THE SUGAR COATING OF COMPRESSED TABLETS

by

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A Thesis Submitted in Partial Fulfillment of the

Requirements for the Degree of

Bachelor of Science

(Pharmacy)

at the

UNIVERSITY OF WISCONSIN

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INTRODUCTION

The purpose of this study was to gain information which might be used in developing working formulas and directions for coating tablets in the manufacturing laboratory of the School of Pharmacy, University of Wisconsin. The study was deemed necessary because of the apparent lack of complete up-to-date information in the literature.

The scope of the study was limited to techniques and formulas involved only in coating the conventional type of tablets with a white sugar coating. Special procedures and formulas necessary for coating dark tablets white, for coating tablets containing hygroscopic or resinous substances, for colored coatings, etc. can be found in the literature or developed in the laboratory at a later date. The procedures, however, are basically the same irrespective of the type of coating or the type of tablets being coated.

All experimental work was done on a small scale. While it is true that some changes may be necessary in transcribing this information for use on a manufacturing scale, it is believed that little difficulty will be experienced since it is the general opinion of most writers that tablet coating is more difficult on a small scale than on a large scale.

The bibliography included in this thesis very briefly summarizes the more important, comparatively recent sources

of information on this subject. It has not been the object of this writer to compile a complete bibliography, but rather to present those references which were found most useful as background material for the experimental work conducted.

EQUIPMENT

Because a standard coating pan of small capacity was not readily available, it was necessary to improvise one that could be adapted to the bench coating island and motor used with the larger pans. This was done by plugging the upper part of the stem of a 6½ inch aluminum vacuum-type coffee brewer top with a large rubber stopper. The stem was coupled to the motor by a piece of brass tubing.

The coating island was a bench-type island on which was mounted a ¼ horsepower electric motor. The motor contained a reduction gear which reduced the speed of the shaft from 1725 R.P.M. to 36 R.P.M.

A source of hot air for drying the tablets was provided by placing a standard household electric fan at the mouth of an air funnel made of heavy galvanized sheet metal into which had been introduced a heating coil. By means of this apparatus, air heated to a temperature of approximately 70 degrees could be blown into the coating pan.

EXPERIMENTAL

The experimental data listed below represents mostly negative results insofar as successful coating is concerned. The knowledge and practical experience gained in carrying out these experiments serves to compensate for the time spent, and much of this information will be found in the discussion following the experimental data.

Lot No. 1

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 200
Syrup used: Formula No. S-1
Powder used: Formula No. P-1
No. of coats applied: 10
Remarks: Gelatin syrups are difficult to work with due to viscosity, stickiness, and the necessity for heat. Resultant coating was uneven and soft.

Lot No. 2

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 300
Syrups used: Acacia Syrup N. F. VIII
Syrup U. S. P. XIII
Syrup 65%
Powders used: Formula No. P-2
Magnesium Oxide
Talc
No. of coats applied: 35
Remarks: Some improvement over Lot No. 1. The last 15 coats were made up of Syrup 65% with no powder dusted on the tablets. These were applied in an attempt to smooth over the rough undercoats.

Lot No. 3

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 1500
Syrups used: Acacia Syrup N. F. VIII
Syrup U. S. P. XIII
Syrup 42.5%
Powder used: Formula No. P-3
No. of coats applied: 5
Remarks: It was discovered that the speed of drying influences the smoothness of the coat.

Lot. No. 4

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 2000
Syrups used: Acacia Syrup N. F. VIII
Syrup U. S. P. XIII
Syrups 50, 60, 70, 80, 90%
Powders used: Formula No. P-4
Talc
No. of coats applied: 39
Remarks: At least 5 coats are necessary before much change can be noted. Talc is important for smoothness. The more diluted the syrup is, the longer it takes to dry the tablets. Tablets should be allowed to revolve without heat directly following powder application.

Lot No. 5

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 1500
Syrup used: Acacia Syrup N. F. VIII
Powder used: Corn Starch
No. of coats applied: 10
Remarks: Starch, when used with Acacia Syrup, makes the tablets stick together very readily.

Lot No. 6

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 1500
Syrups used: Acacia Syrup N. F. VIII
Syrup U. S. P. XIII
Powders used: Talc
Formula No. P-5
Formula No. P-6
Formula No. P-7
No. of coats applied: 20
Remarks: As the percentage of acacia is increased, so is the tendency of the tablets to stick together.

Lot No. 7

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 1200
Syrups used: Acacia Syrup N. F. VIII
Syrups 10, 20, 30, 40%
Powder used: Powdered sucrose
No. of coats applied: 10
Remarks: When powdered sucrose is used a coating is produced which chips off readily when dry.

Lot No. 8

Type of tablets: 5 gr. Aspirin
Control no. of tablets: 34-12247-3
Quantity of tablets: 1200
Syrup used: Acacia Syrup N. F. VIII
Powders used: Powdered Sucrose
Formula No. P-8
No. of coats applied: 5
Remarks: Aspirin tablets were substituted for Sodium Bicarbonate tablets to determine the effect of coating a harder and deeper punched tablet.

