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Research Article

Maltodextrin: A Novel Excipient Used in Sugar-Based Orally Disintegrating Tablets and Phase Transition Process

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Abstract. The recent challenge in orally disintegrating tablets (ODT) manufacturing encompasses the compromise between instantaneous disintegration, sufficient hardness, and standard processing equipment. The current investigation constitutes one attempt to fulfill this challenge. Maltodextrin, in the present work, was utilized as a novel excipient to prepare ODT of meclizine. Tablets were prepared by both direct compression and wet granulation techniques. The effect of maltodextrin concentrations on ODT characteristics—manifested as hardness and disintegration time—was studied. The effect of conditioning (40°C and 75% relative humidity) as a post-compression treatment on ODT characteristics was also assessed. Furthermore, maltodextrin-pronounced hardening effect was investigated using differential scanning calorimetry (DSC) and X-ray analysis. Results revealed that in both techniques, rapid disintegration (30–40 s) would be achieved on the cost of tablet hardness (about 1 kg). Post-compression conditioning of tablets resulted in an increase in hardness (3 kg), while keeping rapid disintegration (30–40 s) according to guidance of the FDA for ODT. However, direct compression-conditioning technique exhibited drawbacks of long conditioning time and appearance of the so-called patch effect. These problems were, yet, absent in wet granulation-conditioning technique. DSC and X-ray analysis suggested involvement of glass-elastic deformation in maltodextrin hardening effect. High-performance liquid chromatography analysis of meclizine ODT suggested no degradation of the drug by the applied conditions of temperature and humidity. Overall results proposed that maltodextrin is a promising saccharide for production of ODT with accepted hardness-disintegration time compromise, utilizing standard processing equipment and phenomena of phase transition.

KEY WORDS: disintegration time; maltodextrin; meclizine; orally disintegrating tablets; phase transition.

INTRODUCTION

The approach of orally disintegrating tablets (ODT) has recently gained much attention as a preferred alternative to conventional dosage forms (1–7). This approach aims at addressing potential issues of patient compliance, taking into account that these products can be ingested simply by placing them on the tongue. This dosage form is designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need for chewing the tablet, swallowing an intact tablet, or taking the tablet with water. This mode of administration would be beneficial to solve the problem of swallowing difficulty encountered by pediatric and geriatric patients, nauseated, psychiatric, bedridden patients, and those with parkinsonism (8–10). The main obstacles, however, encountered during ODT manufacturing include the high fragility of tablets necessitating the use of special packages and the employment of expensive equipment in the manufacturing process (10). These drawbacks are manifested in most ODT-developing technologies, particularly in Zydis tablets manufactured by freeze-drying technique (11).

Recently, few attempts were made to produce sugar-based ODT with the luxury of balanced hardness and disintegration characteristics (3,12–14). These involved the use of saccharides classified by Mizumoto *et al.* (13) into type I saccharides exhibiting low compressibility (*e.g.*, mannitol, lactose, xylitol, and erythritol) and type II with high compressibility (*e.g.*, maltose and trehalose). In most of these attempts, the concept of tablet conditioning has raised up (12–14). This concept involves the exposure of the tablets to specified conditions of temperature and humidity during which certain changes in the internal tablet structure take place. These changes that usually involve crystalline–amorphous transition lead to improvement of tablet hardness while keeping rapid disintegration. Nevertheless, many of the reported methods of preparation of sugar-based ODT with balanced hardness and disintegration characteristics involved a pre-compression treatment such as lyophilization or fluidized bed granulation usually to prepare the amorphous form of the saccharide (13,14). These are time-consuming and expensive processes that require special equipment.

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Maltodextrin is an amorphous saccharide prepared by controlled hydrolysis of corn starch with acid and/or enzyme. Some grades of maltodextrin were utilized as one of the excipients of ODT prepared by freeze drying (15). However, maltodextrin, although being an amorphous sugar, was not so far utilized in the field of sugar-based ODT and phase transition process.

Meclizine hydrochloride is an antiemetic drug indicated in the management of nausea and dizziness associated with motion sickness and vertigo-accompanying diseases affecting the vestibular apparatus (16). Meclizine can be, therefore, considered as a good drug candidate to be formulated in the form of orally disintegrating tablets, as nauseated patients may encounter problems in swallowing conventional tablets. The drug is currently available as conventional tablets taken in 25- or 50-mg doses at 1 to 2 h prior to a potential episode of motion sickness; thereafter, the dose may be repeated every 24 h for the duration of the journey. The drug exists as white or slightly yellowish crystalline powder of melting point ranging from 217° to 224° with decomposition. The drug is soluble 1 in 1,000 of water and 1 in 25 of ethanol (16).

