Influence of the Physicochemical Variability of Magnesium Stearate on Its Lubricant Properties: Possible Solutions

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ABSTRACT

The variability of the physicochemical properties of 13 commercial batches of magnesium stearate (from three vendors) were determined using various physicochemical tests. Differences observed were related to the crystal lattice and the hydration state of the samples as well as the impurities contained in their matrices. A formulation model containing 2% of magnesium stearate was used to determine the lubricant properties of 6 of the 13 magnesium stearate lots received. The tablet press used was a Stokes® Single Station Instrumented F Press. The different lubricant properties observed were related to the particle size of the magnesium stearate lot used. The influence of the crystalline structure on the lubricant properties of magnesium stearate was also shown whereas the influence of the adsorbed water did not appear to determine process capabilities. Two possible solutions were evaluated to reduce the lubricant property differences among the lots tested. By decreasing the particle size of a lot of magnesium stearate, it has been possible to significantly improve its lubricant properties. Magnesium stearate in association with talc also presented an improvement of its lubricant properties.

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INTRODUCTION

Magnesium stearate is widely used as a lubricant in the area of pharmaceutical solid dosage forms. This is mainly due to its ability to decrease friction between the tablet and die wall during the ejection stage of the compression process (1). The adverse effects of magnesium stearate when used in excessive concentrations or blending times are well known. The most common of these adverse effects are a decrease in tablet hardness (2) and an increase in disintegration and dissolution times (3). These negative effects may be avoided by using a minimum amount of standardized magnesium stearate. However, the grade of magnesium stearate (hydration state, fatty acid composition, particle size distribution) can vary, depending on the method used in its manufacture.

To estimate the variability of magnesium stearate, the physicochemical properties of 13 commercial batches of magnesium stearate from three vendors were determined. To evaluate the influence of this variability on its lubricant properties, 6 lots of magnesium stearate were individually blended with a nonsteroid anti-inflammatory drug formulation. The compaction characteristics of the blends were determined using a Stokes® Single Station Instrumented F Press. Finally, two possible solutions were evaluated to reduce the differences in the lubricant property of the lots tested.

MATERIALS AND METHODS

Materials

- Magnesium stearate USP grades (1990).
  -Mallinckrodt Inc. (vendor A), Chesterfield, MO, USA (six lots referred to as lots 1–6)
  -Hüls America Inc. (vendor B), Piscataway, NJ, USA (six lots: 11–16)
  -Mathe Inc. (vendor C), W. Helena, AR, USA (1 lot: 21)
- Tween 20 Ez grade (Fisher Scientific, Fair Lawn, NJ, USA)
- Liquid nitrogen (Technologies Inc., Piscataway, NJ, USA)
- Mixed gas 30% N_2/70% He (Linde Co., PO N 7315 NJ, USA)
- Lactose spray dried: Wisconsin Dairies, Baraboo, WI, USA (lot 49831)
- Avicel PH102: FMC Corp., Philadelphia, PA, USA (lot 50463)
- Sodium starch glycolate: Mendell Co. Inc., Patterson, NY, USA (lot 49849)

- Talc: Cyprus Ind. Co, Englewood, CO, USA (lot 49569)
- NaH_2PO_4: EM Science, Gibbstown, NJ, USA
- Anhydrous $CaSO_4$: WA Hammord Drierite Co., Xenia, OH, USA

Bulk and Tap Densities

Bulk density is defined as the ratio between the weight of the powder and its bulk volume determined by using a graduated cylinder. Tap density is the ratio between the weight of the powder and its tapped volume defined as the maximum packed volume reached. Tap densities were reported at intervals from 1 to 2 thousands taps until the final tapped volume was reached. The tap density test was performed using the Erweka SVM® (Erweka Inst. Inc., Milford, CT, USA).

Particle Size Analysis

The particle size distribution was measured using a suspension technique. Since magnesium stearate is water insoluble, the sample under investigation was dispersed in water using Tween 20 as a suspending agent. A Brinkmann® Particle Size Analyzer (Brinkmann Instruments Co., Westbury, NY, USA) was employed. Each result represents the average of three particle size determinations.

Specific-Surface Area Determination

The specific surface area of a powder material is defined as the total surface (usually in square meters) possessed by the unit weight (usually 1 g) of the material. Specific surface areas were performed on a Quantasorb® Sorption system (Quantachrom Corp., Syosset, NY, USA) using the "one-point Brunauer–Emmett–Teller (BET) method" with a mixture of nitrogen (adsorbate) and helium (inert carrier) in a 3:7 v/v ratio. The degassing of the sample was performed at 40°C for 2 hr under nitrogen flow. Differential scanning calorimetry (DSC) profiles were used to confirm the integrity of the crystalline structure of magnesium stearate. Each experimental result is the average of 10 measurements and 6 calibrations for each sample.

Thermal Analysis

Differential Scanning Calorimetry

Differential Scanning Calorimetry (DSC) analyses were carried out on a Perkin–Elmer DSC 7 (Perkin–

Elmer Corp., Norwalk, CT, USA). The DSC was calibrated daily with high-purity standards (indium and zinc). The following standardized cycle was performed on each 5-mg sample of magnesium stearate contained in an open aluminum pan under nitrogen flow (20 ml/min):

- Heating phase: from 55°C to 210°C, rate 4°C/min, pause 0.2 min
- Cooling phase: from 210°C to 43°C, rate 4°C/min, pause 0.5 min
- Heating phase: from 43°C to 210°C, rate 4°C/min

Thermogravimetric Analysis

Temperatures of 35°C to 210°C at a heating rate of 4°C/min were applied by a Perkin–Elmer thermogravimetric analyzer TGS-2 on magnesium stearate samples at weights of 5–7 mg under a nitrogen flow of 50 ml/min.

X-ray Diffraction Analysis

Using randomly oriented samples, x-ray powder diffractions were performed on a Phillips 12045B/3 (Phillips Norelco, Mahwah, NJ, USA) at the following experimental conditions: $CuK_{\alpha 1}$ radiation, $\lambda = 15.4$ nm (40 kV, 20 mA), Ni filter, speed of the traveling detector 1° 2θ/min, optics 0.006/1°.

Scanning Electron Microscopy

Using a Poloron Ins. E5100 (Poloron Ins., Hatfield, PA), magnesium stearate samples were coated with a 150-Å gold film. Microscopic observations were performed using a Cambridge S360 scanning electron microscope (Leica Ins., Deerfield Park, IL, USA). Magnesium stearate samples and tablet cross sections were examined at magnifications of 500×.

