol (200-600), and is added in an amount of about 1 to 3 gms. per 100 gms. of composition. Plasticizers, such as propylene glycol and glycerin, which are soluble in the hydro-alcoholic media are preferred to those non-soluble plasticizers such as cottonseed oil and corn oil, which have a tendency to separate from the composition.

Coloring agents can be added to the coating compositions when a colored coating is desired. The coloring agents which can be used are any of the non-toxic dyes, lakes, or pigments which have been certified for use in the food, drug, and cosmetic industry. For example, F.D. and C. Blue No. 1, F.D. and C. Yellow No. 1, F.D. and C. Yellow No. 5, F.D. and C. Orange No. 1, D. and C. Orange No. 1, D. and C. Green No. 1 and others. The coloring agents, singly or in combination, are added in an amount of about 1 gm. to 1000 gms. of coating composition.

Flavoring and sweetening agents can be added to impart a pleasant taste to the coating. A few examples of suitable agents and the preferred concentrations are: peppermint oil, 0.4%; oil of wintergreen, 0.2%; anise oil, 0.15%; lemon extract, 0.5%; licorice, 0.5%; imitation cherry, 0.5%; sodium saccharin, 0.2%; and sodium cyclamate, 0.6%.

An opacifier, such as titanium dioxide, can be added to the composition with advantage in a concentration of about 1%. In certain cases, depending on the color of the coating composition and/or the dusting powder used, the coating will be opaque enough so as not to warrant the addition of an opacifier.

The compositions are prepared by wetting the cellulose derivative with part of the alcohol, dissolving the shellac in the remaining alcohol (that is, unless the commercial shellac dissolved in alcohol is used), mixing the two together, and then adding the water and stirring. When additional ingredients are added such as color and flavor, they are added after the water and stirred until well dispersed.

Although the order of mixing is not critical, it is more convenient to follow the before-mentioned procedure. For example, if the cellulose derivative is added to the water without first wetting with alcohol, the length of time required to dissolve the cellulose is considerably extended. Also it is more difficult to dissolve the cellulose if it is wetted with alcohol containing shellac.

The following examples are illustrative of the compositions of the present invention and are not to be construed as limiting.

#### Example 1

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol.....	340
Methylcellulose, 25 cps.....	50
Propylene glycol.....	10
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient,

5

**Example 2**

One thousand grams of the composition are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	314
Methylcellulose, 25 cps.....	60
Glycerin .....	25
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500
F.D. and C. Yellow No. 5.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 3**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	330
Methylcellulose, 25 cps.....	70
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 4**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	350
Methylcellulose, 400 cps.....	40
Polyethylene glycol 400.....	20
Shellac, arsenic-free, 30% w./w. in ethanol.....	87
Deionized water.....	500
Oil of wintergreen.....	2
F.D. and C. Red No. 1.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 5**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Methanol .....	439
Methylcellulose, 1500 cps.....	20
Propylene glycol .....	10
Shellac, arsenic-free.....	20
Color .....	1
Titanium oxide.....	10
Deionized water .....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 6**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	320
Methylcellulose, 25 cps.....	50
Glycerin .....	25
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500
Sodium saccharin.....	2
Oil of wintergreen.....	2
F.D. and C. Red No. 1.....	1

6

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 7**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	350
Methylcellulose, 25 cps.....	50
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 8**

	Gms.
Ethanol .....	250
Methylcellulose, 15 cps.....	100
Shellac, arsenic-free, 30% w./w. in ethanol.....	150
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 9**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	340
Hydroxyethyl cellulose, 25 cps.....	50
Propylene glycol.....	10
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 10**

One thousand grams of the composition are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	314
Hydroxyethyl cellulose, 25 cps.....	60
Glycerin .....	25
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500
F.D. and C. Yellow No. 5.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 11**

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	330
Hydroxyethyl cellulose, 25 cps.....	70
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

**Example 12**

One thousand grams of the composition of the present

7

invention are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	350
Hydroxyethyl cellulose, 400 cps.....	40
Polyethylene glycol 400.....	20
Shellac, arsenic-free, 30% w./w. in ethanol.....	87
Deionized water.....	500
Oil of wintergreen.....	2
F.D. and C. Red No. 1.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 13*

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Grams
Methanol .....	439
Hydroxyethyl cellulose, 1500 cps.....	20
Propylene glycol.....	10
Shellac, arsenic-free.....	20
Color .....	1
Titanium oxide.....	10
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 14*

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	320
Hydroxyethyl cellulose, 25 cps.....	50
Glycerin .....	25
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500
Sodium saccharin.....	2
Oil of wintergreen.....	2
F.D. and C. Red No. 1.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 15*