The aim of the present work was to assess the potential of maltodextrin in production of meclizine sugar-based ODT without the need of special equipment and to investigate the potential of the prepared ODT formulations in achieving the desired compromise between hardness and disintegration time characteristics.

MATERIALS AND METHODS

Materials

Maltodextrin (Maltrin QDTM M500, a fluidized bed agglomerated material with DE=8–12) was obtained from Maltodextrin, Grain Processing Corporation, USA. D-Mannitol was obtained from Algomhoria Co., Alexandria, Egypt. Meclizine and croscarmellose sodium were kindly donated by Pharoania pharmaceuticals, Alexandria, Egypt. Talc and Aerosil were obtained from Alnasr pharmaceuticals, Alexandria, Egypt. All other reagents were of analytical grade and used as received.

Preparation of Maltodextrin-Based ODT

Seven ODT formulations, each weighing 500 mg, were prepared. Each formulation was composed of a mixture of mannitol and maltodextrin in different ratios as a base, "croscarmellose sodium" as a disintegrant, talc as a lubricant, and "aerosil" as glidant. Tablets were prepared by direct compression and wet granulation techniques. Tablet composition is shown in Table I.

Direct Compression

Ingredients of ODT formulations M1, M2, M3, and M4 (Table I) were mixed using a mortar and pestle. Powdered ingredients (except the lubricant; talc) were mixed using doubling up technique (geometric addition). Finally, talc was added and mixed with other components. Blend fractions, each weighing 500 mg, were then directly compressed using a single punch tablet machine (Erweka Appratebau, Gmbh, Frankfurt, Germany) equipped with flat-faced punches with a die diameter of 12 mm. Different adjustments of the machine settings were tried. The adjustment giving the highest possible hardness value giving an intact tablet (around 1 kg) with the highest accepted disintegration time (30–40 s) was selected and applied to all tablet formulations.

Table I. Tablet Formulations Prepared by Direct Compression (M1–M4) and Wet Granulation (M5–M8) Techniques

	Ingredients[a] (mg)		
Formula code	Meclizine	Mannitol	Maltodextrin
M1	0	402.50	50
M2	0	377.50	75
M3	0	352.50	100
M4	0	252.50	200
M5	0	427.50	25
M6	0	402.50	50
M7	0	352.50	100
M8	25	327.50	100

[a] All formulations contain 40 mg croscarmellose sodium, 5 mg talc, and 2.5 mg aerosil

Wet Granulation

Wet granulation process was carried out using low shear granulator (Hobart Corp., Troy, OH, USA). In each of the three ODT formulations (M5, M6, and M7), mannitol and half amount of croscarmellose sodium were homogeneously blended and granulated with maltodextrin solution to provide the required maltodextrin concentration (5%, 10%, or 20% *w*/*w*). Different maltodextrin solutions corresponding to the required concentrations were prepared in order to fix the water amount added to the powder blend. The wet granules were oven dried at 100°C, ground using a mortar and pestle, and sieved. The fraction of granules in the range of 70–300 μm was mixed with the second half of superdisintegrant, talc (1%), and aerosil (0.5%). Fractions, each weighing 500 mg, were then compressed using a single punch tablet machine, as mentioned above.

Post-compression Conditioning

ODT prepared by direct compression and wet granulation techniques were kept in Petri dishes, in an incubator, for 4 and 7 days respectively, at conditions of 40°C and 75% relative humidity. At specified time intervals, samples were withdrawn and tested for changes in hardness, disintegration time, tablet shape, or color.

Preparation of Sugar-Based Meclizine Orally Disintegrating Tablets

The effect of inclusion of meclizine hydrochloride on ODT characteristics was studied. Meclizine hydrochloride was then added to a selected formulation (M7) in a dose of 25 mg to prepare M8 formulation. Meclizine was co-ground with equal amount of mannitol, and the same steps of the wet granulation technique mentioned above were then followed.

Evaluation of the Prepared ODT

Measurement of Tablet Hardness

Tablet hardness test was performed using tablet hardness tester (Vankel PK 200, USA; loading rate 10 N/s, resolution 1 N). Results are expressed as mean tablet hardness (kg)±SD (n=3).

