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REMOVAL OF SURFACE FROSTING FROM SUGAR COATED TABLETS BY STEAMING

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ABSTRACT

A process is described whereby the degree of surface frosting in sugar coated tablets is reduced. Scanning electron microscopy and X-ray diffraction data indicate that the decrease in frosting is due to the conversion of the sugar coat from a crystalline to an amorphous state.

BACKGROUND

Tablet coating is one of the oldest arts used by the modern pharmaceutical industry. Coating serves a variety of purposes, including masking objectionable tastes, improving stability of active ingredients, increasing aesthetic appeal, and enhancing product identification. Sugar coating remains one of the more popular tablet coating methods, both for historical reasons and because of the elegance of the final product.

The apparatus and procedures used in the sugar coating process have, for the most part, remained unchanged since the middle part of the nineteenth century. Because details of the sugar coating process have been discussed previously[1,2], only a brief outline of the procedure is presented here. After the tablets to be coated are charged into a coating pan they are seal coated, which involves the application of several coats of a protective material, usually

in a nonaqueous vehicle. The primary function of the seal coat is to protect the core tablet from moisture exposure during the application of subsequent aqueous-based coats. The seal coating operation is followed by the application of a subcoat to round off tablet contours and to enhance bonding between the seal coat and sugar coat. Application of the sugar coat, which is the next step in the process, involves the application of grossing, heavy syrup, and regular syrup coats. It is during this step that color is imparted to the coat by incorporating dyes into the various coating solutions. Finally, the coated tablets are polished by applying a solution containing various waxes. The polishing operation may be carried out in a regular coating pan or in special wax or canvas-lined pans.

It should be apparent from the discussion in the preceding paragraph that there are a number of variables which must be carefully controlled in order to obtain an acceptable final product. Failure to control these variables properly may, for example, result in the formation of large crystals in the sugar coat, which imparts a frosted appearance to the surface of the tablets. It may be possible to mask or remove mild cases of frosting by polishing; however, more severe cases may necessitate reprocessing the tablets. The objective of this work was to develop a procedure which would allow frosted batches of sugar coated tablets to be recovered without extensive reprocessing.

EXPERIMENTAL

Apparatus Design

The problem of tablet frosting was approached from the standpoint of altering the crystallinity of the sugar coat. This alteration was achieved by dropping the tablets through a 91.4 cm x 16.2 cm (I.D.) steam-jacketed column (Figure 1). This method and design had a number of advantages, including:

1. By dropping the tablets through a column, tablet-tablet and tablet-surface contact were minimized while the sugar coat was in a dissolved state.

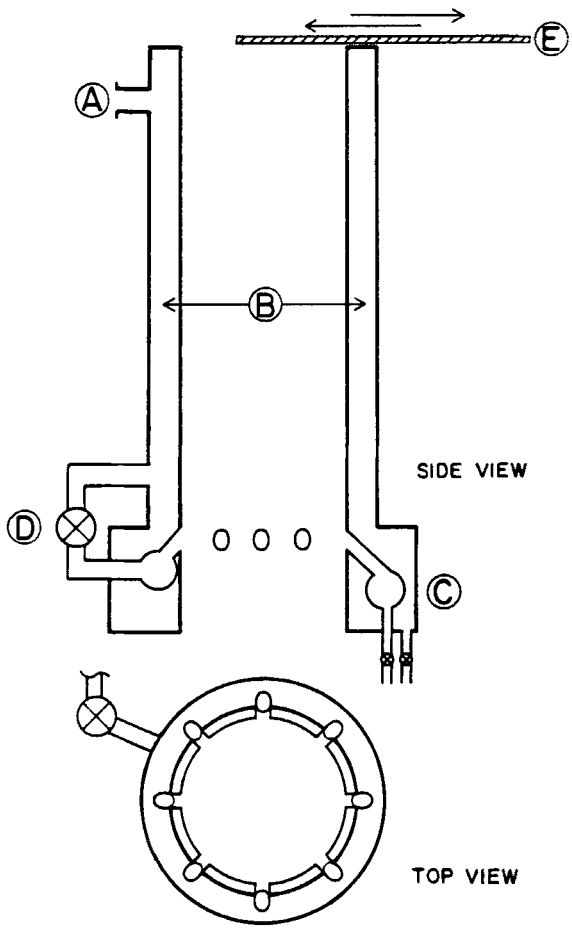

FIGURE 1

Side and top views of the apparatus used in this work. Steam was supplied at a pressure of 6-7 psi and flowed from the inlet (A) to the heating jacket (B). The flow of steam from the heating jacket into the dispersing manifold (C) was controlled by a valve (D). A porous cover (E) provided a means of controlling the temperature within the column.

