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VENEER COATED TABLETS

Harland E. Heilig, North Brunswick, N.J., and Elmer Stuart Brown, Evansville, Ind., assignors to Olin Mathieson Chemical Corporation, New York, N.Y., a corporation of Virginia

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This invention relates to new coated tablets and more specifically to tablets having a new type of film (or veneer) coating, thereon.

It is known in the art of tablet making to provide veneer coating on coated or uncoated tablets. In the case of uncoated tablets the veneer coating acts to protect the tablet from dissolving in the mouth thereby avoiding unpleasant taste sensations which are normally associated with peroral medications, without materially delaying the disintegration of the tablet once it passes the buccal area. In the case of a coated tablet the film or veneer coating acts to protect the tablet from the effects of moisture without appreciably delaying its disintegration, and in addition provides a base which is simultaneously susceptible to the development of a high lustre and also adhesive to any identifying mark which is printed thereon.

Until now, it has been the practice of the art to use as a veneer coating, either straight or modified shellac. While the shellac has some of the properties, such as resistance to penetration by moisture, it does not fulfill the specification for an ideal veneer coating. Thus, the shellac tends to become tacky and this results in agglomeration and loss of elegance in the individual tablets. Moreover, the shellac does not act as a stable base for the indicia which are normally printed on tablets to identify them as to their source and content. Furthermore, because of its tackiness, the shellac renders the handling of the tablets more difficult and thereby increases production costs per tablet.

The purpose of this invention is to provide a new coated tablet containing a veneer coating which has all the advantages of stability, ease of application, adhesiveness to print, and ability to take on a high lustre.

The above and other purposes are accomplished in accordance with this invention by providing a tablet containing a film coating comprising resinous polymers of terpenes having a melting point in the temperature range of 70° C. to 135° C. The coating is applicable to any pharmaceutically useful and acceptable tablet. Tablets so coated have all the advantages above named.

The coating may be easily applied to both uncoated and coated tablets using standard tablet coating equipment. Thus, if desired, a rotating coating pan may be used, in which event the tablets are first deposited therein and a solution of the coating resin is contacted therewith. Any of the low cost petroleum solvents, coal tar solvents, mineral oil, chlorinated hydrocarbons, long chain alcohols and long chain ketones may be used to dissolve the resin. The resin concentration may be in the range of 5-30% by weight of the solvent. The pan is covered for a short time in order to permit the resin to contact the tablets before the solvent evaporates. A warm stream of air may be applied to the rolling tablets. After sufficient time has been allowed, the cover is removed to permit the solvent to evaporate. A stream of moderately warm air may be passed over the tablets at this point for the purpose of hastening evaporation. After thus being dried, the tablets are in condition to be printed, polished or packaged. The tablets thus formed are stable to moisture, easily printed and polished and are completely lacking in tackiness.

In a preferred embodiment of this invention a resin composed essentially of polymers of beta pinenes having a melting point in the range of 85° C. to 125° C. is used

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to form the veneer coating. As the solvent for the resin, there may be used a chlorinated hydrocarbon such as chloroalkanes, and preferably 1,1,1-trichloroethane. The resin solution is prepared by dissolving about 5 to 25% of the resin in the desired solvent. If it is desired to decrease the penetration of the resin into the core of the tablet the viscosity of the resin solution may be adjusted by the incorporation of a thickener. Cellulosic materials such as cellulosic esters are among the thickeners which may be used, and a preferred thickener is ethyl cellulose. The thickener may be added to equal up to about 100% and preferably about 20%, by weight of the resin in the solution of the resin, or alternatively, the resin solution may be added to a solution of the ethyl cellulose.

In addition it should be noted that the thickener advantageously has film forming characteristics of its own thereby increasing the moisture resistance of the coated tablet. Moreover, a minor amount of a dyestuff may be added to the resinous coating, if it is preferred to have a colored tablet. Any compatible, non-toxic dyestuff is suitable. A dyestuff such as quinoline yellow, may be used. The dyestuff may be used in suspension or in a solution of the resin coating.

The coating material is then applied to the tablets. Conventional procedures may be used, such as the coating pan method described hereinbefore. In the event that a high lustre is desired, the tablets, after being veneer coated, may be rolled for additional time, alone, or in the presence of powdered talc, the abrading action thereby producing the desired polish.

