

New Product Announcement

Real Time Ribbon Density Prediction

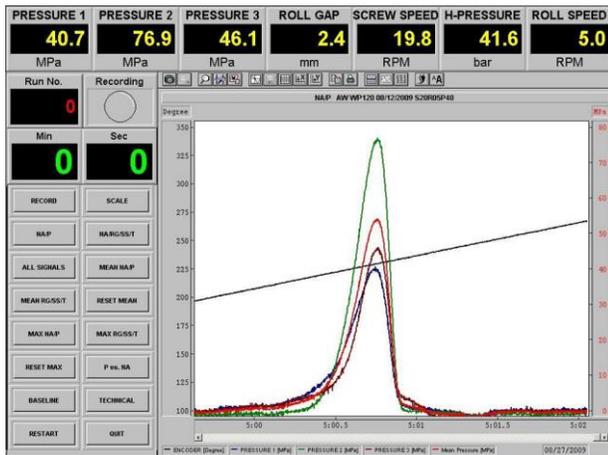
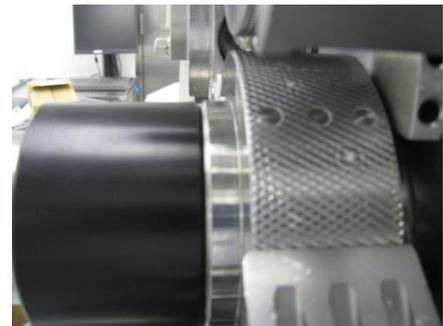
Ribbon density (or solid fraction) is one of the critical quality parameters of roller compaction process that influences the compactibility of granules during tablet formation. We now offer a method of calculating the ribbon density in real time for both R&D and production processes.

The method is based on normal stress measurements that MCC developed in collaboration with Bristol-Myers Squibb. It is described in detail in:

Nesarikar, Vishwas V., Nipa Vatsaraj, Chandrakant Patel, William Early, Preetanshu Pandey, Omar Sprockel, Zihui Gao, Robert Jerzewski, Ronald Miller, and Michael Levin. "Instrumented roll technology for the design space development of roller compaction process." *International journal of pharmaceutics* 426, no. 1 (2012): 116-131.

In addition to standard measurements of roll speed, feed screw speed, hydraulic pressure and roll gap, our novel instrumentation of the roll itself makes it possible to measure normal stress across the roll surface.

Normal stress on ribbon / roll was found to vary directly with hydraulic roll pressure and inversely with the ratio of screw speed to roll speed. Moreover, average normal stress (in conjunction with roll gap values) proved to be an excellent predictor of ribbon density, especially for low drug load formulations.



Predicted ribbon density is calculated for each peak of the normal pressure event, displayed in a digital meter on the computer screen, and reported in Excel format along with all other recorded process parameters.

Once the prediction equation is empirically established on R&D equipment for any particular formulation, it is possible to scale up the calculation to a larger compactor whose roll is not instrumented because the normal pressure can be calculated as a function of roll speed, screw to roll speed ratio, and hydraulic roll pressure.

The scale-up and subsequent ribbon density prediction on production scale equipment is described in the follow-up paper:

Nesarikar, Vishwas V., Chandrakant Patel, William Early, Nipa Vatsaraj, Omar Sprockel, and Robert Jerzewski. "Roller compaction process development and scale up using Johanson model calibrated with instrumented roll data." *International journal of pharmaceutics* 436, no. 1 (2012): 486-507.