TABLE 1

Column Temperatures at Various Degrees of Opening Occlusion

% Occlusion	Interior Temperature (°C)	
	12.7 cm from top	68.6 cm from top
0	56.5	57.0
25	60.4	63.5
50	67.6	68.0
75	77.4	74.0

2. The amount of solvent (water) required to dissolve the sugar coat was minimal because of the high solvent temperature within the column.

3. The apparatus design eliminated water droplets from the incoming steam jet and prevented condensation from forming on the interior wall of the column.

A porous cover was used to impede the escape of steam from the column's interior without causing a pressure buildup. Column temperatures at various degrees of opening occlusion were monitored using a temperature/humidity probe (model HMI 31, Vaisala, Helsinki, Finland). Results of this monitoring are reported in Table 1. The corresponding relative humidities could not be accurately determined because the column temperature exceeded the probe's upper temperature limit for relative humidity measurements.

Tablet Preparation

Core tablets weighing approximately 300 mg were compressed from a mixture of lactose lubricated with 0.5% magnesium stearate on a single-station press (Model F, F.J. Stokes Machine Co., Philadelphia, PA) using a 3/8" concave punch and die set. The

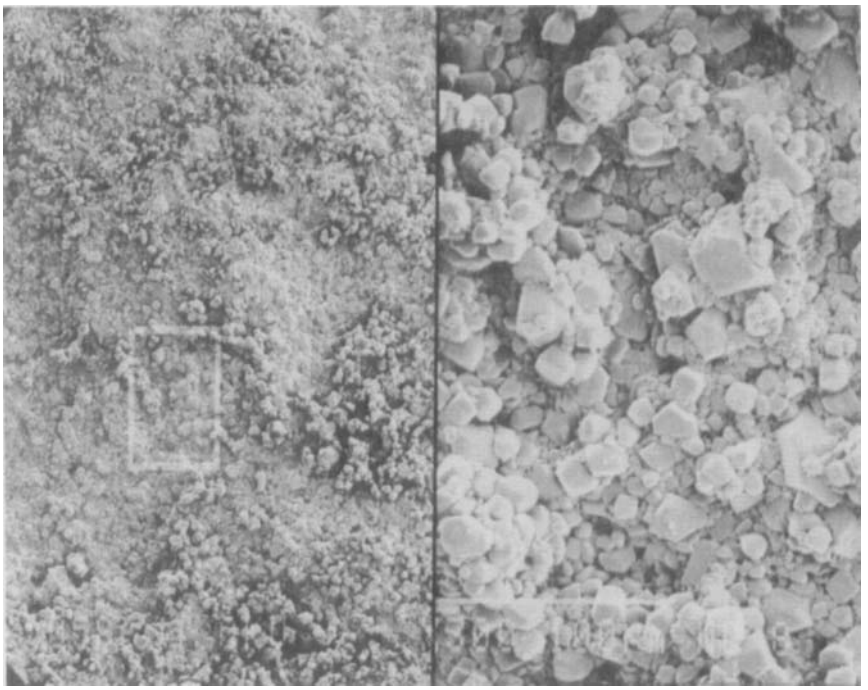

PHOTO 1

Surface topography of a frosted sugar coated tablet. (magnification: left X300, right X1500).

tablets were sealed/grossed with an aqueous povidone solution and sugar coated with an syrup solution colored with 0.1% FD&C blue #3.

Scanning Electron Microscopy

Photomicrographs were taken of the surfaces of untreated tablets and of tablets subjected to various numbers of steam exposures at different degrees of column occlusion. The latter parameter determined the uniformity of temperature and humidity conditions within the column.

X-ray Diffraction

The degree of crystallinity in a sugar coat before and after steaming was assessed by measuring its X-ray diffraction pattern.