Experimental Modification of the Magnesium Stearate Particle Size

Since recrystallization of magnesium stearate is impossible because of the absence of a solvent with sufficient dissolution properties (4), it was not possible to increase its particle size. The particle size of magnesium stearate was reduced using a GEM T-X laboratory mill from Helme Products Inc. (Helmetta, NJ, USA).

Experimental Modification of the Magnesium Stearate Crystalline Structure

In aluminum pans, approximately 3.5 g of two selected lots of magnesium stearate was stored for 55 days under a controlled atmosphere at room temperature (5). Atmospheres of 97% and 0% residual humidity were obtained from saturated water solution of NaH_2PO_4 and anhydrous $CaSO_4$, respectively. A portable thermohygrometer H18064 (Hanna Inst. SpaA, Limena–Padova, Italy) was used to control the residual humidity of the atmosphere.

Preparation of the Blends

Lubricant Used: Magnesium Stearate

A nonsteroid anti-inflammatory drug (NSAID) formulation was chosen because of its high concentration of magnesium stearate (2%). The formulation contained lactose (spray dried), microcrystalline cellulose (Avicel PH102), sodium starch glycolate, and active ingredient. The powders were blended for 30 min using a Plexiglas V blender having a volume of 2000 ml to obtain a 500-g blend sample. A 100-g portion of this blend was then blended with magnesium stearate for an additional 3 min using a small stainless steel V blender having a volume of 240 ml.

Lubricants Used: Magnesium Stearate and Talc

The same formulation was used. Talc (3.5%) was added to the first 500-g blend sample and blended for 4 min. A 100-g portion of this mixture was then blended with magnesium stearate for an additional 3 min using a small stainless steel V blender having a volume of 240 ml.

Compaction Physical Parameter Determination

A Stokes Single Station Instrumented F Press (Stokes Compacting Equipment Division, Warminster, PA, USA) equipped with 11/32 in. round, flat-face, beveled-edge punches (Elizabeth Carbide Die Co. Inc., McKeeport, PA, USA) and instrumented die system (PCB Piezotronics, Depew, NY, USA) was used to characterize the compaction properties of the NSAID formulation blended with the various lots of magnesium stearate. Applied forces (7 and 20 kN) were controlled using the upper punch adjusting knob while tablet weights (250 mg) were controlled using the lower punch adjustment. The following parameters were reached: applied, lower,

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residual, and ejection forces; axial and radial transmission force ratios; compression; elastic and net invested energies; maximum axial and radial pressures. Results represent the average of 10 experimental points. A Student t-test (97.5 level of confidence) was used to compare the forces applied to the blends and the weights of the resulting tablets.

Compact Strength

The load required to fracture the tablets was reached using a Schleuniger 2E hardness tester (Dr. Schleuniger & Co., Marion, IA, USA) calibrated with mechanical tablets. This value was then used to calculate the tensile strength (σ):

$$\sigma = \frac{2 \cdot P}{\pi \cdot D \cdot h}$$

where P is the applied load, D is the compact diameter, and h is the thickness.

RESULTS AND DISCUSSION

Physicochemical Study

Tap densities obtained at various numbers of taps are plotted versus the number of taps in Fig. 1. A total of 4 distinct tap density profiles were observed for the 13 magnesium stearate lots. Except for lot 21, the value of the tap density recorded at 2000 taps was similar to values observed at 500 taps. Tap density values for lots 1–6 were low, suggesting that cohesive bridging was extensive and not easily removed by tapping under these conditions. The facts that lot 21 obtains its optimum tap density faster than lots 1–6, and that the difference between the bulk and tap densities is greater for lot 21 than lots 1–6, confirm that the latter have more interparticle coherence.

The particle size analysis of the 13 lots of magnesium stearate (Table 1) shows three groups of average mean diameter. Each group corresponds to a vendor, except for the mean diameter particle size of lot 14, which is outside the range of vendor B. Of the 13 lots of mag-
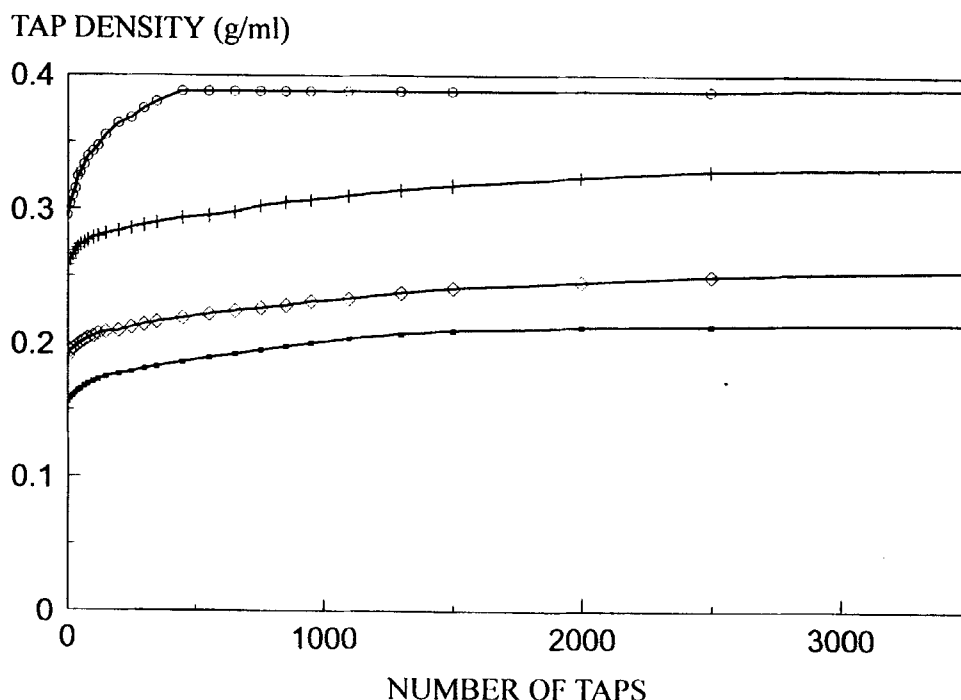

TAP DENSITY (g/ml)

Figure 1. Tap density profiles of various magnesium stearate lots (■, 1-6; ◇, 11, 14; +, 12, 13, 15, 16; ○, 21).

Table 1

Particle Size Analysis and Specific Surface Area Determination of Various Magnesium Stearate Lots from Three Vendors

	Particle Size (μm)		Specific Surface Area (m²/g)	
	Range	Exception	Range	Exception
Vendor A	1.90–2.71		6.84–8.08	
Vendor B	0.96–1.33	Lot 14: 2.52	4.70–5.74	Lot 11: 8.50
Vendor C	3.1		4.30	

nesium stearate tested, lots 11 and 21 had particle sizes that were at the extremes (respectively, 0.96 and 3.10 μm).

