

# A Study on the Effects of Drug Loading Percentage on Content Uniformity in a Powder Layering Process

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## INTRODUCTION

Dry powder layering of Active Pharmaceutical Ingredients (API) offers several advantages when the amount of drug loading is high, including fast processing times, high yield, high content uniformity and low agglomeration. The process is not often used in low-dose API loadings, due to concern that content uniformity may be compromised in processes that may last under 10 minutes. This study focused on whether acceptable content uniformity could be achieved via dry powder layering at low coating levels.

## METHODS

Three batches, one using sugar spheres (Colorcon), one using MCC spheres (Asahi Kasei) and one using Maltodextrin/Starch spheres (GPC) were run in a Freund-Vector Corporation GXR-95 rotary fluid bed. In each batch, 50 KG of core material was loaded into the rotor. Micronized acetaminophen (APAP) was layered onto the core material using a KTron KT-35 Loss-in-Weight powder feeder equipped with Acti-Flow using a 5% PVP K30 solution as a binder. 3 samples were taken at 1%, 2%, 5%, 20% and 40% weight gain (w.g.) during each run. Dissolution was done to determine the % RSD for each sample and determine the content uniformity.

## EQUIPMENT



Freund-Vector Corporation Granurex® GXR-95



KTron KT-35 Powder Feeder

## RESULTS

### DISCUSSION

#### APAP Coating %- Sugar Spheres

Samples	1% w.g.	2% w.g.	5% w.g.	20% w.g.	40% w.g.
1	0.98	1.87	4.52	16.1	29.0
2	1.07	1.98	4.51	15.8	28.5
3	0.96	1.89	4.5	16.0	29.5
AVG	1.00	1.91	4.51	16.0	29.0
RSD	5.8	3.1	0.2	1.0	2.6

#### APAP Coating %- Maltodextrin/Starch Spheres

Samples	1% w.g.	2% w.g.	5% w.g.	20% w.g.	40% w.g.
1	1.29	2.12	5.06	17.4	28.4
2	1.36	2.11	4.95	16.4	29.1
3	1.27	2.11	5.03	17.6	29.3
AVG	1.31	2.11	5.01	17.1	28.9
RSD	3.6	0.3	1.1	3.8	2.5

#### APAP Coating %- MCC Spheres

Samples	1% w.g.	2% w.g.	5% w.g.	20% w.g.	40% w.g.
1	0.88	1.71	4.30	12.1	29.0
2	0.94	1.79	4.20	13.5	28.3
3	0.89	1.75	4.20	13.8	30.8
AVG	0.90	1.75	4.27	13.1	29.4
RSD	3.6	2.3	1.4	6.9	6.7

At the 1% w.g. level, the batches had %RSD of 5.8, 3.6 and 3.6 respectively. At the 2% coating level, the % RSD was 3.1, 0.3 and 2.3 respectively. At 5%, the % RSD was 0.2, 1.1 and 1.4. At the 20% level, the RSD was 1.0, 3.8 and 6.9 and at the 40% level, the RSD was 2.6, 2.7 and 6.7.

## CONCLUSIONS

Each of the batches, with different core materials, showed exceptional content uniformity even at the 1% weight gain level, which only took 3-4 minutes to achieve. The batches continued to exhibit good content uniformity throughout the remainder of each batch, showing that the drug dispersion and exceptional mixing of the powder layering process in a rotor is capable of producing uniform coatings even in very short processing times at low coating levels.