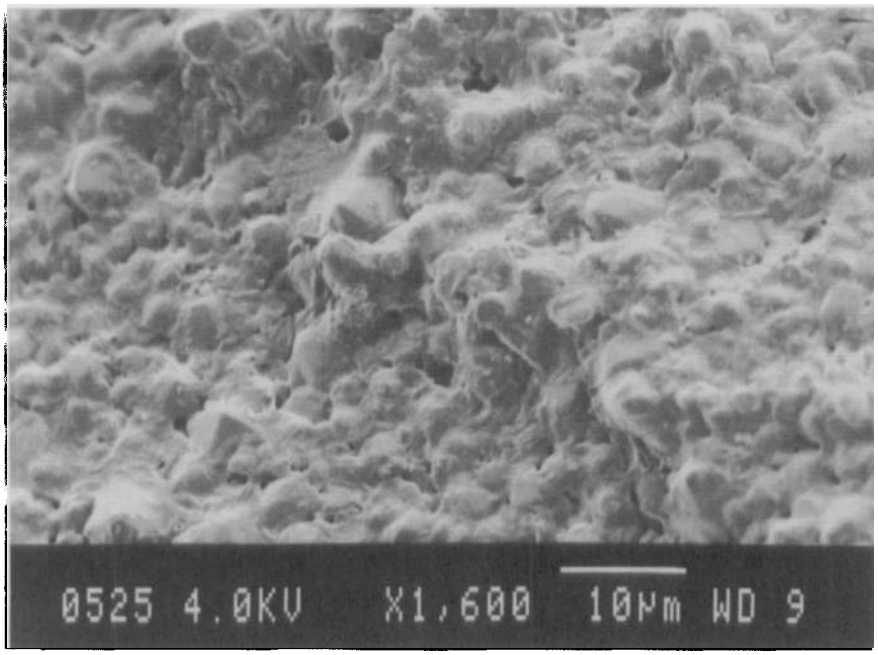

PHOTO 2

Surface topography of the tablet after two passes through the open steaming column. Individual crystals have melded, but the surface remains rough. (magnification: X1600)

Because the coated tablets could not be easily mounted in the diffractometer, these studies were performed with sugar coated glass microscope slides.

RESULTS AND DISCUSSION

Scanning electron microscopy revealed that the surface of an untreated, frosted tablet was rough due to the presence of numerous well-defined crystals (Photo 1). A single passage through the fully-open steaming column had little effect on the surface other than to reduce the sharpness of the crystals' edge definition slightly. Subsequent passes through the fully open column caused

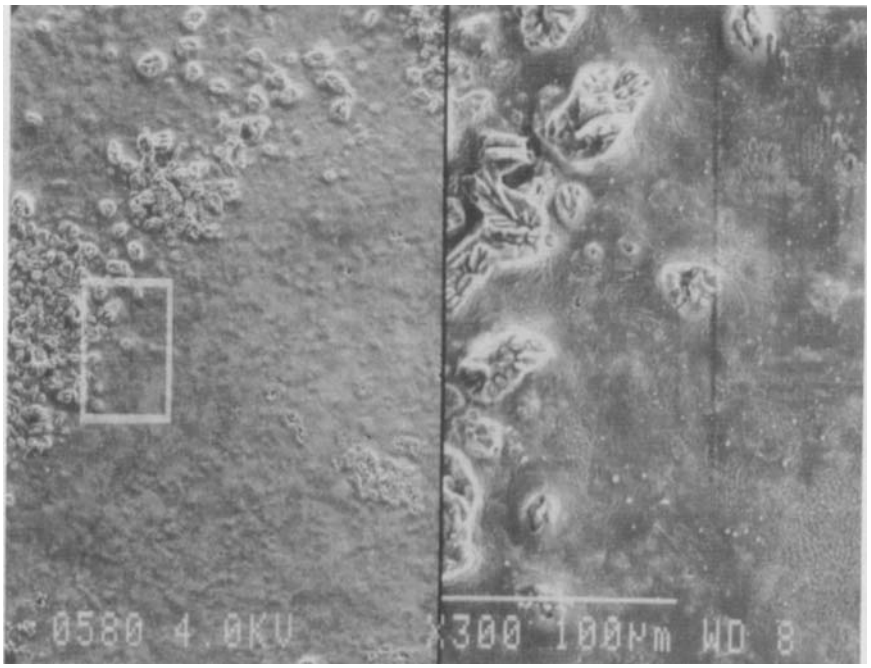

PHOTO 3

Surface topography of the tablet after a single pass through the quarter-open steaming column. An high percentage of the tablet's surface is covered by a smooth sugar layer. (magnification: left X300, right X1500)

the individual sugar crystals to meld, but the overall surface texture remained rough (Photo 2). The surface had a similar rough appearance after a single pass through the half-open column. After two passes through the half-open column, however, areas with no apparent crystallinity were present on the surface. These areas were even more pronounced on the surface of tablets subjected to a single pass through the quarter-open column (Photo 3). The last treatment was the only one which yielded shiny tablets; all others produced tablets exhibiting various degrees of surface frosting. In most cases, however, the degree of frosting in the treated tablets was reduced to a level which could be removed or masked by

