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THIN FILM COATING FOR TABLETS AND THE LIKE

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This invention relates to tablets and other individual dosage forms which are characterized by a thin film coating of a water-soluble plastic composition, and to methods of making such tablets. The invention also relates to a thin water-soluble tablet coating film and to a liquid composition useful for laying down the aforementioned film.

Tablet coating in the prior art is a tedious and a time consuming procedure which requires the laying down of many coats to obtain the desired thickness. Syrup coating is the most widely used method employed in coating tablets. It generally provides distributing a syrup over tablet cores in a coating pan. The tablets are rotated in said coating pan while a supply of hot air is passed thereover to accelerate drying. Following the initial syrup application, a dusting powder is applied to the tablets. The dusting powders usually comprise starch, talc and pulverized gum acacia. After applying the dusting powder, the hot air supply is shut off temporarily until the powder is absorbed on the tablets. The hot air vent is then reopened and the tablets are dried. The syrup application and dusting powder addition are applied in sequence until the desired thickness is obtained. The dusting powder serves two purposes, namely, it prevents one tablet from sticking to another and it helps to "build up" the thickness of the tablet coat.

The dusting procedure may be continued throughout the coating process or, in the alternative, may be terminated at a coating stage short of completion. At whatever point said dusting is terminated, the tablets, nonetheless, have an uneven appearance because the dusting powder builds up on the surface. This uneven appearance is masked by applying cold syrup in a cold air environment. The coated tablets may then be optionally polished in a polishing pan coated with a thin layer of paraffin wax.

If ingredients in the tablet core must be protected against water, a coat of varnish is supplied as a subcoat. If the tablet ingredients are hygroscopic, the coating composition must incorporate the step of subcoating with a gelatin solution and dusting powder.

It is obvious that the foregoing tableting procedure involves numerous steps in building up coat thickness and requires further steps in the event the tablet ingredients require protection against water.

It is an object of this invention to provide a thin film coating for tablets and the like. It is a further object of this invention to provide a simple and efficient coating procedure for tablets and the like. A still further object of this invention is to provide a tablet coating which is quick drying and which is also water soluble when ingested. Still another object of this invention is to provide a tablet coating material which is soluble in organic solvent to facilitate application and which is also water soluble to facilitate disintegration following ingestion.

It has now been found in accordance with the foregoing objects and other objects which will be apparent

that copolymers of ethylene and maleic anhydride and partial hydrolysis products of the foregoing copolymers provide excellent materials for thin plastic film coating. The copolymers employed in this invention contain ethylene and maleic anhydride in equimolar ratio. Hydrolysis of said ethylene-maleic anhydride copolymers results in copolymers which are partially provided with carboxylic acid groups. Both these polymer forms are characterized by water and organic solvent solubility.

The molecular weight and inherent viscosity of the operable copolymers are, of course, dependent on the polymer length. While it known that copolymers having a wide range of molecular weights are useful, we have employed partial hydrolysis copolymers having inherent viscosities between 0.1428 and 0.5824, and respective molecular weight ranges of 1,500–2,000 and 25,000–30,000. The maleic anhydride-ethylene copolymers employed herein have an inherent viscosity of 0.622 and a molecular weight of about 75,000. The inherent viscosity is the log of the ratio of the relative viscosity of the plastic to concentration of the plastic. The inherent viscosity is determined by the modified Oswald-Cannon-Fiske viscosimeter, size 50. The plastic is dissolved in an absolute ethyl alcohol solvent at a concentration of 2% w./v. The temperature of the solution is 25° C.

The foregoing copolymers are soluble in organic solvents such as lower aliphatic alcohols, straight or branched. Among such alcohols are methanol, ethanol, n-propanol, isopropanol and the like. This physical characteristic of the copolymers allows them to be placed quickly in solvent solution and further results in rapid drying to leave a thin film after coating the tablets.

An added feature of this invention provides adding an organic liquid of higher volatility to the copolymer-organic solvent solution. The higher volatile organic liquids accelerate drying of the coating compositions after application to the tablets. Examples of such higher volatile organic liquids are acetone, methylene chloride, methyl-ethyl ketone, ethyl acetate and the like which are miscible with the organic solvent.

