

The design and use of an instrumented mG2 capsule filling machine simulator

I. G. JOLLIFFE, J. M. NEWTON*† AND D. COOPER**

*Pharmaceutical Development Department, Reckitt and Colman Pharmaceutical Division, Dansom Lane, Hull HU8 7DS, * Department of Pharmacy, Chelsea College, University of London, Manresa Road, London SW3 6LX, ** Department of Mechanical Engineering, University of Nottingham, Nottingham NG7 2RD.*

The problems of instrumenting a continuous motion dosator nozzle capsule filling machine (mG2 type) are discussed and the construction of an mG2 simulator is described. A standard filling turret is employed with mechanical modification so that the dosator does not rotate. This allows instrumentation in the form of a strain gauged dosator piston, to measure compression and ejection stresses during filling, as well as distance transducers, to measure the corresponding piston and dosator movements. An experimental method is described for using this machine to study the filling of lactose powders.

Higuchi et al (1954) reported the use of an instrumented tablet press for studying the compression forces used in the formation of tablets. Since then, the use of instrumented tablet presses has become common in pharmaceutical research and in formulation development and, more recently, instrumentation has been used in the automatic weight control of production tablet presses. There are, however, few reports of the instrumentation of automatic hard gelatin capsule filling machines despite the increased popularity of this type of dosage form.

At present, probably the most common type of capsule filling machines are those operating on the dosator nozzle principle. In this, a nozzle is inserted into a powder feed bed, a powder dose is picked up by the nozzle and lifted up out of the feed bed and then the powder dose is finally ejected, by a movement of a piston inside the nozzle, into a capsule body. Compression may be applied to the powder in the nozzle while it is in the feed bed in order to aid powder retention during the transfer process. The measurement of the forces on the piston in the compression and ejection may yield valuable information both for improving formulation and for a better understanding of this type of capsule filling process.

There are two main types of machine operating on the dosator nozzle principle; these are the intermittent, e.g. Zanasi AZ20, and continuous, e.g. mG2 (G37) and Zanasi R5000.

Instrumented capsule filling machines reported previously have been of the intermittent, Zanasi, type. These machines have dosator nozzles in

multiples of two so that, while one set is filling with powder, the other set is ejecting a powder dose into a capsule body. The roles of the two sets of nozzles are then reversed by rotating the filling head through 180° to repeat the filling/ejection operation before rotating through 180° again. Instrumentation of a Zanasi LZ/64 machine was first reported by Cole & May (1972, 1975). In this machine, strain gauges were mounted vertically on the piston of a size OO dosator nozzle in a Wheatstone bridge circuit. The connecting wires led up through a hole bored through the centre of the piston until they were free of the dosator. A special mechanical device was described which prevents the wires becoming tangled during the intermittent rotation of the filling heads. In the experiments, which studied the effect of using lubricants in formulations on the compression and ejection forces, forces up to 400 N were recorded, although forces of 20-30 N were more usual.

A Zanasi LZ/64 has also been instrumented by Small & Augsburg (1977). As above, strain gauges were attached to the piston; however, in this system, the instrumentation wiring was led out through the quarter turn slots in the dosator and tangling was prevented by a simpler mercury swivel contact. Recently, the addition of a displacement transducer has enabled piston movement to be measured (Mehta & Augsburg 1980).

Mony et al (1977) have used a quartz load washer attached to the top of a piston of a Zanasi RZ 59 machine to measure the compression and ejection forces during capsule filling using various excipients with and without lubricants. The quartz load washer, which produces an electric charge by a piezo-electric effect, has the advantage over strain gauges of the

† Correspondence.

response not being subject to the barrelling effect (the small increase in diameter of the piston on compression which causes strain gauges to deform horizontally as well as vertically, as required). However, the size of the load washer means that it must be mounted at the top of the piston, furthest from the point of contact with the powder, which is likely to reduce sensitivity.

The instrumentation of a continuous motion capsule filling machine (e.g. mG2 G36) is much more difficult than for the machines described above, due to the number of moving parts involved. In this type of machine, a continuous chain passes under various turrets to open, fill and close the capsules. The dosator nozzles are arranged around the perimeter of a revolving filling turret which contains cams to raise and lower the dosator nozzle and piston at appropriate points to pick up or eject powder. A revolving circular feed tray has its centre offset from that of the filling turret in such a way that, when a nozzle dips into the feed tray, there is no relative motion between the nozzle and the tray. It also enables ejection to take place further on in the nozzles' rotation without the feed tray obscuring the capsule shell. This rotation of the dosator nozzles presents considerable difficulties to the instrumentation of a standard production machine and was the rationale for the design and construction of the mG2 simulator described here.

