Advances in the Continuous Shaping of Oral Dosage Forms
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The introduction of formulations suitable for extrusion has been a critical enabler for novel pharmaceutical manufacturing processes such as 3-D printing. In this presentation, we describe alternative shaping processes that can be implemented post-extrusion with the objective of achieving high throughputs for the commercial production of oral dosage forms. In all cases intermediates of the tablets called “preforms” are shaped by a calender operating in a synchronous manner with an extruder. Coming out of the calender, the preforms are connected together by flash, thereby forming a continuous sheet advancing on a conveyor belt. In this presentation, we describe two shaping processes to transform the calendered web consisting of connected pre-forms into individual tablets ready for coating. Both processes can be enable continuous manufacturing beginning with he extrudate and ending with pre-coated tablets.

In the first process, the preforms are separated “in line” by a laser beam or array of laser beams. Feasibility studies showed than a laser tuned with suitable parameters is capable of cutting through the flash without causing discoloration, odor, charring or unacceptable API degradant levels. Scaling-up the pilot process has the potential of achieving a throughput of 50,000 tablets/h.

In the second process the pre-forms are mechanically separated from one another with rotating cutting blades and then shaped into their final appearance using an ordinary tablet press. Proof of concept studies showed that the mechanical separation step was achievable using a continuous process. Scaling up the process using a 35 position tableting press has the potential to achieve a throughput of 40,000 tablets/h.