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THE USE OF A NOVEL ROLLER COMPACTOR WITH A CONCAVO-CONVEX ROLLER PAIR TO OBTAIN UNIFORM COMPACTING PRESSURE

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ABSTRACT

The factors affecting the distribution of compacting pressure during the process of dry granulation with a roller compactor, have been elucidated experimentally.

Lactose powder was used with incorporation of a small amount of riboflavine as a pressure indicator.

The rollers used in this study had been designed as a concavo-convex pair that exactly keep their mutual

fit while rotating. The flanges formed by the concavity of the concave roller at its both ends, called "rims" in this paper, were subjected to several experimental variations in the angles of wall slopes, namely, 45°, 65°, 75°, and 90°.

These inclined gripping walls acted as compensators, cancelling the resistance in the powder flow due to the side seals attached to both ends of the rollers.

The overall effect was that the pressure of compaction was adjusted uniformly over the whole width of the rollers, and the best result was obtained at a rim angle of 65°.

In this experiment, however, a rectangular-aperture chute, when equipped at the delivery end of the screw feeder, contributed little to the uniformity of pressure distribution in compaction.

From these observations, the authors have established a new type of roller compacting system that is superior, in the sense of uniformity of compression, to any conventional roller compactor.

INTRODUCTION

The dry granulation process consists essentially of compacting powder to form a solid strip or slug and reducing its size again to achieve proper granules.

The use of the compacting process for a product naturally calls for warning about the pressure sensitivity of the potency and shelf stability of the formulated drug ingredients. This in turn demands the right range of pressure which is adequate for forming the compacted strip to be used in granulation, but not in excess.

Present-day drug manufacturing techniques adopt this dry granulating process in the following cases:

1) Production of granules to be filled into capsules
2) Production of granules to be tableted

This second case, however, includes many technical problems which will have to be solved, and for this very reason, has not gained much popularity.

From the standpoint of processing technique, the merits of dry granulating may be summarized as follows:

1) Simplicity in processing, especially elimination of the drying process
2) Reduction of material loss during processing
3) Facilities for being built into a continuous production system, and
4) Readiness for the "Good Manufacturing Practice"

Secondly, from the viewpoint of quality,

1) Exclusion of water incorporation leads to the elimination of undesirable drug reaction in the wet state

2) Good disintegration behavior of tablets is obtained if processed by this method

On the other hand, however, the following technical difficulties persist.

1) Weight fluctuation of the tablets is significant when particles finer than 100 μm are included in significant amounts

2) Ample use of lubricants often impairs the binding property of powders to be made into tablets

Relating to the first point, a local lack of pressure on a powder under compaction, or an improper size reducing condition following it, tends to increase the unnecessary fine particles left uncompacted.

In consideration of these factors, it is desired to process powders through a roller compactor where naturally less lubrication is wanted. In addition, the compacting pressure should be distributed as uniformly as possible over the whole of the roller-gripped powder mass, and the proportion of leaked uncompacted powder should be kept as low as possible.

Ordinary roller compacting systems suffer from the disadvantage that as much as 20 to 30% of leaked uncompacted powder is usually unavoidable because of the unevenness in compaction.

We have developed, therefore, a device for reaching a very high uniformity of compacting pressure through experimentally elucidating the factors that influence the pressure distribution characteristics. The result has led us to success in establishing a new type of roller compacting system.

EXPERIMENTAL

Materials: Lactose, a frequently used drug additive, was used with incorporation of a small amount of riboflavine. This latter substance behaves as a color indicator for it develops deeper shadings when pressed, depending upon the pressure applied.

The formula of the powder was:

Lactose	99.5% wt.
Riboflavine	0.5 "

Other figures of reference were:

Specific bulk volume (loose)	2.40 cm^3/g
Specific bulk volume (dense)	1.18 "
Mean particle size	11.4 µm

Compacting Machine:

Manufactured by Freund Industrial Co., Ltd.*

Type 4013 Roller Compactor

Roller sizing: as in Figure 2

Roller compactor with rectangular chute: See Figure 3

Operating conditions: See Table 1

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* TELEX 232-2819 FRUEND TOK., 14-2 Takadanobaba 2-chome, Shinjuku-ku, Tokyo, Japan.