Measurement of In Vitro Disintegration Time

Assessment of *in vitro* disintegration time was carried out using the modified dissolution apparatus type II (Hanson Research Corp., Northridge, CA, USA) described by Bi *et al.* (17). One liter of water maintained at 37°C±0.5 and stirred at 100 rpm was used as the disintegration. The end point of disintegration was manifested as the disappearance of the last tablet fragment from the sinker. Results are presented as mean disintegration time±SD (n=3).

Differential Scanning Calorimetry

Differential scanning calorimetry (DSC) thermograms of selected samples were obtained using Differential Scanning Calorimeter (Perkin Elmer, Germany). Samples (10 mg) were accurately weighed, hermetically sealed in an aluminum pan, and heated at a constant rate of 5°C/min over a temperature range of 35°C to 270°C.

X-ray Powder Diffractometry

The X-ray powder diffraction patterns of selected samples were obtained using X- ray powder diffractometer (Jeol XRD, Japan). The radiation source was a copper (<lambda>=1.54184 A) high-intensity X-ray tube operated at 35 kV and 15 mA.

Dissolution Testing of Meclizine ODT

The test was carried out according to meclizine tablet monograph in USP 29 using dissolution apparatus type I. The dissolution medium was 900 ml, 0.01 N HCl maintained at 37°C±0.5 and stirred in the basket at 100 rpm. Aliquots of the dissolution medium (5 ml) were withdrawn at different time intervals (3, 6, 10, 20, and 30 min), replaced with equal volume of fresh dissolution medium, and analyzed ("after" proper dilution) spectrophotometrically at 232 nm, using dissolution medium as a blank. Test was done on meclizine-containing fresh and conditioned tablets in triplicates.

Drug Content and HPLC Assay

An high-performance liquid chromatography (HPLC) method for analysis of meclizine hydrochloride was developed to detect any drug degradation upon conditioning. Separation was performed on C8 column (octylsilane chemically bonded to totally porous silica particles of 5 μm particle size). Detection was achieved using UV–Visible detector at wavelength=232 nm. The mobile phase consisted of a mixture of solvent A and solvent B in a ratio of 2:8 respectively. Solvent A was composed of 0.7% w/v SLS as an ion pairing reagent and 1.43% v/v glacial acetic acid in freshly prepared distilled water filtered with a Millipore filter. The pH was adjusted to 4.3 with NH4OH solution. Solvent B was composed of 100% HPLC grade acetonitrile. The analysis was performed using isocratic conditions with 20% solvent A mixed with 80% solvent B at a flow rate of 1.2 ml/min. A volume of 150 μl of each sample was automatically injected into the analytical column. Samples were injected concurrently within the standard solutions injections.

A meclizine orally disintegrating tablet weighing 500 mg and equivalent to 25 mg meclizine was accurately weighed, finely powdered, and transferred into a volumetric flask. About 60 ml of the mobile phase was added, sonicated for 10 min, then shaken by mechanical means for 30 min and completed to 100 ml with mobile phase. Sonication and filtration using Millipore filter was performed. The drug content was determined using the abovementioned HPLC method. Test was performed on placebo, fresh, and conditioned meclizine ODT and repeated in triplicates.

RESULTS AND DISCUSSION

Effect of Maltodextrin Concentration on ODT Characteristics

Tablets Prepared by Direct Compression

The effect of maltodextrin concentrations (10%, 15%, 20%, and 40%) on the characteristics of ODT prepared by direct compression is described by data shown in Table II. Results show an increase in disintegration time with the increase in maltodextrin concentration, while keeping hardness values around 1 kg, which was insufficient for handling or transportation. The slight increase in hardness value 1.8 kg showed by formula M4 (40% maltodextrin) was accompanied by an unaccepted increase in disintegration time (80 s) that exceeded the limit specified by the FDA for ODT, which is less than 60 s (18). The high compressibility characterizing maltodextrin was not manifested in tablet hardness, which can be attributed to the light compression applied to maintain rapid disintegration, which is the main feature of this dosage form.

