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Automatic weight-control in a rotary tabletting machine

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A Manesty "Betapress" 16-station high speed rotary tabletting machine has been fitted with pressure rolls containing piezoelectric transducers in the axles. The compaction force exerted at each tablet compression event produces an electrical pulse which can be fed to an integrated-circuit pulse-discriminating unit. If, for any reason, the quantity of powder in any die is such that an over- or under-pressure occurs on compaction, the resultant incorrect-magnitude pulse is used to operate a stepping motor which adjusts the feed screw of the rotary machine in the correct direction to restore the desired operating conditions and maintain weight constancy. The degree of over- or under-pressure needed to cause corrective action is readily adjustable. An electromagnetically-operated solenoid valve is also controlled by the pulse-discriminator, so that tablets of incorrect weight are deflected by an air jet as they leave the die table. The ejection force can also be monitored and the signal used to operate an alarm if the force should become too large due to punch-sticking.

Any continuous industrial process will give improved production in quality and quantity if it is closely monitored, and particularly if the monitor output is used to adjust the operating conditions: in this situation, "closed-loop" automatic control is said to be in operation, and the process output will be much more uniform. These considerations apply to the production of tablets using rotary tabletting machines. If any change occurs in the particle size distribution or the bulk density of the powder or granulation fed to the hopper of such a machine, the tablet weight will alter, since the dies are taking constant-volume samples of the feed. Prompt action by the machine operator is then required to keep the output inside the tolerance limits on weight. At the present time, the pharmacopoeial limits on weight are not extremely tight, but the trend is towards a reduction in dosage variation, so that any inexpensive method of improving tablet weight uniformity might well become economically viable in the near future, even if not strictly necessary now.

Instrumenting rotary tablet presses to obtain a continuous record of the compaction pressure applied to the successive punches is not a new idea. Shotton, Deer & Ganderton (1963) used strain gauges bonded to the shank of a punch to monitor the applied pressure. To avoid the need for slip rings, a radio link was used to transmit the signal from the rotating part of the machine to the recording equipment. Knoechel, Sperry & others (1967) placed strain gauges at points on the stationary parts of two Stokes rotary machines and obtained oscillograph traces of punch forces and ejection forces. This system has the advantage that all the compression stations on the machine could be used: in the method of Shotton & his colleagues, at least some of the stations were occupied by the telemetry equipment, and in fact only one punch was operative. Knoechel & others observed a surprisingly large variation in compaction force, which they attributed principally to unequal filling of the dies with powder: such factors as

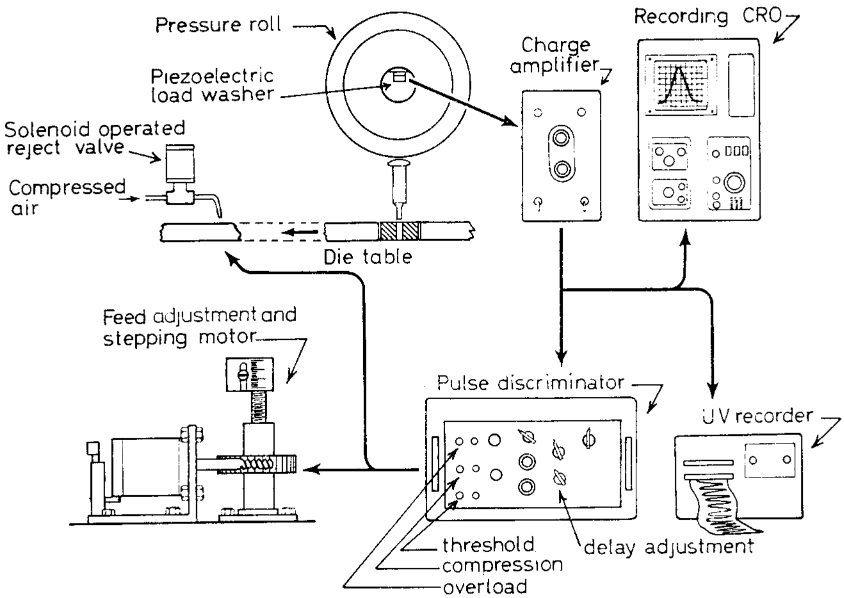

FIG. 1. Diagram of the control loop. The piezoelectric load washer sends pulses to the charge amplifier as a tablet is made. If the tablet weight is incorrect, the pulse discriminator directs correcting pulses to the stepping motor so that the depth of fill is adjusted. A delayed pulse is also sent to the solenoid valve when the die table has moved the correct distance, so that the faulty tablet is deflected and falls into a reject box. The compaction force for each tablet made can be displayed either on the fast u.v. recorder or the recording cathode ray oscilloscope.

inequality of punch length and eccentricity of the pressure rolls were not important. They did not report the use of the derived signals in the automatic control of the machine in operation, but Knoechel, Ross & Sperry (1966) in a patent specification, give an account of how such control might be achieved.