Experimental Procedure:

The roller compactor with a screw type feeder, as shown in Figure 1, was utilized. Variables examined in these experiments as affecting the pressure distribution, were:

1. Attachment of side seals at both ends of the rollers
2. Concavo-convex modification in roller end design
3. Delivery of the powder through a rectangular-aperture hopper

Estimation of Compacting Pressure Distribution:

As the result of the authors' repeated experiments, it had been found that the compressive force applied to the powder mass during compaction can be estimated by measuring the load needed for drilling the resultant compact, if the condition of drilling is strictly controlled.

Standard compressed tablets in this experiment were prepared by compacting a 150 mg sample of powder with a flat die and punch having the cross-sectional area of 1 cm^2.

The drilling loads of these tablets were measured at several pressure levels using Hardness Distribution Tester[*,1)], a drilling load measuring apparatus shown in Figure 4.

* Manufactured by Yamato Scientific Co. Ltd., 2-chome, Nihonbashi Honcho, Chuo-ku, Tokyo, Japan.

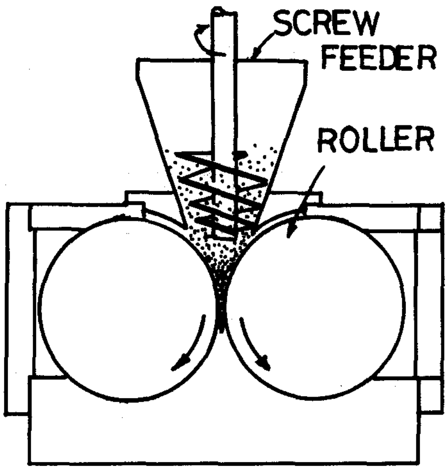


FIGURE 1

Roller Compactor

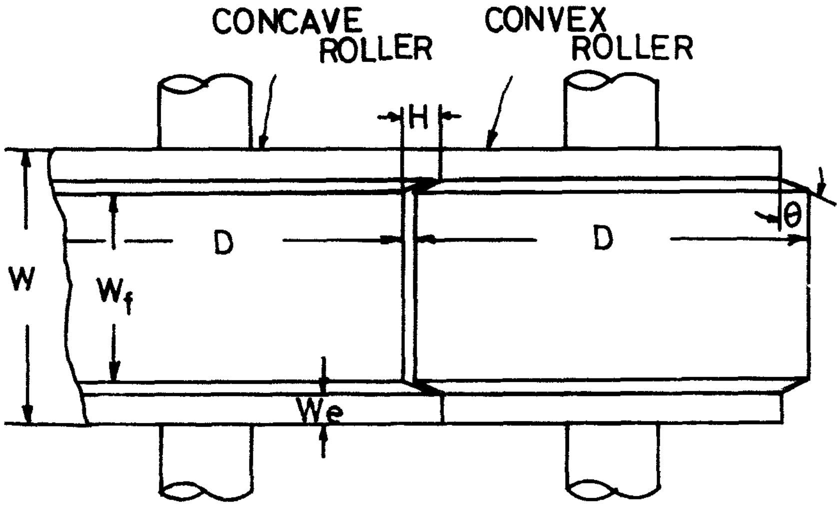
TABLE 1

Operating Conditions

ROLLER REVOLUTION	:	4 RPM
SCREW REVOLUTION	:	12 RPM
COMPRESSIVE FORCE	:	14 TON

The load values L were plotted against the respective compacting pressure P to obtain the P-L relationship.

In this experiment, the values of L in several parts of the sample strip were measured and the respective P values were estimated by utilizing the above-mentioned P-L relationship. And this resulted



No	1	2	3	4	5
θ°	0	45	65	75	90
D mm	400	400	400	400	400
W 〃	130	130	130	130	130
W_f 〃	100	100	100	100	100
W_e 〃	15	8	11.7	13.1	15
H 〃	0	7	7	7	7

FIGURE 2

Size of Concavo-Convex Roller Pair

in the pressure distribution along the roller axes.

