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The effects of humidity and storage time on the behavior of maltodextrins for direct compression

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Abstract

The effects of the relative humidity of the surrounding atmosphere on the powder and tablet properties of different types of physically processed maltodextrins were investigated. The maltodextrins' properties were affected due to moisture sorption and desorption. The density and flow behavior of the maltodextrins were influenced by the moisture content of the powder at the time of testing. Tablets of maltodextrin, after equilibration at 52.8% relative humidity, generally became smaller, denser, and stronger after transfer to low humidity conditions, while they became larger, less dense, and weaker when transferred to high humidity conditions. The effect of storage time on tablet properties of maltodextrins was that the crushing force values decreased with time. This was especially significant from the storage time period from immediately after ejection until 24 h after ejection from the die.

Keywords: Compaction; Humidity; Maltodextrin; Excipient; Storage time; Direct compression; Integrated compaction research system

1. Introduction

Maltodextrins are starch conversion products which are available as directly compressible filler/binder excipients. Parrott (1989) evaluated the maltodextrin, Soludex®, and found the material to have good flowability and compactability, however, decreased tablet strength was observed under elevated humidity conditions for formulations with the maltodextrin. Li and Peck (1990a,b) reported that the method of granulation had an influence on the physical properties of the maltodextrin particles behavior, and that the moisture content of the material exerted an effect on its compaction behavior. They examined moisture levels at relative humidities from 11 to 52%, and found the yield pressure to decrease with increasing moisture content and that the moisture greatly enhanced the plastic deformation of the powder under compression. Increasing the moisture content of the powder also increased the tensile strength of tablets made with maltodextrin. Papadimitriou et al. (1992) evaluated Maltrin M150,

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M500, and M700 maltodextrins in several formulations and observed that the mixtures exhibited excellent flow and compressibility. They also reported that storage of the tablets for 90 days at 45°C had almost no influence on tablet properties.

The changes in tablet strength with time after ejection from the die have been well studied. Rees and Shotton (1970) examined sodium chloride compacts and suggested that strength changes observed with time were due to time-dependent relaxation which provided stress relief within the compact. Alderborn and Ahlneck (1991) described changes in tablet strength with time for some materials, sucrose and sodium chloride, while no change was observed with other materials, calcium hydrogen phosphate dihydrate.

The aim of this work was to examine the effects of the relative humidity of the surrounding atmosphere on powder and tablet properties of several maltodextrins for direct compression. The effects of storage time on tablet properties were also investigated. Common filler/binder directly compressible excipients were used as 'standards' to better illustrate the changes which can occur with the materials on exposure to different relative humidity conditions, and to use for comparison purposes.

2. Materials and methods

The maltodextrins used were: Maltrin M510 lot no. A3533, dextrose equivalent = 9–12, which is a spray dried product, and Maltrin M500 lot no. 094906, dextrose equivalent = 9–12, which is a fluidized bed agglomerated product (both from Grain Processing Co.); Malta*Gran TG lot no. A1009, dextrose equivalent = 10, and Malta*Gran 10 lot no. A1500, dextrose equivalent = 10, which are fluidized bed agglomerated products (Zumbro/IFP Inc.); and Experimental Maltodextrin lot no. I2169X, dextrose equivalent = 15, which is a roller compacted material (Edward Mendell Co.). Experimental Maltodextrin is not yet a marketed product, and the final mean particle size has yet to be determined. Therefore, in this study, sieve cuts of Experimental Maltodextrin with a theoretical mean particle size of 182 μm were used since this was the target size for the final marketed product. The filler/binder excipients used for comparison studies included: Lactose USP Hydrous (Fast-Flo lactose), lot no. 1RM912 by Foremost Whey Products; Dextrates, NF, hydrated (Emdex), lot no. J22X by Edward Mendell Co.; dibasic calcium phosphate dihydrate (Emcompress), lot no. 3083X by Edward Mendell Co; and Corn Starch, NF, powder lot no. 30125H30 by Amend Drug and Chemical Co. Magnesium Stearate N.F., lot no. 2256KCCA by Mallinckrodt Co., was used as a lubricant. The materials were used as received.

