Drug Development and Industrial Pharmacy, 27(1), 81–87 (2001)

COMMUNICATION

Study on Tablet Binding and Disintegrating Properties of Alternative Starches Prepared from Taro and Sweet Potato Tubers

Sanan Subhadhirasakul, Supreeya Yuenyoungsawad, Wichan Ketjinda, Narubadee Phadoongsombut, and Damrongsak Faroongsarng*

Faculty of Pharmaceutical Sciences, Prince of Songkla University, Hat Yai, Thailand 90112

ABSTRACT

To demonstrate the potential alternative sources of starch used in tablet formulations, starches from taro (TS) and sweet potato (SPS) tubers were prepared with obtained yields of 11.0 and 9.6%, respectively. Both TS and SPS met USP22-NF17 identification and specifications. Their equilibrium moisture contents and gelatinization temperatures were comparable with those of commercial starch, whereas amylose contents of TS and SPS were 21.38% w/w and 41.76% w/w, respectively. Both were found to possess similar flow characteristics. To evaluate TS and SPS as granulating agents and disintegrants, tablets with controlled compression loads were prepared by incorporating a starch candidate with dibasic calcium phosphate in paste and powders forms, respectively. Tablets were then evaluated based on compressibility, friability, and disintegration. It was found that the binding and disintegrating performance of both TS and SPS was similar to that of commercial cornstarch.

KEY WORDS: Alternative starch; Taro; Sweet potato; Binder; Disintegrant.

*To whom correspondence should be addressed.

INTRODUCTION

Starch has been used as a tablet excipient since the introduction of conventional tablet formulation (1). Different sources of starch including corn, potato, and wheat have been recognized in the United States and European Pharmacopoeias, and their specifications have been well established (2). The use of alternative starch from other sources such as rice, tapioca, and potato has also been extensively reported in various tablet formulations (3–5). Some of them were promoted as directly compressible starches (4,5). A number of plants for potential sources of starch including *Colocasia esculenta* Scholt (taro) and *Ipomoea batatas* Lamk (sweet potato) have been available year-round in Thailand. Taro and sweet potato exhibited starch compositions of 24 and 22%, respectively (6,7), which were comparable to starch composition in potato (8). The aim of this study was to evaluate the possibility that taro and sweet potato starches could be an excipient used in tablet formulations.

MATERIALS AND METHODS

Tubers of taro (*Colocasia esculenta* Scholt) and sweet potato (*Ipomoea batatas* Lamk) were collected from local market in Hat Yai, southern Thailand. Corn starch powders (Friendship Co. Ltd., Thailand), and dibasic calcium phosphate (Di-tab,® Rhone-Poulenc) were used as a positive control for evaluation and a tablet diluent, respectively. Magnesium stearate was used as a lubricant. Amylopectin (Fluka Inc., Switzerland) and amylose (Sigma Inc., St. Louis, MO) were used as references for amylopectin and amylose tests. Other chemicals used in official tests of specifications were of AR grade and complied with USP specifications.

Starch Preparation

Starches from taro (TS) and sweet potato (SPS) tubers were prepared using the methods as follows: 30 kg of