The above is the authors' first way of estimation of the compressive force during roller compaction.

Independent of this, the degree of color development due to riboflavine was measured as a function of compacting pressure. This pressure-color relationship was utilized as the authors' second way of estimating the pressure distribution.

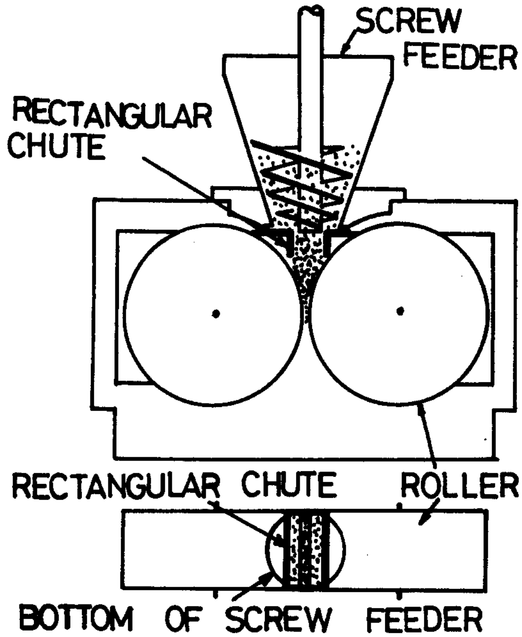


FIGURE 3

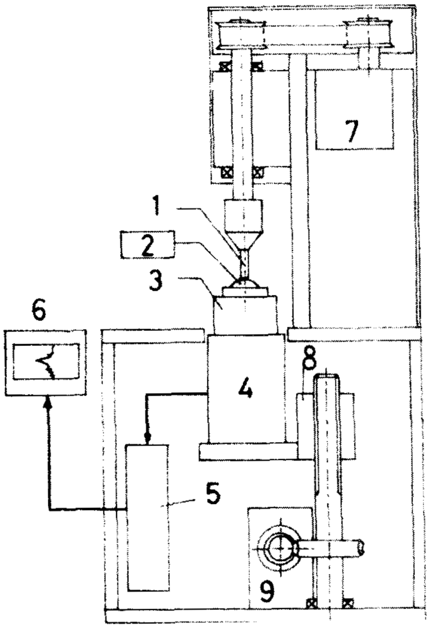
Roller Compacter with a Rectangular Chute

The distribution curves obtained by these two methods showed agreement within experimental errors.

In addition to this, the relative amount of leaked uncompacted powder was measured as a reference.

RESULTS

(a) In Figure 5, the observed compacting pressure distribution in a 1.5 mm thick sample strip in the direction parallel to the roller axes, is shown. The rollers used here belong to Type No. 1 in Figure 2, the most popular one nowadays.



1. Drill 2. Tablet 3. Sample Holder
4. Load Cell 5. Strain Meter 6. Recorder
7. Motor 8. Fixed Speed Elevator 9. Motor

FIGURE 4

Drilling Load Measuring Apparatus

The proportion of leaked uncompacted powder in this case was 22% in weight.

(b) Variations in roller type, including Nos.2, 3, 4, and 5 in Figure 2, were tried to clarify the influence of roller shape, especially the effect of rims, on the pressure distribution characteristics.

