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Rapid Communication

Development and validation of a capsule filling machine simulator

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Summary

Apart from some published work on instrumented (commercially available) capsule filling machines and compaction simulators for tablets, the use of simulators to study the capsule filling process has not been reported. This paper describes the development and validation of such a simulator.

The use of simulators to study the mechanics of tablet compression became increasingly popular in the 1980s, despite the high capital cost of such machines (Bateman, 1988). These simulators offer several important advantages over the use of instrumented production machines, in particular their requirement for only small quantities of test substances and their ability to mimic different compression profiles.

To date, very little work has been published on the development of capsule filling machine simulators although several workers have successfully instrumented existing machines (Augsburger, 1988). Some of the smaller capsule fillers, e.g. the Zanasi LZ64, can be used with relatively small amounts of powder (less than 1 kg) but, in common with all other machines, has the disadvantage that all moving parts are linked by cams and gears so that any alteration in speed proportionately affects all stages of the capsule filling cycle. Thus, the individual stages of precompression, compression and ejection cannot easily be studied independently of one another in any given cycle.

It was therefore proposed to develop an inexpensive, realistic capsule filling machine simulator which would overcome the shortcomings of the traditional instrumented machines and use it to study the behaviour of typical pharmaceutical excipients.

The simulator (Fig. 1) was pneumatically operated and was constructed from a 2.54 cm square steel box section framework firmly bolted to a small rigid bench (Truline Engineering Ltd, Newport, Gwent, U.K.).

The dosator mechanism was a standard Size 0 assembly from a Macofar MT13-2 capsule filling machine (Macofar S.R.L., Bologna, Italy) (any

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size could have been fitted from size 4 to size 0). To simplify construction the dosator mechanism was firmly secured to a cross-member and the powder bowl made to ascend and descend by means of a pneumatic cylinder. The vertical movements of the bowl and the dosator piston were tracked by means of two linear variable displacement transformer transducers (LVDTs) (Types DCT1000-A and DCT3000A, R.D.P. Electronics Ltd, Wolverhampton, U.K.) suitably mounted on a cross-member.

A new innovation on this simulator was that the outer surface of the dosing tube was fitted with semiconductor strain gauges (Type UEP-350-060, Kulite Sensors Ltd, Basingstoke, U.K.) in a full Wheatstone bridge arrangement to measure

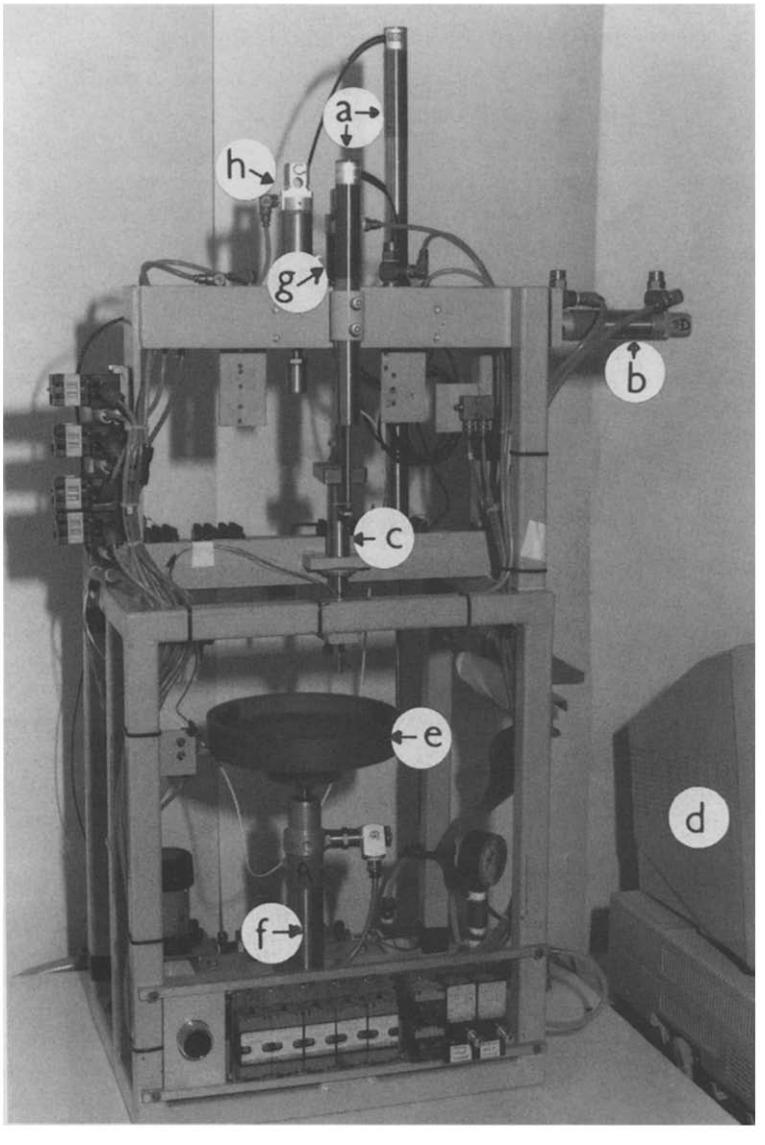

Fig. 1. Overall view of the simulator showing: (a) the two LVDTs; (b) cylinder D which operates the shuttle mechanism; (c) instrumented dosator; (d) Amstrad 1640 computer; (e) powder bowl plinth; (f) cylinder A which raises and lowers the powder bowl plinth; (g) cylinder B (partially hidden) – applies tamp; (h) cylinder C – ejects powder plug.

radial forces. Likewise, the dosator piston was similarly strain gauged to measure compression forces.