The copolymer-organic solvent solution is applied to tablet cores in a rotating coating pan by uniformly distributing the mixture from a container over the tablets. As the coating pan rotates, the solvents evaporate and the coat dries. Thereafter, another coat is applied and dried, and the steps repeated until the tablet attains the desired thickness. The final coating thickness is dictated by the amount necessary to protect the tablet core and, for example, to inhibit objectional tastes. Also, in the event color is imparted to the tablet coating, the thickness will be dictated by the color hue desired. Among the many advantages which can be listed for the procedure are the much shorter time involved in the coating procedure which is attained by having the complete formulation is one liquid mixture, simple application of the liquid mixture, reduced drying time between coatings, and relatively few coatings; other advantages include a thin tablet coating, an effective tablet covering, smaller tablet size and no water introduction to the tablet core. The thin plastic film coating is quickly disintegrated after oral ingestion because the plastic film is readily water soluble. This results in rapid absorption of the tablet ingredients. An additional advantage of tablet films prepared with these particular plastics arises from the fact that said plastic is soluble in organic solvents. Anhydrous liquid compositions can be prepared which rapidly dry after application to the tablet. Thus, the coating time is reduced to four hours with the present solvent-soluble composition as compared to coating times as long as two days with water-soluble syrup compositions.

The anhydrous liquid composition containing the plastic

is of added importance in coating tablets which have water-sensitive ingredients. Formerly, the tablet core would have to be protected with a coat of shellac or gelatin, but employing a water-free composition eliminates this step. A related problem is present in coating tablets containing water-sensitive vitamins. It has been necessary to add vitamins in large excess of tablet specifications to such cores because a certain percentage of the vitamins would be inactivated by the water present in the tableting composition. It is apparent that a water-free tableting composition renders this added expense unnecessary.

Such tablets are also free from sugar which serves to dissuade children from accidentaly ingesting tablets. The sugar-free coating is also desirable for those persons who wish to restrict their caloric intake. To attain sweetness, non-caloric agents such as the cyclamates (Sucaryl®, Abbott) or saccharin or mixtures thereof may be incorporated. Flavoring agents such as vanilla, ethylvanillin, vanillin, heliotropin and the like may be added to the coating formulation.

Various ingredients may be incorporated in the foregoing copolymer-organic solvent solution to attain a more pharmaceutically elegant tablet. Coloring agents may be incorporated in the solution such as non-toxic dyes and lakes and pigments certified for use in food, drug and cosmetic industries. Among such dyes may be listed: Red D and C #37, Green D and C #6, Orange D and C #3, Yellow D and C #11, Red D and C #35, Blue FD & C #1, Orange D and C #4, Red FD and C #1 and Red FD and C #3. The lakes are dyes precipitated on an insoluble metal compound and may be selected from among Yellow D and C Lake #5, Red D and C Lake #30, Orange D and C Lake #17, Green D and C Lake #1 and the like.

Other formulations may include agents which provide gloss such as silicone, resins, long chain fatty acids, long chain metallic soaps and long chain alcohols; and smoothness such as plasticizers. Opaquing agents may be added to overcome the transparency of the film coating. Among useful opaquing agents are titanium dioxide, calcium carbonate, terra alba (dihydrated calcium sulfate), dicalcium phosphate and others known in the pharmaceutical art. Suspending agents such as Bentone 18C and Veegum may be used to suspend the opaquing agents and other insoluble materials. Bentone 18C is a trade name for alkyl ammonium montmorillonite which is a compound of an organic ammonium cation attached by an electrovalent linkage to the mineral, montmorillonite. Veegum as 5% solids in aqueous suspension is a trade name for a complex colloidal magnesium aluminum silicate. Veegum has an absolute viscosity of 200 ± 50 centipoise as determined by the Brobender viscosimeter. Plasticizers are added to render the film coating flexible, thereby overcoming any brittleness of the film coating. Among the suitable and well-known plasticizers are mineral oil, castor oil, polyhydroxy compounds such as polyethylene glycol 200, 300 or 400, propylene glycol, glycerine and the like.