Powder properties of the filler/binder excipients were determined for the materials alone. Compaction experiments were conducted after adding 0.5% magnesium stearate (w/w) as an internal lubricant by blending with the filler/binder excipient mixtures for 2 min in a Turbula T2C mixer (Glen Mills Inc., NJ). Humidity control was achieved by storing the materials in desiccators above saturated salt solutions, which maintained a specified humidity depending on the salt chosen, as per Nyqvist (1983). The excipients were initially dried in a vacuum oven at 80°C for 3–6 h until a loss on drying reading of less than 0.3% was achieved. The materials were then transferred above the saturated salt solutions for a minimum of 2 weeks prior to any testing. The salts used and their relative humidity were: 11.3% (lithium chloride), 30.7% (magnesium bromide), 52.8% (magnesium nitrate), 70.9% (strontium chloride), 75.3% (sodium chloride), 84.3% (potassium chloride), 97.3% (potassium sulfate). 0% humidity was maintained by storage above phosphorus pentoxide powder.

Differential scanning calorimetry (Delta Series DSC-7, Perkin-Elmer Co., Norwalk, CT) was performed at a scan rate of 10°C/min over the temperature range of 25–225°C.

The bulk and tap densities of the powders were determined (100 taps in 100 ml glass cylinder), while the true density was found by helium pycnometry (Multipycnometer Quantachrome Co., Syossett, NY). The densities were determined for the neat excipients as well as for the lubricated mixtures. The flowability of the pow-

ders was measured with an automated powder flow tester, (Powder Flow Tester, type PTG, Pharma-Test, Germany). The reported results for the density and flow experiments are a mean of three replicates.

The excipients, as powders, used in the storage time experiments were stored above 52.8% relative humidity for 2 weeks prior to compaction, then after compaction, the tablets were stored at the same humidity and tested at regular intervals. The initial testing, immediately after ejection, was performed within 2 min of ejection. The tablets were all compacted to 150 MPa mean pressure for comparison purposes.

The materials used in the humidity and storage time experiments were stored above 52.8% humidity for 2 weeks, then compacted into tablets. The tablets were then transferred to either 11.3 or 70.9% humidity chambers, and tested at regular intervals. The tablets were all compacted to 150 MPa mean pressure for comparison purposes.

The powders were compacted into tablets employing an Integrated Compaction Research Sys-

Table 1
Moisture content, flow and density results of the filler/binder excipient powders after storage at three relative humidity conditions

Excipient	Relative humidity (%)	Moisture content (%)	Flow rate (g/min)	Flow rate (ml/min)	Bulk density (g/ml)	Tap density (g/ml)
Emcompress	11.3	0.63	748	866	0.863	0.904
	52.8	0.32	749	883	0.848	0.921
	70.9	0.40	739	872	0.848	0.925
Fast-Flo Lactose	11.3	0.42	548	968	0.566	0.641
	52.8	0.24	505	881	0.574	0.659
	70.9	0.27	554	946	0.586	0.658
Emdex	11.3	0.54	510	815	0.625	0.674
	52.8	1.21	451	736	0.613	0.639
	70.9	1.46	460	732	0.629	0.653
Corn Starch	11.3	6.13	–	–	0.494	0.584
	52.8	10.13	–	–	0.530	0.593
	70.9	12.04	–	–	0.525	0.608
Experimental Maltodextrin	11.3	2.97	241	417	0.577	0.678
	52.8	7.68	237	436	0.544	0.645
	70.9	9.05	166	292	0.568	0.652
Maltrin M510	11.3	3.51	378	735	0.515	0.573
	52.8	8.75	363	759	0.478	0.537
	70.9	9.82	367	754	0.487	0.544
Maltrin M500	11.3	3.74	162	604	0.268	0.322
	52.8	8.41	166	643	0.259	0.315
	70.9	10.37	140	511	0.265	0.312
Malta*Gran 10	11.3	4.23	203	686	0.297	0.354
	52.8	8.45	188	665	0.283	0.341
	70.9	10.03	161	505	0.319	0.374
Malta*Gran TG	11.3	3.91	285	706	0.403	0.467
	52.8	8.93	263	707	0.372	0.434
	70.9	9.90	270	681	0.396	0.459

