Uniformity of Coatings Applied in 46" Wurster Columns

In 1971 this laboratory, then part of Wisconsin Alumni Research Foundation (WARF), made the initial coating trials using a 46" Wurster column. This was the prototype for all 46" Wurster columns produced since that date and many of the design features were developed on this unit. In concept, the 46" Wurster column is a seven-fold scale up of an 18" Wurster column having seven partitions and seven nozzles. 18" and 24" Wurster columns have been used for many years by a number of companies but there was a demand for units with greater capacity. Prior to these tests a prototype continuous Wurster unit had been built and tested. While the continuous concept was demonstrated to be feasible, there were problems involving product uniformity, machine size, and lot identification, which made it unattractive. These drawbacks were the reason that the multiple nozzle unit of larger batch size was built.

In Wurster coating units the proper plate design has long been identified as the key to achieving high quality coatings in minimum time (1-4). In a multiple nozzle unit the situation became more complex as one must not only have the proper plate design for the product being coated, but one must also ensure the uniform distribution of air among the several sections of the plate. The prototype 46" unit was used to evaluate several methods of achieving such uniform distribution and proved that a simple plenum chamber below the plate is simply not adequate for good performance. Among the factors found to be important are:

> Proper plate design with adequate pressure drop across the plate at operating air flows.
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> Uniform presentation of air to the lower side of the plate with no channeling side-to-side or front to back.
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> Adjustable controls to modify the airflow and pressure drop as one changes products or to correct any observed imbalance.

It was found that a balanced smoothly cycling flow of the product being coated is just as critical in the large unit as in the smaller units, perhaps moreso. There are several things one can look for to determine if the large unit is properly balanced:

Level bed of material - if the air flow is stronger on one side of the chamber than on the other, the product being coated will tend to be blown from the stronger side and will accumulate on the weaker side. At best this will simply result in an uneven bed, which is not level across the top. Probably one will observe product flowing down across the slope at the top of the bed presenting a hazard of damaging the coating from tumbling. At worst, the greater bed depth on the weak side will further impede airflow in a portion of the bed already deficient, resulting in collapse of the spout on the weak side. If not corrected immediately this will cause the product to be ruined as the Wurster coating cycle is disrupted.

Spout height is another indicator of the degree of balance one has, or has not, achieved. In a properly balanced 46" unit all seven spouts will be of equal height. If one or more is observed to be stronger (throwing higher) than the others one will probably also observe that the bed of material mentioned above is sloped to that spout.

All coating units should be equipped with well-placed viewing windows near the plate as well as higher in the coating chamber. The flow of product down to the plate should be rapid and smooth at all points in the product bed. Unbalanced flow associated with unbalanced spouts and non-level beds will also show up here. The high portions of the bed are higher because the weak spout is not drawing the product rapidly off the bottom of the bed, this will be observed as sluggish movement of the product near these spouts. In extreme cases the product may even stop moving completely. At the same time, one may observe turbulent flow of product near the strong spouts as too much material feeds into those spouts depleting the bed of material on that side resulting in a path of least resistance for excessive air no longer being forced to the weaker spouts.

In multiple nozzle units two problems can cause particles to not be uniformly coated:

1. In an unbalanced bed some particles are cycling past the coating nozzle more often than others, receiving more coating in the process.

2. One or more nozzles may plug or otherwise malfunction.

A marked loss of coating uniformity from particle to particle would be considered serious for most products. Cosmetic coatings would not be uniform and coatings used to control release would be unreliable. One of the primary advantages of Wurster columns is that this technique applies coatings with a high level of uniformity. This uniformity has permitted the use of lower coating levels to provide a given level of protection because the number of thin spots is reduced (1). The 18" Wurster unit in our lab had proven, over a period of years, to be an effective coating unit with a degree of coating uniformity highly acceptable for pharmaceutical applications. It was felt that coatings applied in the larger Wurster units should be of a quality consistent with the smaller machines.

In 1972 a series of coatings was made to compare the uniformity of coatings applied in the 18" and 46" Wurster columns. A coating was prepared using hydroxypropyl methylcellulose and ethylcellulose (3:1) in a mixed solvent system of methylene chloride and isopropyl alcohol. Red #3 was added to the coating and later extracted from individual tablets after coating. The quantity of Red #3 was compared between tablets as an index of coating uniformity between tablets. The absorbance of the extracted color was measured on a spectrophotometer by an independent testing laboratory. The standard deviation and % deviation were calculated.

In the 18" Wurster unit the coated particles were sampled, as the unit was unloaded. On eight samples form a single load the standard deviation was 0.0784 on a mean value of 1.085 or a variation of 7.2% from particle to particle.

The conditions were scaled to the 46" unit and the same coating applied. Due to limitations in mixing container capacity the amount of coating applied was reduced from 3.3% weight added to 2.5% weight added. Duplicate samples were removed from inside each of the seven partitions prior to unloading the unit. Each sample was assayed for Red #3 as above. The standard deviation was 0.067 on a mean value of 0.883, or a variation of 7.6%. This compares well with the uniformity observed in the 18" unit.

Another test was performed to test loss of uniformity when a nozzle malfunction occurred. For this test the complete coating run was made with nozzle #2 turned off throughout the run

(Nozzles 1 through 6 form a regular hexagon with nozzle 7 in the center). In this test duplicate samples were removed from partitions 2,4, and 6 (alternate partitions around the hexagon). Each set was analyzed in duplicate with some discrepancy in the results. The first set gave a standard deviation of 0.074 on a mean of 0.785, a variation of 9.4%. The second set did not compare as well, a variation of 13.4%, however one of t six reading on this set was quite high with the others comparing well.

Later, another set of samples were run using methylcellulose (5 cps) applied from a water solution. This coating was not pigmented so that numbered tablets could be recovered and weight gains determined directly. Results of these tests are consistent with the colorimetric tests described above.

REFERENCES

1. Wurster Coated Aspirin I and II; J. Pharm. Sci.; Vol. 53, No. 8, August, 1964.

2. U.S. Patent 3,241,520; Particle Coating Apparatus (3/66)

3. U.S. Patent 3,253,944; Particle Coating Apparatus (5/66)

4. Enteric Filmcoats by Air Suspension Coating Technique; J. Pharm. Sci.; Vol. 50, No. 2, February, 1961.