Tablet press developments aim at Improving the yield and reducing changeover times

DEVELOPMENTS IN TABLET FORMING MACHINERY ALL APPEAR TO BE AIMED AT IMPROVED QUALITY, YIELD AND CHANGEOVER TIMES. SOME ARE INGENIOUSLY SIMPLE.

Developments in tablet forming equipment over the past few years may seem to be progressing the equipment in several different ways, but the overall aim is quite clearly to improve quality, and particularly to reduce downtime to cope with smaller batch sizes.

Manesty has introduced its new family of Xpress machines offering improved yield and faster changeover while IMA's revolutionary design, the Comprima, is proving itself not just in pharmaceuticals, but also in confectionery and chemical/industrial products where the novel centrifugal product feed is being found particularly suitable.

Most recently Courtoy, part of Niro Pharma Systems, has launched its Modul press on which the exchangeable compression module can provide a particularly low operator exposure level and allows full changeover in less than 30 minutes.

At the same time Courtoy has also come up with an ingeniously simple system of controlling weight and hardness simultaneously and continuously on a standard tablet press, so generally improving product quality and consistency.

IMA's revolutionary design of tablet press, the Comprima, launched in the mid-1990s, is now finding applications not just in the pharmaceutical industry, but also in confectionery and chemical/industrial products, where its centrifugal product feed is proving to be particularly suitable.

For many years all tablet presses were based on the same basic principle, originally developed by the manufacturer Stokes. It involves the use of a die fitted with upper and lower punches. The die is filled with powder, any excess scraped away and the powder compressed either by lowering the top punch into the die or moving both punches together to compress the powder. Pressure is maintained for a period, then the top punch is lifted out of the die and the tablet ejected by raising the lower punch.

Latest from IMA: *The Comprima 300 for outputs up to 300,000 tablets an hour*

Different product formulations require different pressure dwell times and the only way of achieving this on conventional machines is to alter the speed of the machine.

Overcoming problems

IMA's Comprima tablet press, which was originally intended specifically for pharmaceutical tabletting, incorporates a number of new ideas to overcome problems associated with 'conventional' press designs.

One of the main features of the system is the introduction of the powder into the dies through centrifugal force, rather than gravity, via an enclosed feed system. This keeps powder losses to a minimum, reduces segregation due to the 'mass flow' principle of powder feed, reduces entrapped air in the powder within the dies and, in most cases, allows higher production speeds to be achieved for a given size of machine, particularly with powders that are difficult to handle.

Indeed, IMA has recently further explored this advantage with a major UK pharmaceutical company where trials have shown a 99.7 per cent process yield when handling a range of low density (0.2 - 0.3g/ml), spray dried powders.

In addition, the combined action of two compression rollers and two compression cams enables pre-compression and compaction forces to be maintained over one quarter of the turret rotation. This improves tablet quality and reduces problems such as capping and lamination. In many cases it can also eliminate the need for granulation of the raw material prior to compression.

The punches themselves consist of two parts: the stainless steel shafts forming an integral part of the machine and the punch and die sets, which are the actual size parts. This design means it is possible to carry out a complete size change very quickly. For example, on the largest double-sided model, the Comprima 600, it takes just 60 minutes to remove the punch and die sets and the same amount of time to fit the new tooling.

The use of two part punches and silicon shaft

seals also means there is complete separation between the mechanical drive and the product contact area, avoiding any possibility of contamination of the powder by lubricants and making it possible to provide an optional clean-in-place system.

Automatic CIP

For pharmaceutical use, IMA has developed an automatic CIP system for the Comprima that virtually eliminates operator input to the cleaning operation. An additional 'containment with washing' system is also available and is of particular interest to customers using potent materials such as hormone and cytotoxic products. However, for handling products such as sugar confectionery, where cross contamination is not a problem, Comprima machines can be provided without the cleaning systems and the parts cleaned manually in a short time.

The Comprima range now includes four single-sided models, the Comprima 150, Comprima 200, Comprima 250 and Comprima 300 covering outputs ranging from 150,000 to 300,000 tablets an hour while two double-sided presses, the Comprima 500 and 600 have recently been added to give output up to 500,000 and 600,000 tablets an hour respectively.

IMA says that a significant number of machines have been installed world-wide to date and that customers have reported a fast payback period, especially where high value products are being processed. This is said to be due to the higher yields possible with these machines, usually in excess of 99 per cent.