An important contribution to tablet coating formulations which employ copolymers of the type disclosed herein are anti-tacking agents. Said agents prevent tablets from sticking to one another as they are rotated in the coating pan. It is known in the art that talc and dusting powder compositions are useful for this purpose; however, such powders tend to build up the thickness of the tablet coat and also tend to make the polymer film brittle. It has now been found that esters of fatty acids, long chain fatty acid amides, and long chain fatty acid polyamides prevent polymer coated tablets from colescing. The foregoing fatty acid agents also possess the desirable property of imparting gloss to the tablet coat, and, further, tend to make the tablet coat more flexible and smoother. Among the fatty acid amides found useful for this purpose are the compositions known to the art as Acrawax, Armid 18 and Armid HT. Armid is a trade name for a group of amides derived from 16 and 18 carbon fatty acids, i.e. stearamide and oleamide. Acrawax is a trade name for polyamides of stearic acid. The fatty acid esters found useful for this purpose include glyceryl esters such as glyceryl monostearate, glyceryl monoricinoleate, glyceryl oleostearate, glyceryl laureate and the like.

It has also been found in formulating these tablet compositions that an increase in the concentration of the insoluble solids contained therein, such as titanium dioxide and certain dyes decreases the sticking problem.

It is preferred that the plastic copolymer (resin) in the liquid composition be present in a concentration of 3% to 20%. The lower range provides a significant amount to provide a thin film on the tablet and the higher range still allows manipulation of the liquid mixture without undue viscosity complications. A liquid composition consisting of resin and solvent alone will leave a dry film, after solvent evaporation, comprising 100% of the resin.

Where coating formulations are used which include ingredients in addition to the resin, the liquid composition will still contain about 3% to 20% by weight per volume of the resin, but the dry tablet film will have resin present in amounts less than 100%. Various liquid compositions can be prepared wherein the resin is present in a range of 3% to 20% w./v. Solids insoluble in organic solvents such as opaquing agents and dyes are present in a range of 2% to 15% w./v. Anti-tacking agents usch as the fatty acid amides, polyamides and glycerol esters comprise about 2% to 4% by weight per volume, and suspending agents, plasticizers and other desired additives comprise less than 3% w./v. The foregoing percentages are present by weight per volume in a liquid composition made up to final volume by inclusion of anhydrous solvents.

The terms "weight per volume" and "w./v." are used herein in their customary meaning as understood in the pharmaceutical industry. Both these expressions have identical definitions, that is, the weight of the ingredient per unit volume of suspensions or solution. The expressions are used for convenience in designating the amount of a solid that is to be dissolved or suspended in a liquid to give a definite ultimate volume of solution or suspension. As an example, an ingredient may be indicated as 10% weight per volume or w./v. This means that 10 grams of the solid is dissolved or suspended in a liquid and the liquid is made up to a total volume of 100 ml.

Liquid compositions containing ingredients in the foregoing ranges will, after evaporation of the anhydrous solvents, result in a final hard, dry film wherein the resin comprises 30–70% of the dry film, the insoluble solids consisting of dyes and opaquing agents comprise 10–60% of the dry film; anti-tacking fatty acid amides and glycerol esters are present in amounts of 5–12% and other additives, including plasticizers, amount to about 5%.

Since it has been found that a concentration of at least 15% w./v. of insoluble solids in the anhydrous liquid compositions tend to prevent the tablets from sticking to one another during the coating procedure, a preferred formulation will incorporate the insoluble solids in that amount. Accordingly, a desirable, anhydrous liquid composition will contain 5–10% w./v. of the resin, 15–20% w./v. of insoluble solids and 3–5% of other additives such as suspending agents, anti-tacking agents, flavoring agents and the like. The final dry film product will comprise about 30–40% resin, about 50–60% insoluble solids and 5–15% of anti-tacking agents and other additives.

The following examples are presented to teach the invention in operation, but it should be understood that said examples are not intended to limit the invention in any way.

Example I

A tablet coating solution is made up according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	10 gms. w./v.
Absolute ethyl alcohol	q.s. to 100 cc.

The copolymer is dissolved in the alcohol with aid of heat and agitation. The copolymer-alcohol mixture is applied to a moving bed of tablets in a coating pan by pouring the mixture uniformly over the tablet surfaces. As the tablets rotate, the solvent evaporates leaving a thin, dry, hard film on the tablets. A period of about five minutes is allowed for said film to dry and immediately thereafter a further amount of the mixture is uniformly distributed over the tablet surfaces and the mixture is allowed to dry. This process is repeated several times to apply about ten to twenty coats to the tablets.