Specific surface areas of the 13 lots of magnesium stearate suggest these results are vendor dependent (Table 1). The specific surface area of lot 11 is outside the range of vendor B. The two lots of magnesium stearate having extreme specific surface values are 21 (4.30 m²/g) and 11 (8.50 m²/g). In a previous study (6), it was reported that the specific surface decreased asymptotically with an increase in the mean particle size. In our study, no direct correlation could be found between these parameters. This may be explained by the different shapes of the crystals among the lots tested.

Thermal analysis confirmed the hypothesis of various polymorphic and hydrate forms as well as various impurities (such as magnesium palmitate, magnesium oxide) among the 13 lots of magnesium stearate tested. Seven distinct DSC patterns, presented in Fig. 2, suggest different chemical compositions and crystalline structures. This is especially apparent during the cooling phase of lots 1–6, where a recrystallization takes place. This recrystallization step is absent with the other lots tested. Four different TGA profiles obtained with the 13 lots of magnesium stearate are shown in Fig. 3. Except for lot 11, TGA profiles are vendor specific. Both TGA profiles for lots 11 and 21 show a two-step weight loss. Faster thermal exchanges between small particles, compared to larger ones, explain the loss of weight that occurs at lower temperatures for magnesium stearate lot 11 as compared to 21. The different TGA profiles may be explained by the fact that lots 12–16 were anhydrous forms. Lots 1–6 were monohydrate forms, and lots 11 and 21, with a weight loss of 5% occurring in two phases, were dihydrate forms.

The different crystalline states characterized by the thermogravimetric analysis between magnesium stearate

lots 1–6, 12–16, 11, and 21 were confirmed via x-ray diffraction (Fig. 4). Based on earlier data (7–10), patterns from lots 1–6 suggest a monohydrate crystalline structure. The single broad peak, known as a halo, obtained in the 2θ = 21° area obtained from lots 12–16, suggests that these lots either have a large particle size causing interferences or present a para-crystalline state or an anhydrous crystalline structure. This type of peak shows a structure in which the magnesium atoms of magnesium stearate are arranged in irregularly spaced parallel planes (11). According to the previous TGA results obtained for lots 12–16, the anhydrous crystalline structure seems to be more probable. The 2θ = 21° area obtained with lots 11 and 21 suggest a highly crystalline state that may be related to the dihydrate, as confirmed by the TGA profiles.

The important physicochemical property differences observed between each lot tested may come from the manufacturing method used by the vendors as well as the purity of the raw materials used, such as stearic acid, during the hemisynthesis of magnesium stearate. In fact, stearic acid and salts contain a minimum of 10% of other long-chain fatty acids or their salts (12).

Compression Study

To evaluate the influence of the physicochemical parameters on the lubricant properties of magnesium stearate, 6 lots, selected from the 13 lots previously tested, had their lubricant properties evaluated in a model NSAID formulation using a Stokes Single Station Instrumented F Press. A preliminary study was performed with two lots of magnesium stearate and the formulation model. When forces of less than 15 kN were applied, the formulation system primarily undergoes particle fragmentation, repacking, and plastic deformation. Under forces of more than 15 kN, elastic phenom-
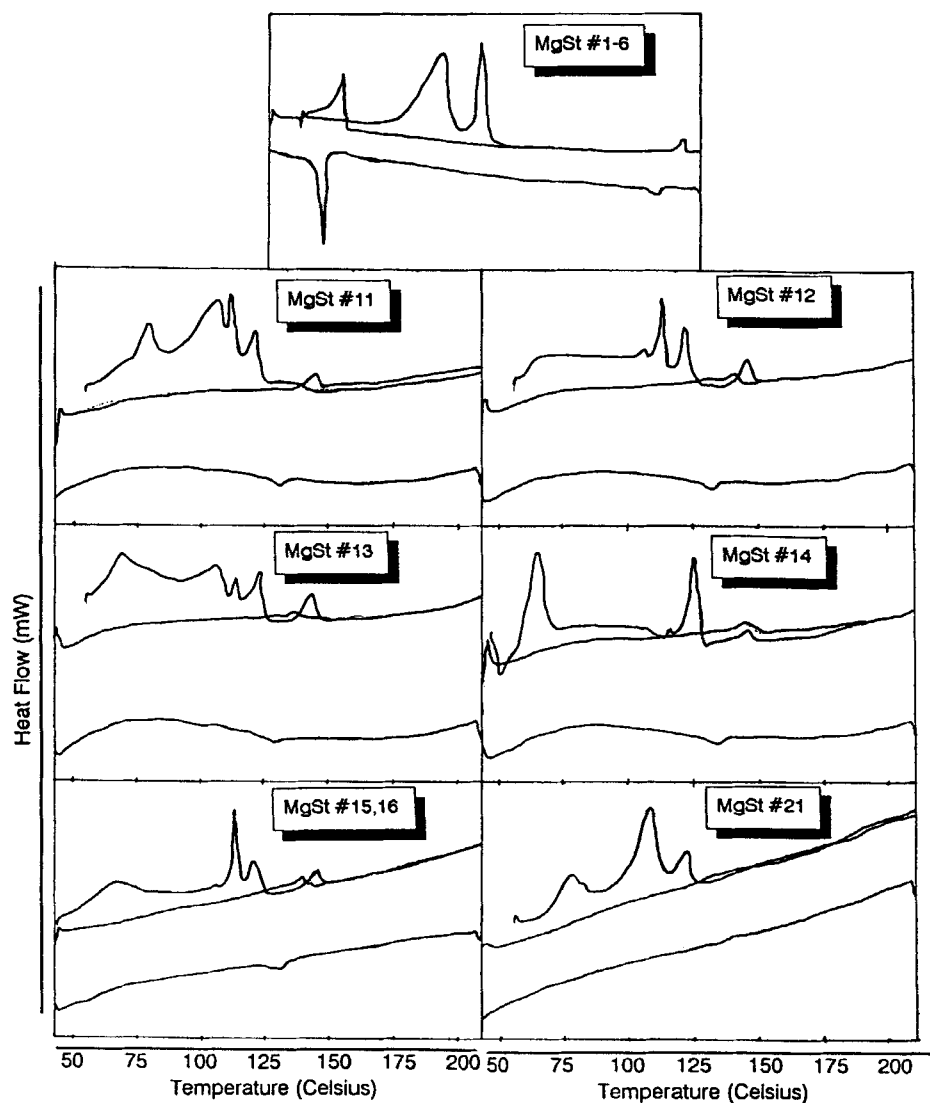
Figure 2. DSC profiles of various magnesium stearate lots.

ena become more important. Therefore, two forces were used for the compaction study: 7 and 20 kN.

