STERIS
Life Sciences

CASE HISTORY #3610

CLEANING OF FLUIDIZED BED EQUIPMENT

BACKGROUND

Fluidized bed processing is widely used in the pharmaceutical and chemical industries. A fluidized bed is a bed of particles with a stream of air passing upward through the particles at a rate high enough to set them in motion and make the bed “fluidized” or behave like a liquid. Although this technology was originally developed for rapid drying, this process is now also extensively used for agglomeration, granulation, pelletization and tablet coating.

The conventional method of cleaning fluidized bed equipment is by dismantling the piece of equipment and manually scrubbing or wiping the surfaces. This is not only time consuming, but also difficult for larger equipment where the expansion chamber, filter housing and dust collector areas cannot be easily accessed. The applications described here are alternatives to the conventional approach.

CASE A : USING A FOAMER SYSTEM FOR CLEANING

OBJECTIVE

A large manufacturer of formulations and tablets, who manually cleaned their fluidized bed granulators, was interested in improving their cleaning process. The existing process consisted of manually cleaning the filter socks, distributor plates and other removable components out-of-place, and then using a ladder and long handled brushes to clean the inaccessible areas of the fluidized bed chamber. This manual cleaning process was extremely inconsistent and at times required five manual cleaning cycles to meet their residue limits. The cleaning agents used were generic alkaline and acidic detergent formulations.

LABORATORY EVALUATION

A laboratory PACE® consulting and evaluation service concerning the cleaning procedures was done by STERIS Corporation. Samples of the product were obtained and a slurry of the product was coated onto 3 x 6" (76 x 152 mm) stainless-steel coupons and allowed to dry. These were then cleaned in the laboratory by using two application methods, a foam application and a spray application. The Customer, who was provided two options, chose to conduct a trial using the foam option. The evaluation for the foam application option consisted of using a cleaning agent, Foam 140® Alkaline cleaner, for the application. This is an alkaline surfactant system which, when used with a suitable foaming spray equipment, generates clinging foam to increase cleaning contact time. It was observed in the evaluation that at 4 oz/gal (3.1%) concentration and 140°F (60°C), the coupon was cleaned in 10 minutes, when significant wetting of the residue by the foam occurred.

FIELD TRIAL

Based on this data, a field trial was conducted using a foam cart available from STERIS Corporation. The foam cart uses a cleaner/water/air mixture to produce a rich, thick foam. It is especially useful for cleaning vertical surfaces and overhead equipment, such as in the fluidized bed chamber. The trial used plant air at 50 psi (345 kPa) and plant potable water at 40 psi (276 kPa). The cleaning agent was used at a concentration of 12% in water. This was done to compensate for a lower available water temperature of 122°F (50°C), the shorter available exposure time and to obtain better foam consistency.

The cleaning process consisted of removing the filter socks, distributor plate assembly and gaskets for cleaning out-of-place (COP). The equipment was then pre-flushed with 122°F (50°C) potable water using a hose. This was followed by spraying the foam onto the equipment. The foam could be directed to reach all the surfaces, including the dome (about 20 feet [6.09 m] high). The foam was allowed to contact the surface for approximately five to seven minutes, after which it was rinsed with potable water for approximately five minutes. Although the drier was visually clean, the process of foaming and rinsing was repeated.

RESULTS

After the cleaning process, the surfaces were thoroughly swabbed at various locations, and the samples tested for the active component using existing protocols. The residue levels obtained for the active component were below the acceptable limit of 5 µg/sq inch. This cleaning procedure is now being refined and is in the process of being validated.

CASE B : USING SPRAY DEVICES FOR CLEANING

OBJECTIVE

Another large manufacturer of dry formulations was interested in conducting a trial to evaluate the feasibility of cleaning their fluidized bed granulator, without taking it apart, by using spray devices to achieve cleaning agent contact with the internal surfaces of the equipment. The existing process consisted of manually brushing the dust collector section, the body, and the plenum, using an alkaline detergent cleaner.

EQUIPMENT

A portable clean-in-place (CIP) system, assembled in-house, was used. The system consisted of five spray nozzles located in the fluidized bed granulator. The location, size and type of the nozzles were determined based on the internal surface area and configuration of the granulator. The total flow, with all nozzles on, was about 77 gpm (291 Lpm). The discharge from the granulator plenum was modified from a 1" opening to a 3" drain to allow for higher flow rates. The discharge from the granulator drained through a 3" pipe to a 100 gallon (379 L) stainless-steel tank with steam heating capability, which was used as the holding and recirculating tank for the rinse water and cleaning solution. The discharge from this tank was connected to a 5 hp, 3500 rpm centrifugal pump, which was connected through an in-line filter to the spray nozzles.

CLEANING PROCESS

The cleaning process consisted of a potable water pre-rinse for five minutes through two of the nozzles. This was followed by a pre-rinse for five minutes through the remaining three nozzles. This staging of the pre-rinse was done to avoid large amount of residue from being dislodged resulting in clogging of the discharge line. The water rinses were done by filling the CIP tank with water, pumping it through the nozzles and then discharging the solution, without recirculation, directly to the drain.

This was followed by a wash cycle for 10 minutes at 140°F (60°C) using the CIP 100® Alkaline Process and Research Cleaner, at a concentration of 1 oz/gal (0.78%). This wash was performed by first using two of the nozzles followed by the other three nozzles. This process was repeated two more times to allow for a total contact time of 30 minutes. The wash cycle was performed with the cleaning solution being recirculated using the 100 gallon (379 L) CIP tank and the centrifugal pump.

The wash cycle was followed by a once-through rinse cycle using potable water at approximately 50°C using all five nozzles at the same time. At the completion of the rinse cycle, the granulator was drained and opened for inspection.

RESULTS

The desired result of this preliminary trial, which was a visually clean surface, was achieved. Some areas for further optimization were identified. These included reducing the water usage from 1330 gallons (5034 L), which was used for this trial, to around 700 gallons (2650 L). Adjustments to the spray nozzle location and orientation, to obtain better coverage on one of the spots in the plenum area below the distribution plates, was also planned.

Based on the success of this trial, the facility is planning to further refine the process and to purchase an automated portable CIP system to improve the efficiency of the cleaning process.

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