Example II

A tablet coating solution is made up according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.584; M.W. 25,000–30,000	10 gms. w./v.
Ethyl alcohol, absolute	q.s. to 100 cc.

The same process steps are employed as in Example I to prepare the coated tablets.

Example III

A tablet coating solution is made up according to the following formula:

Ethylene-maleic anhydride copolymer (inherent viscosity 0.622; M.W. 75,000)	10 gms. w./v.
Ethyl alcohol, absolute	q.s. to 100 cc.

The same process steps are employed as in Example I to prepare the coated tablets.

Example IV

A tablet coating solution is made up according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	10 gms. w./v.
Ethyl alcohol, absolute	50 cc. v./v.
Acetone	q.s. to 100 cc.

The process steps for preparing the above tablet coats are the same as in Example I with the modification that acetone is added to the mixture after the copolymer is dissolved in the alcohol. The same coating techniques are used; however, the higher volatility of acetone results in accelerated drying.

Example V

A tablet coating solution is made according to the following formula:

Ethylene-maleic anhydride copolymer (inherent viscosity 0.622; M.W. 75,000)	10 gms. w./v.
Dye, Yellow D and C #11	0.5 gm. w./v.
Titanium dioxide	4.0 gms. w./v.
Ethyl alcohol, absolute	50.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The process steps of Example 1 are followed for coating the tablets and the copolymer is placed in solution in the same manner as described under Example IV. The dye is dissolved in the resultant mixture and the titanium dioxide is suspended in the solution in very fine particle size by use of a ball mill.

Example VI

A tablet coating suspension is made according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	10.0 gms. w./v.
Titanium dioxide	2.0 gms. w./v.
Bentone 18C	5.0 gms. w./v.
FD and C Yellow #11	0.1 gm. w./v.
Acetone	50.0 cc. v./v.
Ethyl alcohol, absolute	q.s. to 100.0 cc.

The copolymer is dissolved in the alcohol (about 40 cc.) with the aid of heat and with agitation. Thereafter, acetone, titanium dioxide, Bentone and dye are added along with sufficient alcohol to make a final volume of 100 cc. The mixture is placed in a ball mill and is allowed to roll for 8 to 16 hours.

The suspension is applied to a moving bed of tablets in a rotating pan by pouring small portions onto the tablets and allowing it to distribute evenly over the tablet surfaces according to the art of coating tablets. As the solvent evaporates, a thin, dry, hard film is formed on the tablets. Several coats are applied in the same manner with adequate drying between applications.

Tablets coated in this manner are pleasing in appearance and will disintegrate rapidly in water or artificial gastro-intestinal juices.

Example VII

A tablet coating suspension is made according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	10.0 gms. w./v.
Bentone 18C	2.0 gms. w./v.
Titanium dioxide	2.0 gms. w./v.
FD and C Yellow #11	0.5 gm. w./v.
Castor oil	0.2 cc. v./v.
Ethyl alcohol, absolute	50.0 cc. v./v.
Methyl ethyl ketone	q.s. to 100.0 cc.

The copolymer is dissolved in the alcohol with the aid of heat and with agitation. The castor oil, Bentone, titanium dioxide, dye and sufficient methyl ethyl ketone are then added with agitation to make a final volume of 100 cc. The mixture is placed in a ball mill and allowed to roll for 8 to 16 hours.

The same coating technique as described in Example VI is followed and the same results are obtained.

Example VIII

The formulation described in Example VII is prepared except ethyl acetate is used in place of methyl ethyl ketone.

The suspension is made in the same manner and the same coating technique is used as described in Example VI.

Example IX

A tablet coating suspension is made according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.584; M.W. 25,000–30,000)	5.0 gms. w./v.
Titanium dioxide	2.0 gms. w./v.
Bentone 18C	2.5 gms. w./v.
FD and C Yellow #11	0.5 gm. w./v.
Acrawax	1.0 gm. w./v.
Ethyl alcohol, absolute	25.0 cc. v./v.
Isopropyl alcohol, anhydrous	q.s. to 100.0 cc.

Dissolve the copolymer in the alcohol with the aid of heat and agitation. Dissolve the Acrawax in approximately 50 cc. isopropyl alcohol with the aid of heat. Add the isopropyl alcohol solution to the alcoholic one with agitation, then add the titanium dioxide, Bentone and dye and add sufficient isopropyl alcohol to make 100 cc. Place the mixture in a ball mill and allow it to roll for 8 to 16 hours.