From the results presented in Table 2, one can conclude that two magnesium stearate lots, such as 2 and 3, with identical physicochemical characteristics (particle size, specific surface, DSC, TGA, x-ray diffraction) present the same lubricant properties (evaluated by the compression parameters and the tensile strength of the tablet obtained). Two magnesium stearate lots (11 and 21) with different physicochemical characteristics do not

present the same lubricant properties. To determine which physicochemical characteristics mainly influences the lubricant properties of magnesium stearate, lots 2 and 11 have to be compared with lots 6 and 16, respectively. Two magnesium stearate lots (2 and 6) with different particle sizes and specific surfaces present different lubricant properties. Two different magnesium stearate lots (11 and 16) with close particle sizes have the same lubricant properties. Therefore, the particle size of magnesium stearate has a predominant influence
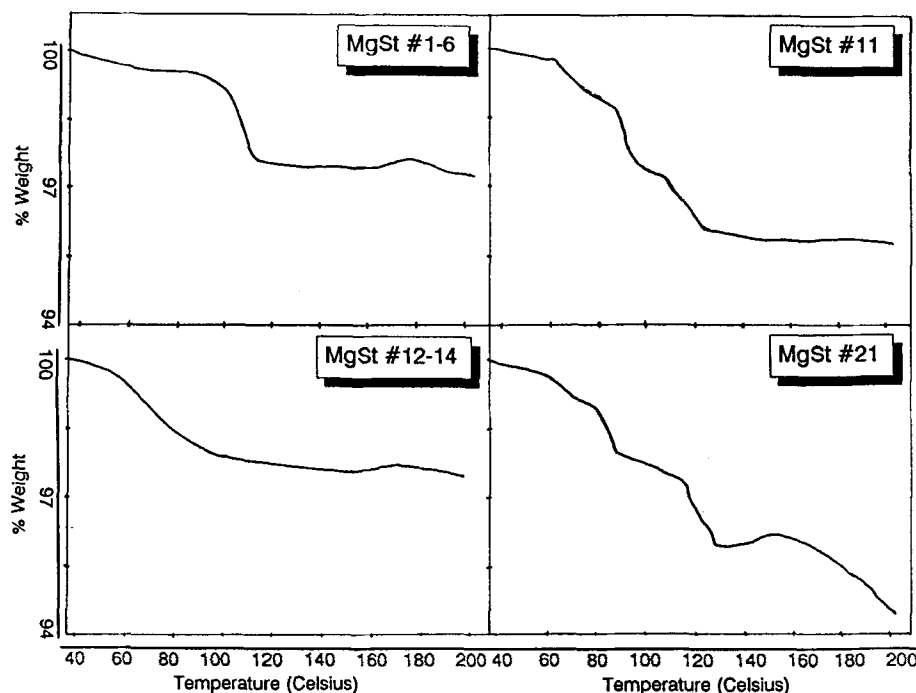
Figure 3. TGA profiles of various magnesium stearate lots.

upon the other physicochemical properties in regulating magnesium stearate lubricant properties.

The particle size of the magnesium stearate lot used is directly related to the radial transmission ratio, defined as the ratio between applied and radially transmitted forces, and the tensile strength of the tablets obtained (Fig. 5). It was not possible to obtain linear relationships with the other compression characteristics studied (axial transmission ratio, residual and ejection forces).

To understand these experimental results, some scanning electronic microscopic examinations were performed. Figure 6 presents four SEM pictures using the same magnifications. The two top pictures represent the formulation model blended with (left) a small mean diameter magnesium stearate lot (lot 11) or (right) a larger mean diameter magnesium stearate lot (lot 21). These two granulations were compressed and the resulting tablets were broken. Tablet cross sections are presented at the bottom of Fig. 6.

Since the mean diameter of magnesium stearate lot 11 is smaller than the average size of the various components contained in the formulation model, a film for-

mation of magnesium stearate occurs. This film can be seen on the surface of each individual granule. During compression, the film makes it difficult for interparticle bonding to occur. The particle–particle contact points are weak. During the hardness test, the failure of the tablet occurred at the weak points within the compact. Subsequently, the fault propagation occurred along these particle interfaces. It follows that the cross section of the fractured tablet shows the irregularities reminiscent of the particle pattern (Fig. 6, bottom left). In contrast, the mean diameter of magnesium stearate lot 21 is within the same range as that of the formulation components. Therefore, coating of the granules is unlikely to occur. Interparticle bonding takes place. During the fracture of the tablet, the crack propagated through a homogeneous structure. Consequently, the resulting cross-section picture shows a smooth surface, suggesting failure through the individual particles and not around their boundary (Fig. 6, bottom right).

To confirm the importance of magnesium stearate particle size on its lubricant properties, we reduced the mean diameter of a magnesium stearate lot from 3 to 1
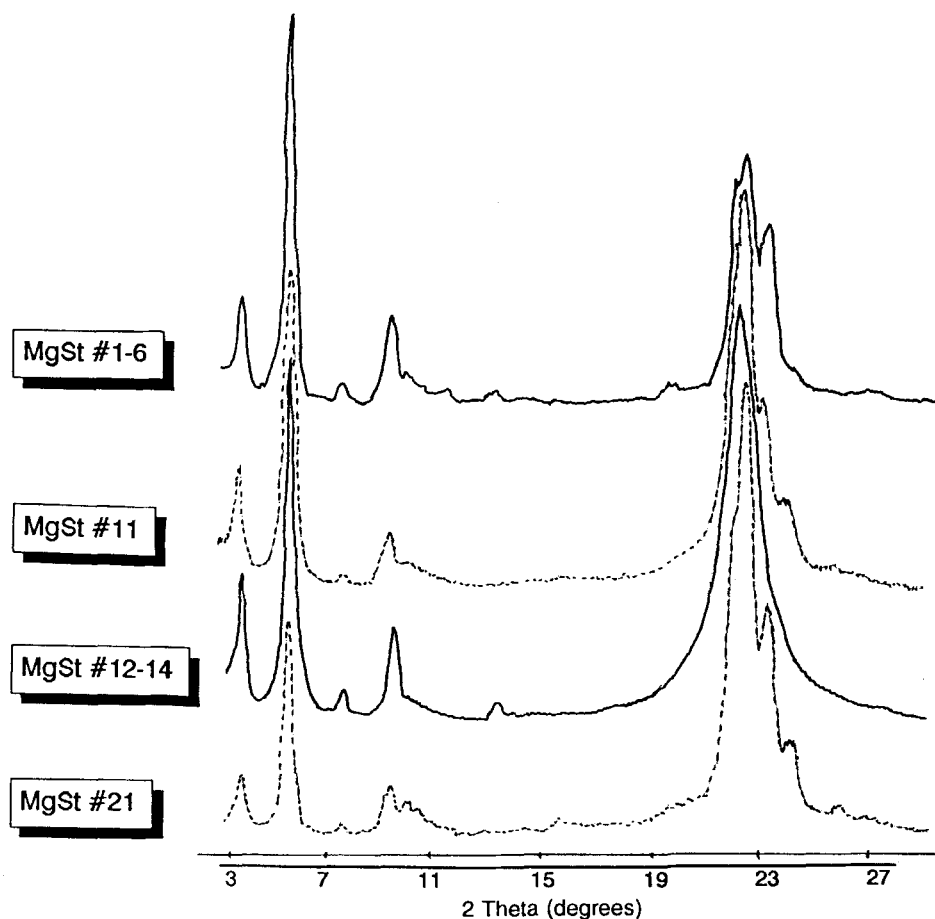
Figure 4. X-ray dfifractograms of various magnesium stearate lots.