The strain gauges and the LVDTs were powered by two stable power supplies (0–15 and 0–30 V, respectively) (Models 611-420 and 610-461, R.S. Components Ltd, Northhampton, U.K.) and their outputs handled by Microlink hardware (Biodata Ltd, Manchester, U.K.) comprising a 16-channel programmable gain amplifier, a high-speed clock module and a 12-bit A-D convertor. This system was capable of receiving data at a rate of up to 25 000 samples per s.

The digital information was processed by an Amstrad PC1640 personal computer installed with a 20MB hard disk, an IEEE interface card (Biodata Ltd, Manchester, U.K.) and a high-speed data collection (HSDC) software package (Biodata Ltd, Manchester, U.K.).

The simulator itself was pneumatically powered by dry compressed air at 60 psi (from a cylinder) and, once the start button was pressed, operated entirely automatically on the cascade principle. All pneumatic components were supplied from one source (Festo Ltd, Teddington, U.K.). There were four pneumatic cylinders: cylinder A which raised and lowered the powder bowl support platen into position; cylinder B which was used to apply a short tamp to the top of the dosator piston and was capable of some length adjustment to facilitate this; cylinder D operated a shuttle mechanism which brought cylinder C, also with adjustable stroke length, directly over the piston at precisely the right time to eject the plug of powder formed in the dosing tube. The ejected plug was intercepted manually for further study. The sequence of events was triggered by strategically placed limit switches.

In addition, the speed of each cylinder could be varied by means of flow control valves and the durations of tamp time and bowl hold time were controlled by two pneumatically operated timers.

The powder to be investigated was first consolidated inside the stainless-steel bowl. The bowl was 6.0 cm deep and of 15.0 cm diameter, permitting a range of powder bed depths from 1.0 to 5.0 cm as found on most commercially available production machines. The powder was then covered by a circular perspex plate which fitted over a central stud and was secured by a locknut.

To allow the dosing tube to penetrate the powder bed as the bowl ascended, a 2 cm diameter hole was cut in the plate 3 cm from the periphery. The bowl was firmly attached to the support platen by means of knurled headed bolts which passed through the platen into nuts welded onto its base.

The distance between the bottom of the dosing tube and the base of the bowl could be varied by means of two adjustable stops which determined the upper resting position of the platen.

Finally, the dosator piston was specially machined, permitting the interchange of different shaped tips, another innovation for this simulator.

As with any new equipment, a thorough validation was undertaken as the first step in the use of the simulator.

Firstly, the distances traversed by the dosator piston and the powder bowl were verified. This necessitated the calibration of the two LVDTs. LVDT1 was capable of a 5 cm movement and LVDT2 of a 15 cm movement. At an input voltage of 20 V, their outputs, measured using a traceable digital multimeter (Model T100B, Beckman Industrial Ltd, Birmingham, U.K.), were found to be directly proportional to distance moved and both gave linear plots ($r > 0.99$). From a knowledge of their time of travel as determined by the computer software, it was later possible to calculate their velocities at any given time.

Preliminary experiments on the Macofar MT13-2 production machine had indicated that the dosator could travel at a maximum velocity of approx. 0.6 m s^{-1} and a minimum of 0.3 m s^{-1} (these velocities are of the same order as those of high-speed rotary tablet machine punches). However, since it would be unlikely for a production machine to run continuously at maximum speed, a more practical range would be 0.3–0.45 m s^{-1} and this velocity is achievable on the simulator.

Secondly, the strain gauges were calibrated by loading the dosator piston with standard 1 kg weights up to a maximum of 12 kg and measuring the millivolt output at each step with the digital multimeter. The calibration procedure was repeated by unloading the piston to ensure linearity.

Likewise, the strain gauges on the outer surface

of the dosing tube were calibrated. This was carried out by inserting a 1.5 cm length of 0.6 cm diameter cylindrical silicone rubber moulding into the open end of the tube and applying vertical loads 1 kg at a time (to a maximum of 12 kg) to the dosator piston whilst the latter was inside the dosing tube.

Each of the 16 channels available in the Microlink programmable gain amplifier (PGA) was capable of accepting any one of 12 different voltage ranges from ± 5 to ± 10 V. Since only four channels were used by the simulator, these were calibrated by applying known voltages from the stable bench power supplies, cross-checked using the digital multimeter at appropriate ranges.

The bulk density of the powder bed was an important variable and the optimum was decided by a series of preliminary experiments on the Macofar MT13-2 production machine.

For the three materials under investigation — Avicel PH102 (FMC International, Cork, Eire), Magnesium Carbonate Heavy (Pennine Darlington Magnesia Ltd, Darlington, U.K.), and Starch 1500 (Colorcon Ltd, Orpington, U.K.) — it was found that on running the machine for 30 min after loading the powder hopper (to a standard depth of 10 cm), the powder density in the lower powder bowl was approx. 80% of the ultimate tapped density (i.e. 2500 taps) (Compaction Density Unit (B.S. 1460), Jencons (Scientific) Ltd, Leighton Buzzard, U.K.), regardless of the material. This value was then chosen as the starting point for each material when loading the simulator bowl. The method of loading and consolidating the powders was standardised and carefully executed each time. Since size 0 tooling was being used on the simulator it was decided to adhere to a standard 1.2 cm plug length regardless of the material under test and to focus the emphasis of the study on the effect of variables such as dosating speed, powder bed density/depth, dosator-bowl clearance and dosator tip shape on plug quality and retention/ejection forces.

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