The maximal pressure value P_{max} and the minimal

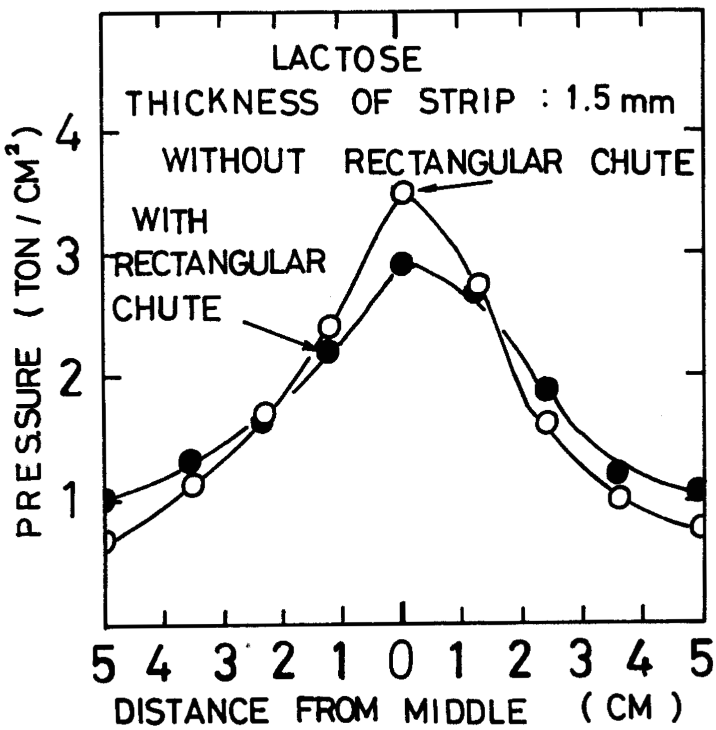


FIGURE 5

Pressure Distribution at the Ordinary Flat Roller Compactor

value P_{min} observed in the range W_f in Figure 2 gave the ratio

$$P_{max} / P_{min}$$

as an ununiformity index.

This index and the amount of leaked uncompacted powder, both being functions of a mediating parameter θ in Figure 2, the angle of inner wall slope of the rims, are illustrated in Figure 6.

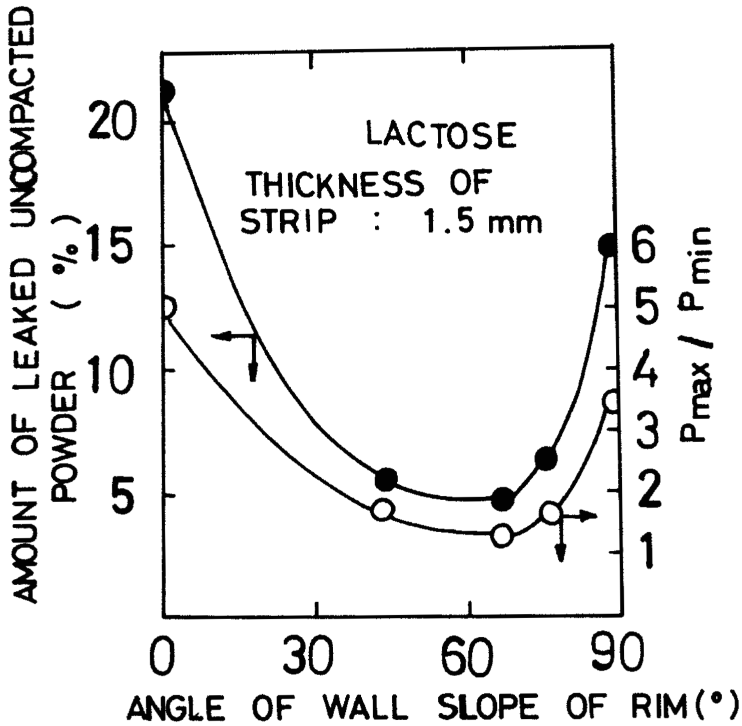


FIGURE 6

Pressure Distribution in Relation to Wall Slope of Rim

In Figure 7, the compacting pressure distribution under the roller No. 3 in comparison with the ordinary flat roller No. 1 in Figure 2, is represented.

(c) As the pressure of compacting is generally higher towards the middle of the roller width, a rectangular-aperture chute was fitted at the end of the screw as an adapter, thus aiming at avoiding this feeding unevenness.

