

Comparative analysis of the tableting process between single rotary tablet press and double rotary tablet press

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Introduction

The ability of a powder to form a tablet of adequate mechanical strength is termed as tableting. It is important that a tablet remain intact during its manufacturing, packaging and transportation processes until it is consumed by the patient. It is also important that the tablet is not excessively strong so that it does not undergo disintegration and dissolution after oral administration. A tablet is produced by compression of granules or powders of drugs with or without excipients. When a powder is compressed, it undergoes processes such as particle rearrangement, particle fracture, and particle deformation. Interparticulate interactions play a major role in tableting. The interparticulate interactions such as van der Waals forces increase when the distance between particles decreases. As the compression force is increased, the particles fracture (depending on the brittle-ductile nature and the strength of the particles). The last phase of consolidation by compression is particle deformation which involves plastic and elastic deformation with an increase in interparticulate interactions by increasing particle contact area. The ultimate success of tableting depends on interparticulate interactions of powder particles, material properties, and compression process (Lieberman, 1990; Schwartz et al., 1989).

Tablets are commonly manufactured by wet granulation, dry granulation or direct compression. They are produced by tablet machines that can be single punch tablet press and multi-station/rotary tablet press (e.g., High-speed rotary tablet machines and multi-layer rotary tablet machines). Single punch tablet press also called eccentric press or single station press is the simplest machine for tablet manufacturing. Multi station tablet press is a mechanical device that unlike the single punch tablet press has several tooling station which rotates to compress

granules/powder mixture into tablets of uniform size, shape (depending on the punch design) and uniform weight. It was developed to increase the output of tablets. Also, high speed rotary tablet presses is a major innovation in tablet pressing technology, achieving very high levels of productivity and speed and offering exceptional refinements in terms of safety, efficiency and quality of output (Watt and Armstrong, 2008).

The aim of this study was to compare the tableting process of tablets on Fette 2090 and Fette 3090. The Fette 2090i and Fette 3090i are both multi-station tablet presses. The significant difference between them is that the 3090i as a new generation tablet press generates a larger number of tablets in a shorter time because it is a double rotary press, unlike the 2090 which is a single rotary press. Fette 3090i has double-sided production, two filling devices, two pre-compression and main compression stations and two tablet discharges. Fette 2090i as a single rotary press has one sided production, one filling device, one pre-compression and main compression station and one tablet discharge. Tablets were produced by direct compression or DC as it is known in the industry. DC is the mixing of raw materials into a uniform blend, which are then compressed into a final tablet. In recent years direct compression has become extremely popular in the tableting industry. This is due in part to its low cost and simplicity. The main goal of this research was to determine how the speed of tableting affects the quality of the produced tablets. Depending on the formulation the tablets can be produced with lower or higher tableting speed. In this case, tablets are produced with a speed of 100 000 pcs/h on Fette 2090i and with a speed of 300 000 pcs/h on Fette 3090i.

Materials and Methods

In this research I monitored the production of three batches of tablets on Fette 2090i and another three batches on Fette 3090i (one batch 1,101,600,000 pcs) The composition of all six series includes the same raw materials. Tablets include the following raw materials: X (active pharmaceutical ingredient (API)- drug substance, lactose monohydrate, microcrystalline cellulose (MCC 102), magnesium stearate. The excipients lactose monohydrate, microcrystalline cellulose and magnesium stearate are materials that are inert and are added to drug substance to increase its volume and provide those desirable properties that are not present in the drug substance alone. Lactose monohydrate is the crystalline form of lactose. Lactose monohydrate has the function of a filler and binder to help form the tablets. Microcrystalline Cellulose (MCC 102) is a partially depolymerised pure cellulose and it's a white, insoluble, odorless and tasteless powder. MCC 102 has the function of a filler in the formulation. Magnesium stearate has the function of a lubricant in the formulation.

Results and discussion

On the Fette 2090i tablets were produced with the following tablet press parameters: Tableting speed 100 000 pcs/h; Rotor speed 44 rpm; Fill-o-matic speed 39 rpm; Main pressure 1.91 Kn; Pre-pressure 2.8 Kn; Main compr. force SREL 3.6%.

The tablets that were produced on the Fette 2090i were with: average weight of 302 mg, average hardness of 8.4 kP, average height of 3.6 mm and average diameter of 10 mm.

On the Fette 3090i tablets were produced with the following tablet press parameters: Tableting speed 300 000 pcs/h; Rotor speed 33 rpm; Fill-o-matic speed 25 rpm; Main pressure 1.71 kN ; Pre-pressure 3.15 kN; Main compr. force SREL 3.3%

The tablets that were produced on the Fette 3090i were with: average weight of 301 mg, average hardness of 8.5 kP, average height of 3.7 mm and average diameter of 10 mm.

From these results, it can be noted that the main compress.force srel% during tableting on both tablet presses is less than 5. On the Fette 2090i with a tableting speed of 100,000 pcs/h it is 3.6, and on the Fette 3090i with tableting speed of 300,000 pcs/h it is 3.3. What is particularly important is that the lower main compress.force srel% prepares more similar tablets on the tablet press in terms of mass uniformity and tablet content. In addition to this, one batch which is 1,101,600,000 pieces on the Fette 2090i with a tableting speed of 100,000 pcs/h is produced in 11 hours, while on the Fette 3090i with a tableting speed of 300,000 pcs/h the production ends in 4 hours which is a significantly

shorter time. The reason for this as I mentioned is that Fette 3090i is a larger tablet press.

Conclusion

In conclusion, in this research it is no significant difference in the tableting process on the Fette 2090 with a tableting speed of 100,000 pcs/h and on the Fette 3090 with a tableting speed of 300,000 pcs/h. Tablets are produced with the same quality in terms of physical parameters hardness, height and diameter. The SREL reading indicates the consistency of tableting operations. The closer the number in parameter 8 is to zero, the better, as higher numbers denote greater variation in fill and compression force from die to die. An SREL of 3,6% on Fette 2090i and 3,3 on Fette 3090i is considered extremely good.

References

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