Tablets Prepared by Wet Granulation Technique

Results depicted in Table II reveal that wet granulation did not improve the hardness of the produced tablets as it

Table II. Effect of Maltodextrin Concentration on the Characteristics of the Prepared Tablet Formulations (n=3)

Formula code	Maltodextrin concentration (%w/w)	Hardness (kg)	Disintegration time (s)
M1	10	0.81±0.01	26±0.50
M2	15	0.80±0.03	35±0.71
M3	20	1.21±0.02	40±0.82
M4	40	1.81±0.05	80±1.53
M5	5	0.90±0.02	35±2.01
M6	10	1.20±0.01	37±2.30
M7	20	0.80±0.03	42±2.72

would be expected. This could be again attributed to the light compaction employed to keep rapid disintegration.

The abovementioned results inferred that during preparation of sugar-based ODT formulations, the achievement of rapid disintegration would be on the cost of hardness and *vice versa*. These results are endorsed by those found by Mizumoto *et al.* (13) and Sugimoto *et al.* (14). The effect of conditioning as a post-compression treatment on the characteristics of the prepared ODT was then investigated.

Effect of Tablet Conditioning on ODT Characteristics

It has been reported in the studies based on conditioning that an amorphous form of the saccharide should exist and a phase transition, manifested as crystalline–amorphous transition, usually occur (13,14). In the current investigation, selected maltodextrin-based ODT formulations prepared by both direct compression and wet granulation techniques were subjected to conditions of 75% relative humidity and 40°C for 4 and 7 days, respectively.

Conditioning of ODT Prepared by Direct Compression Technique

Three ODT formulations (M1, M2, and M3) containing different maltodextrin concentrations (10%, 15%, and 20%, respectively) were selected for further investigation. ODT with higher maltodextrin concentration (M4, 40%) was excluded from the study as it exhibited unaccepted increase in disintegration time (80 s) in the abovementioned study. Selected formulations were subjected to conditions of 75% relative humidity and 40°C for 4 days. Results are shown in Table III. It was observed that hardness increased with conditioning time. The magnitude of this increase was more pronounced at higher maltodextrin concentration. This was indicated by the hardness value of M3 formulation (20%) after 24 h (5 kg) compared to that of M1 and M2 formulations (1.9 and 1.8 kg, respectively). Regarding disintegration time, it was nearly unaffected and remained within the accepted range (about 30 s) for M1 and M2. However, M3 formulation showed an unaccepted increase in disintegration time (80 and 100 s) parallel to that in hardness values 5 and 7 kg after 1 and 4 days of conditioning, respectively.

The increase in hardness of maltodextrin-based ODT upon conditioning (that was called maltodextrin hardening effect) could be explained by the phase transition phenomena of amorphous sugars. This is consistent with the amorphous nature of maltodextrin that was presumed to give the chance for phase transition to occur. The amorphous nature of maltodextrin is reported among its different grades (19). However, the increase in hardness of maltodextrin-based ODT after conditioning was accompanied by the appearance of transparent aggregates or patches on the surface of tablets. This effect was observed to be more pronounced towards higher maltodextrin concentration (20%) and was parallel to the hardening effect. This was confirmed by M3 formulation that exhibited the most pronounced patch effect. These patches were presumed to be merely maltodextrin aggregates that could be considered as points of high hardness irregularly distributed in the tablet matrix and responsible for the increase in tablet hardness. Nevertheless, they were so hard that tablets required chewing rather than licking. In addition, they would impart grittiness during oral disintegration. In the present study, these aggregates were described as "patch effect of maltodextrin." The hardening and patch effects of maltodextrin will be studied in details later on.

Conditioning of ODT Prepared by Wet Granulation Technique

Regarding maltodextrin saccharide, three different formulations prepared by wet granulation technique (M5, M6, and M7), containing different concentrations of maltodextrin (5%, 10%, and 20%, respectively), were subjected to conditioning process. Results are shown in Table IV. An increase in hardness of maltodextrin containing tablets with conditioning time was noticed. The magnitude of such increase was more pronounced towards high levels of maltodextrin. Consequently, tablets with hardness (3 kg) and disintegration time (41 s) were obtained after 1 day of conditioning M7 formula containing 20% maltodextrin. The patch effect in M7 formulation is demonstrated via comparison between Figs. 1 (before conditioning) and 2 (after conditioning).

Compared to direct compression, conditioned tablets prepared by wet granulation technique exhibited the advantage of absence of "patch effect." This may be explained by taking into account that maltodextrin in wet granulation technique is used as a granulating liquid and not in the solid form utilized in direct compression technique. Consequently, after the drying step, maltodextrin particles were presumed to be well distributed in the tablet matrix in a finely molecular state; thus, large aggregates upon conditioning were not expected to appear.