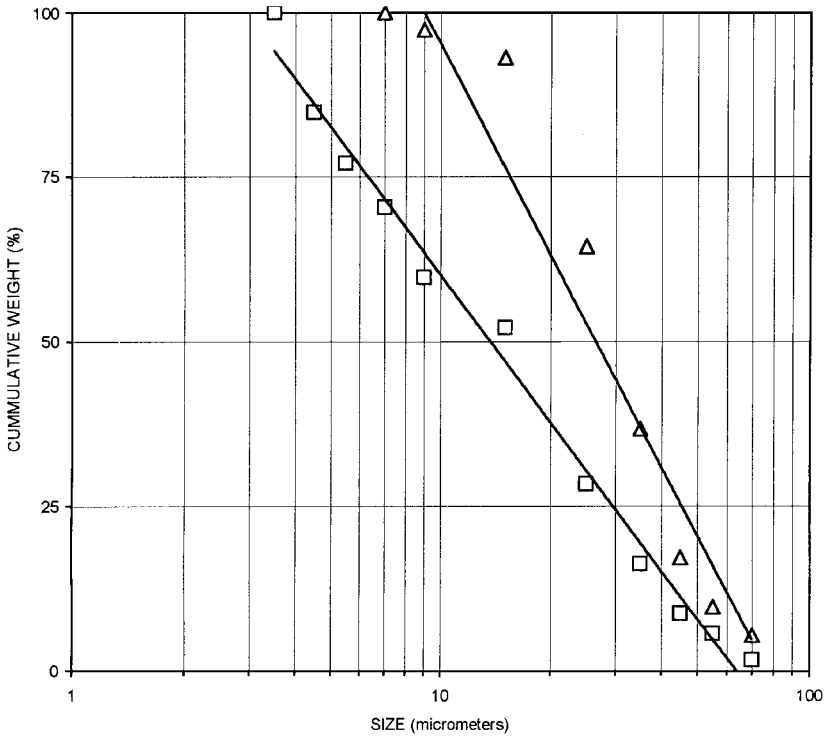

Figure 1. Particle size distributions of TS (squares) and SPS (triangles) showing the logarithmic-normal distributions.

Table 1.

Identification and Characterization of Starch Obtained from Taro and Sweet Potato Tubers

Source	USP 22-NF 17	Taro	Sweet Potato
Starch identification	Positive	Positive	Positive
Residue on ignition (% w/w)[a]	≤0.5	0.16	0.09
pH	4.5–8.0[b]	8.4–8.5	7.4–7.6
Iron content (% w/w)	≤0.002	0.0005	0.0003
Oxidizing substances	≤0.002	Negative	Negative
Sulfur dioxide	≤0.008	Negative	Negative
Microbial test	Negative	Negative	Negative
EMC (% w/w)[a]	—	11.67	12.22
Gelatinization temperature (°C)	—	80.9	79.3
Amylose content (% w/w)	34.16[c]	21.38	41.76

[a] Mean of three determinations.
[b] The specification for pH varies according to sources, i.e., pH values for corn, potato, and wheat starches are 4.5–7.0, 5.0–8.0, and 4.5–7.0, respectively.
[c] The amylose content of cornstarch, which is official in USP22-NF17. All tests compiled with USP22-NF17 except EMC, gelatinization temperature, and amylose content, which are not official in Pharmacopoeia.

tubers were cleaned, peeled, and cut to small pieces. The obtained pieces were milled with 1% w/v saline solution. The mass was then filtered and washed with saline solution several times to eliminate soluble substances, sugars, and mucilage. To remove tubers' proteins from starch, the remainder was washed using 0.01 M sodium hydroxide many times until the Ninhydrin test result was negative. After removing proteins, starch was washed with water to achieve a neutral pH, filtered, air-dried at 40°C., and milled to fine powders.

Starch Identification and Characterization

TS and SPS were identified using a method of starch identification described in USP NF (9). Equilibrium moisture content (EMC), residues on ignition, pH, traces of iron, oxidizing substances, sulfur dioxide, and microbial assay were determined according to USP NF specifications for starch (9). In addition to official specifications, amylose content was determined using the chemical method developed by Juliano (10). The differential scanning calorimetric method described previously (11) (DSC7, Perkin Elmer Co.) was used to characterize the gelatinization temperature of starch samples. Particle size