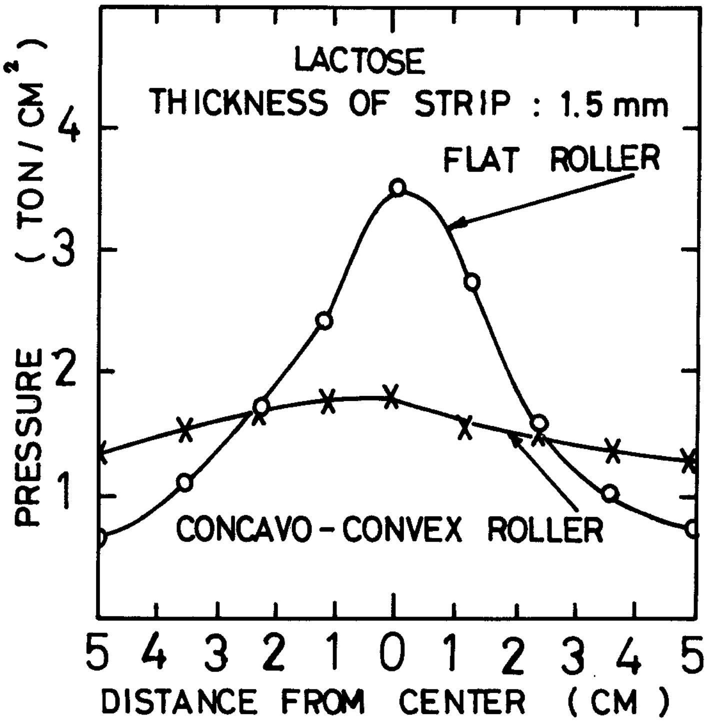


FIGURE 7

Pressure Distribution at the Concavo-Convex Roller Compactor

The proportion of leaked uncompacted powder in this case was 20%.

These results led to the conclusion that the greatest contribution to the uniformity of pressure distribution along the roller axes can be obtained by preparing the concavo-convex rimmed shape of rollers shown as No. 3 in Figure 2.

The information and principle thus aquired in this study have naturally led the authors to the

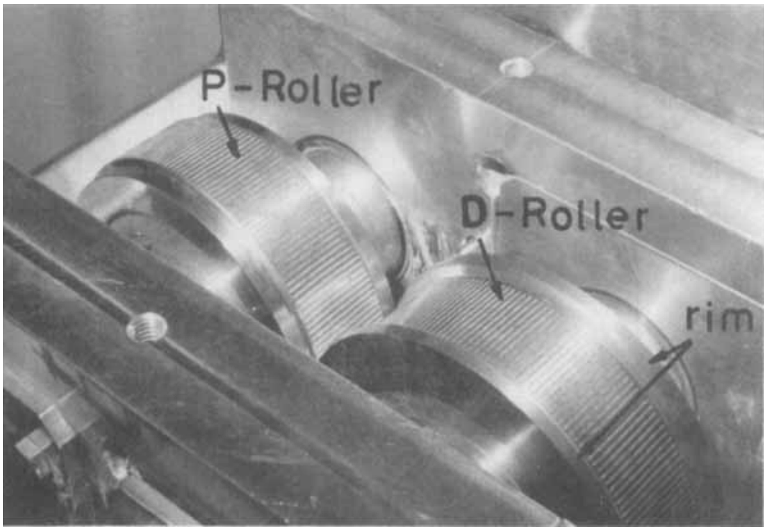


FIGURE 8

"DP-Roller" (See text)

invention of a novel type of roller compacting system, the rolling part of which is presented in Figure 8, where, for the reason that will be stated later, the concave roller is called by the authors "D-Roller", while the convex one "P-Roller"; hence the pair is called "DP-Rollers".

DISCUSSION

In this publication, as is generally received, "the gripping zone" is used to define the space where the powder mass is conveyed by the rollers into the region of their closest contact at approximately the same speed as the roller surfaces move.

Roller compaction in general should satisfy the following two conditions in order to accomplish its aim.

(1) An adequate supply of powder should be guaranteed at the entry into the gripping zone. This means that enough quantity of powder is needed to form a strip of compact after compression.

(2) The powder thus entering the gripping zone should be conveyed fully into the narrowest part of the roller gap.

The first condition (1) is usually planned to be satisfied, in the case of conventional roller compactors, by the forced supply of powder by means of a screw feeder. The fact is, however, that the end sides of the rollers lack the sufficient amount of powder, because the stationary side seals act as a resistance to the powder flow, thus decreasing the powder conveyance into the gripping zone.