Maltodextrin Hardening Effect

The following is a study aiming to explain the changes that maltodextrin underwent during preparation and conditioning process and which led to the increased hardness of maltodextrin-based ODT prepared by wet granulation-con-

Table III. Effect of Conditioning on the Characteristics of Tablets Prepared by Direct Compression

	Tablet characteristics at different conditioning times (days)					
	Hardness (kg)			Disintegration time (s)		
Formula code (maltodextrin %*w*/*w*)	0	1	4	0	1	4
M1 (10%)	0.80±0.02	1.90±0.02	2.62±0.04	26±0.80	29±0.30	32±0.32
M2 (15%)	0.81±0.01	1.80±0.03	3±0.20	30±0.71	31±0.41	33±0.61
M3 (20%)	1.10±0.02	5±0.30	7±0.51	40±0.40	80±0.92	100±0.80

Table IV. Effect of Conditioning on the Characteristics of Tablets Prepared by Wet Granulation

	Tablet characteristics at different conditioning times (days)					
	Hardness (kg)			Disintegration time (s)		
Formula code (maltodextrin %*w*/*w*)	0	1	7	0	1	7
M5 (5%)	0.90±0.02	1.70±0.01	1.71±0.02	31±0.30	32±0.22	31±0.32
M6 (10%)	1.20±0.06	2.30±0.02	2.30±0.02	37±0.12	35±0.21	37±0.21
M7 (20%)	0.90±0.02	3±0.01	3.52±0.04	42±0.40	40±0.50	44±0.02

ditioning process. Selected samples were analyzed by DSC and X-ray diffraction measurement.

Differential Scanning Calorimetry

DSC thermograms for fresh, treated, and conditioned maltodextrin powder samples, obtained over a temperature range from 35°C to 270°C, at a heating rate of 5°C/min, are depicted in Fig. 3. Untreated sample (F1) was maltodextrin fresh powder as supplied. Treated sample (F2) is a solution of maltodextrin prepared in the same concentration used in tablets as a granulating liquid, poured into a Petri dish, and dried at 100°C for 30 min. Conditioned sample (F3) consisted of treated maltodextrin powder subjected to the same conditioning process of ODT (75% RH, 40°C) for 24 h. It is worthy to note that melting point is varying among different grades of maltodextrin. To the best of our knowledge, no reports for Maltrin M500 melting point are available. Therefore, visual inspection of the heating process in the selected heating range was performed by following the heating process of fresh maltodextrin powder in a Petri dish in an oven. It was observed that maltodextrin powder did not melt till a temperature of 220°C, at which charring began without melting. Consequently, endothermic peaks appearing in the thermograms before 220°C were expected to be corresponding to elution of water content.

Maltodextrin fresh powder (Fig. 3, F1) showed a low-intensity broad peak at 37–123°C that decreased in treated maltodextrin thermogram (Fig. 3, F2). This peak was mostly due to evaporation of loosely bound water. The decrease in its intensity in treated sample thermogram (F2) may be attributed to the drying step. However, in the thermogram of conditioned powder (Fig. 3, F3), this peak appeared with a lower intensity than untreated and treated samples. In addition, a new peak was noticed at 160°C that did not appear in the thermograms of other forms of maltodextrin. This may be attributed to elution of strongly bound water in the structure of conditioned maltodextrin that required more heat for liberation. This peak may also be due to changes in the internal structure of maltodextrin by the action of conditioning. DSC results inferred that a change in maltodextrin form took place after conditioning, as indicated from different thermograms of the material before and after conditioning.