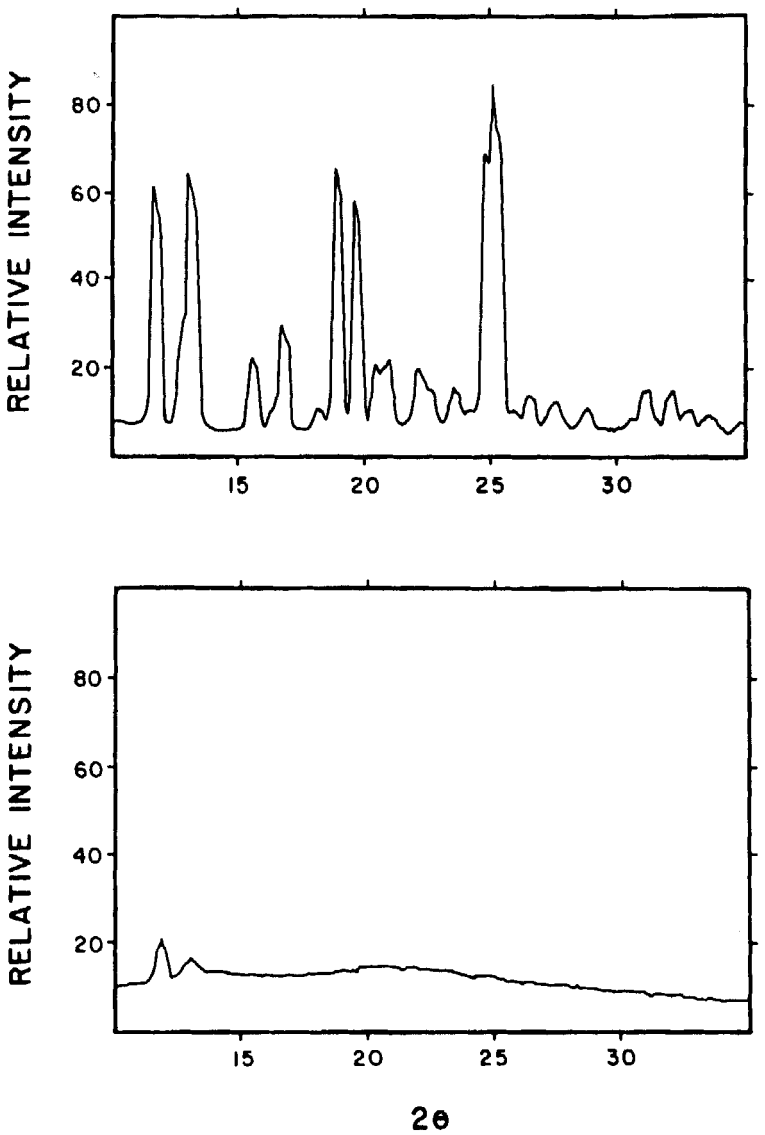

FIGURE 2

X-ray diffraction patterns obtained from an untreated (frosted) sugar coat (top) and the same coat after steaming (bottom).

polishing. It should be noted that the steaming process had the added benefit of increasing the color uniformity of the sugar coat, although the magnitude of this effect was not quantified.

The effect of steaming on surface crystallinity was further examined by X-ray diffraction. The diffraction pattern obtained from an untreated surface exhibited numerous peaks (Figure 2, top), indicating a high degree of crystallinity in the sugar coat. These peaks were absent in the diffraction pattern obtained from the same surface following steaming (Figure 2, bottom), indicating a lack of crystallinity in the sugar coat, i.e. it was amorphous.

CONCLUSIONS

The apparatus and procedure described here provide a simple and rapid method to decrease the degree of surface frosting in sugar coated tablets. The effectiveness of the method is dependent on conditions (e.g. temperature) within the column and on the number of steam exposures a tablet is subjected to. The reduction in frosting is correlated with a loss of crystallinity in the sugar coat, and the results indicate that unpolished tablets having a glossy finish will have large amorphous regions in their sugar coats.

ACKNOWLEDGEMENT

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