SIMULATOR DESIGN AND CONSTRUCTION

The mG2 simulator overcomes the problems of nozzle rotation by reversing the roles of its components, so that the central shaft and the top of the filling turret rotate, whilst the lower part of the turret, holding the dosator nozzles, is stationary. This enables the dosator nozzles to move up and down as usual but, since they do not rotate, it allows instrumentation to be attached and facilitates data capture. The system is further simplified by employing only one dosator nozzle.

The mG2 simulator described here was designed and constructed by the Mechanical Engineering Department at Nottingham University and is based on an mG2 G36 machine. A sketch of the simulator appears in Fig. 1. The single dosator nozzle moves vertically, dipping into a rotating powder bed to pick up powder (with compression if required) and then lifting out of the feed bed. The feed bed then moves away, exposing a linear magazine of capsule bodies which is positioned so that, when the nozzle moves down again, powder can be ejected into a capsule body. The cycle is then repeated. The operation of

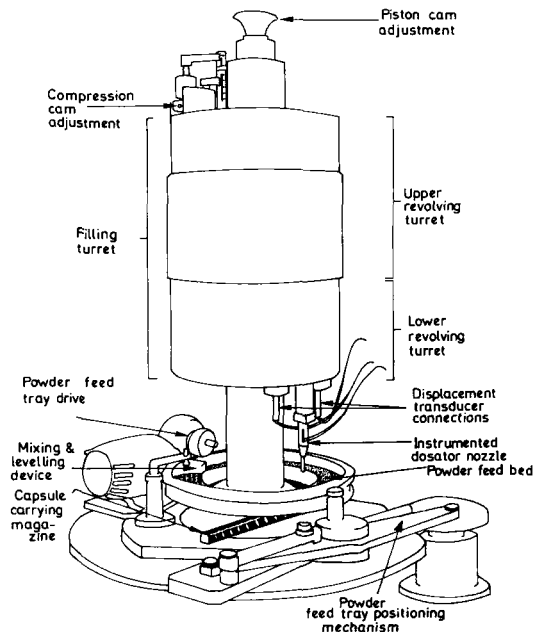


FIG. 1. Diagrammatic representation of capsule filling simulator.

the various components of the machine will now be discussed in detail.

Dosator turret operation

The mG2 simulator employs a complete filling turret from an mG2 G36 production machine. The operation of a production turret operating normally will be described, but the reversal of the roles of certain moving parts in the simulator, mentioned earlier, should be borne in mind. A production machine operates with the central shaft and top of the turret stationary whilst the lower part of the turret, holding the dosator nozzles, rotates. Four cams, fitted to the central shaft and top of the turret, control the movement of the nozzle and its piston. The main cam raises and lowers the complete dosator nozzle so that in one revolution it is lowered into the feed bed, raised to clear the feed tray wall, lowered over the waiting capsule body for ejection and, finally, lifted back over the feed tray wall to begin the cycle again. This piston cam has a similar shape to the main cam resulting in the movement of the piston relative to the nozzle being minimal during most of the cycle. The vertical dosator and piston movement through one revolution is described by Fig. 2. At two points in the cycle two other cams override the piston cam; a fixed ejection cam, which causes the piston to move downwards relative to the nozzle to push out the retained powder, and a compression cam, which

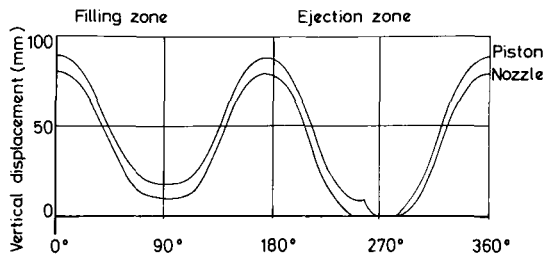


FIG. 2. Dosator nozzle and piston movement during one complete rotation of turret. The instrument is set with no compression applied to the piston in the filling zone; the piston is fixed approximately 10 mm above the nozzle outlet, except during ejection stage.

causes the piston to move downwards to compress the powder within the nozzle whilst the nozzle is dipping into the powder feed bed. (The zones where these two cams act is marked on Fig. 2.) The compression applied by the piston can be varied by adjustment of the height of the compression cam. Similarly, the height of the piston cam can be adjusted so that the height of the piston relative to the nozzle is altered. If this is less than the height of the powder bed, the powder bed will be compressed, as discussed later. (Fig. 2 shows the piston set 10 mm above the nozzle outlet.)

