Physical Factors Affecting the Subcoating of Compressed Tablets I

Instrumentation

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The objective of this study is to measure the effect of the many physical factors involved in subcoating; this paper deals with a description of an instrument designed for the study. The relative smoothness (or the relative absence of roughness) is being used as the index for evaluation of the subcoating. This has necessitated the development of an instrument which makes possible the quantification of roughness. The "tablet roughness recorder" is a specially designed distance transducer for recording an enlarged profile of a small part of the surfaces of a series of tablets. The area enclosed by these profiles or curves can be measured; thus, comparisons can be made between different batches of tablets. This establishes the relative significance of the physical factors. Their exact quantitative influence can then be individually studied.

In recent years there has been considerable interest in the development of new methods and equipment for tablet coating (1–7). However, the process of tablet coating in conventional pans has undergone very little change, particularly along the lines of better controlled and instrumented equipment and procedures. An important reason for this lack of improvement and change in the basic operations of pan coating might stem from the absence of fundamental studies aimed at elucidating the physical phenomena that affect the process. Several years ago Koren and Benton (8) showed that it was possible to standardize the method of coating. However, extensive standardization, modernization of equipment, and eventually automation could best be achieved if they were based on quantitative fundamental studies.

This study is designed to evaluate quantitatively the physical factors that affect the subcoating process. Subcoating has been selected as the first operation to be studied. Not only does it have more variables than the other steps in the coating process, but also it is the first major step in the entire coating operation—hence, it greatly affects the quality of the other steps.

EVALUATION OF THE SUBCOATING

The uniformity of deposition of the subcoating materials on the tablet appeared to be the most likely criterion for the evaluation of the efficiency of subcoating. The uniformity of the deposition would be related to the relative roughness of the subcoated tablet surface.

The evaluation of the relative roughness, however, is a more complex problem. It has necessitated the development of a special instrument and technique for recording and evaluating the roughness of the tablet surface.

The instrument (hereafter referred to as the roughness recorder) records a nine times magnified equitorval profile of a portion (4.2 ± 0.2 mm.) of the top central surface of a tablet. The area enclosed by the profile or the curve and a chosen base line is measured and serves as the index of roughness of the tablet surface. Comparison of the average indices of batches of tablets coated under varying physical conditions provides a quantitative method for the evaluation of the factors affecting the coating.

ROUGHNESS RECORDER

The roughness recorder consists of the following three main parts.

Signal Source (*S* **in Fig. 1**).—It yields a constant output of 3 v. at 1000 c.p.s.

Roughness Detector (*R* **in Fig. 1**).—The track (*T*) (shown in Figs. 1 and 2) is so arranged that a row of tablets up to $^7/_{16}$ of an in. can be placed to a cardboard or metal strip (14 by $1^1/_4$ in.). The strip can be moved with motor *M* at a constant speed of 3 mm. per minute.

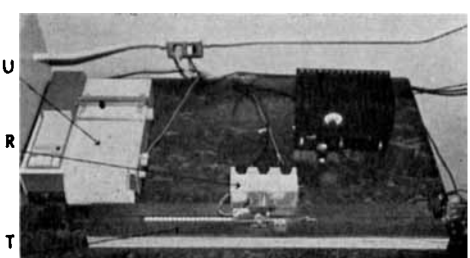

Fig. 1.—The roughness recorder.

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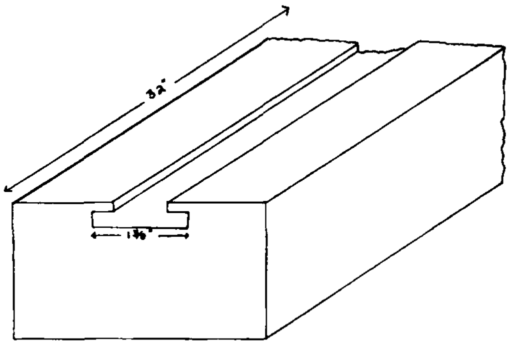

Fig. 2.—The track.

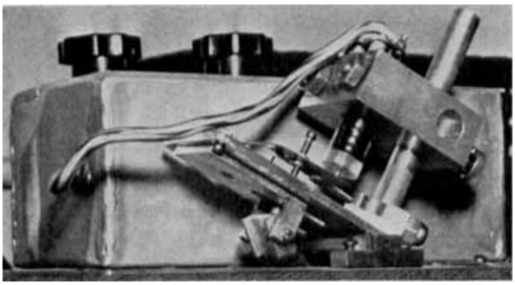

Fig. 3.—The detector.