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	350
Hydroxyethyl cellulose, 25 cps.....	50
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 16*

	Grams
Ethanol .....	250
Hydroxyethyl cellulose, 15 cps.....	100
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 17*

One thousand grams of the composition of the present

8

invention are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	350
Sodium carboxymethylcellulose, 25 cps.....	50
Propylene glycol.....	10
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 18*

One thousand grams of the composition are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	314
Sodium carboxymethylcellulose, 25 cps.....	60
Glycerin .....	25
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500
F.D. and C. Yellow No. 5.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 19*

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	330
Sodium carboxymethylcellulose, 25 cps.....	70
Shellac, arsenic-free, 30% w./w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 20*

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Grams
Ethanol .....	350
Sodium carboxymethylcellulose, 400 cps.....	40
Polyethylene glycol 400.....	20
Shellac, arsenic-free, 30% w./w. in ethanol.....	87
Deionized water.....	500
Oil of wintergreen.....	2
F.D. and C. Red No. 1.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 21*

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Grams
Methanol .....	439
Sodium carboxymethylcellulose, 1500 cps.....	20
Propylene glycol.....	10
Shellac, arsenic-free.....	20
Color .....	1
Titanium oxide.....	10
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

*Example 22*

One thousand grams of the composition of the present

invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	320
Sodium carboxymethylcellulose, 25 cps.....	50
Glycerin .....	25
Shellac, arsenic-free, 30% w/w. in ethanol.....	100
Deionized water.....	500
Sodium saccharin.....	2
Oil of wintergreen.....	2
P.D. and C. Red No. 1.....	1

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

#### Example 23

One thousand grams of the composition of the present invention are prepared from the following types and amounts of ingredients:

	Gms.
Ethanol .....	350
Sodium carboxymethylcellulose, 25 cps.....	50
Shellac, arsenic-free, 30% w/w. in ethanol.....	100
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

#### Example 24

	Gms.
Ethanol .....	250
Sodium carboxymethylcellulose, 15 cps.....	100
Shellac, arsenic-free, 30% w/w. in ethanol.....	150
Deionized water.....	500

The ingredients are mixed together in the above order with continuous stirring. The mixture is stirred for at least 30 minutes after the addition of the last ingredient.

The coating compositions of the present invention, as illustrated by the preceding examples, can be applied by the usual coating procedures using conventional coating equipment to provide the various advantages of the invention as indicated previously.

The most common method of application is the "ladle technique" whereby the coating composition is applied by pouring small quantities of coating material onto the tablets as they are tumbling in a coating pan. Each application of coating material is made in an amount sufficient to cover each tablet with a thin film of material. A dusting powder can be applied, if desired, after each application and a current of warm air blown over the tablets to dry them. When using the compositions of the present invention, as few as 5 or as many as 25 applications of coating material will form a satisfactory tablet coat with 10 applications being preferred.

Any of the dusting materials common in the art can be used, such as talc, calcium sulfate, and calcium carbonate. A preferred dusting composition is one comprised of calcium sulfate 95% and powder acacia 5%. This preferred composition is not only an excellent dusting material but, also is a good opacifier.

The coating can be polished by conventional means using such agents as beeswax, stearic acid, onesta wax, carnauba wax, cetyl alcohol, and others. A preferred waxing composition is comprised of carnauba wax, chlorowax, and mineral oil dissolved in tetrachlorethylene.

#### Example 25

Ten thousand average size (3/8 inch punch) tablets are placed in an 18-inch coating pan and the pan allowed to rotate at about 30 revolutions per minute. About 2 fluid ounces of the coating solution of Example 1 are ladled over the tablets. The tablets are allowed to roll until covered with the composition and they have become tacky, and are then dusted with coating powder. When

the coating powder has been taken up by the tablets, a current of warm air is blown over the tablets until dry. The procedure is repeated until 10 applications of coating material have been applied. The tenth application of coating material is not followed by an application of dusting material. The tablets are dried at 110° F. overnight and then polished by rolling in canvas-lined tubs with the application of 2 fluid ounces of polishing composition.

Following the procedure of Example 25, tablets can also be coated using one of the coating compositions shown by Examples 2-24 in place of the composition of Example 1.

What is claimed is:

1. A solid medicinal dosage form coating composition for applying an even and uniform film coating which does not appreciably lengthen in disintegration time on ageing comprising a hydro-alcoholic solution of a water soluble cellulose derivative selected from the group consisting of methylcellulose, hydroxyethyl cellulose and sodium carboxymethylcellulose and suspended shellac.

