

New Consistency In Granulation

Granulation is primarily used to render powders to a form, facilitating their flowability and handling. A typical granulation contains several ingredients: powdered excipient, small amounts of active ingredients, and a liquid binder that locks the powders together as granules and prevents segregation. The size and uniformity of the granules is dependent on the mix action, particle size of the powder, type of binder used, and the degree of dispersion.

Typically the granulating industry required separate equipment to pre-disperse, blend, then granulate powders. Several problems were inherent with this multi step granulation process:

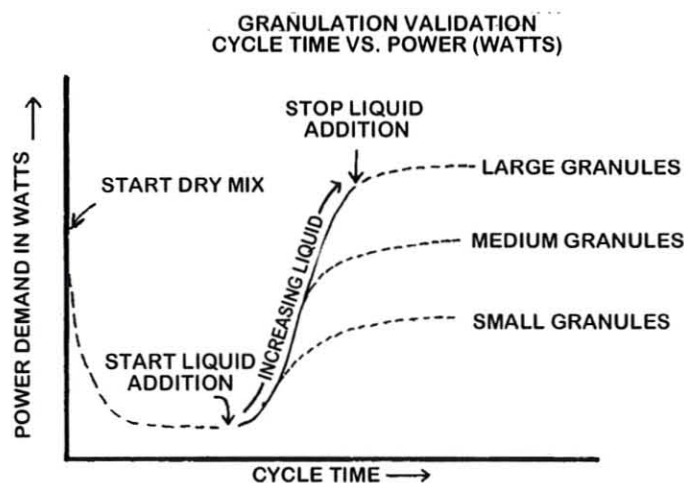
- 1) Each step required separate vessels, each with its own cost, individual cleanout, and regulatory validation.
- 2) Granulation was more of an art than a science. The operator had to determine the degree of wetness achieved and judge the amounts of liquid and mix time necessary. Thus, granulation runs were not consistently reproducible. The dried granular product often had to be screened, removing over and under-sized particles, yielding the desired finished product, i.e., the granules of narrow particle distribution and uniform density necessary for proper control.

Clearly, multi step granulation is inefficient.

Littleford Day has two series of mixer/granulators, vertical and horizontal each proven to be ideally suited for granulating available from standard 5 to 25,000 liters. Both series are equipped with plow like mixing tools that develop an intermediate intensity mix action that is gentle, yet thorough. This action when supplemented by high shear devices (choppers) capable of quickly disperses minor liquid or powder ingredients. Both the plows and chopper shafts are mounted through air purge seals which maintain an ingress of air around the shafts at all times. This nearly eliminates the chance of any material getting into the seals thus minimizing the possibility of cross contamination. The use of air purge seals along with sanitary design, highly polished stainless steel on all product contact surfaces, etc. makes cleanup a matter of filling the unit half full of water, solvent or appropriate liquid and letting the action of the plows and choppers clean the unit.

Littleford Day, having pioneered Recording Wattmeters in conjunction with plow granulators used in conjunction with a recording wattmeter have elevated granulation from an art to a science. Providing higher efficiency enhanced output and repeatability. As seen in Figure 1, a typical granulation, the excipient and the powered active ingredients are delivered to the static granulator. Mixing begins utilizing the plows until the power curve levels, indicating the dispersion is complete. Then the agglomerating liquids are sprayed into the active chopper field where they are quickly dispersed into the batch's ingredients, thus bringing about the desired finished granulation simultaneous with its corresponding increase in power.

FIGURE 1



The degree of granulation, correlating directly with the power used, is dependent upon the amount of agglomerating liquid added to the batch and the amount of wet mix time utilized. The resultant three dimensional action of the plows causes "snowballing"; the shearing action of the chopper generates uniform, small granules.

As seen in Figure 1, particle size grows as mixing time and liquid is increased. Plows and choppers are utilized until the desired granule size is achieved, indicated again by a leveling of the power curve.

Since the longer wet mix time more thoroughly wets the granules it reduces the liquid required to reach the desired particle distribution and density specifications. The following chart lists some general guidelines for granulation.

FOR A GIVEN:

Liquid Level	More Wet Mix Time = Increased material wetting, higher power used, more uniform particle distribution.	Less Wet Mix Time = Decreased material wetting, lower power used, less uniform particle distribution.
Wet Mix Time	Higher Liquid Level = Increased material wetting, higher power used, larger granule size.	Lower Liquid Level = Decreased material wetting, lower power used, smaller granule size.

Identical granulations generate identical power curves. This fact takes the guesswork out of knowing when the proper granulation objective has been achieved.

