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METHOD FOR COATING TABLETS

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5 Claims. (Cl. 117-85)

This is a continuation of application Serial No. 32,516 filed on May 31, 1960, now abandoned.

This invention relates to tablet coatings and to a method of obtaining a pharmaceutically-elegant tablet. More particularly, this invention relates to the gloss-coating or shining of a previously-coated pharmaceutical tablet.

The tablet-coating art has recently become aware of the advantages of employing the air-coating method for applying coating solutions to tablets. Among the many advantages is the elimination of the familiar coating pans and drying ovens, not to overlook the time-saving element. An example of such a method for air-coating tablets is described in U.S. 2,648,609. Another technique for applying a coating solution by the air-coating method is described in co-pending application Serial No. 11,364, now U.S. Patent 3,112,220, of which applicant is a joint inventor.

It is well-recognized in the tablet-coating art that a coating should have a glossy finish in order to have a pleasing appearance. When the pan-coating method is employed for coating, the finished tablets are shiny due to the buffing action which is exerted on the tablets by tumbling in the pan. On the other hand, when an air-coating method is employed, the tablets receive no buffing action and consequently the finish on the tablet is dull and unattractive. This is true whether a plastic film-coating as described in U.S. 2,881,085, or a standard sugar coating, is applied to the tablets. Further, whether the tablets are coated with certain plastic films or a sugar coating, and whether the coating is applied in the pan or by the air coating method, these coatings may be sensitive to high temperatures and humidity upon storage, and become tacky.

It is therefore an object of the present invention to provide gloss on a pre-coated tablet by the air-type coating method. It is another object of this invention to provide a tablet coating which provides improved high-temperature and moisture resistance. It is a further object of this invention to provide elegant pharmaceutical tablets with a gloss coating which does not prolong the disintegration time of the tablet.

These and other objects are accomplished by the method of applying a protective coating to previously-coated tablets comprising formulating a fluid coating composition consisting essentially of hydroxypropylmethylcellulose containing 5-15% by weight of 2-hydroxypropoxyl groups and 27-32% by weight of methoxyl groups and a low-boiling, non-aqueous solvent for said hydroxypropylmethylcellulose, and directing a mixture of warm air and said coating composition upwardly through a bed of said tablets to cause fluidization of said tablets, for a period of at least 10 minutes. The above method of applying the protective coating or gloss coating comprises the newer air application method wherein the bed of tablets is maintained in fluidized form and the coating composition is introduced in the form of a spray.

Briefly stated, the method comprises the forming of a columnar bed of tablets to be coated wherein the bed is preferably greater in height than it is in the horizontal cross-sectional dimension. An air stream is directed upwardly through a portion of this bed with sufficient force

to move the tablets in that portion upwardly, thus forming a fluidized spout of tablets. The spout extends above the top of the bed with the tablets falling therefrom back onto the top of the bed. In the parts of the bed adjacent the spout, the tablets move downwardly. The cellulose coating material is atomized and introduced into the upwardly moving stream of air. The atomized cellulose fluid is deposited on the tablets in the upwardly moving spout with the deposited liquid being dried by the air.

In the above definition of the process, reference is made to the use of warm air. The temperature of this air is preferably between 30° and 80° C. to provide for fast evaporation of the low-boiling solvent used in the coating composition. The low-boiling non-aqueous solvent referred to above is preferably a solvent or solvent mixture which has a boiling point below about 80° C., e.g. ethanol, methanol, methylene chloride, chloroform, benzene, ethyl acetate, and mixtures thereof. The coating solution should contain between 10 and 50 grams of the hydroxypropylmethylcellulose per liter, and the amount of fluid coating solution employed should be between 0.1 and 0.5 liter per kilogram of tablets.

To better understand the method of the present invention, reference is made to the following example which is meant as an illustration only.

Typical gloss-coating solution.—To a mixture of equal parts of methylene chloride and ethanol is added 20 grams of hydroxypropylmethylcellulose with agitation. After a clear solution is formed, additional methylene chloride/ethanol (1:1) is added to produce a total volume of one liter, and the mixture is thoroughly stirred.

Typical coated tablets.—A batch of 3 kg. of vitamin tablets weighing an average of 0.603 gram is placed in the coating chamber of an air-suspension tablet-coating apparatus with a coating chamber diameter of 15 cm. Air of 60° C. is pressed into this chamber at 4.2-4.7 m.³/min. The air-nozzle has an orifice of 1.75 mm. diameter; the coating composition is introduced into the upwardly moving stream of air through a nozzle of 0.7 mm. diameter whereby it is atomized and deposited on the tablets. The coating solution has the following composition:

	Grams
Hydroxypropylmethylcellulose of 50 c.p.s. -----	40.0
Yellow D & C Lake #5 -----	60.0
Titanium dioxide -----	40.0
Saccharin sodium -----	2.0
Ethyl vanillin -----	8.0
Castor oil -----	2.5
Methylene chloride/ethanol 1:1, q.s. to 2 liters.	

