Table 1. Risk assessment of Potential CPPs and controls for drying operation

Process control	Acceptable range	Why chosen
Air flow	100-150 ft^3/min; target point is 125 ft^3/min.	Important for consistent drying results. Acceptable range shown for pilot scale, probably greater for production scale. Lower flow rates do not suspend particles for drying; higher flow rates can dry product too rapidly and send excessive amount of product into filter socks. Flow rate easily controlled to prevent out of range flow rates. Not critical to product quality.
Inlet drying air temperature	37 – 45 °C; Target point is 41 °C	Important for consistent drying results. Lower temperatures take longer for drying to be completed but do not adversely impact product quality; higher temperatures can lead to over-drying of product and erosion of particle size. **Upper temperature limit is regarded as critical.**
Drying time	Not defined	Drying time is dependent on other factors (temperature, air flow, amount of moisture still to be removed from product particles), so drying time is not regarded as a critical control, but drying time will be monitored for information.
Moisture in dried product by in-process NIR measurement	2.0 – 4.0% by LOD	Continuous in-process measurement of water contained in dried product provides accurate assessment of progress of drying operation. **Regarded as critical control to ensure proper drying endpoint is reached.** Final product temperature to be monitored for information.

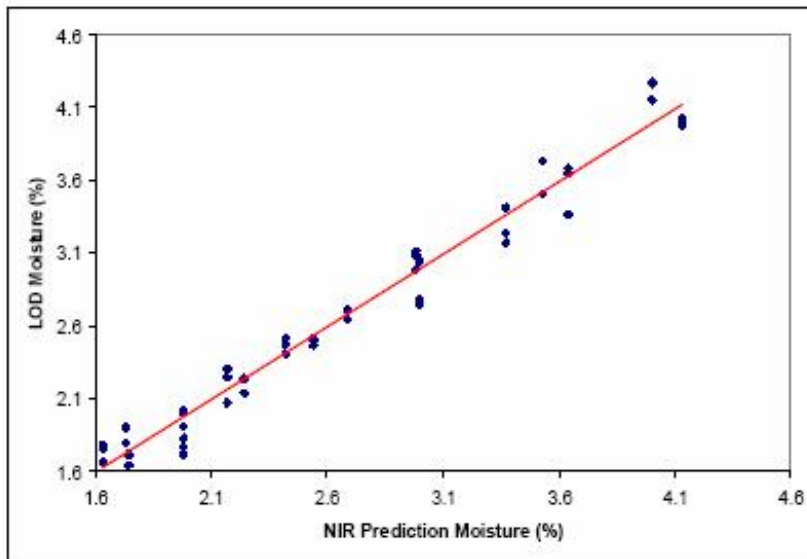### 3. The Process Analysis
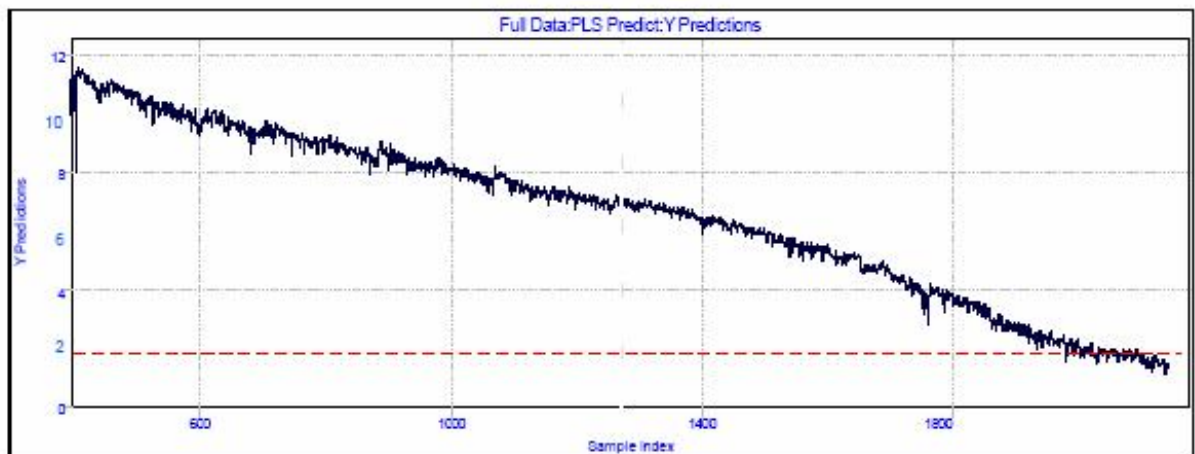

Figure 3. Predicted NIR versus measured LOD

Figure 4. Predicted moisture content of a granulated mixture being dried

3. The **Process Analysis** portion includes examination of conformance or validation batches and a validation report, to be prepared after the conformance batches have been prepared and analyzed. In addition to the usual criteria for product acceptability, equivalence, and consistency, an assessment of drying uniformity may be an appropriate part of the homogeneity analysis of the conformance batches. The PLS regression study used a large number of batches and samples, giving a high R^2 value indicating a strong correlation between the NIR and the corresponding LOD result. This could be used to justify a concurrent validation approach requiring three conformance batches for this first portion of