Lot No. 9

Type of tablets: 5 gr. Aspirin
Control no. of tablets: 34-12247-3
Quantity of tablets: 900
Syrup used: Acacia Syrup N. F. VIII
Suspension used: Formula No. S-2

Powder used: Formula No. P-7
No. of coats applied: 22
Remarks: Use of a suspension of powders in a syrup gave somewhat better results.

Lot No. 10

Type of tablets: 5 gr. Aspirin
Control no. of tablets: 34-12247-3
Quantity of tablets: 1200
Suspensions used: Formula No. S-2
Formula No. S-3
No. of coats applied: 15
Remarks: The suspensions were allowed to dry without the addition of a powder.

Lot No. 11

Type of tablets: 5 gr. Aspirin
Control no. of tablets: 34-12247-3
Quantity of tablets: 1200
Suspensions used: Formula No. S-4
Formula No. S-5
Formula No. S-6
Formula No. S-7
No. of coats applied: 20
Remarks: Methyl cellulose suspensions appear to have no advantage over other suspensions.

Lot No. 12

Type of tablets: 5 gr. Aspirin
Control no. of tablets: 34-12247-3
Quantity of tablets: 1200
Suspensions used: Formula No. S-7
Formula No. S-8
No. of coats applied: 2
Remarks: Coating was rough after only 2 applications.

Lot No. 13

Type of tablets: 5 gr. Aspirin
Control no. of tablets: 34-12247-3
Quantity of tablets: 600
Suspension used: Formula No. S-9
Powder used: Formula No. P-9
No. of coats applied: 28
Remarks: A smooth coat was obtained using these formulas. Powder was blown on with an atomizer. Hot air was turned off during

the addition of powder and suspension.

Lot No. 14

Type of tablets: 5 gr. Sodium Bicarbonate
Control No. of tablets: 15-22147-3
Quantity of tablets: 1200
Suspension used: Formula No. S-9
Powder used: Formula No. P-9
No. of coats applied: 23
Remarks: Starting with a clean pan, good results were obtained using the same procedure as with Lot. No. 13. Sodium Bicarbonate tablets are more easily coated because of their smaller edge.

Lot No. 15

Type of tablets: 5 gr. Sodium Bicarbonate
Control no. of tablets: 15-22147-3
Quantity of tablets: 1200
Suspension used: Formula No. S-9
Powder used: Formula No. P-9
No. of coats applied: 5
Remarks: In coating this lot the same formulas used for Lots No. 13 and No. 14 were used. The powder was added from a spatula rather than spraying from an atomizer. After five coats the tablets were unevenly coated. Thus it was proved that the method of application of the powder is the determining factor in producing a smooth finish.

Powder Formulas

No. P-1	
Calcium Carbonate	5 parts
Corn Starch	1 part
No. P-2	
Talc	5 parts
Acacia	1 part
No. P-3	
Acacia	4 parts
Talc	5 parts
No. P-4	
Acacia	
Talc	equal parts
No. P-5	
Talc	9 parts
Acacia	1 part
No. P-6	
Talc	4 parts
Acacia	1 part
No. P-7	
Talc	7 parts
Acacia	3 parts
No. P-8	
Acacia	2 parts
Talc 30%	3 parts
Powdered Sucrose	5 parts
No. P-9	
Powdered Sucrose	36 Gm.
Corn Starch	12 Gm.
Talc	2 Gm.

Syrups and Suspension Formulas

No. S-1

Gelatin	7.5 Gm.
Acacia	7.5 Gm.
Sugar	6.0 Oz.
Water	4.0 Oz.

No. S-2

Corn Starch	69 Gm.
Light Precipitated Chalk	69 Gm.
Sucrose	572 Gm.
Distilled Water	290 cc.

No. S-3

Talc	10 Gm.	
Starch	30 Gm.	
Light Precipitated Chalk	20 Gm.	
Methyl Cellulose Suspension	2%, 100 cps.	100 cc.

No. S-4

Acacia	30 Gm.	
Talc	70 Gm.	
Methyl Cellulose Suspension	2%, 100 cps.	100 cc.

No. S-5

Talc	70 Gm.	
Starch	30 Gm.	
Methyl Cellulose Suspension	2%, 100 cps.	100 cc.

No. S-6

Light Precipitated Chalk
Acacia Syrup N. F. VIII

No. S-7

Light Precipitated Chalk
Methyl Cellulose Suspension 2%, 100 cps.

No. S-8

Starch
Methyl Cellulose Suspension 2%, 100 cps.

No. S-9

Sucrose	181.6 Gm.
Corn Starch	9.0 Gm.
Talc	3.0 Gm.
Distilled Water, q.s. to make	180 cc.

DISCUSSION

Type of tablets best suited to coating. The type of compressed tablet which can be sugar coated successfully is somewhat limited. The main requirement is that the tablet be compressed with a deep punch so that it has high convex faces and as thin an edge as possible. The thickness of the edge largely determines the number of coats necessary to produce a well coated tablet. This will in turn affect the length of time and quantity of syrup or suspension and powder required. Before a tablet can be considered to be well coated the edges must be thoroughly rounded off and all surfaces extremely smooth.