The mechanical portion of the detector is shown in Figs. 3 and 4. It consists of the probe *A* which protrudes down over track *T* through the hinged guide *G*. The probe moves in a vertical plane as it encounters the roughness or convolutions on a tablet surface. The movements of this probe are mechanically magnified by lever *C* and transferred to a second probe *B;* this in turn moves between two coils arranged in a balancing bridge housed in assembly *D*.

Assembly *D* can be raised or lowered to the proper setting on post *E*. Lever *C* can also be raised and lowered to calibrate the span setting on recorder by turning cam *F*.

The electrical circuitry of the detector is shown in Fig. 5. The balancing bridge is driven by the input from the signal sources and feeds into a bridge detector which in turn feeds into a recorder. The movements of the second probe cause variations in the inductance of the coils, resulting in proportional change in the output voltage of the bridge. This is recorded as the tablet profile.

In operation, the bridge is balanced by first switching the input to the bridge corner at point *X* and adjusting *R*-1 and *R*-2 to a zero setting, the point at which a minimum tone is heard through the headset. The input is then switched to position *Y* and *R*-3 and *L*-1 are similarly adjusted. Finally, the input is switched back to position *X*. It may be necessary also to readjust the height of assembly *D* on post *E* from time to time to check its zero setting. This adjustment should, of course, be carried out prior to the adjustment of *R*-1, *R*-2, *R*-3, and *L*-1.

Thus, when the instrument is adjusted, there is no current flowing through the bridge. Now any movement of probe *B* will result in the increase of the inductance of one of the coils wound around the probe and a decrease in the inductance in the other, producing a voltage across the output terminals. The output voltage is fed to the rectifying bridge which has the effect of removing 1000 c.p.s. and leaving the modulation envelope to be fed to the recorder. The modulation envelope then is determined by the roughness of the surface under the probe *A*.

The Recorder (*U* **in Fig.** 1).—The recorder used in the instrument is the Beckman potentiometric strip-chart recorder. This recorder has an adjustable span which must be calibrated prior to the operation. This is done using cam *F*. Lever *C* in the detector is raised as high as possible with the cam and held in that position while the recorder pen is brought to a predetermined position in the top part of the span. The cam is then turned to allow the lever to return to its lowest position, at which point the zero setting of the instrument is fixed.

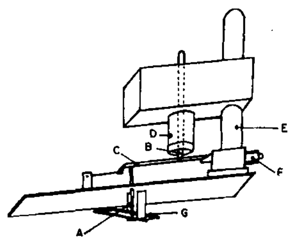

Fig. 4.—Mechanical portion of detector.

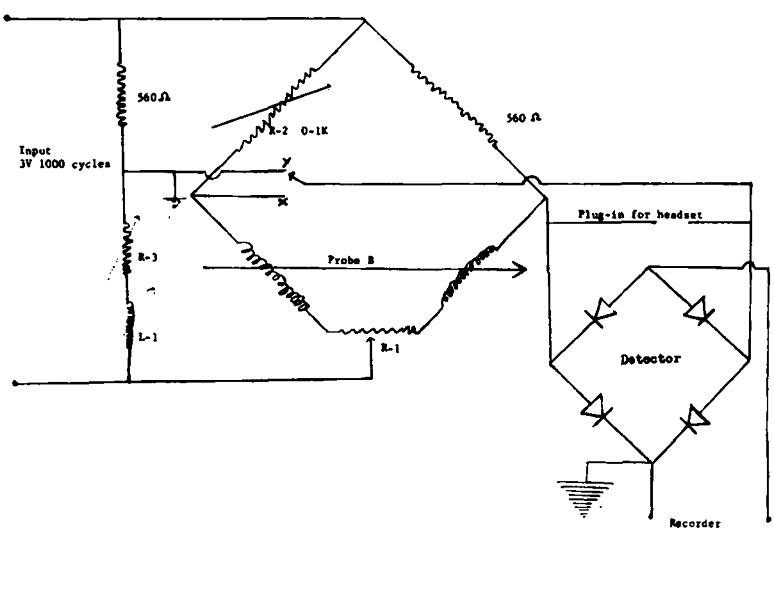

Fig. 5.—Electrical circuit of detector.

