A NOVEL PROCESS FOR APPLYING METHYLMETHACRYLATES (MMA) TO MULTI-PARTICULATES AT A HIGH SPEED UTILIZING A ROTOR PROCESSOR

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PURPOSE

To develop a novel process for applying methylmethacrylates (MMA) to multi-particulates using a rotor processor.

METHODS

Beads containing 15% acetaminophen by weight were coated in the Granurex GX-40 (Vector Corporation) rotor processor. Five different coating formulations were used in these trials: Eudragit L-100, Eudragit L-100 55, Eudragit NE 40 D, Eudragit EPO, and Eudragit L 30 D 55. Glidants normally required to be suspended in the formulations for processing were omitted. Using a KT-20 (K-Tron) precision powder feeder, the glidants were fed onto the beads during polymer application as required for processability. Batches for L-100, L-100 55, L-30 D 55, and NE-40D were coated to a polymer content of 25% w/w, and batches of EPO were coated to a polymer content of 15% w/w. Following each coating, application efficiencies were calculated, and dissolution testing was completed.

FORMULATION AND PROCESS CONDITIONS

Polymer	Solvent	Plasticizer Used/ Amount	Rotor Speed (RPM)	Air Temp (°C)	Product Temp (°C)
L-100	Acetone	TEC/10%	300	60	34
L-100 55	Acetone	TEC/10%	300	60	34
L 30 D 55	Aqueous	TEC/10%	300	60	26
NE-40 D	Aqueous	None	300	40	25
EPO	Aqueous	None	300	45	29

EQUIPMENT

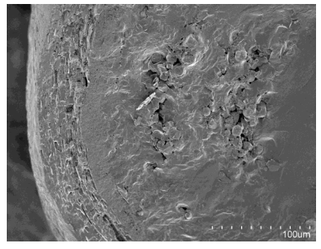
Vector Corporation Granurex GX-40

RESULTS

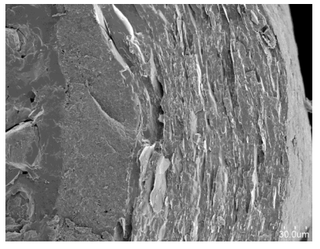
PROCESS DATA

Polymer (Eudragit)	Polymer in Solution as Applied (%)	Spray Rate (g/min)	Polymer Addition Rate (g/min)	Polymer Solids Applied (g)	Glidant Applied (g)	Airflow, Slit/ Fluid (CFM)	Coating Efficiency (%)	Total Time (min)	Coating Applied (%)
L-100 55	10	75.5	**7.55**	666	202	35/95	98.3	100	25
L-100	10	78.6	**7.86**	666	195	35/95	97.1	95	25
NE 40 D	40	22.1	**8.84**	666	244	35/95	97.5	75	25
L 30D 55	30	54.0	**16.20**	666	139	35/95	97.8	55	25
EPO	10	52.0	**5.20**	352	152	35/95	96.9	75	15

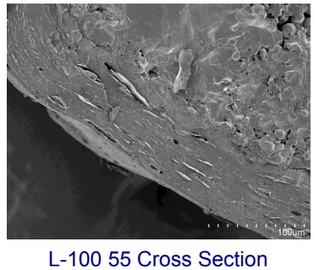
SEM IMAGES



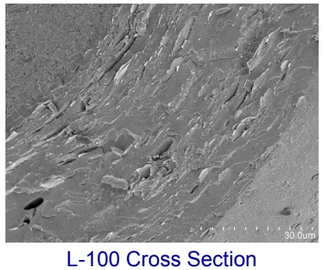
L-30 D 55 Cross Section



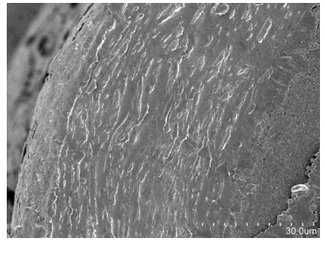
EPO Cross Section



L-100 55 Cross Section



L-100 Cross Section



NE 40 D Cross Section

DISSOLUTION PROFILE

CONCLUSIONS

The amount of glidant required for each process as recommended by the manufacturer was reduced by 25-50% by applying it in dry form versus including it in the coating formulation. By eliminating glidant in the coating formulations, any build-up in the solution lines and in the spray gun were eliminated greatly reducing processing issues and cleaning time. Additionally, for the aqueous polymer systems, adding the glidant separately allowed the use of each system at its full strength as supplied by the manufacturer instead of diluting them to a lower polymer level.