tem (Mand Testing Ltd, Stourbridge, U.K.) which utilized a 'sawtooth', i.e., constant velocity waveform, of double ended design operating at a punch velocity of 100 mm/s. This type of profile was chosen because it allowed all of the materials to be subject to the same punch velocity during the compaction event, without the need of adjusting the punch profiles for each material due to variations in the bulk densities. A standard flat-faced round 10.3 mm set of BB tooling was used. Comparisons between mixtures were made with the amount of powder compacted as 0.2 cm^3 in constant true volume at 0% porosity. The deformation of the system, i.e., punches, load cells, and other components in linear series with the punches, was accounted for by a 'punch on punch' method. Deformation of the upper and lower punch was determined up to 40 kN, and these values were then fitted to polynomial equations which best described the phenomena. These equations were then used to compensate for system deformation in order to obtain accurate displacement measurements during compaction testing.

The physical testing of the tablets was performed 24 h after ejection to allow for viscoelastic expansion. The physical measurements and tests included: weight (model 100A XE series, Denver Instrument Co., Arada, CO, U.S.A.); compact thickness and diameter, by micrometer (Material Control Inc., U.S.A.); and crushing force (VK 2000, VanKel Ind., Edison, NJ, U.S.A.). The reported values of crushing force (Newtons) and ejected tablet porosity (%) are a mean of 10 tablets.

3. Results and discussion

3.1. Effect of humidity on powder properties

Differential scanning calorimetry (DSC) results of maltodextrin powders after storage at 11.3 and 70.9% relative humidity conditions did not show any significant endothermic events. The maltodextrins all behaved similarly to corn starch, with a gradual peak seen near 100°C due to the desorption of water.

Table 1 shows the results of powder flow and density experiments at the three relative humidity conditions examined; 11.3, 52.8, and 70.9%. Emcompress, Fast-Flo lactose and Emdex were used as examples of commonly available directly compressible filler/binder excipients. Corn starch is a very poorly flowing material and would not flow, while its density increased slightly with increasing moisture content. Experimental maltodextrin was the maltodextrin most adversely affected by humidity, and exhibited decreased flow on exposure to increasing relative humidity conditions. The other maltodextrins were all affected by humidity to varying extent depending on the material.

The densities of the maltodextrins were higher at 11.3 and 70.9% humidity than at 52.3% humidity. A potential explanation of this phenomena could be because of packing effects at the lower and higher humidity conditions. Under low humidity conditions, low cohesive effects would occur due to minimal sorbed moisture and very efficient packing would develop. At high humidity conditions, cohesive effects would be significant, however, water has been sorbed to a great extent and adds weight to the material, thus causing a higher density to be observed. At the midrange humidity, cohesive effects would be evident, however the water content is not significant enough to cause a high density.

The flow experiments indicated that the maltodextrins were all influenced by moisture load, due to moisture being picked up from he surrounding atmosphere and cohesive effects between particles caused low flow rates to be seen. Emdex was the other commonly used excipient which was also strongly influenced by the humidity level, and it experienced detrimental flow and density characteristics at high humidity because of cohesive effects due to sorbed moisture. The maltodextrins, when used as direct compression excipients, must be used in humidity controlled environments in order to avoid sorption of water and the resulting detrimental effects on powder flow. Fig. 1 is a sorption isotherm of all the maltodextrins tested. They exhibited very similar profiles to each other despite differences in their method of processing. The maltodextrin powders began to 'gel', by visual observation, after storage

for 2 weeks under relative humidity conditions greater than 75%.

3.2. Effect of humidity on compaction and post-compaction properties

The effect of the relative humidity of the atmosphere on the ejected tablet dimensions, weight and crushing force was investigated on tablets made from powder equilibrated above 52.8% humidity, and the results are shown in Table 2. Changes in the tablets' porosities, as well as their volume, were reported because the tablets sorbed/desorbed moisture from the atmosphere and experienced dimensional changes depending on the relative humidity conditions in the desiccator. Volume change is an important parameter to consider because the tablets often had both weight, due to water uptake, and dimensional changes simultaneously occurring. These phenomena allowed the examination of similar tablet porosities between the three humidity storage conditions, in spite of large differences in the tablets' weight, dimensions, and crushing force.

