

The influence of the humidity in the process chamber during solid coating of particulars

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Abstract

Coating of particulars (pellets or nonpareils) is used in the pharmaceutical industry to evenly distribute the active drug or to modify the drug-release characteristics of the solid dose. The most efficient and accurate method of coating the particulars is bottom spray coating, where the coat is applied as droplets to build up the layer on the pellets of nonpareils.

Investigation has shown that the important process parameters are the surface temperature on the core and the surrounding relative humidity in the process chamber. The process consists of an active pharmaceutical ingredient (API) which is suspended as a slurry in the spray suspension. The suspension is then sprayed concurrently with the particulars, which are pneumatically transported upward in the equipment. The droplets of the spray suspension will then impact with the particulars due to the differences in their velocity. After being applied to the surface of the particular, the solvent is removed by evaporation. The evaporation rate will depend on the heat and the mass transfer between the pneumatic transport – the loosely bonded solid will be worn off by the attrition from the surface of the particulars. To achieve a good binding of the solid to the particulars, the evaporation rate has to be controlled.

In many cases, the solvent must be without Water, because either the API will dissolve or lose activity in Water. The relative humidity in the process chamber can only be determined by calculation. The particulars mean size growth rate can be measured using the back scattered light from an inline laser. A model is made to compare the ideal mean size growth rate with the growth rate measured by the inline laser. The result from this comparison is then correlated with the calculated relative humidity in the process chamber.