To complement the Comprima tablet press, in 2000 IMA bought German manufacturer Kilian whose machines operate on the traditional principle, with gravity feeding of the dies through an adjustable fill-shoe. The Synthesis series of presses represents the most recent Kilian development, and are said to provide excellent accessibility to the processing area, as well as easy cleaning and maintenance. In addition, the die tables are interchangeable, also contributing to short cleaning times and elimination of risk of cross contamination between different products.

Third member of family

Manesty launched the third member of its Xpress family of presses – the Xpress 300 – at the Total exhibition in March last year, following the introduction of the Xpress 500 and 700 models in 2002 and 2003 respectively.

This latest addition, says Manesty, means that the Xpress range now offers users increased production flexibility to run small, medium and large batch sizes on both single and double-sided presses.

With removable turrets the Xpress range also provides users with the opportunity to have multiple configurations so providing the advantage of scale with no need to purchase a new press, says the company. "Aside from ease of cleaning and operation, higher yields and a lower cost of ownership, the Xpress range allows for compliance with cGMP, GAMP and 21 CFR part 11."

The press is controlled by the mpower integrated technology developed by Manesty and also incorporates a Microsoft Windows operating system. This new press control technology is said to be particularly user friendly and demand the minimum amount of training and operator intervention.

Removable turret: *New Manesty Xpress 300*

Ancillaries for the Xpress range include a new on-line weight, thickness and hardness testing unit.

Courtoy's latest press is the Modul machine on which all product contact parts are mounted in an exchangeable compression module (ECM), to provide fast changeover and containment that results in an operator exposure level (OEL) as low as 1 microgram/m^3.

At the end of a batch the operator simply disconnects the ECM, swings it out of the way and replaces it with a clean unit. The used ECM can then be removed to a remote washing station while production continues on the machine. The whole operation takes less than 30 minutes, says Courtoy.

The standard Modul machine achieves a containment level of l0 microgram/m^3. However, two further versions of the ECM are now available – the High Containment ECM and the High Containment ECM with wash off line capability – which both achieve an OEL of 1 microgram/m^3.

"This unequalled level of containment allows very potent drugs, such as hormones or anti-cancer drugs, to be processed safely with less need for the operators to wear uncomfortable and restricting air suits," says Courtoy. "Using an isolated ECM in the machine also removes the need for dust covers, so visibility is much better and it is easier to access for maintenance. It also keeps the use of expensive clean-room space to a minimum."

Changeover in 30 minutes

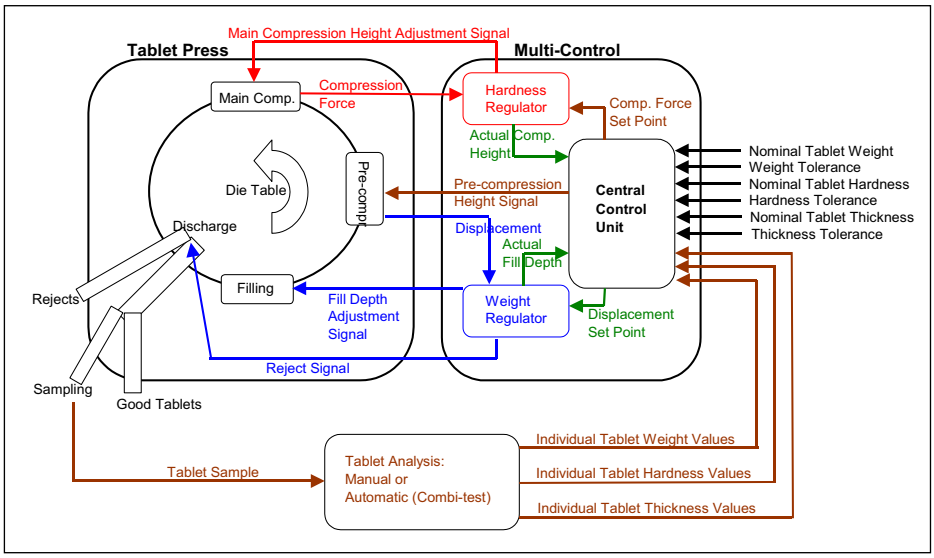
Courtoy points out that the changeover time of just 30 minutes – compared, it says, with up to 8 hours for conventional presses – allows users to process small batches of high value or highly toxic powders economically, possibly enabling some products to be provided in tablet form for the first time.