Emcompress was used as a reference material and the only change noted was a slight weakening of the tablets under the high humidity conditions. This result agrees with the findings of Ahlneck

Table 2
Effect of storage conditions, at three relative humidities, on compacted tablets of the filler/binder excipients (CF, crushing force; E, tablet porosity; V, tablet volume)

Excipient	Time (days)	11.3% humidity			52.8% humidity			70.9% humidity		
		CF (N)	E (%)	V (cm^3)	CF (N)	E (%)	V (cm^3)	CF (N)	E (%)	V (cm^3)
Emcompress	0	–	–	–	53.7 ± 2.2	27.1	0.256	–	–	–
	15	61.2 ± 4.1	30.7	0.260	60.8 ± 2.8	27.9	0.256	56.9 ± 3.3	28.1	0.256
	30	55.5 ± 5.4	28.4	0.256	63.9 ± 2.4	28.2	0.256	62.8 ± 5.1	28.5	0.256
	60	70.2 ± 5.6	28.5	0.256	68.8 ± 5.5	28.0	0.256	62.0 ± 1.6	28.4	0.256
Fast-Flo Lactose	0	–	–	–	67.7 ± 1.9	17.0	0.238	–	–	–
	15	64.9 ± 3.0	18.1	0.238	64.0 ± 3.0	18.2	0.238	69.2 ± 2.3	17.0	0.237
	30	74.3 ± 4.5	17.4	0.237	73.7 ± 3.5	18.3	0.238	90.6 ± 6.3	17.4	0.236
	60	83.0 ± 6.2	18.1	0.238	79.6 ± 4.0	18.0	0.238	97.3 ± 4.3	17.3	0.236
Experimental Maltodextrin	0	–	–	–	198.3 ± 3.5	12.2	0.225	–	–	–
	15	265.9 ± 25.1	10.7	0.222	161.2 ± 9.1	13.2	0.228	144.3 ± 6.1	12.0	0.239
	30	249.3 ± 13.0	10.5	0.219	133.4 ± 6.7	12.5	0.229	177.1 ± 9.1	6.9	0.230
	60	278.5 ± 16.2	10.6	0.220	119.6 ± 6.0	12.4	0.229	165.1 ± 10.3	4.0	0.226
Maltrin M510	0	–	–	–	102.8 ± 2.2	13.4	0.221	–	–	–
	15	98.6 ± 6.9	13.5	0.218	82.4 ± 3.5	17.4	0.230	64.9 ± 2.2	19.0	0.246
	30	111.2 ± 10.7	12.6	0.217	80.2 ± 3.4	16.8	0.230	64.9 ± 3.8	19.5	0.247
	60	111.0 ± 7.4	13.7	0.218	78.8 ± 3.1	16.3	0.230	66.3 ± 0.9	20.3	0.246
Maltrin M500	0	–	–	–	172.2 ± 2.3	9.4	0.214	–	–	–
	15	165.9 ± 21.8	8.6	0.212	123.0 ± 10.7	12.0	0.219	91.8 ± 10.6	14.2	0.234
	30	176.3 ± 9.4	9.2	0.209	107.5 ± 5.1	11.7	0.219	88.5 ± 8.8	14.0	0.238
	60	188.9 ± 14.1	8.7	0.210	107.5 ± 10.8	12.5	0.223	84.5 ± 11.3	14.1	0.235
Malta*Gran 10	0	–	–	–	168.9 ± 2.9	8.6	0.213	–	–	–
	15	150.4 ± 19.6	8.2	0.206	128.9 ± 9.7	9.5	0.216	89.2 ± 9.1	12.6	0.228
	30	162.6 ± 9.7	7.7	0.205	102.0 ± 8.8	10.0	0.214	100.0 ± 5.2	12.1	0.231
	60	197.9 ± 11.4	6.7	0.206	93.0 ± 4.0	9.9	0.214	102.4 ± 2.1	11.4	0.231
Malta*Gran TG	0	–	–	–	91.8 ± 3.8	12.8	0.217	–	–	–
	15	83.9 ± 11.0	11.6	0.214	69.2 ± 2.5	15.4	0.223	58.4 ± 7.9	17.9	0.239
	30	93.0 ± 6.1	12.0	0.213	70.0 ± 8.2	14.6	0.223	60.0 ± 4.1	17.6	0.240
	60	90.6 ± 5.9	13.4	0.211	71.8 ± 7.1	15.0	0.225	61.0 ± 10.0	18.9	0.239

