An investigation of the effect of different plasticizer systems on the dry powder coating of Acetaminophen beads with Eudragit E PO using a novel rotor processor

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PURPOSE

The purpose of this study was to determine the effect of two different plasticizer systems on the film formation and overall processablilty of Eudragit E PO during a dry powder coating.

METHODS

3kg of 30/35 mesh sugar spheres were loaded into a Vector GXR-35 Rotary Granulator/ Coater. 409g of micronized acetaminophen was loaded into a K-Tron KT-20 Powder Feeder and dry layered onto the spheres, using a 5% PVP K-30 binding solution in water. Following the drug layering, the spheres were separated into 1 KG batches, and loaded into the GXR-35. 400g of Eudragit E PO was loaded into the powder feeder and dry coated onto the drug loaded spheres using two binding/plasticizing solutions: 10% Triethyl Citrate (TEC) and 10% Dibutyl Sebacate (DBS) in water. Tween 80 was added to both solutions at a 0.5% level as an emulsifying agent. Samples were taken at 100g, 200g, 300g and 400g of E PO applied for each plasticizer system. Samples were cured for 0, 2, 4 and 24 hours at 40ºC in an oven. Process yields were calculated and equipment was inspected for losses following each coating. The surface and cross-sectional morphology of the coated pellets was observed via scanning electron microscopy.

PROCESS CONDITIONS

Plasticizer system	Rotor Speed (RPM)	Airflow (CFM)	Process Air Temperature (ºC)	Product Temperature (ºC)
10% DBS in water	250	8-10	20-25	17-20
10% TEC in water	250	8-10	20-25	17-20

EQUIPMENT

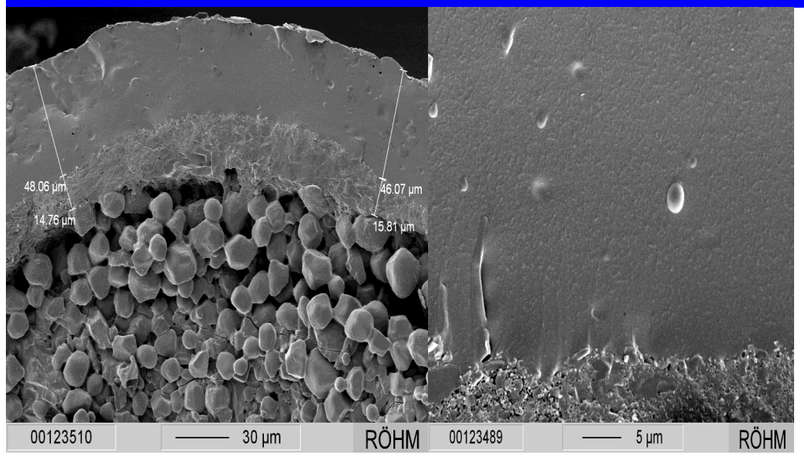
Vector Corporation Granurex GXR-35

RESULTS

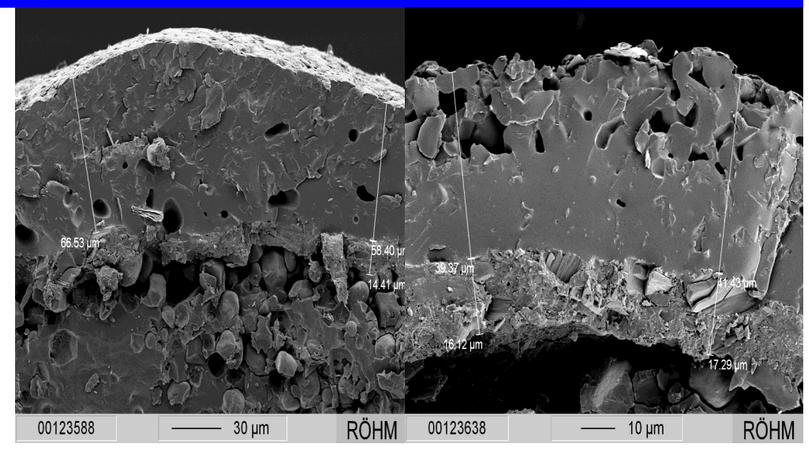
PROCESS DATA

Plasticizer System	EPO Applied (g)	Total Plasticizer Applied (g)	Dry EPO Addition Rate (g/min)	Plasticizer system Spray Rate (g/min)	Process efficiency (%)	Process Time (min)	Coating Applied (%)
10% TEC in Water	400g	33g	**10.0**	8.0	98.2	40	40
10% DBS in Water	400g	33g	**10.0**	8.0	96.1	40	40

SEM IMAGES



EPO/DBS Cross Section SEM images



EPO/TEC Cross Section SEM images

SEM investigation revealed that the DBS beads had a fully coalesced film at each of the coating levels, regardless of curing time. The TEC beads showed a film formation, but the film had multiple cracks and striations throughout the coating. The processing yields were 98.2% for the DBS system and 96.1% for the TEC system, based on polymer weight gain. The processing chamber was clean for the DBS system, with any losses retained on the filters. The TEC system showed a film buildup on the rotor and had a tendency to agglomerate, which led to the lower overall process yield.

CONCLUSIONS

While both plasticizing systems showed an ability to facilitate film formation of the E PO polymer, the more complete film formation and the processing advantages of the DBS system show that it is a better choice for the dry powder application of E PO.