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COATING MATERIAL FOR TABLETS AND COATED TABLETS

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This invention relates to the coating of tablets which are primarily used therapeutically and more particularly to compositions suitable for coating tablets and tablets which have been coated thereby.

Heretofore tablets such as compressed tablets have been coated with sugar by a lengthy and time-consuming process which consists in tumbling the tablets in a simple sugar syrup to wet the surfaces of the tablets; thereafter air is blown into the coating pans to partially dry the syrup. When the syrup becomes tacky a powdered filler is added. This filler is absorbed by the syrup and builds up the coating, at the same time keeping the tablets from sticking together.

During the first portion of the coating process considerable air is used to dry the tablets. When the initial coating has been built up and the final shaping and coating of the tablets is under way, considerably less air is used. The partially coated tablets are moistened with the syrup and are tumbled about so that they eventually assume an even, rounded shape.

After the tablets have been given the desired shape, they are given several coats of sugar syrup alone and colors may be added to these coats. After these coats have been dried the tablets are polished with a suitable solvent wax mixture.

In carrying out coating procedures, a coating which amounts to approximately half the weight of the compressed tablet is usually employed. It is necessary to put such a coating on the tablets in order to give the protection which the coating gives either from moisture or to compounds in the tablets or to mask the taste of the tablets.

In coating tablets it is difficult to get a satisfactory coating on sharp edges or corners and a tablet is not considered to be suitably coated unless the coating on the sharp edges and corners is of suitable thickness and strength. This means that in order to get an adequate coating on the corners or sharp edges it is necessary to apply an excessive amount of coating to other portions of the tablets. On an average only about 70% as much material will remain on these edges and corners as on the rest of the tablet so that about 40% more material is used than would be required if the coat were even.

The coating process is slow because the coatings must be built up in even layers. The operator can apply only very thin layers because the syrup cannot be applied in thick layers and cannot take up very large amounts of the powdered filler. After each application of syrup and filler it is necessary to dry the tablet. The time for drying a subcoat may vary from one-half hour to more than two hours and the later drying steps may take even longer. A total of from sixty to eighty hours may be necessary.

An object of this invention is to provide a new and improved coated tablet. Another object of this invention is to provide such a tablet which has a coating which is more elastic than previously known coatings and which is more resistant to fracture. Another object of the invention is to provide such a tablet which has a relatively thin coating thereon which can be applied in a shorter time, thus eliminating costly operations. Another object of the invention is to provide such a thin coating which has the necessary opacity for concealing the internal portion of the tablet, thus giving a tablet of attractive appearance. Another object of the invention is to provide a coating composition for tablets which can be simply and easily applied and which will

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give a coating of the necessary thickness for a coating in a minimum time. Another object is to provide such a coating material which will permit the use of a thin, elastic coating which is resistant to fracture.

Other objects and advantages of the invention will be apparent from the following specification:

In carrying out this invention, a small amount of sodium carboxymethylcellulose is added to the syrup which is used in coating the tablets. It has been found that if from 2 to 7 parts by weight of sodium carboxymethylcellulose are added to each 200 parts by weight of sugar in making the syrup that a final coating which is adequate for the tablet and which is thinner than coatings made by the conventional method can be built up on the tablet in a much shorter time than in following out heretofore standard procedures. The addition of the sodium carboxymethylcellulose makes for a more elastic and stronger coating, so that adequate coverage can be obtained in fewer applications, thus reducing the amount of material and the time required for the coating process.

It has been found that when such a coating is applied the addition of from 0.5 to 3 parts by weight of titanium dioxide to the sugar and sodium carboxymethylcellulose will improve the covering properties of the coating so that a thinner coating can be employed and it will provide adequate coverage to give a tablet having an attractive appearance.

When such a coating is applied to a tablet, the resistance of the corners and the sharper edges of the tablets to chipping is increased from 20% to 45% and the resistance to fracture may be increased up to 300%. Because of this, it is possible to reduce the overall coating on the tablet so that material saving is effected in materials, since the amount of coating on the smooth surfaces of the tablet may be reduced along with the rest of the coating.

When these new coating compositions are employed, it is possible to save up to about 60% of the man hours involved and up to about 50% of the drying time.

In preparing the coating solutions in accordance with this invention, 100 parts by weight of water are employed with each 200 parts by weight of sugar. From 2 to 7 parts by weight of sodium carboxymethylcellulose may be used and it has been found that 3 parts by weight of sodium carboxymethylcellulose will give very satisfactory results.

The sodium carboxymethylcelluloses which are employed represent additions of $-\text{CH}_2\text{COONa}$ groups to cellulose materials of various molecular weights. These carboxymethylcellulose compounds differ in viscosity, Low and medium viscosity solutions whose 2% solutions in water have a 25° C. viscosity of approximately 20 to 70 and 200 to 700 centipoises, respectively, can be used in the present invention. The low viscosity type is preferred because mechanical difficulties are encountered when the high viscosity materials are used.

The following are suitable syrups for use in carrying out this invention—

No. 25 subcoating syrup:	Pts. by Wt.
Sodium carboxymethylcellulose medium viscosity	3.0
Distilled water	100
Sugar	200

No. 19 color coating syrup (green):	Pts. by Wt.
Sodium carboxymethylcellulose low viscosity	6.0
Titanium dioxide	0.5
FD and C green No. 2	q.s.
FD and C yellow No. 1	q.s.
Distilled water	100
Sugar	200

No. 60 color coating syrup (brown):	Pts. by Wt.
Sodium carboxymethylcellulose medium viscosity	3.0
Distilled water	100
Brown oxide	q.s.
Sugar	200

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No.	21 color coating syrup (red)	Pts. by Wt.
	Sodium carboxymethylcellulose low viscosity	6.0
	FD and C red No. 1	q.s.
	Titanium dioxide	0.5
	Distilled water	100
	Sugar	200

As pointed out above, 2 to 7 parts by weight of sodium carboxymethylcellulose may be employed instead of the 3 to 6 parts given in the above examples.