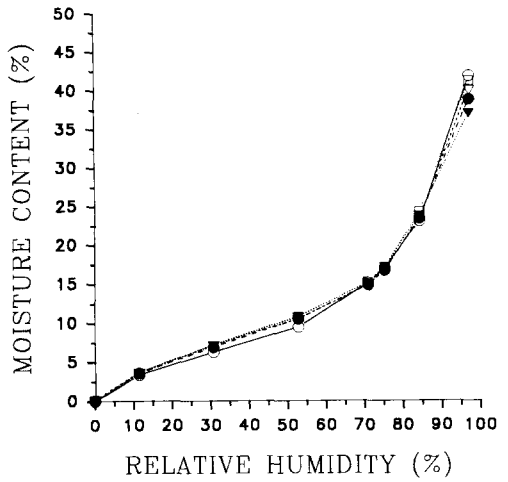

Fig. 1. Sorption isotherm of the maltodextrins. (○) Experimental Maltodextrin; (△) Maltrin M510; (▽) Maltrin M500; (●) Malta*Gran TG; (▼) Malta*Gran 10.

and Alderborn (1989) who found no change in the tablet strength of Emcompress at low humidity, while a decrease in strength was only seen at the highest humidity used (100% RH). Fast-Flo lactose exhibited slightly stronger tablets at 70.9% humidity, along with a slightly lower porosity and smaller tablet volume. The maltodextrins were all greatly affected by the relative humidity of the atmosphere in the chamber. The maltodextrins all followed a general trend of the tablets becoming smaller, denser and stronger at the low humidity conditions, while becoming larger, more porous, and weaker under high humidity conditions. This change became more pronounced with storage time at low and high humidity conditions, especially when compared with the initial tablet characteristics. There also was a time dependent effect on the three parameters measured.

The sorption, and desorption of water obviously affects the compaction and postcompaction properties of tablets. Chowhan (1980) studied the effect of moisture induced hardness increases with a wet granulation formulation. He found a reasonably linear relationship between the hardness increase and percent moisture loss. He theorized that the results indicated that the hardness increase in tablets mainly occurred due to partial moisture loss after compression, and that some of the solution (due to moisture) of the soluble excipients is forced into void spaces between compressed granules. Recrystallization of the excipients from the saturated solution results in the formation of bridges at the point of contact, leading to a hardness increase. Jones (1979) in a review paper described that moisture sorption can allow a material to solubilize, and that on desorption, the material can recrystallize and cake. For water soluble materials (i.e., sugar and salts), a solution of excipient occurs as a liquid bridge at high humidities, and following moisture desorption, can recrystallize to produce a solid bridge. Lordi and Shiromani (1984) examined crystalline salts and found that moisture had a significant effect on the tablet strength. They found that at high humidities, tablet strength decreased, and this phenomenon was attributed to the dissolving of interparticulate bonds. This resulted in separation of points of contact, and an overall decrease in magnitude of the molecular forces of attraction.

Although maltodextrins are primarily amorphous materials, the concept that water causes separation of points of contact is valid, and this could cause a weakening of intermolecular forces. These intermolecular forces would then be capable of increasing when moisture is removed, i.e., under low humidity conditions, causing distances between the particles to become closer, or at least no longer having the 'shielding' effect due to multilayers of water. At high humidity conditions, when water begins to form multilayers, soft weak tablets form, however, at low humidities, the multilayers evaporate leaving a lower number of water layers which allows increased tablet bond strength, as well as the significant effect of binding which occurs due to the dissolved excipient forming solid bridges on drying.