μm using a GEM T-X laboratory mill. The lubricant properties of the new lot obtained were determined and compared with the original lot (Fig. 7). Results are presented as a percentage of variation from the original lot. For applied forces of 7 and 20 kN, the reduction of the magnesium stearate mean diameter permits an improvement of its lubricant properties (increase of axial transmission ratio, decrease of radial transmission ratio, residual and ejection forces) which is explained by a better film formation. This improvement of the lubricant

properties also produces an increase of the deleterious effects of magnesium stearate (increase of elastic energy, decrease of tablet tensile strength). To establish that the variations observed with the modified lot were only coming from the modification of the particle size, its physical properties (such as DSC, TGA, x-ray diffraction) were determined and compared to the results obtained with the original lot. No modifications were observed except a shift to lower temperatures of the DSC and TGA patterns because of faster thermal exchanges

Table 2

Influence of the Physicochemical Properties of Magnesium Stearate on its Lubricant Properties

		Magnesium Stearate Lot No.							
		2	3	11	21	2	6	11	16
		A	A	B	C	A	A	B	B
Vendor		2.7	2.7	1.0	3.1	2.7	2.3	1.0	1.2
Particle size (μm)	Upper	7.3	7.8	8.5	4.3	7.3	8.3	8.5	5.4
Specific surface (m²/g)	Force								
DSC, TGA, x-ray diffraction	(kN)	Identical		Different		Identical		Different	
Axial transmission	7	0.82	0.82	0.85	0.76	0.82	0.84	0.85	0.85
	20	0.87	0.87	0.89	0.83	0.87	0.87	0.89	0.89
Radial transmission	7	0.19	0.19	0.12	0.22	0.19	0.17	0.12	0.12
	20	0.19	0.20	0.11	0.24	0.19	0.19	0.11	0.13
Residual force (N)	7	48	54	35	190	48	30	35	37
	20	27	28	27	132	27	33	27	31
Ejection force (N)	7	254	251	215	384	254	250	215	232
	20	321	315	267	347	321	289	267	281
Tablet tensile strength	7	0.13	0.13	0.09	0.16	0.13	0.12	0.09	0.10
(kP/mm²)	20	0.32	0.32	0.22	0.36	0.32	0.31	0.22	0.24
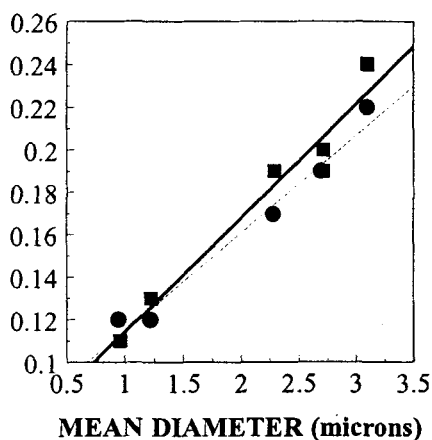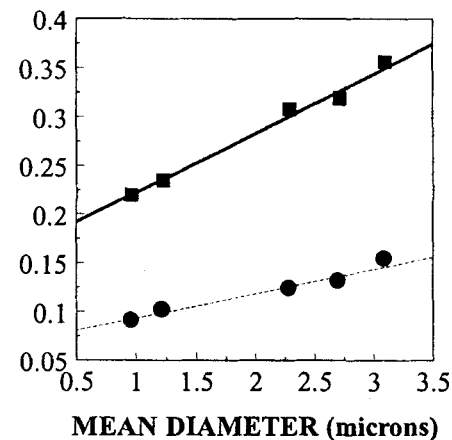
Figure 5. Influence of magnesium stearate mean diameter on radial transmission and tablet tensile strength.
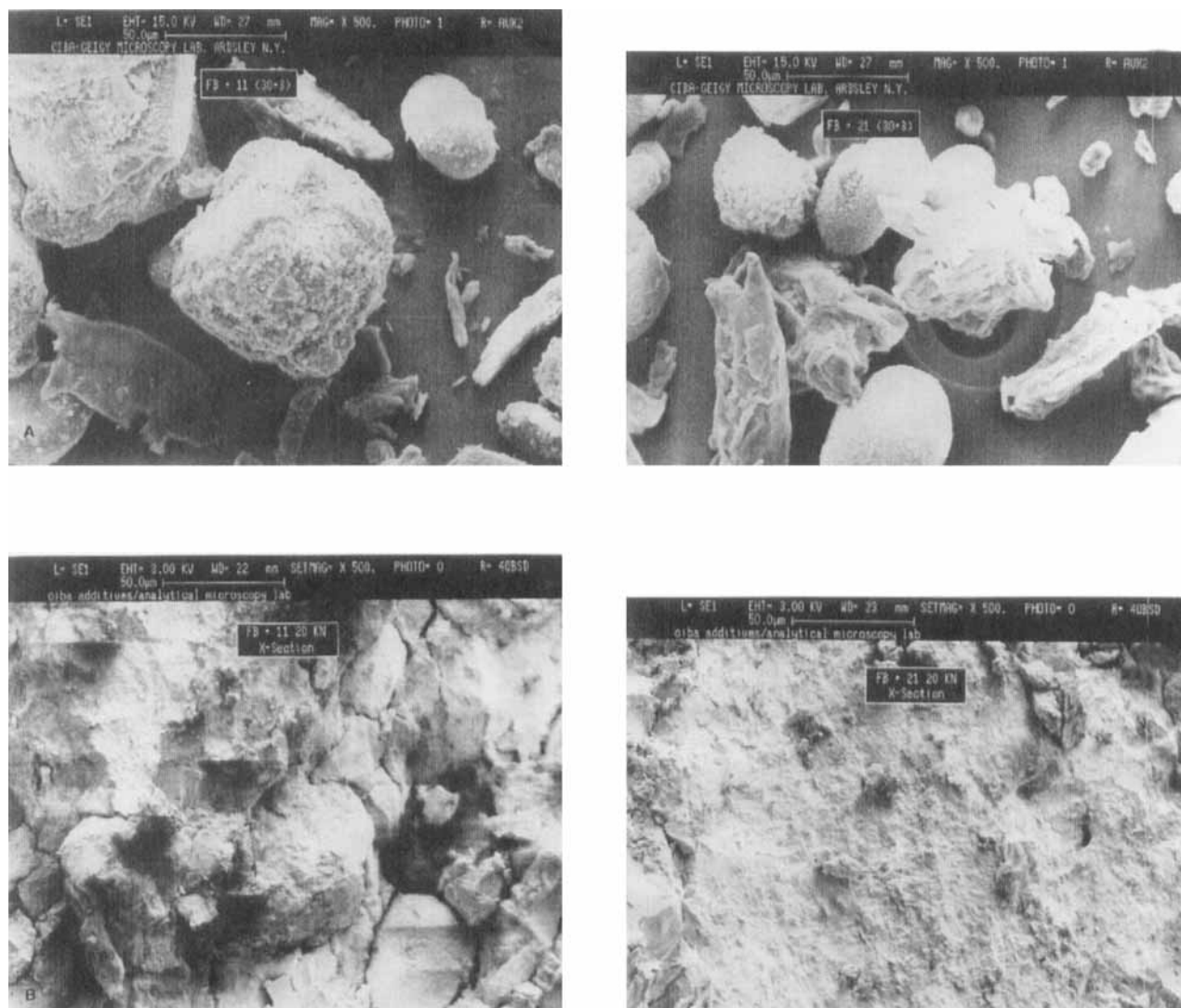
Figure 6. Scanning electron micrographs: (top) formulation model blended with magnesium stearate lots 11 and 21; (bottom) cross sections of the resulting tablets.

