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# PHARMACEUTICAL TECHNOLOGY OF STARCH: INVENTION OF DIRECTLY COMPRESSIBLE STARCH(เทคโนโลยีเภสัชกรรมของแป้ง : แป้งดัดแปลงสำหรับใช้ในการตอกยาเม...

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# PHARMACEUTICAL TECHNOLOGY OF STARCH: INVENTION OF DIRECTLY COMPRESSIBLE STARCH

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## Abstract:

*Physico-chemical modification of various native starches were performed and theirs compressibility were assessed in comparison with other modified starches commercially available. Modified rice starch derived by the process in this study exhibited the high degree of compressibility.*

**Key word index:** Starch, Physico-Chemical Modifications, Compressibility.

## Introduction

In pharmaceutical system, starch is, at first, used directly in native form without modification as an important adjuvant in the formulations of solid dosage form, e.g., diluent, binder, disintegrant. As a consequence of the characteristics of starch can be altered by chemical, physical and/or enzymatic means to improve its intrinsic properties or to impart a new one. So many attempts have been made to modify starches by various processes in order to make their properties more appropriate and effective for pharmaceutical uses such as to be employed as directly compressible vehicles in direct compression process, highly effective disintegrants, bioadhesive materials, and retarding agent in sustained release products (1-3).

Thailand is an agricultural country, producing a tremendous amount of starches annually. As located in the tropical zone, the various varieties of starches are cultivated commonly. Starch powders from different native sources may not have identical properties with respect to their uses as additives in pharmaceutical dosage forms. It is essential to direct the research area toward pharmaceutical technology of starches by extensive investigation on development and modification of various starches available locally for pharmaceutical purposes. This report is a part of the research project in pharmaceutical technology of starch which is concerned with the investigation of the various native starches which may have potential to be developed as effective pharmaceutical additive in direct compression process of tablet dosage form.

## Experimental

**Materials:** All of the materials employed in this study were obtained from commercial sources and used as received: glutinous rice starch, rice starch (Choheng, Thailand), tapioca starch (Chao Phya, Thailand), corn starch, mung bean starch (Thailand), Starch 1500 (Colorcon, U.S.A.), Era-tab (Choheng, Thailand).

**Methods:** Starches were modified by physico-chemical treatments and the physical properties were evaluated as follows: Morphology of the modified starch produced were observed by scanning electron microscopy (JSM-T220A, JEOL, Japan). Compressibility of modified starches (300 mg) were assessed by compression on Carver laboratory press (Perkin-Elmer, model C, Fred & Carver Inc., U.S.A.) using 10.1 mm. flat faced, circular punch. The compressional forces were ranged from 1,000, 1,500 and 2,000 lbs. The hardness of compacts were determined using the Schleuniger-2E hardness tester (Switzerland). Disintegration time of tablets were measured in water using U.S.P. disintegration test apparatus (Hanson Research Corporation, model QC-21, U.S.A.). Six determinations were undertaken in each case.

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## Results and Discussion

Preliminary investigation on physico-chemical modification of various native starches were performed. The compressibility of such modified starches were presented in Table 1. Modified rice and glutinous rice starch exhibited satisfactory degree of compressibility and fast disintegrating properties. Tapioca, corn and mung bean starch showed low mechanical strength of the compacts. However, the modification of glutinous rice starch was a troublesome process because of its sticky and viscous. So only rice starch has been selected for further investigation.