The same coating technique is used as in previous examples and comparable results were obtained.

Example X

A tablet coating suspension is made according to the following formula:

Ethylene maleic anhydride copolymer (inherent viscosity 0.622; M.W. 75,000)	5.0 gms. w./v.
Bentone 18C	2.0 gms. w./v.
Titanium dioxide	2.0 gms. w./v.
D and C Red Lake #3	0.1 gm. w./v.
Water dispersible silicone wax (Silicone X–521, Linde)	0.2 gm. w./v.
Ethyl alcohol, absolute	55.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The copolymer is dissolved in the alcohol with the aid of heat and with agitation. Silicone X–521, Bentone, titanium dioxide and dye are added along with sufficient acetone to make a final volume of 100 cc. The mixture is placed in a ball mill and allowed to roll for 8 to 16 hours.

The same coating technique is used as in previous examples and comparable results were obtained.

Example XI

A tablet coating suspension is made according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosit 0.1428; M.W. 1,500–2,000)	5.0 gms. w./v.
Titanium dioxide	2.0 gms. w./v.
Bentone 18C	2.5 gms. w./v.
FD and C Yellow #11	0.5 gm. w./v.
Acrawax	1.0 gm. w./v.
Ethyl alcohol, absolute	25.0 cc. v./v.
Isopropyl alcohol, anhydrous	q.s. to 100.0 cc.

The suspension is made as described in Example VI, and the coating technique also duplicates the method disclosed in Example VI.

Example XII

A tablet coating suspension is made according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.584; M.W. 25,000–30,000)	5.0 gms. w./v.
Bentone 18C	2.5 gms. w./v.
Titanium dioxide	2.0 gms. w./v
FD and C Yellow #11	0.5 gm. w./v.
Propylene glycol	2.0 cc. v./v.
Castor oil	0.2 cc. v./v.
Sorbitan monoleate (Span 80)	0.6 cc. v./v.
Ethyl alcohol, absolute	25.0 cc. v./v.
Isopropyl alcohol, anhydrous	q.s. to 100.0 cc.

The copolymer is dissolved in the alcohol with the aid of heat and agitation. Propylene glycol, castor oil, Span 80, Bentone, titanium dioxide and dye are then added along with sufficient isopropyl alcohol to make a final volume of 100 cc. The mixture is placed in a ball mill and allowed to roll for 8 to 16 hours.

The same coating technique and results as described in Example VI are applied.

Example XIII

A tablet coating suspension is made according to the following formula:

Prtial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.584; M.W. 25,000–30,000)	5.0 gms. w./v.
Titanium dioxide	2.0 gms. w./v.
Bentone 18C	2.0 gms. w./v.
D and C Red Lake #3	0.3 gm. w./v.
Magnesium stearate	0.5 gm. w./v.
Ethyl alcohol, absolute	25.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The copolymer is dissolved in the alcohol with the aid of heat and with agitation. Titanium dioxide, Bentone, dye and magnesium stearate are then added along with sufficient acetone to make a final volume of 100 cc. The mixture is placed in a ball mill and allowed to roll for 8 to 16 hours.

The same coating technique and results as described in Example VI are followed.

Example XIV

A tablet coating suspension is made according to the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	7.5 gms. w./v.
Bentone 18C	2.0 gms. w./v.
Titanium dioxide	15.0 gms. w./v
D and C Blue #6	0.1 gm. w./v.
Acrawax	2.0 gms. w./v.
Glyceryl monostearate	0.5 gm. w./v.
Mineral oil	1.0 cc. v./v.
Ethyl alcohol, absolute	30.0 cc. v./v.
Methylene chloride	q.s. to 100 cc.

The resin is dissolved in the alcohol with the aid of heat and with agitation. Bentone, titanium dioxide, dye, Acrawax, glyceryl monostearate and mineral oil are then added along with sufficient methylene chloride to make 100 cc. The mixture is placed in a ball mill and allowed to roll for 8 to 16 hours.

The same coating technique as described in Example VI is followed.