The company has also come up with an ingeniously simple system of controlling weight and hardness simultaneously and continuously on a standard tablet press, so improving product quality. The two control loops are physically separated to work on separate areas of the press, with weight controlled at pre-compression and hardness controlled at main compression.

The system, now optionally available on the Multi-Control 4 controls of the Modul press, is based on the existing tablet weight control principle for Courtoy presses which, unlike the control systems on most tablet presses, does not rely on measuring the compaction force at the main compression station for tablet weight control.

The reason for this, says Courtoy, is that the principle of "force measurement under fixed thickness" is limited in terms of precision, validation and transfer to other machines.

"Indeed, the relationship between tablet weight and compaction force under fixed thickness is non-linear and must be established



Weight and hardness control: *The two primary and secondary control loops for Courtoy's new system*

empirically, while it also depends on machine stiffness and machine temperature," the company points out.

So, in the early 1970s, Courtoy decided to adopt a different principle for tablet weight control on rotary presses, based on measurement of "thickness variations under fixed compression force" instead of "force variations under fixed thickness", and measurement at the pre-compression station instead of at the main compression station.

The most important characteristic of this principle, explains the company, is the linear relationship between what is measured – thickness variation – and what is to be controlled – tablet weight.

"Indeed, the height of the powder slug at pre-compression is linear with its weight when all these slugs are pre-compressed with exactly the same compaction force. It is clear that thickness tolerance limits as a function of weight tolerance can now be established in a straightforward manner. This results in higher precision of the control loop, as there are no rounding errors, and easier parameter establishment and validation, as tolerance limits are calculated automatically by the control system."

Furthermore, the relationship between tablet thickness at pre-compression and tablet weight is said to be virtually independent of machine stiffness, making transfer between machines much easier, while the influence of machine temperature is also negligible, eliminating tablet weight variations as a result of the machine warming up at the beginning of a production run.

Another important advantage claimed is that the primary control loop is re-calibrated by changing the pre-compression height – instead of main compression height in the case of force control – so leaving the thickness or hardness of the final tablet unaffected.

Since the Courtoy weight control loop requires the measurement of thickness variations – in other words, displacements – at the pre-compression station, the main compression station forms no part of the weight control system. Therefore, the main compression height is set to the correct tablet thickness at the beginning of the batch and can then be left unchanged for the entire duration of the batch.

Constant thickness

This is called "tabletting under constant thickness", whereby the main compression force – and subsequently tablet hardness – will vary with powder characteristics. Manual or automatic in-process sampling and analysis will then detect when tablet hardness goes out of tolerance and will stop the press.

Alternatively, the press can run in "tabletting under constant hardness" mode by activating a second primary control loop: a force transducer on the final compression station measures the individual main compression forces and calculates a moving average.

This moving average signal is then used to adjust the main compression height in order to keep the moving average between the pre-set limits.

In this way, the extra control loop – called the "hardness control loop" – will correct tablet thickness with the aim of keeping the main compression force – and subsequently the tablet hardness – stable.

Any thickness variations are, of course, only allowed within the pre-set tolerance on tablet thickness. An alarm and machine stop signal are therefore generated should it become necessary to breach these thickness limits to keep the compression force within its own tolerance limits.

"Indeed, such a situation would mean that the powder characteristics had changed to such an extent during the production run that was impossible to maintain all three relevant tablet parameters – weight, hardness and thickness – within their pre-set tolerance limits," points out Courtoy. "The process would therefore anyway need to be stopped and powder characteristics and quality checked."

The hardness control loop is re-calibrated after manual or automatic sampling and analysis, by changing the set point of the main compaction force.

When the hardness control loop is switched off – putting the machine into constant thickness mode – the individual compression forces and their average value can still be displayed graphically on the operator panel. A stop function is then available, stopping the press when the average compression force goes outside the pre-set stop limits.

All of this, says Courtoy, means that the weight control loop and the hardness control loop are totally separated, since they measure process variables at different compression stations and act on independent parameters of the compression cycle.

"Because the two loops are separated and both are running continuously, there is an independent, continuous and simultaneous control of both tablet weight and tablet hardness, giving the opportunity for improved control over tablet quality and consistency." ■

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