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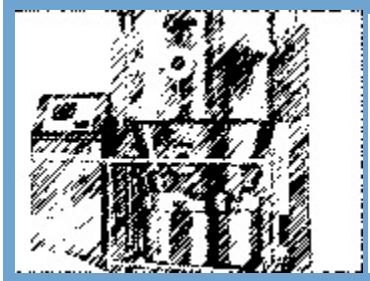


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Insight into considerations for identifying ranges for critical process parameters in fluidized bed processing:

On the following list, which would you consider to be critical process parameters (circle all that apply)?

A. Process air volume
B. Process air volume during shaking
C. Process air temperature
D. Solution spray rate
E. Product differential pressure
F. Filter shake interval

Answers: "A, C, D"

"A": Process air volume delivers the energy needed for evaporation and carries away the evaporated moisture. It also governs the fluidization pattern. Typically, changes are infrequent (though an initial 'ramp' may be employed in a fluid bed spray granulation to avoid filter occlusion) and the magnitude small. "B": Process air volume goes to zero in machines that interrupt fluidization to shake and simultaneously, spraying stops. When the shaking time expires, fluidization re-starts as does spraying. Therefore, there is essentially no impact on the process itself. If the machine is equipped with a split filter housing that permits continuous fluidization, there is an influence on process air volume during shaking of one side or portion. On a 'clean' filter, one with less than 100 mmWC of differential pressure, the dip in air flow during shaking will be nominal. As filters accumulate product (powders, film, etc.), the pressure trends upwards. At higher pressures (about 300 mmWC and above), the dip in process air volume is more pronounced. However, it is for only a short duration (a few seconds) and comparatively infrequent (every 30-60 seconds or more). In nearly all processes, the dip is immaterial, and should not be constrained by the 'operating range' identified for this parameter. The operating range should be defined to bracket the behavior for the time interval between filter shakes. **"C":** Process air temperature is a critical process parameter. In combination with the process air volume and spray rate it dictates the accumulation of moisture by the batch. **"D":** The spray rate is also a critical process parameter and should operate in a relatively narrow range (preferably +/- 2% of target). Large, momentary swings in spray rate are often an indication of some type of nozzle defect (poor performance, a common problem with respect to product quality). **"E":** Product differential pressure is a dependent variable (a non-critical process parameter) that reflects the openness of the product retention screen and the behavior of the batch. It will oscillate due to the compressible nature of air (a natural fluctuation seen in fluid bed processing, exacerbated by larger, deeper product beds). Product dP may rise in response to an increase in batch weight (by moisture in spray granulation or potency in layering) and/or the accumulation of particles or film in the retention screen at the base of the product container. It is not practical to identify an operating range due to the likelihood of variability during a batch as well as batch-to-batch (there is often an upward trend). However, it is useful for identifying cleaning intervals and for retrospective troubleshooting, therefore, its recording is strongly recommended. **"F":** The filter shake interval is not generally considered a critical process parameter. However, it should be of a duration that is sufficiently short (less than about 2 minutes). In this manner, the material accumulated may be returned to the product bed so that it may be exposed to the liquid being sprayed to produce agglomerates/granules.