Example XV

A tablet coating composition is made from the following formula:

Partial hydrolysis product of a maletic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	7.5 gms. w./v.
Bentone 18C	2.0 gms. w./v.
Titanium dioxide	7.5 gms. w./v.
Terra alba	7.5 gms. w./v.
D and C Blue #6	0.1 cc. v./v.
Mineral oil	1.0 cc. v./v.
Armid 18	3.0 gms. w./v.
Ethyl alcohol, absolute	20.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The ingredients are combined and tablets are coated as described in Example VI with comparable results.

Example XVI

A tablet coating composition is made from the following formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	7.5 gms. w./v.
Bentone 18C	2.0 gms. w./v.
Titanium dioxide	10.0 gms. w./v.
FD and C Blue #1	1.0 gms. w./v.
FD and C Yellow #5	6.0 gms. w./v.
Mineral oil	1.0 cc. v./v.
Armid HT	2.0 gm. w./v.
Glycerol monostearate	1.0 gm. w./v.
Ethyl alcohol, absolute	20.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The ingredients are combined and the tablets are coated as described in Example VI with comparable results.

Example XVII

A tablet composition is made according to the formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; m.w. 1,500–2,000)	7.5 gms. w./v.
FD and C, Blue #1	1.0 gm. w./v.
FD and C, Yellow #5	6.0 gms. w./v.
Veegum	2.0 gms. w./v.
Acrawax	2.0 gms. w./v.
Ethyl alcohol, absolute	20.0 cc. v./v.
Propylene glycol	0.5 cc. v./v.
N-propanol, absolute	25.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The resin is dissolved in ethyl alcohol with the aid of heat and agitation; thereafter, dyes, Veegum, Acrawax, and propylene glycol are added along with the normal propanol and sufficient acetone to make a final volume of 100 cc. The mixture is placed in a ball mill and is allowed to roll for 8 to 16 hours.

The liquid composition is applied to tablets as described in Example VI with comparable results.

Example XVIII

A tablet composition is made according to the formula:

Partial hydrolysis product of a maleic anhydride and ethylene copolymer (inherent viscosity 0.1428; M.W. 1,500–2,000)	7.5 gms. w./v.
FD and C, Blue #1	1.0 gm. w./v.
FD and C, Yellow #5	10.0 gms. w./v.
Titanium dioxide	10.0 gms. w./v.
Veegum	2.0 gms. w./v.
Acrawax	2.0 gms. w./v.
N-propanol, absolute	50.0 cc. v./v.
Acetone	q.s. to 100.0 cc.

The resin is dissolved in normal propanol with the aid of heat and agitation; thereafter, dyes, Veegum, Arcrawax, titanium dioxide are added with sufficient acetone to make a final volume of 10 cc. The mixture is placed in a ball mill and is allowed to roll for 8 to 16 hours.

The liquid composition is applied to tablets as described in Example VI with comparable results.

The foregoing examples describe a novel and highly unusual coating for tablets which provide a copolymer soluble in both anhydrous solvent and water. These copolymer attributes result in effective and efficient coating and further result in quick disintegration of the tablet following oral ingestion. The compositions and methods disclosed herein eliminate the problem of long and involved coating and drying procedures normally used in the tablet coating art. The film is uniformly thin on the tablets and eliminates the previous massive subcoating and sugar coating steps.

Others may practice the invention in any of the numerous ways which will be suggested by this disclosure to one skilled in the art. All such practice of the invention is considered to be a part hereof provided it falls within the scope of the appended claims.

We claim:

1. The method of coating tablets and the like with a thin plastic film which is soluble in water and organic solvent which comprises applying to tablets an anhydrous solvent solution of a copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000.

2. The method of coating tablets and the like with a thin plastic film which is soluble in water and organic solvent which comprises applying to tablets an anhydrous solvent solution containing about 3% to 20% w./v. of a copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000.

3. The method of coating tablets and the like with a thin plastic film which is soluble in water and organic solvent which comprises applying to tablets a coating composition consisting essentially of about 3% to 20% w./v. of a copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer in an anhydrous alcohol solvent wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000.

4. The method of coating tablets and the like with a thin plastic film which is soluble in water and organic solvent which comprises applying to tablets a coating composition consisting essentially of 5% to 10% w./v. of a copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000 dissolved in an anhydrous solvent solution of alcohol mixed with an organic liquid of high volatility.