**Table 1** The compressibility of various modified native starches at compressional force of 1000 lbs.

| Type of modified starch | Hardness of the Tablet, kp (SD.) | Disintegration time, minute (SD.) |
|---|---|---|
| Tapioca | 4 (0.85) | 2 (0.27) |
| Corn | <1 | 2 (0.25) |
| Rice | 7.5 (0.97) | 1:10 (0.28) |
| Glutinous Rice | 7.2 (1.13) | 1:35 (0.38) |
| Mung Bean | <1.0 | 10 (0.76) |

Subsequent improvement of the process of modifications, the higher compressible rice starch powder was obtained and then evaluated in comparison with commercially available modified starches, Starch 1500 and Era-tab. Scanning electron photomicrograghs of treated modified rice starch, Starch 1500 and Era-tab are illustrated in Figure 1 and 2. Treated modified rice starch (Fig. 1B) and Era-tab (Fig. 2A) are minigranulations of starch grains forming into agglomerates. However, Era-tab is composed of more spherical starch agglomerates. Starch 1500 (Fig. 2B) possesses irregular shape and varies widely in size. The difference in granular morphology of these modified starch was due to the difference in process of modifications.

The hardness of the tablets prepared from treated modified rice starch, Starch 1500 and Era-tab at various compactional forces are depicted in Figure 3. It appeared that treated modified rice starch could be compressed to higher mechanical strength at the same level of compressional force. The hardness of treated modified rice starch compacted at 1000 and 1500 lbs exceeded 20 kp (the exact values were unable to measured as the maximum scale readings of the tester is at 20 kp).

The relationships between the disintegration time and compressional force of various modified starches are presented in Figure 4. The disintegration times increased slightly when compressional forces were increased except of Starch 1500. As can be seen in Figure 3 and 4, treated modified rice starch tablets exhibited fast disintegrating property within 4 minutes even if the hardness of the tablets were greater than 20 kp. As the consequence of theirs higher hardness property, disintegration of the tablets prepared from treated modified rice starch, therefore, were longer than of Era-tab at the same compressional force.

In conclusion, treated modified rice starch produced by the process developed in this study has been the most compressible starch with rapid disintegration. The extensive investigations are being carried out to compile all aspects of technical profile of this treated modified rice starch.

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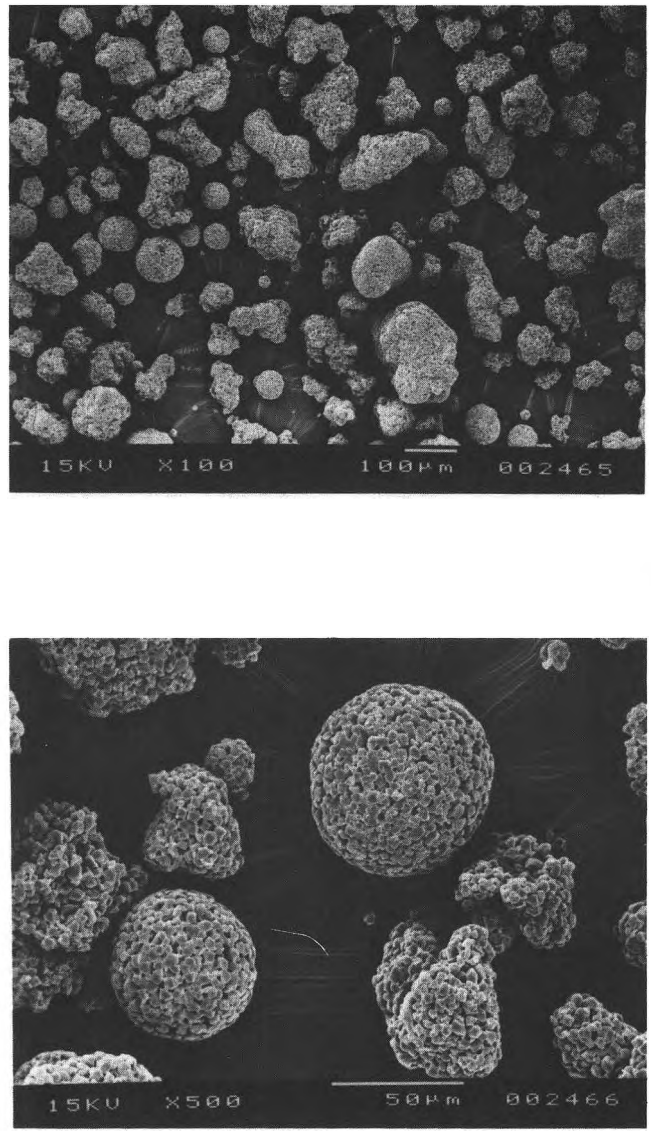