due to the decrease in the particle size. The absence of crystal modification during the milling lies in the absence of heat generated during pulverization (13).

The fact that the mean diameter of magnesium stearate was the predominant factor on its lubricant properties does not mean that other parameters, such as wa-

ter (adsorbed or included in the crystal lattice), could not also interfere. To find the influence of the moisture content and the crystal hydrate form of magnesium stearate on its lubricant properties, magnesium stearate samples from lots 11 and 21 (respectively, having the smaller and larger mean diameters of the six lots tested)
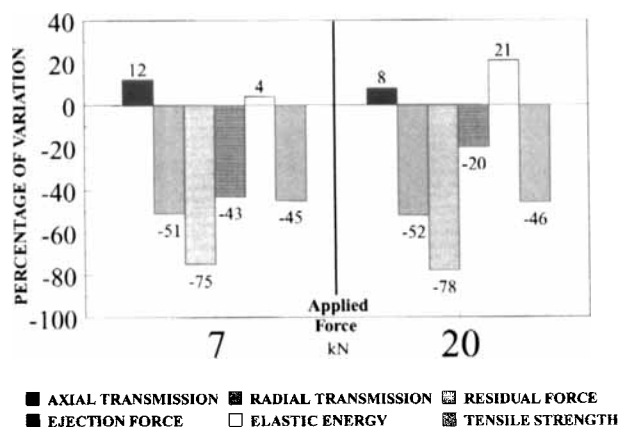
Figure 7. Influence of magnesium stearate mean diameter reduction on the compression parameters.

were stored for 55 days under 0% and 97% relative humidity at room temperature. New lot numbers were assigned to the lots exposed to these conditions (lots 111, 211: lots 11 and 21 stored under 0% relative humidity; lots 112, 212: lots 11 and 21 stored under 97% relative humidity). After 55 days, the weight pattern over time of the two lots placed under the two storage conditions had reached a plateau. X-ray diffraction and thermal analysis (DSC, TGA) were performed on lots 111, 112, 211, and 212, and compared to the results obtained with the lots 11 and 21 (Figs. 8 and 9). Results indicate that under a 0% relative humidity atmosphere, the adsorbed water is removed without effecting the crystal structure of lots 11 and 21. Under 97% relative humidity atmosphere, x-ray analysis results show a crystalline structure modification in the $2\theta = 19°$ area. This modification was confirmed by the DSC results, where a new peak appeared around 60°C, and by the TGA results, where the weight loss of magnesium stearate lots 112 and 212 occurred in three steps rather than two as seen with lots 11 and 21.

Compaction parameters and tablet characteristics obtained with the model formulation using magnesium stearate lots 111, 112, 211, and 212 at 7 and 20 kN were compared with a new series of experiment with lots 11 and 21. Results are reported in Table 3.

Results show that adsorbed water (lots 11 and 21 compared to lots 111 and 211) does not appear to be of great importance, especially at 20 kN, whereas the addition of a crystalline water molecule (lots 112 and 212 compared to lots 11 and 21) in an already dihydrate magnesium stearate structure seems to decrease the lubricant efficiency. The addition of a crystalline water molecule in the crystal lattice could change the properties of the magnesium stearate (such as packing or film formation abilities) as a result of transformation from orthorhombic and/or monoclinic structure into a crystal with a more hexagonal packing (4).

Magnesium stearate and talc are frequently used together in formulations. Magnesium stearate is used for its excellent lubricant properties but exhibits little glidant action whereas talc presents good glidant properties but is known as a poor lubricant (14). It was of interest to know if talc would influence the lubricant properties of magnesium stearate. To that end, we tried to determine if talc could increase or decrease the lubricant property differences of two magnesium stearate lots (11 and 21). These two were chosen because of their very different mean diameter. Magnesium stearate and talc were, respectively, used at concentrations of 2% and 3.5%. Five groups of tablets, containing different combinations of these two lubricants, were prepared using the formulation model. Differences between the compaction parameters obtained with lots 11 and 21 were compared to those obtained between T + 11 and T + 21. The variation between the differences was then calculated using the following formula:

$$\text{Variation} = \left(\frac{11T - 21T}{11 - 21} - 1 \right) \times 100$$

where $11T$ and $21T$ are the compaction parameter values obtained using talc and lot 11 and 21 as lubricants, respectively; 11 and 21 are the compaction parameter values obtained using lot 11 and 21 as lubricants, respectively.