5. The method of claim 4 where the alcohol is absolute ethanol and the highly volatile liquid is acetone.

6. The method of coating tablets and the like with a thin plastic film soluble in water and organic solvent which comprises applying to tablets an anhydrous solvent solution of a copolymer coating composition consisting essentially of a partial hydrolysis product of equimolar proportions of maleic anhydride and ethylene having an inherent viscosity of 0.12 to 0.58 and a molecular weight between 1,500 and 30,000.

7. The method of coating tablets and the like with a thin plastic film soluble in water and organic solvent which comprises applying to tablets an anhydrous solvent solution of a copolymer coating composition consisting essentially of equimolar proportions of maleic anhydride and ethylene having an inherent viscosity of about 0.62 and a molecular weight of about 75,000.

8. The method of claim 6 with the additional step of adding an organic liquid of high volatility to the anhydrous solvent solution.

9. The method of claim 7 with the additional step of adding an organic liquid of high volatility to the anhydrous solvent solution.

10. The method of coating tablets and the like with a thin plastic film soluble in water and organic solvent which comprises applying a coating composition comprising an anhydrous alcohol solution containing 5% to 10% w./v. of a copolymer selected from the class consisting

of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000; and at least 15% w./v. of inert physiologically acceptable solids insoluble in said solution.

11. The method of claim 10 with the additional step of adding an organic solvent of high volatility to the anhydrous solvent solution.

12. The method of coating tablets and the like with a thin plastic film soluble in water and organic solvent which comprises applying a coating composition comprising an anhydrous alcohol solution containing 5% to 10% of a copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000; at least 15% w./v. of physiologically inert solids insoluble in said solution; and about 3% w./v. of an anti-tacking agent selected from the group consisting of polyamides of long chain fatty acids and fatty acid amides.

13. The method of claim 12 where the copolymers have an inherent viscosity range of 0.12 to 0.62 and a molecular weight range of 1,500 to 75,000.

14. A coated solid medicament having as the coating material a thin plastic film of a physiologically acceptable composition comprising a water-soluble, organic solvent-soluble copolymer selected from the class consisting of a copolymer of equimolar proportions of maleic anhydride and ethylene, and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000.

15. A coated solid medicament having as the coating material a thin plastic film of physiologically acceptable composition comprising a water-soluble, organic solvent-soluble copolymer of equimolar proportions of maleic anhydride and ethylene having an inherent viscosity of about 0.62 and a molecular weight of about 75,000.

16. A coated solid medicament having as the coating material a thin plastic film of physiologically acceptable composition comprising a water-soluble, organic solvent-soluble copolymer comprising a partial hydrolysis product of equimolar proportions of maleic anhydride and ethylene having an inherent viscosity of 0.12 to 0.58 and a molecular weight of 1,500 to 30,000.

17. A coated solid medicament having as the coating material a thin plastic film of physiologically acceptable composition comprising 3 to 7 parts copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of .12 to .62 and a molecular weight of 1,500 to 75,000; 1 to 6 parts of physiologically inert solids insoluble in anhydrous solvent; and ½ to 2 parts fatty acid amides.

18. A coated solid medicament having as the coating material a thin plastic film of a physiologically acceptable composition comprising 3 to 4 parts copolymer selected from the class consisting of equimolar proportions of maleic anhydride and ethylene and partial hydrolysis products of said copolymer wherein said copolymer has an inherent viscosity of about .12 to .62 and a molecular weight of about 1,500 to 75,000; 5 to 6 parts of physiologically inert solids insoluble in anhydrous solvent; and less than 2 parts of fatty acid amides.

19. A coated solid medicament having as the coating material a thin plastic film of physiologically acceptable composition comprising 3 to 4 parts of a copolymer consisting of a partial hydrolysis product of equimolar proportions of maleic anhydride and ethylene having an inherent viscosity of 0.12 to 0.58 and a molecular weight between 1,500 and 30,000; 5 to 6 parts of physiologically inert solids insoluble in anhydrous solvent; and less than 2 parts of fatty acid amides.

20. A coated solid medicament having as the coating material a thin plastic film of physiologically acceptable composition comprising 3 to 4 parts of a copolymer consisting of equimolar proportions of maleic anhydride and ethylene having an inherent viscosity of about 0.62 and a molecular weight of about 75,000; 5 to 6 parts of physiologically inert solids insoluble in anhydrous solvent; and less than 2 parts of fatty acid amides.

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