

A Comparison of a Theophylline Powder Layering Process Utilizing Sugar/Starch cores and Novel Maltodextrin/Starch Cores

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PURPOSE

To compare the processing and results of using two different core materials, sugar/starch cores and maltodextrin/starch cores, in a dry powder layering process of theophylline.

METHODS

A 3 kg batch of 40/50 mesh sugar/starch cores were loaded into a Vector Granurex® GXR-35 Rotor Granulator. A K-Tron KT20 Powder Feeder was loaded with 529g of theophylline which was dry layered onto the spheres using a binding solution containing 5% Kollidon® PVP K-30 (BASF) in water. The process was repeated using a 3 kg batch of 250-300 micron maltodextrin/starch spheres (MALTRIN® M520 Maltodextrin/PURE-DENT® B815 Corn Starch NF from Grain Processing Corporation) as the core material. Following the drug layering, both batches of drug layered spheres were coated with a 20% coating of Eudragit® L-30 D 55 (Evonik) for enteric protection. Dissolution, size and shape analysis, and SEM cross sections were done and combined with process data to compare the two core materials.

FORMULATION AND PROCESS CONDITIONS

Core Material (3 KG)	Theophylline Amount (g)	PVP K-30 Amount (g)	Rotor Speed (RPM)	Air Temp (°C)	Product Temp (°C)
Sugar/Starch	529	12.5	250	50	17
Maltodextrin/Starch	529	12.5	250	50	17

EQUIPMENT



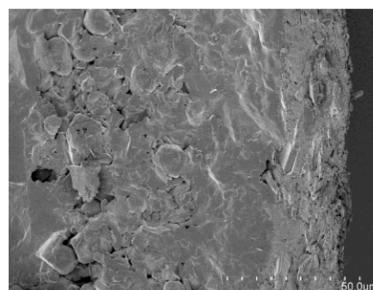
Vector Corporation Granurex GXR-35

RESULTS

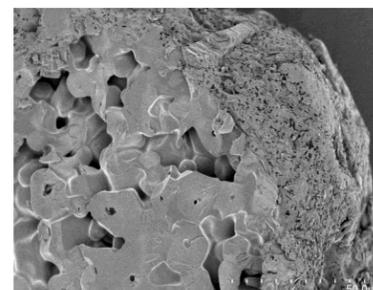
PROCESS DATA

Core Material	Theophylline addition rate (g/min)	PVP Spray Rate (g/min)	Drug Layering Efficiency (%)	Finished Size (microns)	Drug Layer-Process Time (min)	Aspect Ratio (0.0-1.0)	Sphericity (0.0-1.0)	Polymer Coating Applied (%)	Total Process Time (min)
Sugar/Starch	14.0	8.0	97.5	320-450	37	0.94	0.93	20	97
Maltodextrin/Starch	14.0	8.0	97.0	270-320	37	0.90	0.92	20	97

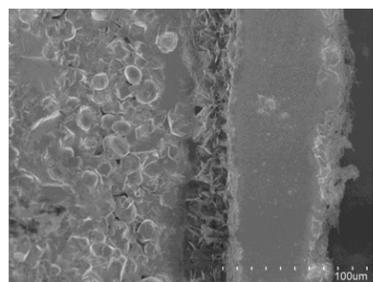
SEM IMAGES



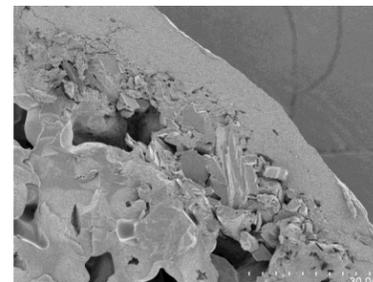
Sugar/Starch Theophylline Layer



Maltodextrin/Starch, Theophylline layer

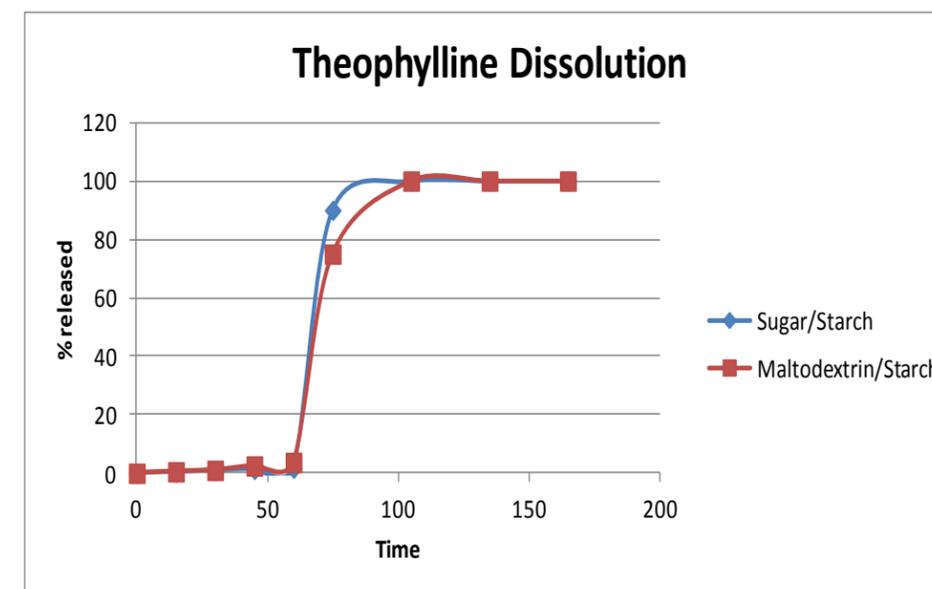


Sugar/Starch L 30D 55 Layer



Maltodextrin/Starch, L 30D 55 Layer

DISSOLUTION PROFILE



CONCLUSIONS

The results of the testing clearly showed that the Maltodextrin/Starch cores behaved very similarly to the sugar starch cores in the dry powder layering process. The processes with both sets of cores had very efficient results, and produced uniformly coated products. The dissolution testing showed that the release rates were nearly identical for both sets of cores. The Maltodextrin/Starch cores did show some slight processing advantages in that they showed less tendency to agglomerate during the drug layering step. The testing showed that Maltodextrin/Starch cores could be used as a suitable replacement for Sugar/Starch cores.

The theophylline was successfully applied to both types of core materials, however, the sugar starch cores showed more of a tendency to become tacky and agglomerate during the drug layering step. The Maltodextrin/Starch cores did not show any sticking problems throughout the run. Both types of cores exhibited very high processing efficiencies, with each having 97% processing yields. Dissolution testing showed nearly identical drug release from the two types of cores. Size analysis showed that the Maltodextrin/Starch cores were slightly more uniform in size following the drug layering, which is likely due to them being more uniform in size prior to processing.