In the automatic control system described here (see Fig. 1), a piezoelectric load washer, mounted inside the axle on which the pressure roll turns, gives a pulse output which is proportional to the compression force operative at the compression of each tablet. The pulses are amplified and fed to a discriminator unit. This has an adjustable upper and lower limit which brackets the required compaction force and therefore the required tablet weight for a given material. Compaction force and tablet weight are almost linearly related to one another. If the pulse height is within the set limits, no action is taken. If a pulse is over the upper limit, indicating a high weight, an impulse is sent to a stepping motor which is connected by gearing to the depth of fill adjustment screw. The impulse is in the direction required to raise the screw and reduce the amount of powder in the dies. Similarly, the screw is lowered for an impulse which is below the lower limit. Thus the tablet weight is held constant to within the preset limits, or within the weight variation characteristic of a particular granulation, whichever is the greater.

In addition, when a tablet is made at a compaction force outside the preset limits, a small solenoid valve is impulsed a short time afterwards, the time delay being an adjustable multiple of the interval between compactions. The valve allows a short blast of compressed air to be directed at the tablet which is outside specification just as it is leaving the machine, approximately 90° away from the nip of the pressure rolls. The air jet deflects the faulty tablet onto a reject chute.

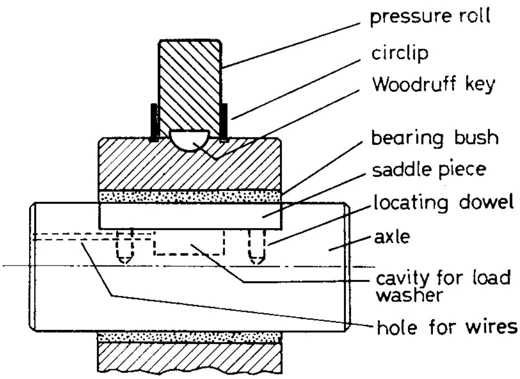

FIG. 2. The construction of the pressure roll fitted with a load washer. The tabletting force applied to the roll passes through the bearing bush and the saddle piece to register on the load washer.

Provision is also made to monitor the tablet ejection force, and to take appropriate action if it should rise above acceptable limits for any station.

Apparatus

The machine used was a Manesty "Betapress", having 16 stations. Detailed trials were made using 12 mm diameter flat-faced punches. The tooling was new, and the punch lengths were constant to better than 0·025 mm. Later, punches of different diameters and varying degrees of concavity were installed and tested.

Pressure roll. The disadvantage of obtaining signals from points on the body of the machine is that they tend to be small and subject to error; obtaining larger signals from the punches means complexity in transmitting them. A compromise between these two extremes in which the instrumentation is placed on the pressure roll was described by Deer, Ridgway & others (1968). This type of construction was adopted in the present system, though with some modification to make the resultant pressure wheel assembly look more like the standard pressure roll normally fitted to the machine.

The construction is shown in Fig. 2. The pressure transducer, a piezoelectric crystal load washer (Kistler type 903A) is held in a cavity machined in the pressure roll axle, the electrical signal being conducted out by wires running through holes drilled along the axle. The load washer is positioned by accurately-ground packing pieces, so that its upper face stands slightly proud of the plane upper surface of a cut-away section of the axle. The cut-away section is replaced by a saddle-piece, free to move up and down onto the face of the load washer, but prevented from moving laterally by two dowel pins. The outer surface of the saddle-piece is ground to the same profile as that which the axle originally had, so that the entire assembly can be surrounded by a bronze bearing bush, on the outside of which runs the pressure roll. Because the total dimensional change in the load washer is less than 0·5 μm on going from the unloaded state to the maximum working load of 6000 kg, the assembly functions quite well within the range of deflection of the bearing bush. The overall diameter of the axle is 5·08 cm instead of the normal 2·54 cm and the pressure roll carrier is bored out to accept this larger diameter.