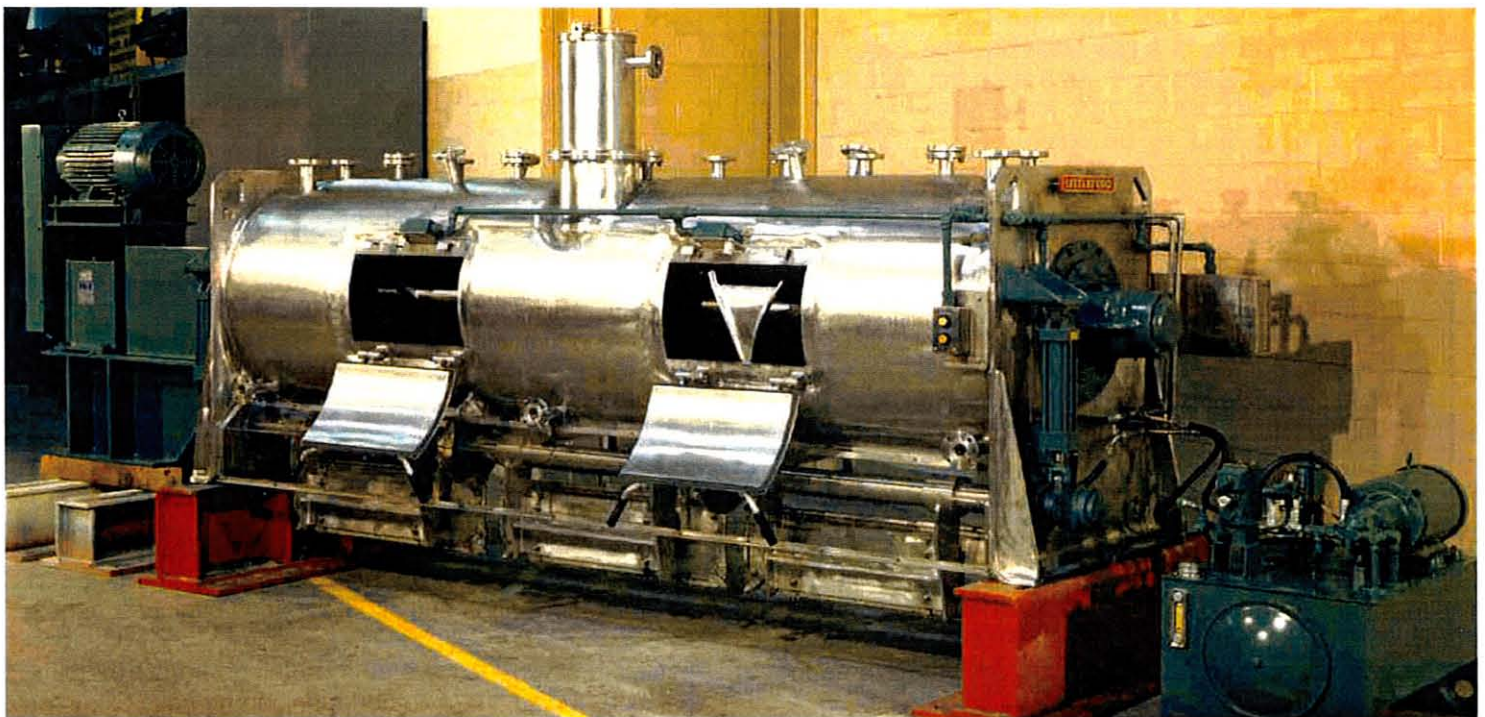
Littleford Day granulators create a mechanical fluidized bed mix action producing a homogenous blend, reducing the coefficient of deviation. When drying is required, this fluidized bed plow action, yields heat transfer coefficients as much as ten times greater than other dryers. State-of-the-art, highly efficient vacuum and or internal pressure machines, routinely incorporating plows are also available from Littleford Day.

Littleford Day provides validation documentation consisting of Mill Test Reports (MTR), machine run-off test reports, and inspection by a Regional Manager at the customer's plant with every order.

Optional instrumentation includes watt totalizing, programmable logic controls, recording wattmeter, chart recorders, and load cell mounting, etc. Installation Qualification and Operational Protocol (IQOQ) is also offered.

All Granulation equipment is routinely manufactured in accordance with "GMP" and can be specified to meet or exceed all of the different sanitary regulations as detailed by the FDA, 3A, USDA, and BISSF, making Littleford Day equipment the best granulation equipment on the market today.

For research and development, product formulation, quality control, or direct production scale-up needs, visit our Technical Center. For testing granulating process in your own manufacturing environment, rent a Littleford Day trial Granulator.



Littleford Day
Where Processing Ideas Become Reality

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