Results, presented in Fig. 10, show that talc reduces the lubricant property differences between the two magnesium stearate lots tested. This effect comes from an improvement in the lubricant properties of the less efficient lot 21 and not by a reduction in the lubricant properties of the more efficient lot 11.
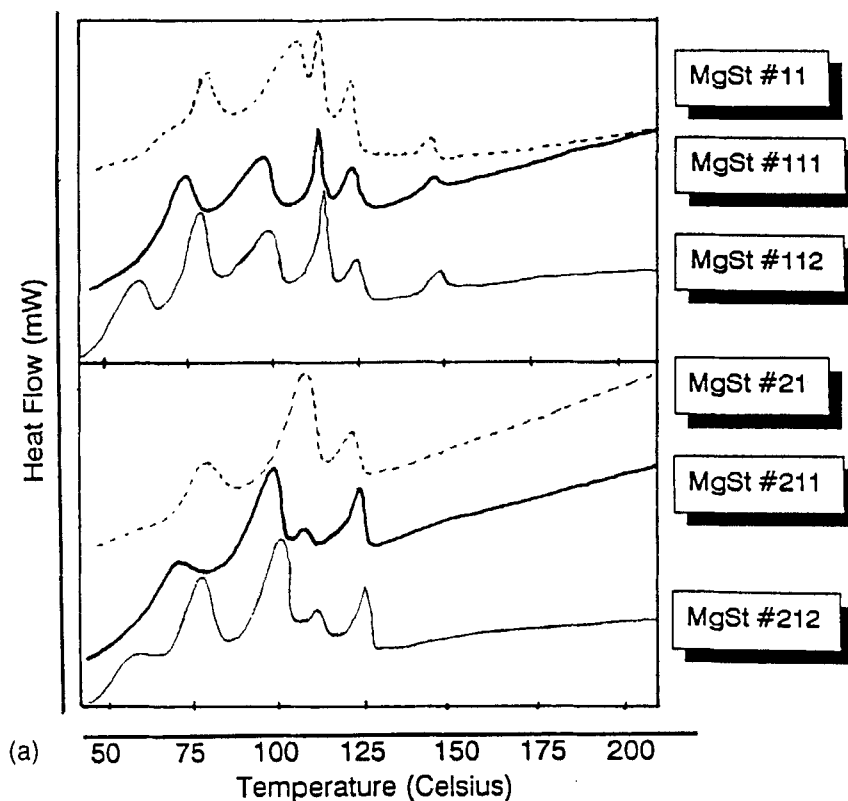
Figure 8. DSC (a) and TGA profiles (b) of magnesium stearate lots 111, 112, 211, and 212 (lots 111, 211: lots 11 and 21 stored under 0% relative humidity; lots 112, 212,: lots 11 and 21 stored under 97% relative humidity, 55 days, room temperature).

As previously described (15), when the amount of magnesium stearate is insufficient to coat the granulation particles, its preferential location is in the cavities of the granulation particles. This is the location of the very small quantity of fine particles of lot 21. During the blending operation, talc displaces magnesium stearate from these cavities and therefore promotes film formation. In contrast, almost all the particles of magnesium stearate lot 11 are fines, and the film is already achieved. The addition of talc leaves it almost unchanged.

CONCLUSION

Testing of each of 13 lots of magnesium stearate from three different vendors resulted in the following findings: (i) magnesium stearate supplied by different vendors are unlikely to present the same physical properties, and (ii) variations in physical properties can be expected to be found within lots of magnesium stearate supplied by the same vendor.

Six of these lots were tested in a NSAID formulation using a Stokes Single Station Instrumented F Press. It
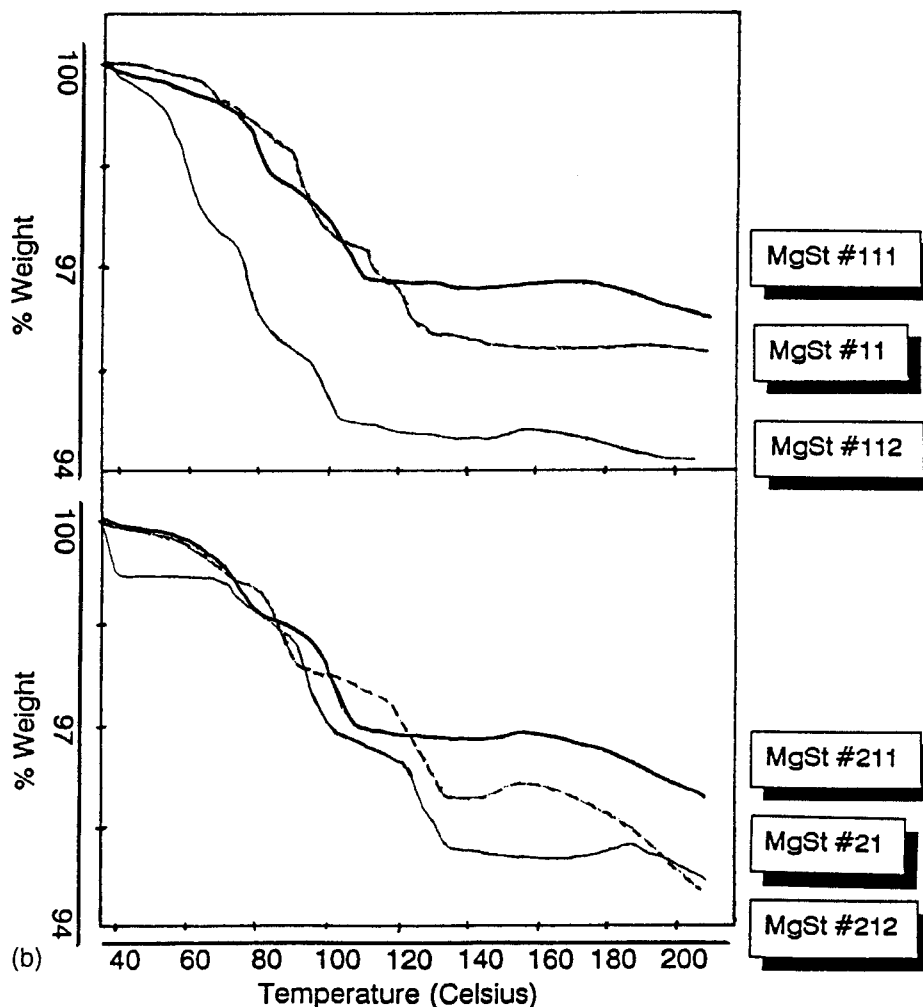
Figure 8. Continued

has been shown that the particle size mean diameter of a lot of magnesium stearate was the key factor influencing its lubricant efficiency. The crystalline structure also influenced the compaction characteristics of the formulation but with less of an impact than the mean diameter.