**Figure 1** Scanning electron photomicrograph of treated modified rice starch; A: × 100, B: × 500.

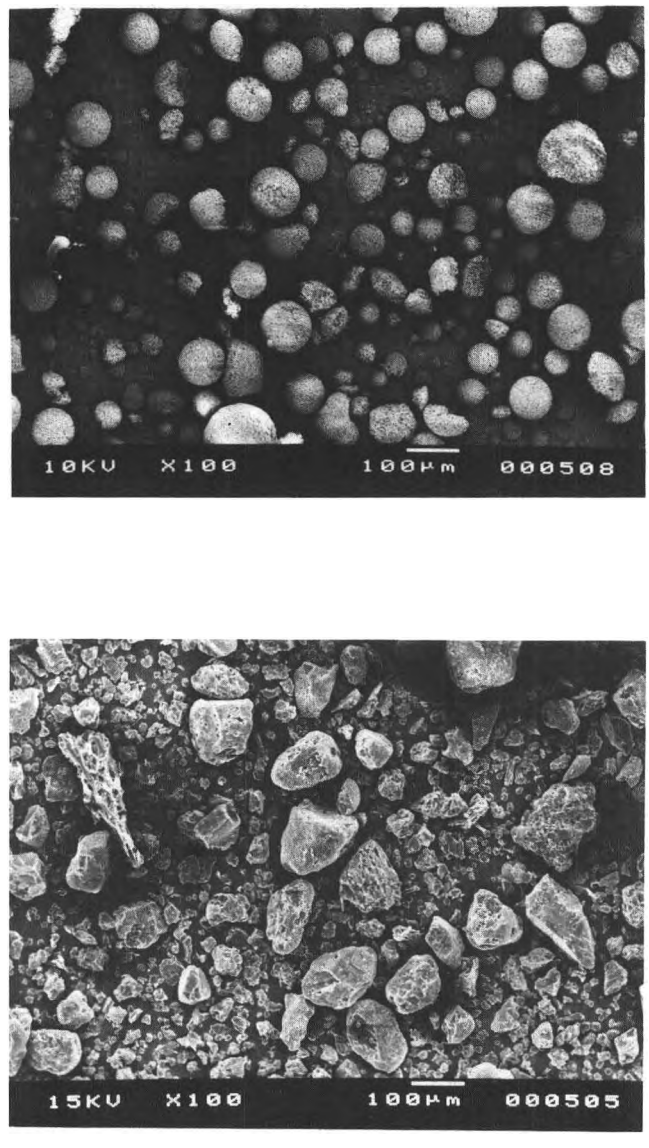


**Figure 2** Scanning electron photomicrograph of Era-tab(A) and Starch 1500(B).

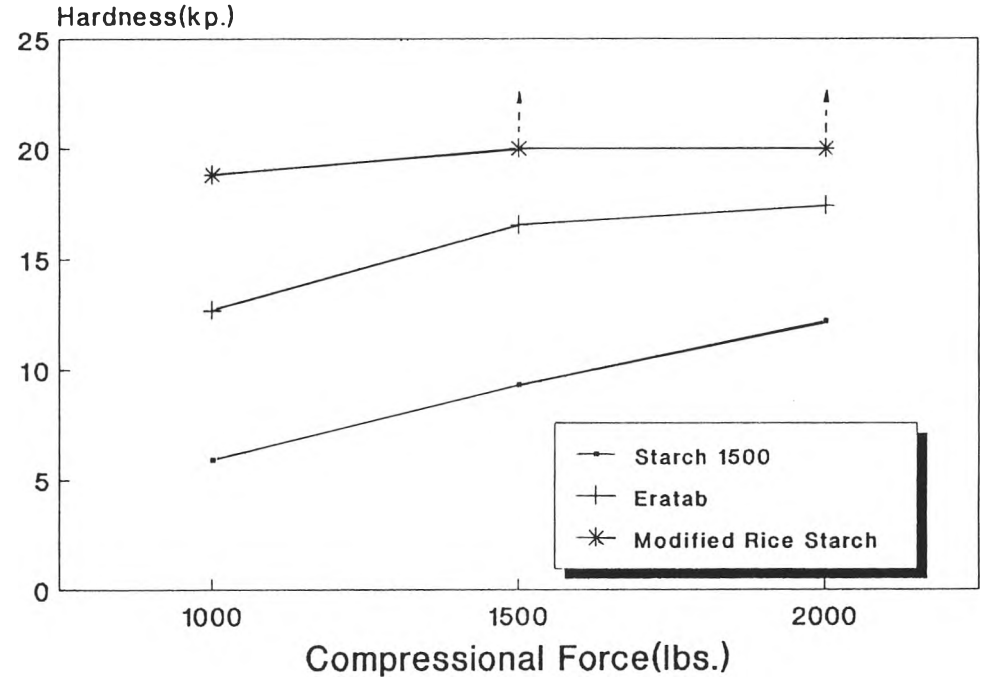


**Figure 3** The compressibility of treated modified rice starch, Starch 1500 and Era-tab (the arrow sign indicated the hardness of treated modified rice