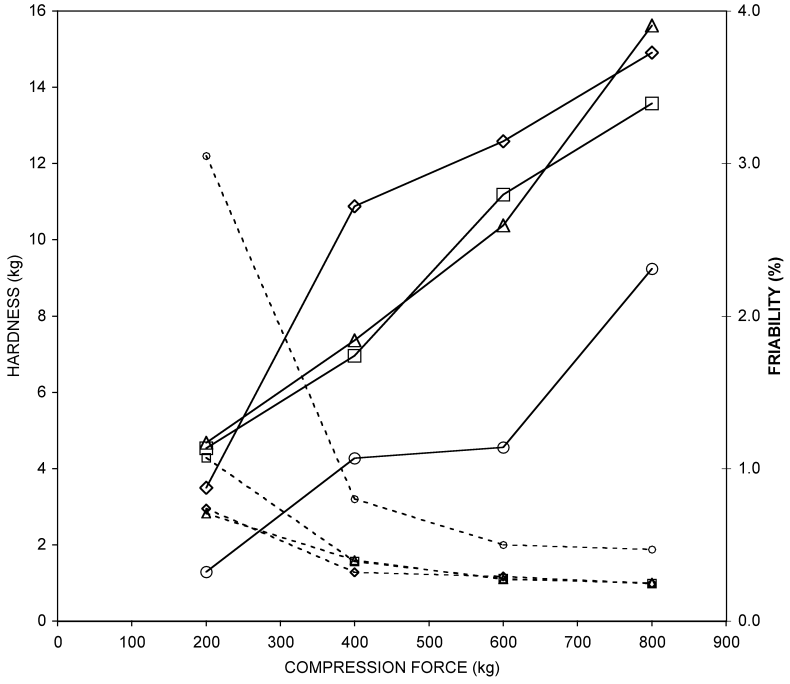

Figure 2. Compressibility (solid lines) and friability (dotted lines) profiles of tablets prepared by various starch pastes. Diamonds indicate TS; squares, SPS; triangles, cornstarch; and circles, negative control.

Table 2.

Densities and % Compressibility of Obtained Starches

Characteristics	Taro	Sweet Potato
Bulk density (g/ml)	0.59 (0.007)	0.60 (0.014)
Packed density (g/ml)	0.76 (0.000)	0.79 (0.007)
% Compressibility[a]	22.37 (0.010)	24.10 (0.017)

[a] % Compressibility = (packed density − bulk density)/packed density.
All values calculated from two determinations.
The numbers in parentheses are SD values.

and distribution of each of the samples were determined using centrifugal particle size analyzer (Shimazu model SA-CP-2, Japan). Bulk and tapped densities were also determined (Vanderkamp^R jolting apparatus).

Tablet Preparation of TS and SPS for Granulating Agent and Disintegrant Evaluations

Tablets of binary mixture of each of TS, SPS, and positive control (cornstarch) samples and dibasic calcium phosphate were prepared. A granulating agent candidate, i.e., 10% w/w starch paste, was prepared by distributing either TS, SPS, or cornstarch in cold water in approximately the same quantity. The dispersion was then adjusted to the desired concentration with boiled water. Additional heat may be necessary to obtain a translucent paste. For tested tablets in granulating agent evaluation, a quantity of paste (equivalent to 2% dry basis of granulation mixture) was wet-kneaded with dibasic calcium phosphate (small-scale planetary mixer, Kenwood Inc.) and sifted through 14-mesh screen. The wet granulation was then air-dried overnight at $40 \pm 1^{\circ}$C. Then the dried granulation was