The coating operation is completed when all the coating suspension is exhausted, or within about 15 minutes. A short drying cycle follows, to strip residual solvent from the coating chamber. The tablets are now covered by a plastic, colored, hard film-coating but have a dull appearance objectionable to many consumers.

Gloss coating.—The dull, coated tablets are, without removal from the coating chamber of the above air-coater, coated with the clear "typical gloss-coating solution" shown above. Air of 60° C. is introduced into the coating chamber at about 4.5 m.³/min. and after about 10 minutes the tablets are elegant, shiny and, due to their gloss, easier to swallow than the dull pre-coated tablets. Appropriate digestion studies show that there is no measurable time difference between the disintegration times of the dull-coated and of the shiny gloss-coated tablets.

Substantially the same results are obtained when the solvent system in the "typical gloss-coating solution" is replaced by chloroform/ethanol, benzene, ethyl acetate, or methanol. Also, by replacing the pre-coating formula

given above with other standard coating solutions or suspensions, the same beneficial effect is obtained with the gloss-coating of the present invention.

It is particularly interesting and noteworthy that the gloss-coating of the present invention adheres to pre-coated tablets regardless of the components in the pre-coating film; whether the initial film contains hydroxypropylmethylcellulose as the main film-forming component or as a minor component, or whether hydroxypropylmethylcellulose is totally absent in the initial film, the gloss-coating composition applied by the present method forms a shiny, protective and non-peeling film over the initial coating.

The hydroxypropylmethylcellulose used in the present process has, among others, the advantages of being soluble in organic solvents and in water. The water-solubility is of importance for the rapid disintegration of the tablet in the body's digestive liquids, and the solubility in organic liquids makes the formulation of a gloss-coating solution very simple: the protective film dries rapidly onto the tablets, and the gloss-coating operation takes only a very short time. Further, due to the high solubility of the hydroxypropylmethylcellulose in the body fluids, rapid excretion from the patient's body is achieved.

The gloss-coating film provides the tablets so finished with a protective layer that improves the stability of the tablets against moisture and high temperatures, even though the gloss-coating film needs to be no thicker than about 10 microns. The film so applied is non-brittle and completely transparent so that color identifications or other insignia pressed onto the tablet surface are plainly visible. A further advantage of the present process is its applicability in an apparatus that is frequently used for the initial coating operation. However, care should be taken that the initial coating is completely dried before the gloss coating of the present process is applied. It is thus possible to use the air-suspension method for coating pharmaceutical tablets with any desired film suspension or solution, and after the tablets are dried in the same coating chamber by the supply of dry warm air the film-coating composition of the present process can be applied without ever requiring the removal of the tablets from the coating apparatus. The gloss coating so applied not only has esthetic value but also serves as a seal to protect the colored coating from deleterious storage conditions without measurably influencing the disintegration time of the tablet.

Others may practice the invention in any of the numerous ways which will be suggested to one skilled in the art by the present disclosure. All such practice of the

invention is considered to be a part hereof, provided it falls within the scope of the appended claims.

I claim:

1. The method of applying a protective glossy coating to previously coated and dried tablets comprising the steps of

formulating a fluid coating composition consisting essentially of hydroxypropylmethylcellulose containing 5-15% by weight of 2-hydroxypropoxyl groups and 27-32% by weight of methoxyl groups as the sole film-forming component, and a non-aqueous solvent for said hydroxypropylmethylcellulose, said solvent having a boiling point below about 80° C.,

directing a stream of air of a temperature between 30 and 80° C. upwardly through a bed of said coated tablets to cause fluidization of said tablets, and introducing said fluid coating composition into said stream of warm air for a period of at least 10 minutes to form a protective coating.

2. The process of claim 1 wherein the coating solution contains between 10 and 50 grams of hydroxypropylmethylcellulose per liter of coating solution.

3. The process of claim 1 wherein said fluid coating composition is applied in the amount of between 0.1 and 0.5 liter per kilogram of tablets.

4. The process of claim 1 wherein said warm air has a temperature between 30° and 80° C. when entering the bed of said coated tablets.

5. The process of claim 1 wherein said coating composition is applied to the fluidized bed of tablets for a period between 10 and 90 minutes.

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