Formulation of a Pharmaceutical Binder Solution using Gansons Coating Suspension Preparation System (GCSPS)

Background

In the pharmaceutical industry, granulation is important in formulation development and creates the basis for performance of the final dosage form. This operation must be sufficiently robust to yield consistent results throughout the commercial lifetime of the finished product. Granulation is a size enlargement step and involves wetting the powder mixture with a suitable binder to facilitate cohesion, granule growth, improvement in strength and minimize tablet friability. Hence, preparation of a homogenous binder solution is of utmost importance to achieve reliable results.

Challenge

One of our pharma clients was using a conventional propeller agitator for formulation of Hydroxypropyl cellulose (HPC) binder solution, which entailed two hours for process completion. Additionally, it involved slow addition of powder in the solvent vortex with the use of an eductor funnel for wetting the polymer.

Objective

The primary objective of this study was to compare the mixing efficiency of the Gansons Coating Suspension Preparation System against the conventional stirrer for preparation of a binder solution.

Gansons Solution

The Gansons Coating Suspension Preparation System (GCSPS), a high shear mixer that possesses a unique disperser mixing head design, exhibits a four-stage mixing action. This ensures quick wetting, dispersion and solubilization of powders in the specified
solvent. In this trial, HPC (a water-soluble binder) was quickly added to the vortex of Rotosolver RS – 02 followed by addition of the surfactant at a specific tank geometry. The polymer and the surfactant were completely dissolved in water within 15 minutes at a frequency of 60 Hz.

Figure 1. (a) Addition of HPC to Water   (b) Addition of Surfactant to Water
   (c) Final Binder Solution using Gansons Coating Suspension Preparation System

Results

- Process Time

The use of GCSPS led to an 88% reduction in binder preparation time in comparison to the conventional process. Also, the HPC powder along with surfactant could be rapidly added to the vortex (Figure 1a and 1b) unlike the former process where powder addition in small increments in the vortex was essential to prevent lumping of the polymer.

- Retention of Functional Properties

A smooth, homogenous dispersion of HPC was obtained at the end of the process with absence of polymer agglomerates at the base and sides of the vessel (Figure 1c). Also, no significant change in functional properties and viscosity of the polymer was observed upon usage of a high shear stirrer for binder preparation.
Conclusion

Water soluble polymers like hydroxypropyl cellulose exhibit a tendency to lump or agglomerate and inhibit further wetting of polymer particles. GCSPS enabled quick dissolution of these particles and preserved their functional properties. Furthermore, the binder solution of Hydroxypropyl cellulose was formulated in 1/6th of the time required for conventional mixers. Hence, Gansons Coating Suspension Preparation System was successfully employed for the preparation of polymer binder solutions.

For more information on this case study or any other Gansons products, please contact:

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