Operation

The following steps are involved in using the instrument:

A tablet strip is prepared by affixing 25 tablets from a batch on a 14 by $1^{1}/_{4}$-in. thin piece of cardboard. A drop of glue is put on each of the tablets; they are placed in a straight line along the center of the cardboard strip.

The tablet strip is placed on the track and connected to the motor which pulls it along the track.

The power supply to the signal source and the recorder are turned on and the instrument allowed to "warm up" for 10 minutes.

The zero and span settings of the recorder are set, and the detector is zero balanced.

The track motor and the recorder are started and the profile of the tablets recorded.

The operations are repeated with additional tablet strips until recordings of the desired number of tablets have been obtained. The roughness index of the batch can then be calculated.

Reproducibility of Recordings

Repeated runs made with the same tablet strip of subcoated $^{3}/_{8}$-in. deep concave tablets gave identical results. The detector portion of the instrument was so balanced that total weight on the tablet at the point where it was contacted by probe *A* was less than 4 Gm. This was insufficient to scratch or damage a tablet surface of normal hardness. Thus, not only are the records true representations of the surface roughness, but also repeat runs on the same tablet strip may be obtained if necessary.

Analysis showed that there was no significant difference between the data on roughness index obtained from several different 100-tablet samples of the same batch of tablets. However, the data on roughness index for batches of tablets coated under different conditions have been different, even when their surface roughness could not be differentiated by visual observation.

Interpretation of Data

Figure 6 shows a typical recording obtained from a subcoated tablet and the method used in reading the recorded curve. It will be noted that in the central part of the curve the recordings tend to be somewhat more linear than the normal convexity of the tablet surface because of the mechanical effect of the hinged guide (*G* in Fig. 4). A similar recording obtained from a polished metal disk having the same general shape and size as the subcoated tablets showed a smooth profile.

In order to read the curve it was first bisected by the line *AB*. Lines *CD* and *EF* were drawn parallel to *AB* and 1.5 cm. from it. Lines *CD* and *EF* were connected by line *GH*, which was so located that it touched the lowest point of the curve between *CD* and *EF* (point *X*). Line *GH* was drawn at a right angle to lines *CD* and *EF*. The area enclosed by the recorded curve and lines *CD*, *EF*, and *GH* (shaded area) was then measured with a planimeter. This procedure standardizes the area measurement by having it apply to the same portion of the recorded curve for each tablet. The average area for 100 tablets of a batch is designated as the "roughness index"

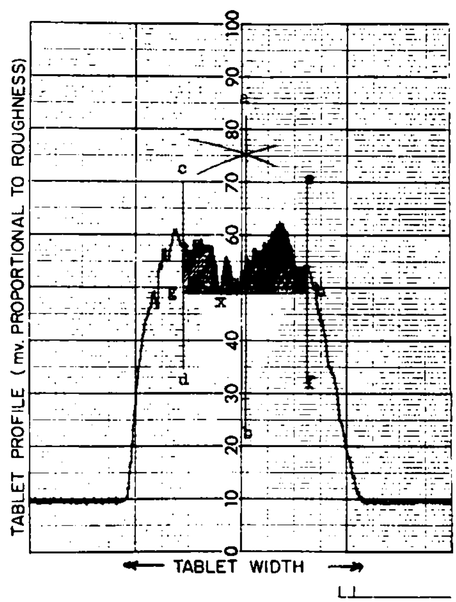

Fig. 6.—Method for reading the area.

for the batch. The index would be zero for a completely smooth surface and increase in value as the roughness increases. It can be used for comparing the degree of roughness of different batches.

The method used for reading the curve was chosen for two reasons: (*a*) the same middle portion of a curve may be read for each tablet, and (*b*) a small area of the recording may be measured because it is assumed that each tablet is uniformly coated up to the thickness represented by point *X*, and the roughness occurs above this point. This is obvious because point *X* represents the deepest depression on the subcoated tablet surface.

Another Application of the Roughness Recorder

The roughness recorder should prove useful as a control instrument for checking the roughness of coated tablets. The Beckman potentiometric recorder used in this instrument can be equipped with an external circuit controller. With this accessory, consisting of two (upper and lower limit) external circuit switches, the instrument becomes a monitor which automatically activates a warning or compensating system when the pen records surface roughness beyond predetermined limits. Each controller operates an independent microswitch that can be used to activate separate external circuits when the pen crosses a preselected point in its travel.

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