As to the second condition (2), powder-roller friction, together with the action of the screw, actually drive the powder mass into the roller gap. But here again the presence of the side seals is a resistance to the flow of powder, and reduction of the amount of powder driven into the gripping zone is usual.

As a whole effect, therefore, the ununiformity of compacting pressure, due to the lack of powder mass gripped at the roller ends, is considered to be attributed mainly to the presence of side seals.

As already mentioned in the text, the authors experimented with a concavo-convex roller pair combination and application of a rectangular-aperture chute.

The rectangular aperture produces a uniform supply of powder along the rollers, while a concave or a rimmed roller holds the powder mass in its concavity, and carries it safely into the gripping zone between the rollers, protecting it from the adverse effect of the side seals.

In the authors' experiment, the effect of the rectangular-aperture chute was evidently overwhelmed by the modified powder-roller-frictional conveyance brought about by the newly designed concavo-convex roller combination.

A more elaborate explanation of the above-mentioned compacting mechanism follows.

In this type of roller design, the height of the rim defines the amount of powder to be gripped. On the other hand, the additional presence of the inner walls of the rims means an "extra" area of powder-roller contact, and an increase in powder-roller frictional drive in the neighborhood of the side seals.

This is of course a favorable counteraction to the above-mentioned side seal effect.

To elaborate the point, this increased frictional driving is, in turn, a function of the height and slope of the inner wall of the rims.

Therefore, a proper selection of rimmed roller design is expected to lead to the satisfaction of the conditions (1) and (2), resulting in an optimal cancellation of the influence of the side seals.

In practical operations, the narrowest roller gap is frequently adjusted to 1.5 to 3 mm. Additionally, it is observed in many cases that the apparent specific density of the powder at the gripping zone entry is approximately one half that of the powder just leaving the gripping zone. This means that the gripping zone entry is about 3 to 6 mm wide - also twice the narrowest gap (see Figure 9).

Flowability of the powder is an important variable in satisfying the conditions (1) and (2), and, as may be expected, the best design is dependent on the physical properties of the powder in question. The data in this article are based on experiments with lactose, one of the most frequently utilized additives to tablets. The values $\Theta = 65°$ and $H = 7$ mm hold also for other materials, for instance, starch, ethoxybenzamide, cephalexin, amino acids, and β-oxybutyl-p-

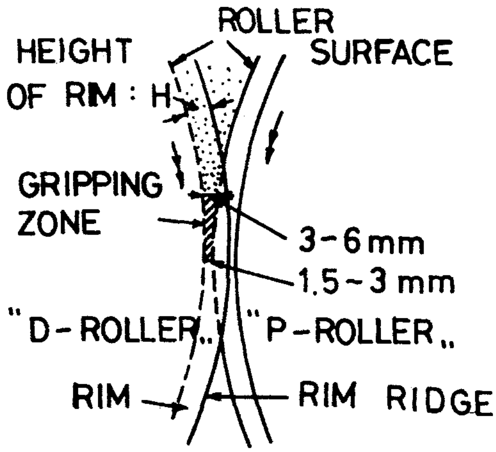


FIGURE 9

Height of Rim in Relation to Gripping Zone

phenetidin, if proper adjustment is done of operating conditions such as the roller gap, screw rotation, or rolling speed, resulting in the desired uniformity in compression.

Overcompression on the rim ridges is avoidable by some modification in side seal design.

Here the name "DP-Rollers" extends the conception of the "die and punch" in tableting, because the concavo-convex roller pair combination very much resembles a die and punch in action. The concave roller, just as a die, holds the given amount of powder; while the convex one, just as a punch, compresses the powder being held to a compact mass.

Thus, the experimentally optimal design of 65° and 7 mm for the inner wall slope of the rim and its ridge height, respectively, are explainable.

With the advent of this new system, difficulties inherent in dry granulation are expected to be reduced greatly, and the system will attain more and more popularity because of ease in dry production of strips or flakes.

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