In the simulator, the central shaft and top of the turret are driven, causing the dosator nozzle (and piston), in the stationary lower part of the turret, to move up and down. The rotation speed of the turret is variable and can be adjusted by means of a variable speed gearbox. By using an instrumented piston (described later), compression and ejection forces can be measured.

Instrumentation

Stress measurement—instrumented dosator piston. Compression and ejection stresses were measured using a number 3 size dosator nozzle with strain gauges attached to the piston. The strain gauges are attached as close as possible to the piston tip to promote sensitive and accurate measurement of the stresses exerted on the powder by the piston (Fig. 3). The section of the piston on which the strain gauges are mounted is of reduced diameter which, in addition to providing clearance for the gauges, increases the deformation under load giving greater sensitivity. A slot in the dosator barrel provides access for the wiring to the strain gauges. The wires are supported by a pin screwed into the piston and emerging through the slot. This pin also prevents the piston from rotating.

The strain gauges are of the sensitive, semi-conductor type. Four gauges make up the arms of a Wheatstone Bridge circuit; two vertically mounted gauges measuring the stress and two horizontally mounted gauges compensating for temperature effects.

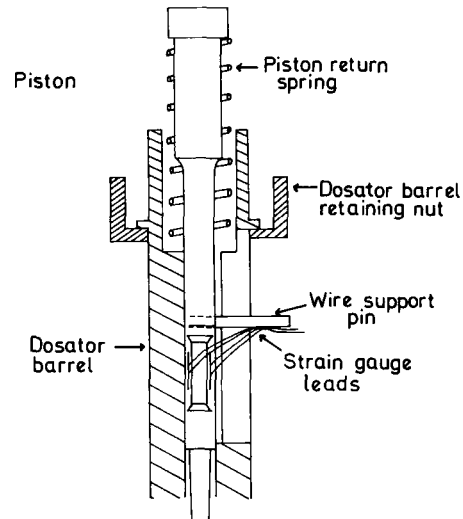


FIG. 3. Diagrammatic representation of instrumented dosator nozzle.

This instrumentation is connected to a bridge amplifier which provides a constant input voltage of 3.00 V and amplifies the bridge output over several ranges. The output from the bridge amplifier is fed into a u.v. recorder.

This system is capable of measuring stresses in the range of 20 to 8000 kNm⁻² using amplification of $\times 100$ to $\times 500$. The lower limit is set by electrical noise on the recorder trace at high amplifications and stresses greater than 8000 kNm⁻² were rarely met, except when powder compaction occurred. The instrumented piston was calibrated by a static loading method.

Measurement of movement—distance transducers. The movement of the piston relative to the nozzle and the whole dosator relative to the turret is recorded by two potentiometer-type distance transducers. These are attached to the connecting rods which transmit the motion of the cams to the dosator nozzle and piston. Input voltages are supplied to the transducers by constant voltage supplies and the output is fed into the u.v. recorder, mentioned earlier, so that simultaneous recording of stresses and movement occurs. The recording of the movement of the dosator nozzle is used mainly as an event marker, but

the movement of the piston was calibrated (using slip gauges) enabling accurate measurements of the piston movements to be made.

Powder feed tray operation

The rotation of the dosator nozzles on production machines occurs on a different radius, centre and speed to the rotating feed tray. Besides ensuring there is no relative movement between the nozzle and the feed tray at the point of nozzle entry (Fig. 4), this also ensures that several rotations of the feed tray occur before the point of entry of the nozzle coincides with a previous site of powder removal.

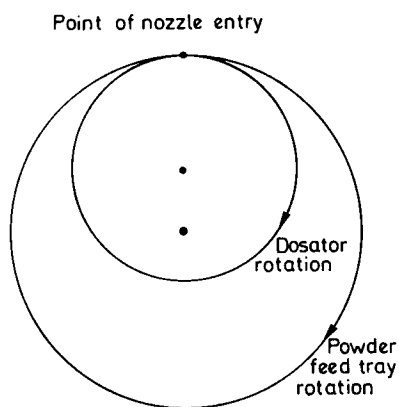


Fig. 4. mG2 feed tray and dosator rotation illustrating the matching movements at the point of nozzle entry.