Pulse discriminator. As each tablet is compacted, the load washer produces an electric pulse by the piezoelectric effect, the voltage being quite high, but the available current being so small that a special amplifier (Kistler type 568 Universal charge

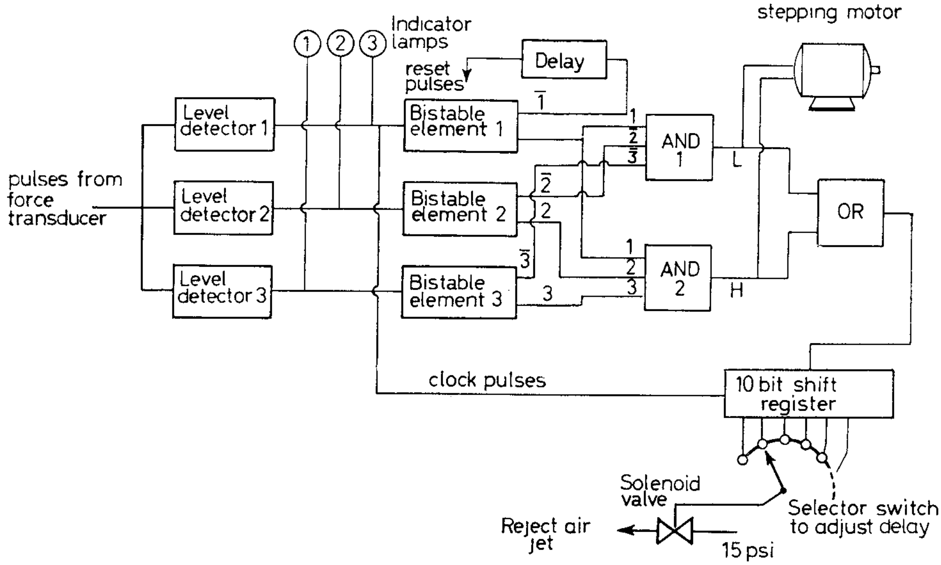

FIG. 3. The pulse discriminator. Pulse heights are screened by the level indicators, stored and processed by the bistable elements, AND gates and OR gate so that the stepping motor controlling the depth of fill of the dies is driven in the correct direction. After time delay in the shift register, pulses are sent to the solenoid-operated air jet as required to reject the out-of-specification tablets.

amplifier) having an input impedance of 10^{14} ohms is required. The amplifier produces a much stronger pulse which can be handled subsequently by more conventional circuitry. This pulse-handling is carried out by means of the circuit shown in simplified form in Fig. 3 which is built almost entirely of commercially-available integrated-circuit logic elements.

Pulses from the charge amplifier are amplified further by a boost amplifier and are fed to the left-hand side of the circuit (Fig. 3) reaching level detectors 1, 2 and 3 in parallel. These level detectors respond to the voltage attained at the peak of each pulse by emitting a pulse from their outlet terminals if the input voltage exceeds a preset adjustable level. The pre-setting adjustment is made by variable resistors (not shown). Level detector 1 is set at a low level, so that it responds to every compaction event. Level detector 2 is set to the desired low force or weight limit, and level detector 3 at the overweight limit. The level detector output pulses are arranged to light indicator lamps, so that the general situation on weight control can be immediately seen on looking at the control panel of the pulse discriminator. The output pulses also pass to the array of three bistable elements. These accept a pulse or no pulse, remember which they received, and display a voltage on one or other of their output terminals according to what was on the input. The six outputs of these are connected as shown to the six inputs of the two AND gates. These emit a pulse only if they receive one on all their inputs simultaneously. Thus if an input pulse triggers all three level detectors, AND gate 2 will receive pulses 1, 2 and 3 and emit a pulse at H. This pulse will reach the stepping motor and turn it one step so as to reduce the die fill, since an overweight tablet has been made. Similarly, if AND gate 1 receives pulses indicating level 1 has been reached, but not levels 2 and 3 (shown as $\bar{2}$ and $\bar{3}$), it will emit a pulse at L and rotate the stepping motor by one step in the other direction, since an underweight tablet has been made.

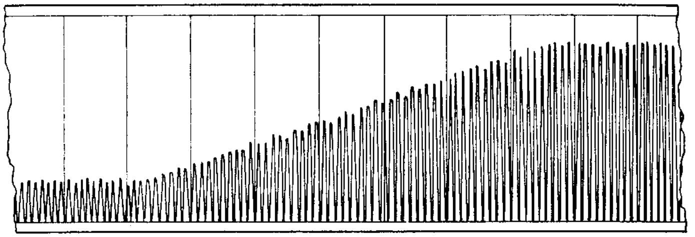

FIG. 4. A typical chart record showing the return of the compaction force to its preset level after a disturbance is introduced.

