A Comparison of Acetaminophen Granulations Using Various Dextrose Equivalence Maltodextrins as the Binder in Three Different Wet Granulation Processes

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Freund-Vector GMX-25


Freund-Vector VFC-SFC-35 Insert with VFC-3


Freund-Vector VCF-3

PURPOSE

To compare the binding properties of three different dextrose equivalence (DE) maltodextrins in acetaminophen granulations utilizing three different wet granulation processes.

METHODS

Maltodextrins with 5, 10 and 18 DE values, (MALTRIN® M040, M100 and M180, Grain Processing Corporation), were used at a 10% binder concentration level and applied in an aqueous solution to granulate acetaminophen (0081 semi fine powder, Mallinckrodt). Three separate granulation processes were utilized; high shear (Freund-Vector GMX-25), top spray (Freund-Vector VFC-15), and rotor granulation (Freund-Vector Spir-A-Flo SFC-35 insert). The water percentage was adjusted for each piece of equipment. Viscosity was measured on all binding solutions using a Brookfield Viscometer. All batches were 5 kg total and produced in triplicate. Granulations were dry-sized through a 12 mesh screen (Freund-Vector Screen Granulator). Particle size analyses and uniformity were tested using Sympatec QICPIC. Granulations were tableted on a Vector Colton 2216 tablet press equipped with standard cup tooling using a typical acetaminophen tablet formulation. Tablets were tested for weight uniformity, hardness, friability and disintegration.

RESULTS

Although lower DE maltodextrins produced higher viscosity, all binding solutions were easily sprayed.

SOLUTION VISCOSITY DATA

MALTRIN® Maltodextrin	Solution Viscosity (cp)	
Concentration	37.5%	20.0%
M040	65	15
M100	34	14
M180	24	10

Maltodextrins in all granulating processes produced acceptable granulations and all granulations produced quality tablets. Differences were seen in particle size and granule density before drying. MALTRIN® M040 maltodextrin seemed to be the strongest binder based on initial particle size and density appearance in the three granulation processes. This was most apparent in the high shear process. Once sized, QICPIC data showed little difference between binders but more of a difference between granulation processes. The high shear process yielded granulations with a larger mean particle size and a broader range of particle size distribution. The rotor process produced granulations with the smallest mean particle size and the tightest particle size range. The top spray process produced particle sizes between that of the other two processes. Tablets made from the granulations were all similar with a target weight of 500 mg and tablet hardness results in the 10-14 kp range.

CONCLUSIONS

While different granulation processes can produce different particles, all DE maltodextrins tested were excellent binders for wet granulations and all granulations yielded acceptable tablets.

Particle Size QICPIC Data (X_{10})

MALTRIN® Maltodextrin	High Shear		Top Spray		Rotor	
M040	Mean	136.11	Mean	166.13	Mean	85.06
	RSD	36.37	RSD	68.20	RSD	9.18
M100	Mean	178.31	Mean	145.65	Mean	97.85
	RSD	181.40	RSD	33.66	RSD	1.55
M180	Mean	109.63	Mean	106.53	Mean	121.48
	RSD	20.88	RSD	11.39	RSD	7.09

Particle Size QICPIC Data (X_{50})

MALTRIN® Maltodextrin	High Shear		Top Spray		Rotor	
M040	Mean	686.41	Mean	405.60	Mean	228.98
	RSD	167.99	RSD	99.26	RSD	22.15
M100	Mean	603.48	Mean	405.89	Mean	273.15
	RSD	397.73	RSD	65.41	RSD	15.14
M180	Mean	624.38	Mean	287.01	Mean	299.40
	RSD	281.24	RSD	22.80	RSD	41.33

Particle Size QICPIC Data (X_{90})

MALTRIN® Maltodextrin	High Shear		Top Spray		Rotor	
M040	Mean	1327.84	Mean	717.54	Mean	565.53
	RSD	158.62	RSD	171.47	RSD	66.84
M100	Mean	1397.73	Mean	831.69	Mean	613.30
	RSD	307.16	RSD	121.71	RSD	28.05
M180	Mean	1178.42	Mean	693.59	Mean	592.46
	RSD	492.64	RSD	159.63	RSD	70.52