To achieve this on the simulator, the whole feed tray is moved in a complex motion through a linkage to the main turret drive. This movement positions the feed tray under the nozzle for picking up the powder but moves it out of the way for ejection to occur. Feed tray rotation is driven by a separate motor, controlled by a thyristor controller which allows the matching of the feed tray position to that of the nozzle so that there is no relative movement between the two at the point of nozzle entry.

Powder is filled into the feed tray from a vibratory feeder at 100 to 150 g min⁻¹ and is mixed and levelled by a device shown in Fig. 5.

Powder collection

Powder ejection, on the simulator, occurs when the feed tray has moved away from under the nozzle to expose a removable magazine containing twenty capsule bodies. The magazine is a straight metal bar running on bearings and notched on one side to

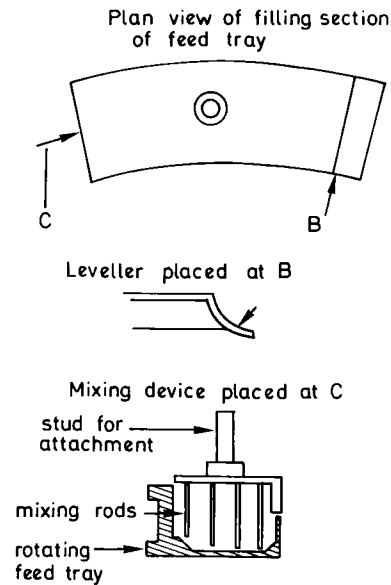


Fig. 5. Diagram of the simulator feed tray filling section plus mixing and levelling devices.

provide points for the drive lever to act. Twenty holes in the top hold the capsule bodies. A rod and cam linkage to the main turret drive moves the magazine along one position before each ejection, to present a fresh capsule to the ejecting nozzle.

If the magazine is not fitted, a tray connected to a vacuum cleaner is exposed for collecting the ejected powder.

Machine adjustments

Compression force can be applied to the powder in the nozzle in two ways:

(a) *Pre-compression*. An initial compression can be applied to the powder to increase its bulk density by adjusting the height of the piston in the nozzle to a height less than the depth of the powder bed.

(b) *Compression*. Compression may also be applied instead, or in addition, to (a) by an active downward movement of the piston whilst the nozzle is in the powder bed. Use of the term compression in the work described here applies to this latter type (b).

Application of pre-compression (a) is particularly useful in dealing with beds of high porosity, where compression (b) alone may result in the piston penetrating the surface of the powder bed causing powder to be trapped behind the piston. Pre-compression in this case could make the powder bed sufficiently firm to withstand further compression.

GENERAL METHOD

The size number 3 instrumented nozzle was used in all experiments to fill size number 2 capsule shells. Generally, a turret speed of 30 rev min⁻¹ was employed and the gap between the tip of the nozzle and the feed tray base was kept constant at 0.1 mm.

Adjustment of compression

To avoid disturbing the powder bed when trial runs were being made, all adjustments to machine settings had to be made before filling the feed tray. Only type (b) compression was studied here because pre-compression forces are often small and excessive pre-compression may cause powder to be pushed out from below the nozzle during insertion into the powder bed. In addition, application of both types of compression complicates the process as separation of the two effects would be difficult. Pre-compression effects are eliminated by raising the piston cam as far as possible causing the piston to remain high in the nozzle for most of the cycle, except when ejection and compression cams over-ride the piston cam.

The amount of compression applied is adjusted by raising or lowering the compression cam. This was adjusted approximately using the machine calibrations and precisely using measurements from the piston movement transducer. The value given by the machine compression scale was given the symbol Cm.

Feed bed preparation

The powder samples were prepared by passing through a sieve of a suitable size to break down any agglomerates. Sufficient powder to fill the feed tray and the levelling device was weighed out. This powder was poured into the vibratory feeder hopper and then fed into the feed tray, rotating at its operating speed, at 100–150 g min⁻¹. The powder feed rate was kept within this range in an attempt to produce similar packing of powder in the feed bed each time. (The effect of variation in powder feed bed bulk density has been studied by Woodhead 1980.)

When filling was complete, the feed tray was allowed to rotate for at least another five revolutions to ensure homogeneity.