Tablet strength decreases have been reported by Alderborn and Ahlneck (1991) for saccharose tablets. The formation of thick multimolecular layers of water at the particle surfaces caused the intensity of the intermolecular attractive forces between the particle surfaces in the tablet to be disturbed, thus reducing tablet strength. This hypothesis could hold for the maltodextrins, since they sorb large amounts of water, especially at high humidity conditions. Experimental mal-

todextrin tablets exhibited the most unusual behavior at 70.9% humidity after 2 weeks of storage, and visual inspection of the tablets showed an opacity change from opaque white to translucent. The porosities also significantly decreased and the strength of the tablet increased. This occurred in spite of the fact that experimental maltodextrin powder did not change opacity on exposure to the same humidity conditions.

Table 3 lists the results of compaction testing of the maltodextrins and other excipients in which the powders were initially conditioned at two humidities, 11.3, and 70.9%. Emcompress was again used as a reference material, and only small changes in tablet behavior were noted as a result of humidity conditioning. Fast-Flo lactose formed significantly stronger tablets under low humidity conditions, than at high range humidity conditions. The compaction behavior of Emdex was similar to that of lactose in that stronger tablets were formed under the low humidity conditions than at the higher humidity conditions. Corn starch compacts had zero strength at 11.3% relative humidity conditions, but the compacts did have some slight strength at 70.9% humidity.

Tablet strength differences were due to the presence of water which influenced bonding within the tablet matrix. At low humidity, there is little water available, while as the water load increased, bonding between the points of contact was facilitated. Two possible reasons for the lower tablet crushing force at the high humidity conditions could be that hydrodynamic resistance might occur from the water during compression, and this energy might then be released on decompression, thus disrupting tablet bonds. The second potential reason is because water may dissolve some bonds, and weaken others so that in spite of attaining low tablet porosity, the tablets still had a low strength.

The deformation mechanisms of the powders used in this study were investigated using the Heckel equation (1961) which can be expressed in terms of porosity [ϵ] as:

$$\ln(1/(1-D)) = KP + A$$

where $1-D$ is the pore fraction or porosity (ϵ), P denotes the applied pressure, K is proportional to the reciprocal of the mean yield pressure (P_y) (Hersey and Rees, 1970), and A represents a function of the initial porosity.

Materials with a high yield pressure are classified as brittle fracturing or fragmentary, while materials with a low yield pressure are classified as plastic/elastic deforming substances.

The 'in die' results from Heckel plotting of experiments from Table 3 and the resulting calculated values of yield pressure are illustrated in Table 4. Emcompress showed only a slight change in its Heckel values as a result of the two different humidity conditions, as was expected from an insoluble fragmentary material. The maltodextrins all behaved similarly to each other, with an increased moisture load from storage under high

Table 3
Effect of the powder storage and subsequent compaction at two different relative humidity conditions and the resulting tablet properties of crushing force and porosity

Excipient	11.3% humidity		70.9% humidity	
	Crushing force (N)	Ejected tablet porosity (%)	Crushing force (N)	Ejected tablet porosity (%)
Experimental Maltodextrin	56.7 ± 3.5	22.2	134.1 ± 9.8	7.7
Maltrin M510	40.4 ± 1.6	22.2	88.1 ± 3.0	5.1
Maltrin M500	74.1 ± 4.7	20.1	105.9 ± 8.5	4.0
Malta* Gran TG	43.7 ± 6.6	22.3	94.6 ± 12.6	4.7
Malta* Gran 10	80.0 ± 10.0	19.7	119.9 ± 12.4	2.7
Fast-Flo Lactose	85.3 ± 2.7	15.7	70.3 ± 4.4	15.3
Emdex	195.5 ± 32.3	13.6	126.0 ± 11.8	13.2
Emcompress	56.0 ± 2.2	23.0	58.0 ± 3.6	22.1
Corn Starch	0.00 ± 0.0	27.4	17.3 ± 7.6	19.0

Table 4
Yield pressures (MPa) of the filler/binder excipients which were stored at two different relative humidity conditions

Excipient	11.3% humidity	70.9% humidity
Experimental Maltodextrin	157	82
Maltrin M510	104	55
Maltrin M500	86	49
Malta*Gran TG	101	61
Malta*Gran 10	98	43
Fast-Flo Lactose	186	177
Emdex	142	135
Emcompress	327	310
Corn Starch	114	64

humidity conditions causing an increase in the plasticity of the powder, as shown by the decreases in yield pressures. The low humidity conditions caused the materials to have the most brittle behavior, while increasing the moisture load caused the materials to plastically deform to a much greater extent. This behavior was also seen with the parent material of the maltodextrins, corn starch. It should be borne in mind that yield pressure, as calculated by the Heckel method is a comparative, not absolute value.