X-ray Diffraction Measurement

As a trial to explain the hardening effect imparted by maltodextrin upon conditioning, X-ray diffraction patterns of maltodextrin untreated (R1), treated (R2), and conditioned powders (R3) were obtained as shown in Fig. 4. Diffractograms of the three forms of maltodextrin powder confirmed the amorphous nature of the material that was evident by the diffused or hollow structure X-ray pattern (19). Results indicated no difference in crystallinity of the three forms and that maltodextrin retained its amorphous nature throughout treatment and conditioning process. However, although no difference in crystallinity among the fresh, treated, and conditioned forms was observed, this did not necessitate that the three forms possessed the same properties. This was supported by the results obtained by Papadimitriou *et al.* (19) who reported that different maltodextrin grades showed no difference in crystallinity, though differences in compressional behavior and degree of polymerization have existed. In the

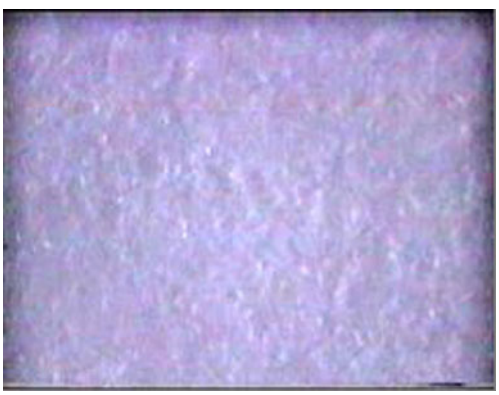

Fig. 1. Maltodextrin-based ODT prepared by direct compression before conditioning

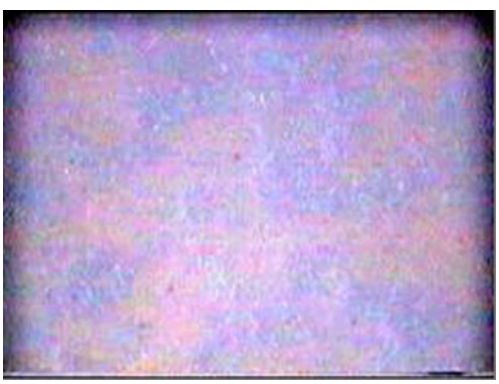

Fig. 2. Maltodextrin-based ODT prepared by direct compression after conditioning

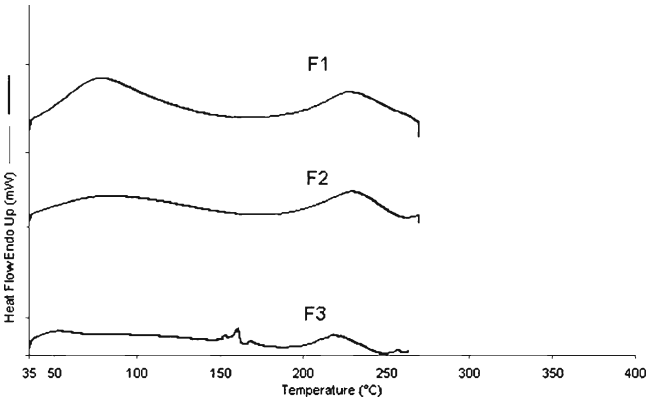

Fig. 3. DSC thermograms of *F1* untreated maltodextrin, *F2* treated maltodextrin, and *F3* conditioned treated maltodextrin samples