Feed bed bulk density

The complicated shape of the feed tray and its attachment to the simulator prevents determination of its bulk density by simple weighing and volume measurements; therefore, a sampling technique was used. A brass cylinder supported by a tripod was

inserted vertically to the bottom of the powder bed. A tightly fitting plunger was pushed down the cylinder compressing the powder in such a manner that, on removal of the cylinder from the powder bed, a complete plug of powder was removed from the powder bed. From powder feed bed depth measurements (with vernier calipers) and the cross sectional area of the bore of the sampling cylinder, the original volume of the powder sample could be calculated. Hence, by weighing the powder plug removed the bulk density of the feed bed could be calculated. (Six samples were taken from each feed bed. This method was validated by sampling from powder beds of known bulk density.)

After sampling, the feed bed was again rotated for at least five revolutions to ensure the holes left after sampling were uniformly filled.

Nozzle preparation

Nozzles were cleaned in water and then carbon tetrachloride and dried before use.

The effects of powder coating the nozzle surface during filling have been discussed previously (Jolliffe & Newton 1980). To study the build up of powder on the nozzle wall during filling with the simulator, the nozzle was weighed initially and then after filling for several periods, until a constant weight of powder coat had formed. Filling experiments were conducted both with clean nozzles and those on which a constant weight of powder had been built up.

U.v. recorder adjustment

The positions of the distance transducer traces were adjusted to be on the recorder scale by running the machine before filling the feed tray. The response of the instrumented piston required final adjustment just before use since the output from the semiconductor strain gauges tended to drift. This adjustment was made using the bridge zero control. Selection of an amplifier gain suitable for producing traces to be on scale but large enough to be measured was by trial and error. A chart speed of 500 mm min⁻¹ was used as this gave a clear separation of the traces at a turret speed of 30 rpm.

Capsule filling

When the preparations described above had been completed, the magazine containing 20 capsule bodies was fitted in place and the feed tray drive, u.v. recorder and, finally, the main machine drive switched on.

As soon as the 20th capsule had been filled, the magazine was removed and the recorder and

machinery switched off. Each capsule was fitted with a cap and numbered for subsequent correlation with the recorder measurements.

The contents of each capsule were weighed to ± 0.1 mg. The stresses and displacements were calculated from the trace heights using the appropriate calibration factor. A typical section of u.v. recorder trace is shown in Fig. 6.

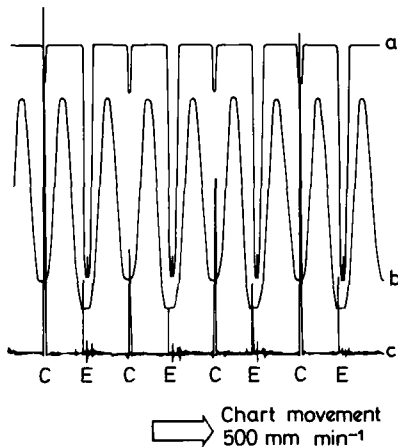


FIG. 6. An example of the u.v. recording obtained from the simulator instrumentation. (a) Vertical displacement of the piston relative to the nozzle. (b) Vertical displacement of dosator nozzle. (c) Stress exerted by piston. C = compression, E = ejection. Operating conditions: $C_m = 1.5$, $Pr = 0.22$. Preliminary running time 15 min.

TREATMENT OF RESULTS

In practice, stress measurement is affected by the acceleration of the piston up and down. Attempts to measure this by attaching an accelerometer failed to provide much useful information and so this transducer was removed. To allow for these acceleration effects, a recording of the responses with the machine running with an empty feed tray was made before each filling run and the mean trace heights obtained ('blank' readings) were subtracted from each subsequent measurement made with a full feed tray at the same compression setting.

Stresses were calculated by dividing the force in Newtons by the cross-sectional area of the nozzle in metres. The use of stresses facilitates comparison with other systems.

The trace of the piston movement on its compression stroke was measured and, using a calibration

factor, converted into actual movement in millimetres. From measurements of powder bed depth, gap below the nozzle and height of the piston in the nozzle when no compression is applied, it was possible to calculate the compression ratio, Pr (Takagi et al 1969).

$$Pr = \frac{(\text{original powder bed depth}) - (\text{powder bed depth after compression})}{\text{original powder bed depth}}$$

Powder coating occurred only on the area of the bore of the nozzle surrounding the powder when it had been compressed. The area coated varied, therefore, with the machine compression setting. To allow for this, the weight of powder coat per unit length of coated wall was calculated. (Cross-sectional area is constant, therefore length can be used in place of wall area.) The length of compressed powder in contact with the wall was calculated from piston movement measurements.

Mean capsule fill weights, mean compression and ejection stresses, and their variance, were calculated. These values are plotted as a function of compression ratio for each experiment.

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