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METHOD OF SUGAR COATING PHARMACEUTICAL TABLETS

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ABSTRACT OF THE DISCLOSURE

Tablets are sugar coated by applying sugar syrup directly to the tablet cores without subjecting the cores to any prior application of an adhesive or other subcoating treatment, or other preliminary treatment for the purpose of rounding or covering any sharp edges or corners thereof.

This invention relates to the coating of pharmaceutical tablets with a sugar syrup in solution or suspension form and more particularly to the sugar coating of pharmaceutical tablet cores by applying directly to such tablet cores under hydraulic pressure a sugar syrup of the required formulation, drying the coated tablet cores and repeating the spraying and drying steps until the tablets have a predetermined finished weight.

The sugar coating of pharmaceutical tablets is well known and has been practised for many years. In conventional sugar coating techniques it is essential that all sharp edges and corners be covered or rounded before the finishing syrup coating is applied. This has heretofore been done by applying an adhesive coating which usually consists of gelatin, acacia, sugar and water and followed by a subcoating powder which adheres to the sharp edges and rounds off the tablets. This subcoating powder is usually a blend of insoluble powders, adhesive powders and lubricants. A typical subcoating powder contains calcium carbonate, talc, kaolin, sugar, acacia, lactose, etc., and the application of the subcoating powder requires a high degree of skill and is the most crucial phase of the entire sugar coating operation. It is particularly important for the subcoating layers to be built up evenly and to be dried thoroughly. It will therefore be appreciated that a satisfactory and effective coating over the sharp edges of the pressed tablet is quite difficult to obtain and a large number of individual coatings are required. In ordinary subcoating operations the time required for building up a suitable subcoating varies greatly according to the skill of the particular tablet coater and may take as much as 72 hours to complete.

The object of the present invention is to make it possible to apply a sugar coating to tablets without using a subcoating or any other pretreatment procedure. In this way the whole tablet making process is considerably shortened and reduced in cost and, in addition, the danger of moisture penetration into the core is minimized.

It has been found that by hydraulically spraying a sugar syrup direct onto the tablet cores at a nozzle pressure of about 800 to 1500 pounds per square inch without employing any subcoating or other preliminary preparation of the tablet cores excellent tablets can be produced which may have as little as 10 percent by weight of sugar coating based on the total tablet weight. By so applying a sugar syrup under high hydraulic pressure, the drying of the coating is expedited and simplified due to the rapid evaporation of water from the fine mist spray delivered by the spray gun. By following the method of the present invention, the tablets can be coated more rapidly and with fewer coating steps as well as requiring less coating material. The method is also of such

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nature that the exposure of the tablets to aqueous sugar solutions for prolonged periods of time is eliminated.

This is in direct contrast to finished sugar coated tablets made by conventional techniques wherein the coating amounts to approximately twice the weight of the core. By following the novel method of the present invention, pharmaceutical tablets can be given an adequate sugar coating with as little as 10 percent of the finished tablet weight.

The hydraulic spray equipment used in carrying out the invention is capable of spraying heated sugar syrups and sugar syrup suspensions at a nozzle pressure of about 800 to 1500 pounds per square inch through a fine nozzle orifice. It is not absolutely essential to use this particular type of equipment however, since any suitable or similar spray equipment can be employed. While it is not absolutely necessary to heat the sugar syrup or sugar syrup suspension, it is preferable to do so, in which case a temperature is used in the range of about 80 to 170 degrees F. The sugar syrup or sugar syrup suspension may also contain any suitable approved coloring material. The spraying operation is carried out for a period of time ranging from 1 to 120 seconds following which drying is carried out for a period of time ranging from 1 to 15 minutes depending on the number of tablets being coated in a given batch. The spray coating and drying steps are repeated for a sufficient number of cycles to produce tablets of the required total weight but, as pointed out above, it is possible to provide an adequate sugar coating which amounts to as little as 10 percent of the total tablet weight. The sugar syrup solutions and suspensions are made in accordance with accepted laboratory procedures and for heating they are circulated through a heater of any appropriate or known type. The following sugar solutions and suspensions have been successfully sprayed onto tablet cores without subcoating, rounding or other pretreatment.

Example 1

	Gms.
Sucrose powdered	91.00
Distilled water	54.75
FD & C color	Q.s.

Example 2

FD & C Red #3	0.300
Diocetyl sodium sulfosuccinate	0.005
Titanium dioxide	50.000
Distilled water	125.000
Simple syrup, q.s.	250.000

Example 3

Powdered sucrose	200
Simple syrup	500
FD & C color	Q.s.

Example 4

Liquid sucrose	100
FD & C color	Q.s.

The above nonlimitative examples utilized FD & C colors but D & C dyes are equally suitable as well as the insoluble lakes of the two above types of colors. The concentration of the color, dye or lake may vary as desired depending upon the intensity of color required. This is known per se.

In a particular coating operation, the coating solution or suspension is circulated through a heater until its temperature is raised to approximately 150° F., tablets are placed in a conventional coating pan and heated to 100° F. and the heated coating solution is then hydraulically sprayed onto the tablets at a nozzle pressure of 1000 pounds per square inch for 3 seconds following which the

tablets are dried for 5 minutes and the spraying and drying cycle repeated for the necessary number of times to give a predetermined total tablet weight. The tablets were then polished in standard polishing pans in accordance with standard polishing procedure.

While it has been found best to follow the foregoing procedure it is to be understood that the invention is not limited thereto since the method can be carried out manually or it can be programmed and controlled by automatic timing and recycling devices.

What is claimed is:

1. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose directly to unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight.

2. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose directly to unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight wherein the total weight of the coating amounts to about 10 percent of the total tablet weight.

3. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose directly to unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight wherein the total weight of the coating amounts to about 10 percent of the total tablet weight, each spraying being carried out for a period of time ranging from 1 to 120 seconds and each drying lasting from 1 to 15 minutes depending on the number of tablets being coated.

4. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose heated to a temperature of about 80 to 170° F. directly onto unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of

about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight.

5. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose directly to unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight, the sugar syrup being a colored sugar solution.

6. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose directly to unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight, the sugar syrup being a colored sugar suspension.

7. A method of sugar coating pharmaceutical tablets without using either an adhesive subcoating, or any subcoating powder, and without rounding, or any other pretreatment procedure which consists of the steps of applying a sugar syrup free of any adhesive or lubricants, gelatin, acacia, calcium carbonate, talc, kaolin, or lactose directly to unpretreated, unsubcoated, unrounded tablet cores having all sharp edges and corners uncovered and unrounded by hydraulic spraying at a nozzle pressure of about 800 to 1500 pounds per square inch and drying the spray coated tablet cores, and repeating the spraying and drying steps until the tablets have a predetermined finished weight, the said method eliminating subcoating, pretreating and rounding operations and minimizing moisture penetration into the cores.

References Cited

UNITED STATES PATENTS

312,041	2/1885	Upjohn	167—82
2,262,087	11/1941	Bartlett et al.	167—82
2,648,609	8/1953	Wurster	99—166
2,693,437	11/1954	Spradling	167—82
2,693,436	11/1954	Spradling	167—82
2,736,288	2/1956	Clay et al.	118—19
2,925,365	2/1960	Nicholson et al.	167—82
3,054,724	9/1962	Raff	167—82
3,112,220	11/1963	Heiser et al.	117—100
3,141,792	7/1964	Lachman et al.	118—6
3,185,626	5/1965	Baker	167—82

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