3.3. Effect of storage time on compact properties

Fig. 2 and 3 are graphs showing tablet crushing force changes with time when the tablets were stored above 52.8% relative humidity conditions. Fig. 2 shows the results for a storage time period of up to 90 days, while Fig. 3 is the initial region of Fig. 2 in expanded form. Emcompress was used as a standard reference material, and only a slight change in tablet crushing force with time was noted. Fast-Flo lactose was originally also used as a reference, however, it exhibited an almost constant increase in crushing force with storage time, especially for the 24 h period of immediately after ejection until 1 day after ejection.

The maltodextrins all displayed a completely different type of profile as compared to Emcompress or Fast-Flo lactose, with significant decreases in crushing force occurring from the time period of immediately after ejection until 1 day

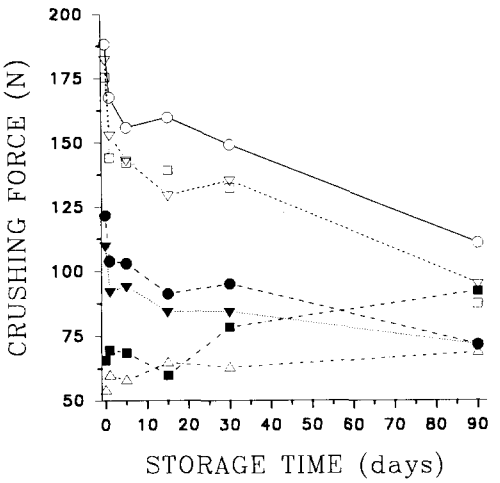

Fig. 2. Storage time vs tablet crushing force for the filler/binder excipients (RH = 52.5%). (○) Experimental Maltodextrin; (□) Maltrin M510; (▽) Maltrin M500; (●) Malta*Gran TG; (▼) Malta*Gran 10 (△) Fast-Flo lactose; (■) Emcompress.

after ejection. The maltodextrins continued to experience crushing force decreases even up to the final test point at 90 days storage. The initially weaker tablets made from Maltrin M510 and Malta*Gran TG showed the least slope decrease from the plotting of crushing force vs storage time as compared to the other, initially

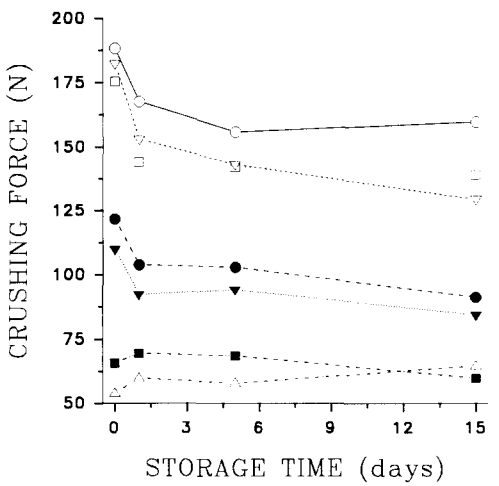

Fig. 3. Expanded initial region, 0–15 days, of Fig. 2 (RH = 52.5%). (○) Experimental Maltodextrin; (□) Maltrin M510; (▽) Maltrin M500; (●) Malta*Gran TG; (▼) Malta*Gran 10 (△) Fast-Flo lactose; (■) Emcompress.

much stronger maltodextrins. This small change in crushing force explains why the results of Papadimitriou et al. (1992) demonstrated no change in tablet strength with time. Their crushing strength values of 39.2–58.8 N showed little loss of strength with storage time, and the results of this study showed only a small loss of crushing force with time especially when tested after the 1 day time period data point.

Fig. 4 and 5 are plots of the ejected tablet porosity vs storage time and they help to explain some of the crushing force decreases shown in Fig. 2 and 3. Emcompress and Fast-Flo lactose are primarily brittle materials, and so would be expected not to have much change in tablet porosity occur with time, whereas the plastically deforming materials should experience time dependent viscoelastic expansion after ejection from the die. The roller compacted maltodextrin was the most fragmentary of the maltodextrins examined, and it correspondingly had the smallest change in tablet porosity with storage time of the maltodextrins.