These pulses at H and L also go to the OR gate, which passes them as a pulse (or, for a correct weight tablet, as no pulse) to the shift register. This stores the pulse–no pulse sequence and makes it available as a series of voltages on its 10 output terminals. At the arrival of each new item of information, and under the timing control of the clock pulse, the series is moved along by one. The clock pulse is obtained from each compaction, irrespective of the compaction force. Thus the weight sequence of the last 10 tablets made is always available, and not until an eleventh tablet is made is the record of the first one lost from the system. The selector switch enables the solenoid valve to be activated according to what happened at a tabletting event a selected number of intervals earlier. An out-of-specification tablet needs to be rejected when it reaches the take-off chute. On the Betapress with 16 stations, this is 4 tablets later, but on other machines, the timing will vary. Thus as acceptable tablets reach the take-off chute, the voltage at the selector is such that they are left alone. As unacceptable tablets reach the take-off chute, a voltage is available at the selector to activate the solenoid valve, and a blast of air deflects them laterally into a reject chute.

The entire system operates at the speed of the clocking pulses, which is the machine speed. All time-delays, if set correctly for one machine speed, will be self-adjusting when the machine speed is altered; in other words, the control system locks onto the tablet production frequency.

The stepping motor has a helical bevel gear mounted on its shaft, which drives, at 5:1 reduction, a gear mounted on the machine adjustment screw which raises or lowers the cam governing the depth of fill of powder in the dies. One revolution of the motor corresponds to 200 steps, and the feed screw has 20 threads per inch, so that each step corresponds to a depth change of only $0{\cdot}5 \times 10^{-4}$ inch.

Results of tests, and discussion

The machine was first tested for its ability to return the tablet weight to within the preset limits after a gross disturbance. The disturbance was introduced by altering the feed screw position by an over-ride mechanism, and also by changing the particle size and bulk density of the granular feedstock. During the return to the set point, the tabletting force was continuously monitored. An example of a recording is shown in Fig. 4. The system returned to the set point at the rate of 20% weight correction in 80 s at 700 tablets/min, and was obviously capable of dealing with disturbances larger than those which might be expected to occur under normal working conditions.

On an uncontrolled rotary machine, as the machine speed is increased, the tablet weight falls. Such an interaction of speed and weight is completely eliminated on the controlled machine. Fig. 5 shows the mean weight of tablets produced on the controlled machine as a function of machine speed, and it can immediately be seen that the weight

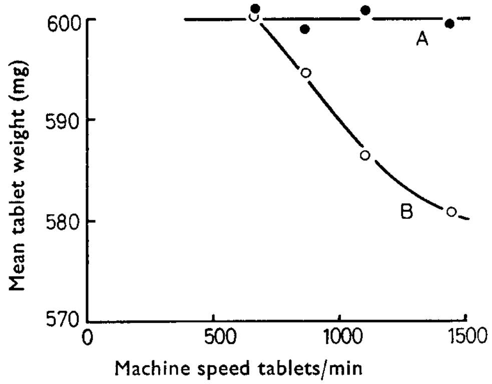

FIG. 5. Mean tablet weight as a function of machine speed. Curve A, control system operative; B, no control.

decrease of about 4% caused by increasing speed is prevented when the control system is in operation.

A frequency distribution of tablet weight for accepted and rejected tablets is shown in Fig. 6. These were made from a commercial placebo granulation (lactose 50%, sucrose 33%, maize starch 16%, magnesium stearate 1%, supplied by Thomas Kerfoot Ltd., Ashton under Lyne). Curve A is for the accepted tablets which have a mean weight of 517 mg, and a range of 500 to 527 mg. The distribution curve is not normal; it has a flattened top and steeper sides, since the tablet weights are approximately evenly distributed between 511 and 521 mg; the rejection mechanism only begins to make itself felt outside these limits. The distribution curve B for the rejected tablets is strongly bimodal, as would be expected. Curve B represents about 120 tablets, whereas curve A represents about 1200 tablets; since the curves are plotted with percentages as ordinates the difference of scale is not immediately apparent. A disappointing feature of these curves is that they show that some tablets within the acceptable weight limits are being rejected, and some tablets outside the limits are being accepted.

