

IMPROVED WET MASSED TABLETING USING PLASTICIZED BINDER

J.I. Wells, D.A. Bhatt & K.A. Khan, Beecham Pharmaceuticals, Great Burgh, Epsom, Surrey.

The compression characteristics of granules produced by wet massing depend largely upon the strength and physical properties of the binder, which is distributed throughout the aggregates in a sponge like matrix (Seager et al 1979). The addition of a plasticizer is expected to change the mechanical properties of the binder matrix and this paper reports the effect of including plasticizers in the granulating fluid on the tableting properties of dicalcium phosphate, lactose and paracetamol.

Four plasticizers at 0.2% (propylene glycol, PEG 400, glycerin, and hexylene glycol) were incorporated in a wet massed formulation containing 95.3% paracetamol, 2% sodium starch glycollate, 2% PVP as binder and 0.5% magnesium stearate. Plasticizer concentration was also investigated using 0, 0.04, 0.1 and 0.4% propylene glycol. The most profound effect occurs with paracetamol (Table 1) which has poor compression properties and is prone to capping and lamination. Good tablets are only obtained if the bonds absorb the elastic recovery of paracetamol without rupture (Doekler & Shotton 1977).

Table 1: Effect of plasticizers (0.2%) on tableting properties of paracetamol

Plasticizer	Compaction Pressure MNm ⁻²							
	60		120		180		240	
	σ	F%	σ	F%	σ	F%	σ	F%
-	0.527	10.225	1.206	10.270	1.289	11.426	1.195	13.165
Propylene glycol	0.729	6.092	2.582	3.962	2.773	4.449	2.672	5.453
PEG 400	1.557	3.856	2.324	3.620	2.690	3.133	2.737	3.149
Glycerin	1.108	5.059	1.875	4.327	2.272	4.999	2.133	5.164
Hexylene glycol	1.064	5.070	1.913	3.730	2.192	3.828	2.158	4.592

Including a plasticizer in the binder increased the tensile strength (σ), raised the capping pressure and reduced the friability (F%) of all tablets. Tablets containing 0.04% propylene glycol were only marginally stronger, but above this level, tensile strength was increased significantly and was related to the concentration of plasticizer. PEG 400 and propylene glycol were more effective than glycerin or hexylene glycol in increasing tablet strength. Friability was reduced to the same extent however, quite independently of the plasticizer concentration or type. A low friability is generally more important than crushing strength since it determines handling characteristics.

Dicalcium phosphate tablets containing binder plasticizer were marginally softer than those without, consistent with a predominant bonding mechanism of fragmentation. Since the granules containing plasticizer are expected to be more plastic, a consequent reduction in fragmentation leads to tablets of lower strength. Nonetheless, the friability was reduced significantly due to the greater ductility of the tablets containing plasticizer. Lactose bonds by both fragmentation and plastic flow and both the tensile strength and friability were improved by binder plasticization.

In conclusion, the addition of a plasticizer in the binder improves the mechanical properties of good and poorly compressible materials, and has considerable potential in improving wet massed tablet formulations.

Doekler, E., Shotton, E. (1977) J.Pharm.Pharmac. 29: 193-198

Seager, H., et al (1979) Int.J.Pharm.Tech.Prod.Mfr. 1: 36-44

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