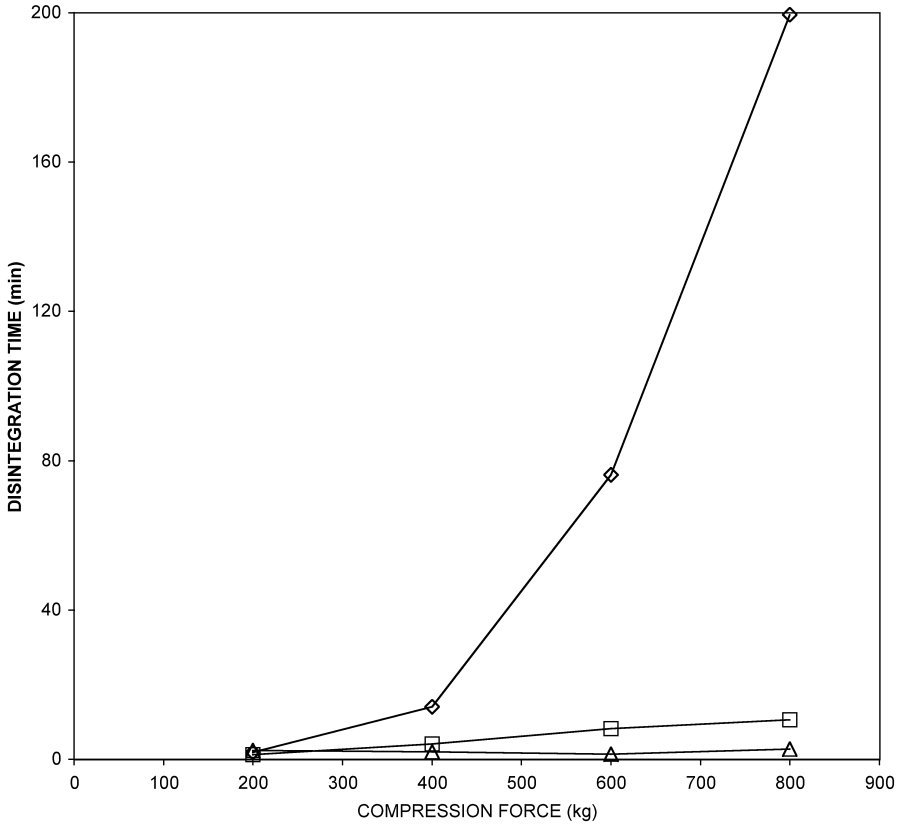

Figure 3. Disintegration time profiles of tablets prepared by various starch pastes. Diamonds indicate TS; squares, SPS; and triangles, cornstarch. Note: Disintegration time of tablets without starch (negative control) at minimum compression force was 9.5 min, whereas those at other compression force higher than 200 min that were off the scale.

Table 3.

Average Weight of Tablets Prepared by Various Starches

Starch	Tablet Weight (mg) Granulating Agent Evaluation Mean (SD)	Tablet Weight (mg) Disintegrant Evaluation Mean (SD)
Taro	250.4 (5.9)	244.3 (6.5)
Sweet potato	249.3 (7.3)	241.7 (5.2)
Corn	247.7 (6.8)	241.7 (6.9)
Negative control	242.1 (7.3)	247.7 (6.8)

sifted through 16-mesh screen. A negative control granulation was also prepared by replacing starch paste with water.

In the case of disintegrant evaluation, TS, SPS, or cornstarch at 7% w/w was blended with 91% w/w dibasic calcium phosphate for 15 min. The mixture was wet-kneaded with 10% w/w cornstarch paste prepared previously. The paste was added to a proportion of 2% w/w (dry basis) of granulation. Wet granulation was sifted through 14-mesh screen and air-dried overnight at 40°C. Then the dried granulation was sifted through 16-mesh screen. The dry granulation was blended with TS, SPS, or positive control in proportion between granulation and candidate of 93% to 7%. The negative control formulation was also prepared by replacing starch with dibasic calcium phosphate in the same quantity.

Four batches of 250-mg tablets with controlled compression forces of 200, 400, 600, and 800 kg were made (in-house instrumented single-punch tablet machine, Manesty model F3, with 3/8-in round and flat-faced tooling) for each formulation. Before tablet compression, 0.2% w/w magnesium stearate was added to the granulation and mixed for 5 min (small-scale, V-shape blender). Tablets were then sampled to determined weight variation, and disintegration time complied with USP specifications. Twenty tablets were sampled to determine hardness (Erweka tablet hardness tester), and

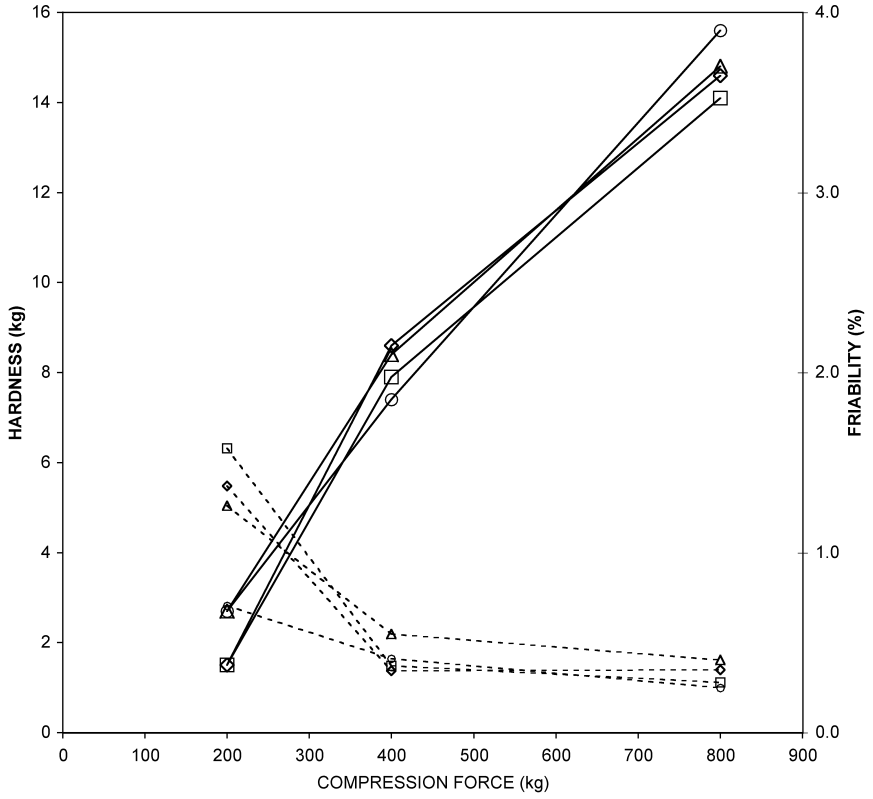

Figure 4. Compressibility (solid lines) and friability profiles (dotted lines) of tablets prepared by various starches as a disintegrant. Diamonds indicate TS; squares, SPS; triangles, cornstarch; and circles, negative control.