Two solutions could be suggested to reduce the impact of the variability of the particle size of magnesium stearate on the compaction properties of the model studied: utilization of a standardized magnesium stearate mean diameter and use of talc in association with magnesium stearate. Further studies should be performed to
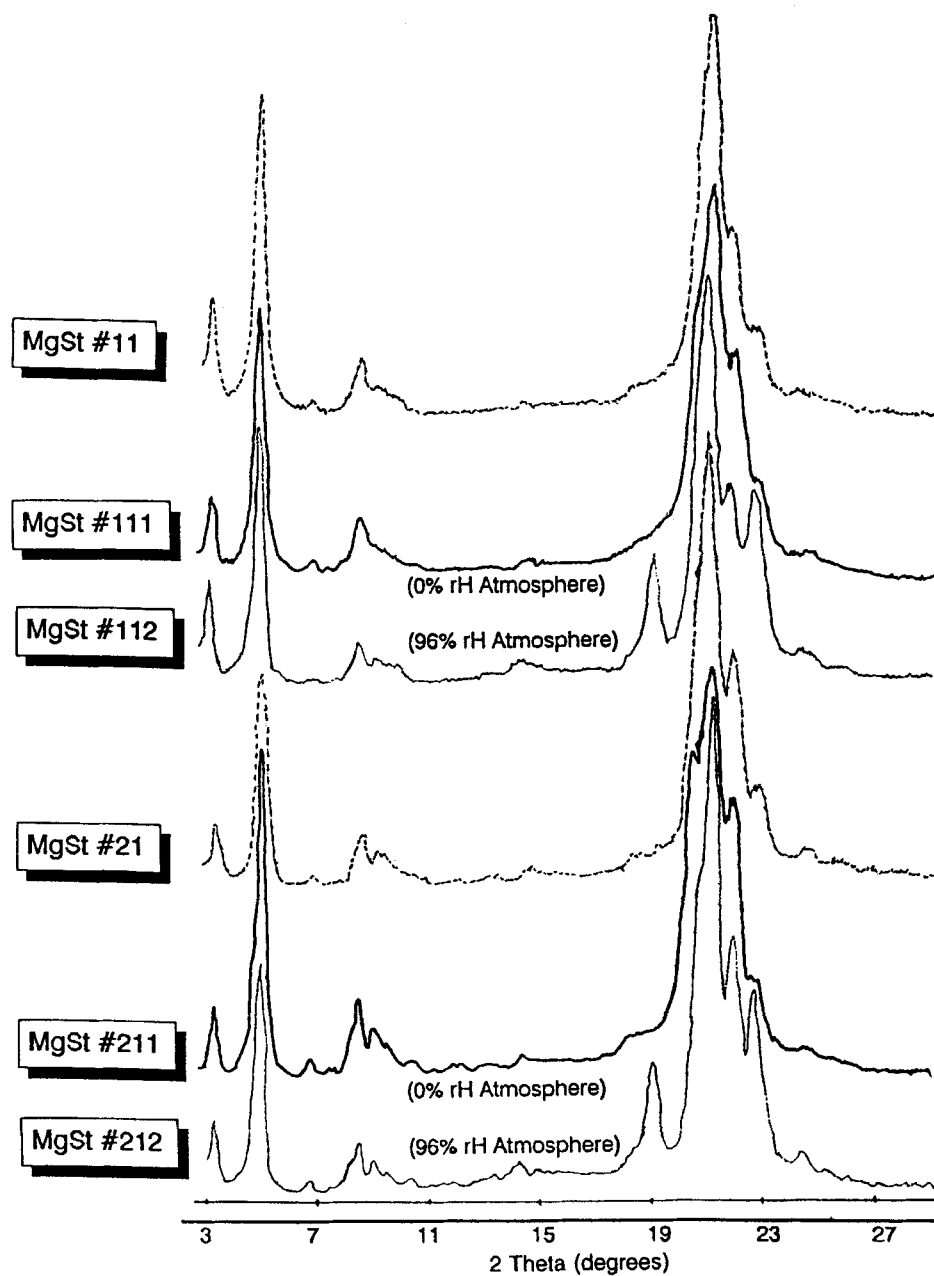
MgSt #11

MgSt #111

MgSt #112

(0% rH Atmosphere)

(96% rH Atmosphere)

MgSt #21

MgSt #211

MgSt #212

(0% rH Atmosphere)

(96% rH Atmosphere)

3   7   11   15   19   23   27

2 Theta (degrees)

Figure 9. X-ray diffraction variations of magnesium stearate lots 111, 112, 211, and 212 (lots 111, 211: lots 11 and 21 stored under 0% relative humidity; lots 112, 212: lots 11 and 21 stored under 97% relative humidity; 55 days, room temperature).

Table 3

Influence of Adsorbed Water (111, 211) and Crystalline Water (112, 212) on the Lubricant Properties of Magnesium Stearate

| DSC TGA X-ray diffraction	Upper Force (kN)	11 Different Different Identical	111	11 Different Different Different	112	21 Different Different Identical	211	21 Different Different Different	212
Axial transmission	7	0.90	0.90	0.90	0.89	0.83	0.85	0.83	0.78
	20	0.92	0.92	0.92	0.92	0.87	0.86	0.87	0.85
Radial transmission	7	0.11	0.11	0.11	0.14	0.18	0.19	0.18	0.21
	20	0.13	0.13	0.13	0.16	0.20	0.20	0.20	0.23
Residual force (N)	7	30	32	30	26	164	95	164	277
	20	30	31	30	23	133	116	133	168
Ejection force (N)	7	224	223	224	245	376	297	376	430
	20	277	279	277	275	408	356	408	438
Tablet tensile strength	7	0.10	0.11	0.10	0.11	0.14	0.16	0.14	0.16
(kP/mm^2)	20	0.22	0.23	0.22	0.23	0.35	0.35	0.35	0.36
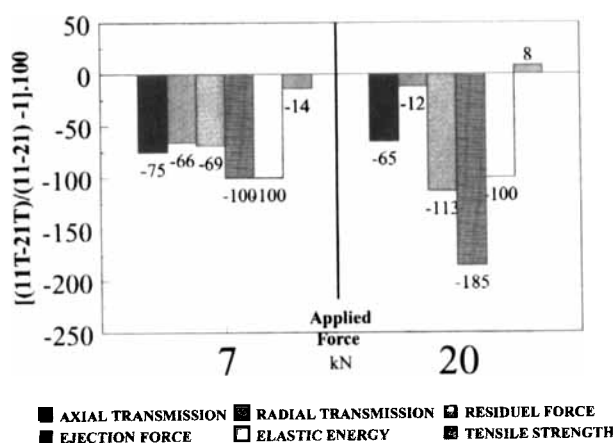
Figure 10. Influence of talc on the lubricant property differences between two magnesium stearate lots.

determine the nature of the bond between magnesium stearate and the granules. Van der Walls forces should be particularly studied.

ACKNOWLEDGMENTS

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