2. A composition of matter comprising a hydroalcoholic solution of a water soluble cellulose derivative selected from the group consisting of methylcellulose, hydroxyethyl cellulose and sodium carboxymethylcellulose and suspended shellac, said cellulose derivative being present in a concentration of from about 2 to about 10% (w./w.) of said composition and said shellac being present in a concentration of from about 40% to about 100% by weight of said cellulose derivative.

3. A solid medicinal dosage form having thereon a coating comprising intermixed shellac and a water soluble cellulose derivative selected from the group consisting of methylcellulose, hydroxyethyl cellulose and sodium carboxymethylcellulose.

4. A solid medicinal dosage form having thereon a dry coating comprising intermixed shellac and a water soluble cellulose derivative selected from the group consisting of methylcellulose, hydroxyethyl cellulose, and sodium carboxymethylcellulose.

5. A coated tablet wherein the coating comprises intermixed shellac and a water soluble cellulose derivative selected from the group consisting of methylcellulose, hydroxyethyl cellulose and sodium carboxymethylcellulose in the proportion of 100 parts by weight of said cellulose member to from about 40 parts to about 100 parts by weight of said shellac.

6. A solid medicinal dosage form coating composition for applying an even and uniform film coating which does not appreciably lengthen in disintegration time on ageing comprising a hydro-alcoholic solution of methylcellulose and suspended shellac.

7. A composition of matter comprising a hydro-alcoholic solution of methylcellulose and suspended shellac, said methylcellulose being present in a concentration of from about 2 to about 10% (w./w.) of said composition and said shellac being present in a concentration of from about 40% to about 100% by weight of said methylcellulose.

8. A solid medicinal dosage form having thereon a coating comprising intermixed methylcellulose and shellac.

9. A solid medicinal dosage form having thereon a dry coating comprising intermixed methylcellulose and shellac.

10. A coated tablet wherein the coating comprises intermixed methylcellulose and shellac in the proportion of 100 parts by weight of methylcellulose to from about 40 parts to about 100 parts by weight of shellac.

11. A solid medicinal dosage form coating composition for applying an even and uniform film coating which does not appreciably lengthen in disintegration time on ageing comprising a hydro-alcoholic solution of hydroxyethyl cellulose and suspended shellac.

12. A composition of matter comprising a hydro-alcoholic solution of hydroxyethyl cellulose and suspended

## 11

shellac, said hydroxyethyl cellulose being present in a concentration of from about 2 to about 10% (w./w.) of said composition and said shellac being present in a concentration of from about 40% to about 100% by weight of said hydroxyethyl cellulose.

13. A solid medicinal dosage form having thereon a coating comprising intermixed hydroxyethyl cellulose and shellac.

14. A solid medicinal dosage form having thereon a dry coating comprising intermixed hydroxyethyl cellulose and shellac.

15. A coated tablet wherein the coating comprises intermixed hydroxyethyl cellulose and shellac in the proportion of 100 parts by weight of hydroxyethyl cellulose to from about 40 parts to about 100 parts by weight of shellac.

16. A solid medicinal dosage form coating composition for applying an even and uniform film coating which does not appreciably lengthen in disintegration time on ageing comprising a hydro-alcoholic solution of sodium carboxymethylcellulose and suspended shellac.

## 12

17. A composition of matter comprising a hydro-alcoholic solution of sodium carboxymethylcellulose and suspended shellac, said sodium carboxymethylcellulose being present in a concentration of from about 2 to about 10% (w./w.) of said composition and said shellac being present in a concentration of from about 40% to about 100% by weight of said sodium carboxymethylcellulose.

18. A solid medicinal dosage form having thereon a coating comprising intermixed sodium carboxymethylcellulose and shellac.

19. A solid medicinal dosage form having thereon a dry coating comprising intermixed sodium carboxymethylcellulose and shellac.

20. A coated tablet wherein the coating comprises intermixed sodium carboxymethylcellulose and shellac in the proportion of 100 parts by weight of sodium carboxymethylcellulose to from about 40 parts to about 100 parts by weight of shellac.

20

No references cited.

UNITED STATES PATENT OFFICE  
CERTIFICATE OF CORRECTION

Patent No. 3,043,747

July 10, 1962

Stuart Long

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 1, line 19, for "768,552" read --- 768,852 ---; column 7, line 67, for "100" read -- 150 ---.

Signed and sealed this 13th day of November 1962.

SEAL)  
Attest:

ERNEST W. SWIDER  
Attesting Officer

DAVID L. LADD  
Commissioner of Patents