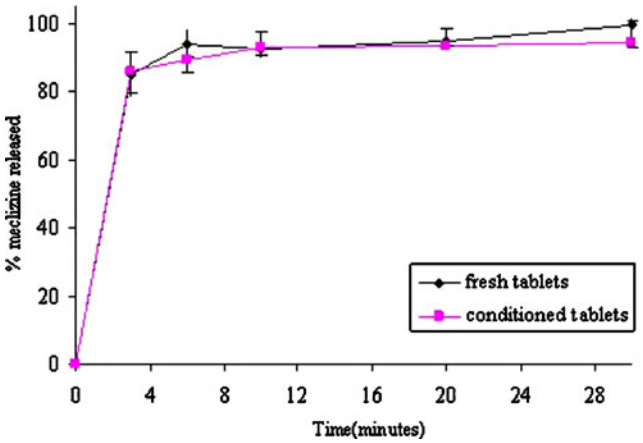

Fig. 5. Dissolution profile of fresh and conditioned meclizine tablets

present work, differences among the three forms were indicated from morphological shape and DSC thermograms. Regarding the difference in shape, untreated maltodextrin appeared as an opaque white powder, while the treated form was glassy and brittle. Conditioned maltodextrin, on the other hand, was less transparent glassy and pliable. Increased tablet hardness imparted by conditioned form compared to treated form suggested the existence of difference in cohesive property. In fact, the changes that the amorphous maltodextrin underwent under processing conditions of solubilization, drying, and subsequent conditioning could be explained by exploiting the phenomenon of phase transition. It was reported by Labuza (20) that when a sugar is in solution and is dried, it is in the amorphous glassy state. At high enough moisture or temperature, it is crossing over the glass transition temperature (Tg), and the material then can enter the rubbery state. This phenomenon is noticed within amorphous sugars picking up moisture, which act as a plasticizer and greatly influence the free volume. This will subsequently result in a decrease in Tg to or below the operation temperature. In the rubbery state, dried amorphous sugars tend to diffuse rapidly because of increased diffusion rates above Tg, a condition resulting in particle caking that was manifested, in the present work, as a patch effect. It has been reported by Sperling (21) that significant changes in the local movement of polymer chains take place at the Tg, resulting in a number of property difference between the two phases. Viscosity, for example, drops dramatically to allow greater chains mobility. In addition, the free volume is believed to increase substantially due to increase in thermal expansion coefficient (22). Such increase in free volume will allow faster diffusion of particles in the rubbery state, a phenomena confirmed by results obtained by Roozen *et al.* (23) using electron spin resonance. They reported a significant increase in the rotational mobility of spin probes within maltodextrin/water mixture at Tg.

The abovementioned facts can explain the high diffusion rate of particles in the rubbery state of maltodextrin within the tablet upon exposure to conditioning process that is proposed to enhance the process of solubilization and recrystallization resulting in formation of solid bridges (24) and subsequent caking and hardening effects. The elastic/plastic deformation behavior was reported for the maltodextrin grade utilized in this work (Maltrin M500). Furthermore, the effect of moisture to facilitate such deformation in maltodextrin was also reported (25).

Orally Disintegrating Tablets Containing Meclizine

Meclizine-containing tablets (M8) exhibited characteristics of 3.5-kg hardness and 30-s disintegration time after 24 h of conditioning. Evaluation of the obtained tablets was based on the following tests.

Dissolution Test of Meclizine ODT

The dissolution profiles of fresh and conditioned meclizine-containing ODT are shown in Fig. 5. Both tablets provided about 85% drug release after 2 min. Results showed no significant difference in the amount dissolved between

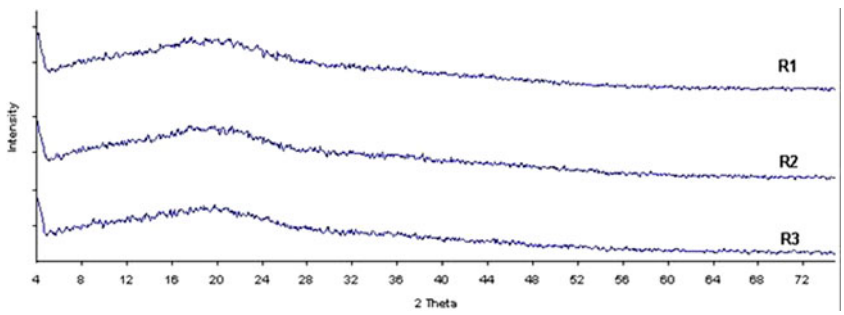

Fig. 4. X-ray diffraction patterns of different forms of maltodextrin: *R1* untreated, *R2* treated, and *R3* conditioned treated samples

fresh and conditioned tablets, indicating that conditioning had no hindering effect on the drug release.

High-Performance Liquid Chromatography

The drug content of the tablets was found to be 95% ± 0.014. Running HPLC analysis, drug showed 100% recovery in the conditioned tablet chromatogram compared to that of fresh one. A symmetric peak corresponding to meclizine was obtained, and drug was eluted at 5.30±0.06 min.

CONCLUSIONS

Maltodextrin-based ODT of meclizine with accepted hardness and disintegration characteristics were successfully prepared, utilizing no special apparatus. Maltodextrin, as evident by X-ray diffraction patterns, existed in almost completely amorphous nature from the beginning till the end of the operation, requiring no special treatment for amorphous form preparation. Maltodextrin, therefore, can be considered as an optimum saccharide for manufacturing of sugar-based ODT utilizing phase transition phenomena, using simple equipment. Direct compression-conditioning technique produced tablets with accepted hardness yet was accompanied by problems of long conditioning time and appearance of the so-called patch effect. Wet granulation-conditioning technique, on the other hand, exhibited alleviation of the patch effect problem while keeping rapid disintegration. Maltodextrin hardening mechanism was proposed to be based on phase transition process manifested as glass-elastic deformation.

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