Changes in tablet strength with storage time have been examined by Nystrom and Karehill (1986) with sodium chloride, and they suggested that the increase in compact strength with time could be due to two separate bonding mechanisms. The initial strength would be due to one bonding mechanism, followed by a time dependent increase in strength due to a continuous formation of bonds of the second type of bonding. The maltodextrins examined in this study all had an initial rapid increase in tablet porosity, from the time period of immediately after ejection until 1 day after ejection, after which only small changes in porosity were seen. This initial change was probably due to viscoelastic expansion of the material and can explain the large loss in crushing force which was seen during that time period. The porosity changes observed after 1 day were slight, and were not sufficient to explain the consistent maltodextrin tablet crushing force decreases with time. Bonds weakened within the tablet without concurrent changes in tablet size or other gross changes, such as to cause an increased tablet porosity. A time dependent particle deformation mechanism occurred within the tablet in order for the crushing force decreases to be measured.

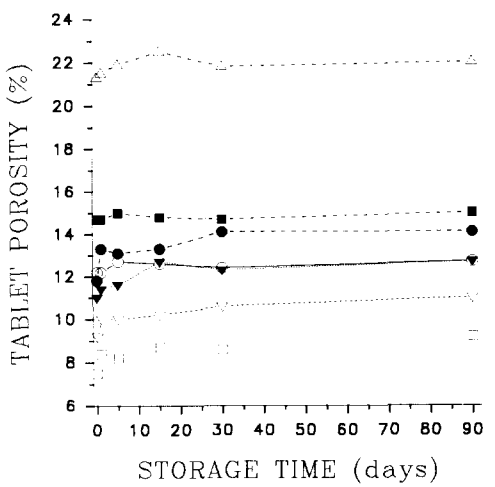

Fig. 4. Storage time vs tablet porosity for the filler/binder excipients (RH = 52.5%). (○) Experimental Maltodextrin; (□) Maltrin M510; (▽) Maltrin M500; (●) Malta*Gran TG; (▼) Malta*Gran 10 (△) Fast-Flo lactose; (■) Emcompress

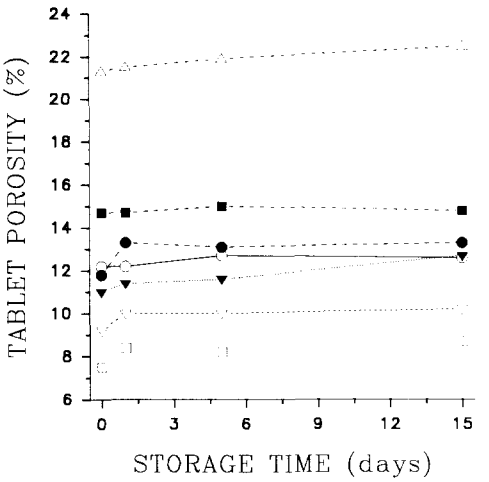

Fig. 5. Expanded initial region, 0–15 days, of Fig. 4 (RH = 52.5%). (○) Experimental Maltodextrin; (□) Maltrin M510; (▽) Maltrin M500; (●) Malta*Gran TG; (▼) Malta*Gran 10 (△) Fast-Flo lactose; (■) Emcompress.

4. Conclusions

Maltodextrins appear to sorb and desorb moisture from the atmosphere to a significant extent,

and this water is held as unbound water. The moisture content of the maltodextrins strongly influences its compaction behavior and post-compaction characteristics.

Exposure of maltodextrin tablets, equilibrated to 52.8% relative humidity, to changes in the relative humidity of the atmosphere caused the maltodextrins to become smaller, denser, and stronger when exposed to the low humidity conditions. The tablets became larger, more porous, and weaker at the high humidity conditions.

Compaction behavior of the maltodextrins was more fragmentary under low humidity conditions, while becoming primarily plastically deforming as the humidity, and subsequently moisture content, was increased.

The maltodextrins all exhibited decreased tablet crushing force with storage time, which could only be partially explained by the concurrent change in tablet porosity.

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