It should be noted that when medium viscosity types of sodium carboxymethylcellulose are used the lower concentrations are preferably employed; while when the low viscosity types are employed they are preferably used in the upper range of concentrations.

The titanium dioxide can be varied from 0.5 to 3 parts by weight.

The following examples illustrate specific applications of the invention to the coating of tablets:

Example I

About 100,000 compressed tablets which have only a shellac sealing coat are placed in a coating pan. These represent about 137 pounds. These tablets are then given four applications of about two pounds each of a subcoating syrup consisting of 3 parts by weight of sodium carboxymethylcellulose of medium viscosity as above defined, 100 parts by weight of distilled water and 200 parts by weight of sugar.

Between applications the coatings are dried in the conventional manner with an air blast and powder is employed.

The tablets are rounded by the application of about three pounds of the same solution. They are dried during this operation without any air blast.

Just before complete drying of the tablets, another application of syrup is made, and the tablets are allowed to dry without any air blast.

To the dried tablets a color coating is applied which consists of 6 parts by weight of sodium carboxymethylcellulose of low viscosity, 0.5 part by weight of titanium dioxide, coloring material, 100 parts by weight of distilled water and 200 parts by weight of sugar. About nine separate applications are made of this syrup with about two pounds for each application, decreasing the quantity until the last two applications consist only of the quantity necessary to wet the surface of all the tablets. An air blast is used continuously until the last three applications.

When the tablets are dried they are given an application of wax polishing solution.

The subcoating and coloring require about four hours.

Example II

About 60 pounds of uncoated ammonium chloride tablets are placed in a coating pan and about 10 fluid ounces of a subcoating syrup consisting of 3 parts by weight of medium viscosity sodium carboxymethylcellulose, 100 parts by weight of distilled water and 200 parts by weight of sugar are applied. Sufficient coating powder to allow the tablets to roll freely is added. An air blast is applied until the tablets are dried.

This process is repeated. The tablets are then removed from the coating pan and dried at 100° F. and 4% relative humidity overnight.

The dried tablets are then returned to the coating pan. Four applications of 10 fluid ounces each of the same syrup are applied. Dusting powder is added between applications in a conventional manner, and the tablets are dried by an air blast between applications.

The rounding operation is carried out by applying 20 fluid ounces of the same syrup using a coating powder, but without applying an air blast.

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When these tablets are dried two applications each of 16 fluid ounces of the enteric coating described in United States Letters Patent No. 1,907,203 are applied. After drying in an air blast the tablets are removed and dried overnight at 100° F. and 4% relative humidity.

The coloring operation is accomplished with four separate 8-fluid-ounce applications of coloring syrup, using a continuous air blast, followed by one 12-fluid-ounce application of the same syrup with no air blast and then three 8-fluid-ounce applications, drying the tablets between applications, using an air blast.

Any one of the three color-coating syrups described above may be used in this operation.

After the tablets are dried they are polished by the addition of a wax polishing solution.

These examples of the syrup and the actual coating processes are merely illustrative of the syrups and processes and the syrups and processes may be varied without departing from the invention. For instance, the contents of the syrups may be varied as outlined above and the titanium dioxide may be used or omitted, depending upon what is desired in the finished product.

There is no intention in describing the specific examples to be limited to the specific examples. The invention is defined in the claims.

What is claimed is:

1. A medicinal tablet having a coating thereon comprising intermixed sugar and sodium carboxymethylcellulose and titanium dioxide in the proportions of 200 parts of sugar to 2 to 7 parts of sodium carboxymethylcellulose to 0.5 to 3 parts of titanium dioxide and characterized by elasticity and resistance to fracture.

2. A medicinal tablet having a coating thereon comprising intermixed sugar and sodium carboxymethylcellulose in the proportions of 200 parts of sugar to 2 to 7 parts of sodium carboxymethylcellulose and characterized by elasticity and resistance to fracture.

3. A composition for coating compressed medicinal tablets or the like comprising a solution in water of sugar and sodium carboxymethylcellulose in the proportions of 200 parts of sugar to 2 to 7 parts of sodium carboxymethylcellulose and having suspended therein titanium dioxide.

4. A composition for coating compressed medicinal tablets or the like comprising a solution in water of sugar and sodium carboxymethylcellulose in the proportions of 200 parts of sugar to 2 to 7 parts of sodium carboxymethylcellulose.

References Cited in the file of this patent

UNITED STATES PATENTS

Number	Name	Date
2,253,800	Myers	Aug. 26, 1941
2,362,761	Medl	Nov. 14, 1944
2,591,742	Thomas	Apr. 8, 1952

FOREIGN PATENTS

Number	Country	Date
389,518	Great Britain	Mar. 16, 1933

OTHER REFERENCES

"Sodium Carboxymethyl Cellulose," Hercules Powder Co., Wilmington, Del., 1944, page 3.

"Tablet Making," Little et al., 1949, pp. 82, 83 and 85. Hollabaugh et al., Industrial and Chemical Engineering, pp. 943 to 947, October 1945.

Mantell, Water Soluble Gums, pp. 152 to 155 (1947). Rowell, Drug and Cosmetic Industry, vol. 63, pp. 459, 460, 549 to 551.