20 tablets were tested for friability (Roche friabilator, 100 revolutions).

RESULTS AND DISCUSSION

Starch Preparation, Identification, and Characterization

Primarily, the yields of starch preparation, based on crude weight, from TS and SPS were 11.0 and 9.6%, respectively, which were comparable with that of commercially available potato starch production (8). The details for starch identification and characterizations are tabulated in Table 1. It was seen that TS and SPS met USP22-NF17 specifications. Their EMC values were comparable with those of commercially available starch (2). The gelatinization temperature of pharmacopoeial official starches were reported as between 63 and 73°C (2), which was slightly different from that reported in this study (Table 1). It may be because of the differences in method used and different sources of materials.

The particle analyses showed the logarithmic normal distributions graphically plotted in Figure 1 with geometric diameters located between ± 1 SD of TS and SPS of (15.1, 44) and (27.1, 55.1) μm, respectively. To characterize TS and SPS flow properties and their effect on tablet uniformity, Carr's compressibility index (percent of compressibility) of an individual starch and corresponding tablet weight variation were respectively determined. Densities and percent of compressibility of each obtain starches and the corresponding tablet weight variations are tabulated in Tables 2 and 3, respectively. Both TS and SPS exhibited poor flowability that was comparable with that of commercial starch, and there were no significant differences in weight and variation among tablets under test. Thus, TS and SPS used in this study did not significantly alter bulk characteristics and flow properties of granulation resulting in homogeneous tablet weight.

TS and SPS Evaluation for Granulating Agent and Disintegrant

Figures 2 through 5 illustrate compressibility, friability and disintegration profiles of tablets prepared by various starch pastes as granulating agents and those containing various starches as disintegrant, respectively. Tablet

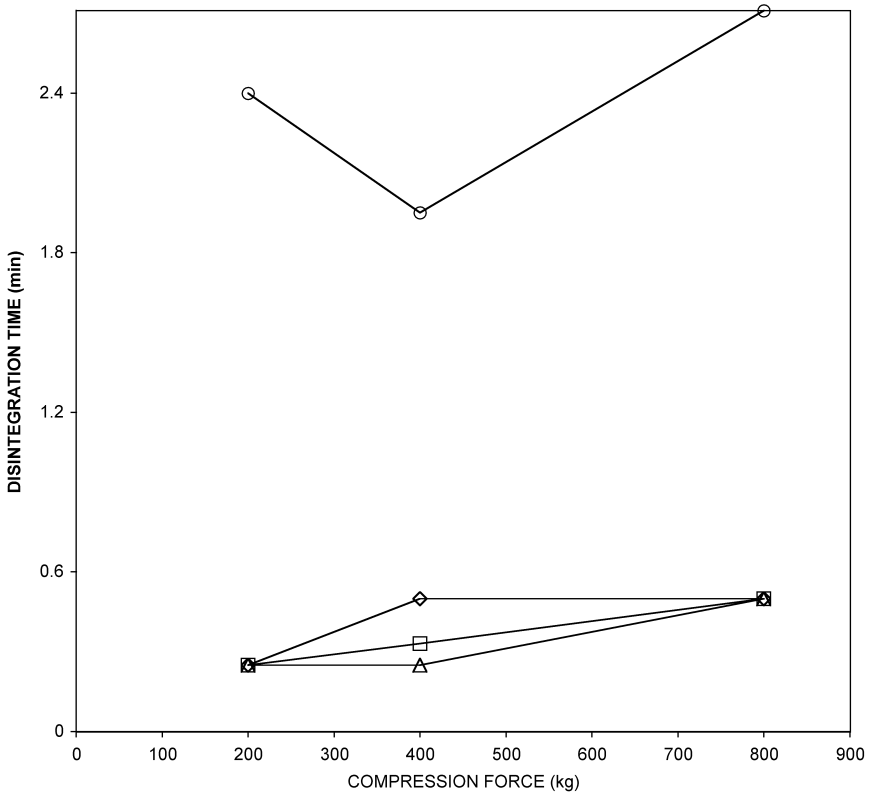

Figure 5. Disintegration time profiles of tablets prepared by various starch pastes. Diamonds indicate TS; squares, SPS; triangles, cornstarch; and circles, negative control.

