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A Comparison of Spray Dried and Agglomerated Maltodextrins of Various Dextrose Equivalence as Binders in Top Drive Acetaminophen Granulations using Cold Water as the Binding Solution

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PURPOSE

To compare the binding properties of spray dried maltodextrin versus agglomerated maltodextrin of three different dextrose equivalence (DE) in a model acetaminophen granulation system utilizing a top drive wet granulation process where the binder was added dry and cold water was used as the binding solution.

METHOD



Spray dried maltodextrins with 5, 10 and 18 DE values (MALTRIN[®] M040, M100 and M180, Grain Processing Corporation) and agglomerated maltodextrins with 5, 10 and 18 DE values (MALTRIN QD[®] M440, M500 and M580, Grain Processing Corporation) were used at a 10% binder concentration level and added to the acetaminophen as a dry powder. The binding solution was cold water. The active pharmaceutical ingredient was semi-fine acetaminophen (Mallinckrodt 0081). The granulations were produced in a top drive, high shear granulator (Freund-Vector GMX-25) and dried in a fluid bed dryer (Freund-Vector VFC-15M). The water percentage was adjusted for changes in DE, if required. The batch size was 5 kg total and batches were produced in triplicate. The granulations were wet milled through a 0.375 inch (3/8 inch) square screen cone mill (Quadro[®] Comil[®] U-10). All granulations were dried to a product temperature of 35°C. Granulations were dry sized through a 14 mesh screen. Bulk density and particle size analyses were tested on all granulations using Sympatec QICPIC and Malvern Mastersizer 3000 particle size analyzers.

RESULTS

Sympatec QICPIC Particle Size

MALTRIN [®] maltodextrin	X ₁₀	X ₅₀	X ₉₀
M040 (5 DE spray-dried)	91	302	860
M440 (5 DE agglomerated)	73	327	1021
M100 (10 DE spray-dried)	70	167	740
M500 (10 DE agglomerated)	84	312	999
M180 (18 DE spray-dried)	83	198	737
M580 (18 DE agglomerated)	58	205	801

Malvern Mastersizer Particle Size

MALTRIN [®] maltodextrin	X ₁₀	X ₅₀	X ₉₀
M040 (5 DE spray-dried)	68	258	774
M440 (5 DE agglomerated)	68	346	1193
M100 (10 DE spray-dried)	51	153	591
M500 (10 DE agglomerated)	81	330	1040
M180 (18 DE spray-dried)	69	188	870
M580 (18 DE agglomerated)	49	208	750

All maltodextrins tested produced acceptable granulations. As a dry binder, the agglomerated maltodextrins (MALTRIN QD[®] products) are lower in bulk density and larger in particle size than the spray dried maltodextrins (MALTRIN[®] products). The low DE agglomerated maltodextrin required more water to activate the binding properties than was needed with the higher DE agglomerated products. However, all the lower DE maltodextrins produced a larger particle size finished granulation. Differences in particle size were observed before wet and dry sizing, but once sized, QICPIC and Malvern data both showed little difference between the granulations.

Since the agglomerated maltodextrins are more soluble and wet out faster in the granulation process, the agglomerated maltodextrins produced a slightly larger particle size granulation over the spray dried maltodextrins. The bulk density results were consistent for all granulations.

Bulk Density

MALTRIN [®] maltodextrin	g/cc
M040 (5 DE spray-dried)	0.50
M440 (5 DE agglomerated)	0.50
M100 (10 DE spray-dried)	0.46
M500 (10 DE agglomerated)	0.49
M180 (18 DE spray-dried)	0.47
M580 (18 DE agglomerated)	0.48

CONCLUSION

Maltodextrins of various particle size, bulk density and DE are successful binders in top drive wet granulation using cold water as the binding solution.