The following examples are presented for the purpose of illustrating the invention, it being specifically understood that they are presented for purposes of illustration, not limitation.

Example I

Five kilograms of No. 3 sugar coated tablets, prepared by the conventional coating methods, are placed in coating pan which is then started rolling. Approximately 20 ml. of a 10% solution of a resin composed of pinene polymers having a melting point of about 85° C. (Piccolyte S-115) in 1,1,1-trichloroethane is added to the rolling tablets. The mouth of the coating pan is immediately covered for one minute. The cover is removed and the coated tablets are allowed to roll until they are free from "tack" and the danger of sticking or clumping together is passed. Cold air is applied at this point. When the tablets are free from tack they are removed and placed on trays in a circulating warm air oven at approximately 40° C. until all solvent has been removed. The tablets are then polished by placing them in a waxed coating pan (the wax lining consisting of 1 part by weight of carnauba wax and 3 parts by weight of beeswax) and polished by allowing the tablets to roll until a suitable lustre is attained. Judicious application of warm air to the rolling tablets aids in wax pick up and expedites polishing.

The tablets may then be printed using a suitable machine designed for this purpose, and then repolished as described above. A second resin-coat may be applied over the printing, prior to polishing.

Example II

The solutions are the same as in Example I, except that a 20% solution of resin is used.

Three kilograms of No. 3 tablets are carefully dusted and placed in a 16" coating pan which is then set in motion. Sufficient resin solution is added to evenly cover the tablets. The pan is momentarily covered until the solution is evenly distributed. The cover is removed, cold air is applied and the tablets are allowed to roll until all tack is gone. The tablets are removed from the pan and evenly placed on trays in an adequately ventilated area until all traces of solvent are gone.

Example III

55 ml. of a solution of 2½ % ethyl cellulose and 0.05% quinoline yellow is made using 1,1,1-trichlorethane as the solvent. 55 ml. of a 15% solution of a resin of β-pinene (M.P. 85° C.) in the same solvent is mixed with the ethyl cellulose solution with the aid of heat and then cooled to room temperature. The mixture is applied to the tablets at room temperature, as follows:

3 kg. of No. 2 sodium chloride tablets are placed in a 16" coating pan. Sufficient resin-ethylcellulose solution is added to completely cover the tablets (110 ml.). As soon as the tablets are rolling freely, air is applied until the tablets are completely dry and free from solvent odor. Samples are withdrawn and tested for disintegration (average disintegration time in distilled water at 37° C. is about 3 minutes). A second coat is then applied (about 60 ml.) and the drying procedure followed. Average disintegration time after two coats is about 4 minutes.

The tablets have a smooth even coating and a lustrous appearance and fulfill the requirements for an acceptable film-coated tablet.

Example IV

5 kilograms of conventional vitamin mineral tablets are sugar-coated in the usual manner. After slowly drying the final syrup coat to minimize the crystallization of the sugar, 50 ml. of a 10% solution of the resinous polymer of beta-pinene (M.P. 85) is added to the rolling tablets. The tablets are dried by application of cold air until all traces of solvent odor are gone. Polishing the tablets is accomplished by allowing the tablets to roll in a rotating wax lined pan, the pan being lined with a 3:1 mixture of beeswax and carnauba wax. The tablets are then imprinted with the desired indicia using the Hartnett printing equipment. The film accepts the ink readily.

The printed tablets are superior to corresponding tablets which are glazed with pharmaceutical grade shellac and then printed. This superiority is represented by greater clarity of the indicia design and absence of voids in the indicia.

What is claimed is:

1. A coated pharmaceutically acceptable tablet in which the coating comprises a film of a resin of terpene polymers melting in the range of about 70° C.-135° C.

2. The composition of claim 1 in which the film is deposited on a coated tablet.

3. The composition of claim 1 in which the film is deposited on an uncoated tablet.

4. The composition of claim 1 in which the terpene consists essentially of beta pinenes.

5. The composition of claim 4 in which the film coating additionally contains a minor amount of cellulosic esters.

6. The composition of claim 5 in which the film coating contains a minor amount of a non-toxic, compatible dyestuff.

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