This appears at present to be unavoidable, since compaction pressure and weight, although strongly correlated, give a regression rather than a unique functional relation-

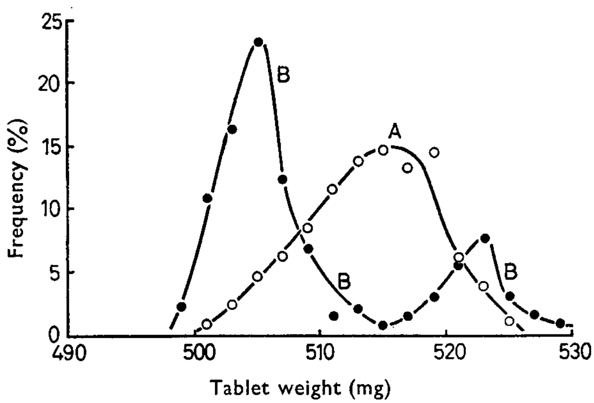

FIG. 6. Percentage frequency distribution curves of tablet weight. Curve A is for the 1200 accepted tablets, and curve B is for the 120 rejected tablets.

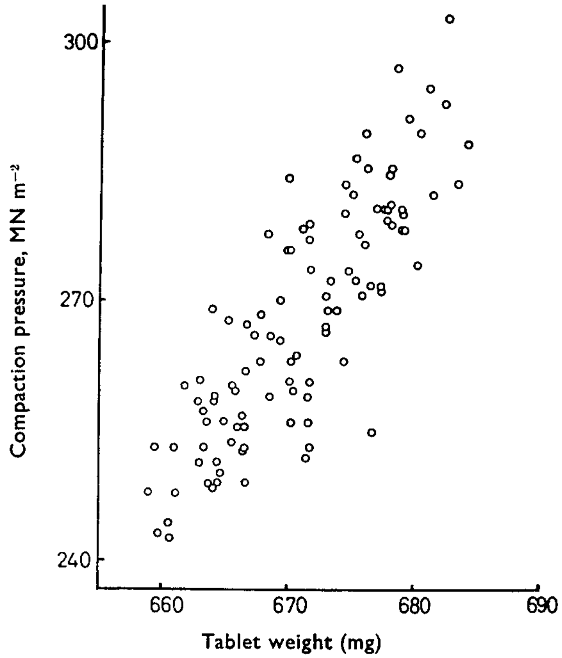

FIG. 7. The correlation of compaction pressure and tablet weight for a serially-collected sample of 128 tablets of a lactose granulation.

ship. This can be seen from Fig. 7, where compaction pressure is plotted against tablet weight for a series of about 120 tablets. These were collected serially from the machine in a long glass tube, so that each tablet could be weighed individually, and correlated with the compaction force at which it was made. Tablet weight is a function of compaction pressure, but only within the limits of variation introduced by such machine factors as inequality of punch lengths and eccentricity of the pressure roll surface, plus the variation due to the process of taking a small volumetric sample from a granular material. In general, it is this latter variance which limits the accuracy of control which is attainable.

However, the scale of Fig. 6 must be considered. The number of acceptable tablets which were rejected forms only about one-tenth of the total of 10% which were rejected. It is thus only about 1% of the 1200 accepted tablets, and would be a negligible loss in production. The peaks of the rejection curve come at the extremes of the acceptance curve, so that the control system is dealing well with any outlying rogue tablets. Admittedly the entire weight variation is well within the B.P. limits in this work, but the B.P. test is so structured that in order to have a negligible chance of a random sample of 20 tablets failing the test, the weight control must be held to $\pm 2\%$ (Evers, 1952) or better, and in general, it is the outlying tablets that cause concern. Thus if the B.P. limits should ever be narrowed, the control system would deal with the tails of the roughly Gaussian weight distribution quite effectively.

The part of curve B indicating underweight rejection is larger than that indicating overweight rejection. This is due to the control system tending to drive to one extreme of the acceptable range, or to remain at or near that extreme which it first reaches. Normally the machine will start to produce below the acceptable weight, so that the lower weight limit will be the first one reached, and thereafter the mean weight will be held closer to the lower weight limit. This is reflected in the skewness of the acceptable tablet curve too. It is, of course, an economic advantage to operate chiefly at the lower weight limit.

Detailed tablet weight correlations have at present only been made for flat tablets, but the control system has been shown to operate satisfactorily, and in particular the air-jet rejection system has been proved to work with flat-bevelled, shallow concave and deep concave punches. Tests are continuing. Considerable effort is being devoted to producing simpler and cheaper versions of the system. The method of obtaining an electrical signal proportional to the compaction force is capable of being greatly simplified, and a much less complex transducer arrangement is currently being built.

Acknowledgement

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