Preparation of tablets. Keeping in mind that one of the prime requirements is smoothness, it is well to give thought to the physical appearance of the tablet just prior to coating. Sharp edges must be rounded off. This can be attained by rotating the tablets in a dry pan for five or ten minutes and then sifting to remove excess powder and broken tablets. The tablets themselves must, of course, be dry and free from extraneous matter.

Formulas. The ingredients used in the coating formulas must meet three requirements. First, they must be nontoxic and of a nature which is not irritating to the mucous membrane of the alimentary canal. For this reason the in-

corporation of too much talc into a formula should be avoided. The second requirement is that the coating must disintegrate in a reasonable length of time following administration. Thirdly, ingredients must be used which combine to make a smooth coating.

Because of the discovery toward the end of this study that the method of application of the powder is of prime importance, it is impossible to recommend a syrup or suspension and powder as being "the best". However, since good results were obtained using suspension No. S-9 and powder No. P-9, the combination of these two formulas is suggested. Both formulas meet the requirements cited above. Regardless of what formula is used for a powder, before the powder is applied to the tablets it should be passed through a fine sieve. In this study a number 80 sieve was used; however, when coating on a larger scale the size could probably be increased.

Method of Coating. In the experimental work done, the importance of the methods of coating was clearly demonstrated. The skill and art employed by the coater influences to a great extent the elegance of the coated tablet. The following is the suggested procedure as derived from the experimental work:

After the sharp edges have been removed and the tablets sieved, they are again placed in a clean coating pan.

The number of tablets which can be coated at one time depends upon the size of the pan. Unless a sufficient number is used, the tablets will slide, rather than roll. At the same time, overloading the pan should be avoided, keeping in mind that the bulk of the tablets increases as the size of the coat is built up on each tablet. It is well to start with a comparatively clean pan as the crust of a coated pan is liable to break off in small pieces and adhere to the tablets as they roll. After the tablets are rolling well, the syrup or suspension is applied in small portions until all the tablets are thoroughly wetted but continue to roll without undue clumping. The next step is to apply the powder as evenly as possible. This is extremely important if a smooth coating is to be obtained. Experimentally, it was shown that when coating a small number of tablets (2,000 or less) the most effective method is to blow the powder on with an atomizer or insufflator. The amount of powder used should be just enough to completely cover all of the tablets. Excess powder will go to the back of the pan and can be removed from time to time by scooping out or, better, by sifting the tablets. This will also remove any broken tablets. Following the addition of powder the tablets should continue to roll without clumping. If clumping occurs, the tablets can be separated by hand. If they stick to the side of the pan they can be removed with a spatula. Next, the hot air blast is turned on and the tablets allowed to roll until

completely dry. When dry, the hot air is turned off and the procedure repeated beginning with the addition of syrup or suspension. The number of coats and the time required depends upon the thickness of each coat, the number of tablets, and the thickness of the tablet's edge.

Finishing coats and polishing: To further insure a smooth coating several coats of syrup or suspension can be applied allowing the tablets to dry slowly without the hot air blast. Dust particles can be excluded from the inside of the pan by fastening a piece of muslin over the mouth. A polished surface is obtained by rolling the tablets in a canvas lined polishing pan and adding a small quantity of a solution of wax (beewax, carnauba wax or combinations of both.) in acetone, gasoline, or other suitable solvent. Experimental work covering this step was not included in this study.

SUMMARY AND CONCLUSION

1. An experimental study of the methods, techniques, and formulas used in the sugar coating of compressed tablets is described.

2. The following generalizations can be made:

(a) The smaller the edge of the tablet, the more easily the tablets are coated.

(b) The quantity of syrup or suspension used should be just enough to thoroughly wet all the tablets but still allow them to roll without undue clumping. The amount of powder used should be just enough to completely cover all of the tablets with a fine coating.

(c) The importance of applying the powder evenly and finely has been demonstrated.

(d) Clumping of tablets causes uneven coating.

(e) The sign of a well coated tablet is a well rounded edge and smooth surfaces.

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Smoothing-coat
Color-coat
Polishing

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Steps in the Process
Color Preparations for Coating
Recoated Tablets
Precautions

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Special Coating Equipment
Preparation of Tablets
Preliminary Treatment
Coating White Tablets White
Color Coat on White Tablets
White Coating on Dark Tablets
Colored Coating on Dark Tablets

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The Sugar Coating of Tablets and Pills

Bulletin: Stokes Machine Co., Philadelphia

A comprehensive description of sugar coating which includes the following headings:

Equipment
Coating Pans
Polishing Machines
Fan Blowers
Cooking Apparatus
Preparation of Stock Solutions and Sub-Coating Powders
Tablets
General Description of the Process
Special Treatment for Coating Tablets Which Absorb Moisture
Re-Coating Tablets
Time Required for Coating
General Precautions.

Approved Louis W. Busse

Associate Professor of Pharmacy

Date June 8, 1948