LUBRICITY MEASUREMENTS OF MAGNESIUM STEARATE

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Batch to batch variation of magnesium stearate can greatly affect the workability of pharmaceutical formulations. Variation in the physical properties of commercially available samples of magnesium stearate was reported by Butcher and Jones (1972) and Muller (1977). Increasing the percentage of lubricants to overcome poor lubricity often leads to dissolution difficulties due to the hydrophobic nature of magnesium stearate and in addition compression problems may arise. Poor lubricant batches can only be detected at the tableting stage since there is, as yet, no simple lubricity test for lubricant materials.

The present work investigates a method for evaluating lubricity of different batches of magnesium stearate, utilising a Universal Testing Instrument (Instron 1122). Shear strength of lubricant material (Train and Hersey 1960), temperature changes during tablet production (Juslin and Krogerus 1971), and the forces or various combinations of the forces involved in compression and ejection have been utilised to evaluate lubricity. Ejection energy was chosen as the evaluating parameter for this investigation since it appears to give the best prediction of tendency to stick to the die wall during the entire ejection process, and will allow sharper differentiation between similar lubricants.

Ejection energies of 200mg samples of A) magnesium stearate compressed alone, and B) 1% lubricant admixture with lactose BP, were measured. Tablets were formed in a $\frac{3}{8}$" tungsten-carbide die at a compression rate of 2mm/min, to a constant compaction force of approximately 60MPa. Ejection speed used was 5mm/min.

LUBRICANT BATCH		1	2	3	4	5	6	7	8	9	10	11
MEAN EJECTION ENERGY IN J/M^2 OF SURFACE IN CONTACT WITH THE DIE	A	1110	1050	655	1600	920	1460	750	900	1080	800	950
	B	5319	3036	4612	4434	4456	3222	2371	4938	2767	4105	3444

Table 1:- Ejection energies of tablets prepared from eleven different batches of magnesium stearate A) when lubricant compressed alone and B) when in 1% admixture with lactose BP.

With a batch reproducibility of ± 10%, both evaluations produced a wide range of ejection values, depending upon the batch used. Each produced a rank order for the lubricant batches as shown below.

TEST	RANK ORDER										
EJECTION ENERGY J/M^2		- 800+				-1000+					-1300+
A	3.	7.	10.	8.	5.	11.	2.	9.	1.	6.	4.
EJECTION ENERGY J/M^2		-3000+				-4000+					-4800+
B	7.	9.	2.	6.	11.	10.	4.	5.	3.	8.	1.

There was no correlation between the two sets of figures. This indicates that excipients play an important part in determining the practical efficiency of a tablet lubricant and that simple ejection energy measurements alone are not a reliable guide to the lubricity of a material.

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Juslin, M.J. & Krogerus, V.E. (1971) Farm.Aikak. 80: 197-209
Muller, B.W. (1977) Pharm.Ind. 39: 161-165
Train, D. & Hersey, J.A. (1960) J.Pharm.Pharmac. 12: 97T-104T