prepared from the pastes of TS, SPS, and cornstarch exhibit compressibility profiles as well as friability profiles superior to those without starch, whereas TS and SPS exhibited the profiles comparable with those prepared using a commercial cornstarch (Fig. 2). It was noted in the low level of controlled compression force that tablets prepared using SPS exhibited a percent of friability slightly higher than that of cornstarch and TS. It was suggested previously that amylopectin rather than amylose might play an important role in binding properties of starch paste (12). Starch with higher portion of amylose in case of SPS may not be as good a binder as other starch, especially when tablets were made by low compression forces where granulation was not completely deformed. On the contrary, at high compression forces, tablets prepared using SPS disintegrated faster than did others (Fig. 3). This supports the previous suggestion significantly.

For disintegrant evaluation, it was observed that there was no significant difference in compressibility among tablets being tested (Fig. 4). In low-level compression force, the friability of negative control tablets was lesser compared with that of tablets with starch (Fig. 4). Because starch powders were added to granulation before compression, there were more fine powders present that, in turn, cause high friability. All starch formulations disintegrated rapidly compared with negative controls (Fig. 5). For each level of compression force, no significant differences in disintegration time of tablets containing starch were observed although different sources of starch contained different portions of amylose.

CONCLUSION

Starch prepared from TS and SPS tubers met USP22-NF17 specifications. Their EMC values and gelatinization temperatures were comparable with those of official starches. Starches from these two sources had been evaluated comparatively as granulating agents and disintegrants against commercially available cornstarch, and in comparison, their functions were not significantly different. It was concluded that they could be used as an alternative starch in a tablet formulation. Although SPS exhibits a high portion of amylose, tablets made from SPS showed compressibility, friability, and disintegration profiles similar to those of TS and cornstarch.

ACKNOWLEDGMENTS

The authors would like to thank Prince of Songkla University, Hat Yai, Thailand, for financial support. Special thanks are given to the department of Pharmacognosy, the department of Pharmaceutical Technology, and the division of central laboratory research of the Faculty of Pharmaceutical Sciences, Prince of Songkla University, for providing laboratory sites. The authors are also grateful to The Phatthlung Rice Research Center and Region Eight of the Office of Agricultural Research and Development for providing the determination of amylose contents.

REFERENCES

1. Shangraw, R. Manuf. Chem. **1986**, *57* (12), 22.
2. *Handbook of Pharmaceutical Excipients*, 2nd Ed.; Wode, A., Weller, P.J., Eds.; The Pharmaceutical Press: Washington, DC, 1994, 485.
3. Bos, C.E., Bolhuis, G.K.; Van Doorne, H.; Lerk, C.F. Pharm. Weekblad. **1987**, *9*, 274.
4. Bos, C.E.; Lerk, C.F.; Duineveld, C.A.A. Drug Dev. Ind. Pharm. **1992**, *18* (1), 93.
5. Mitrevej, A.; Sinchaipanid, N.; Faroongsarng, D. Drug Dev. Ind. Pharm. **1996**, *22* (7), 587.
6. Simpson, B.B. *Economy Botany: Plants in Our World*, McGraw-Hill Book Company: New York, 1986, 219.
7. Radley, J.A. *Starch Production Technology*, Applied Sciences Published Ltd.: London, 1976, 213.
8. Swinkels, J.J.M. *Industrial Starch Chemistry*, Avebe: The Netherlands, 1990, 8.
9. *The United States Pharmacopoeia* 22. ed. National Formulary 17. ed. The United Pharmacopeial Convention Inc.: Washington, DC, 1990, 2309.
10. Juliano, B. Cereal Sci. Today, **1971**, *16*, 334.
11. Faroongsarng, D.; Wongphoowarak, W.; Mitrevej, A.; Pharm. Dev. Tecnol. **1999**, *4* (4), 513–518.
12. Pourkavoos, N.; PhD Thesis, Purdue University, 1990, 10.