starch tablets were greater than 20 kp at compressional force of 1,500 and 2,000 lbs.).

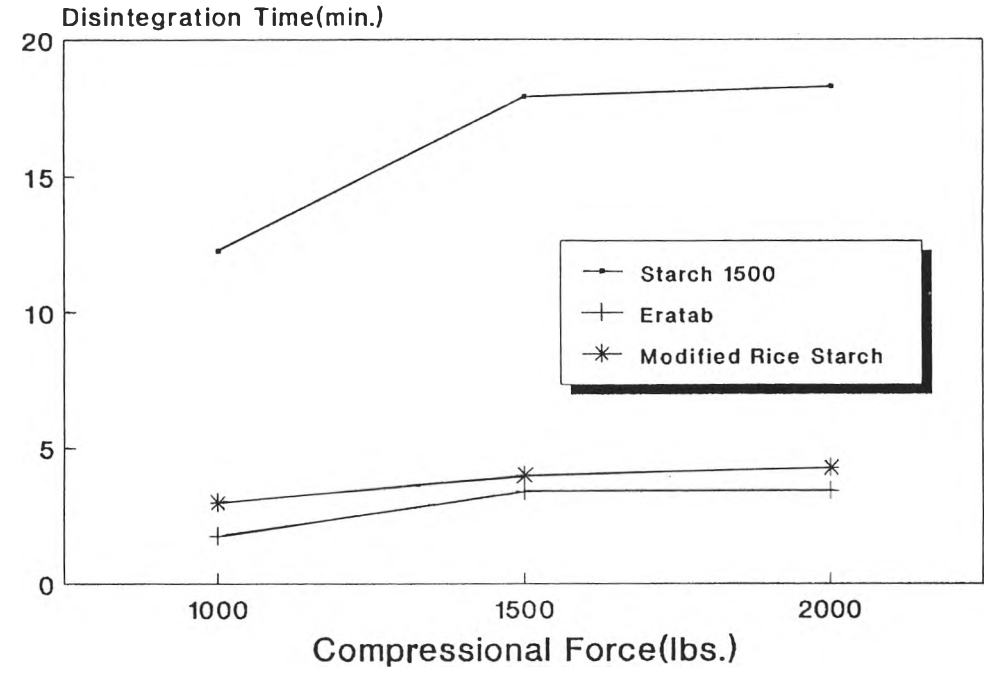


**Figure 4** Compressional force-disintegration time profiles of various modified starches.

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# เทคโนโลยีเภสัชกรรมของแป้ง : แป้งดัดแปลงสำหรับใช้ในการตอกยาเม็ดโดยตรง

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**บทคัดย่อ**

*ดำเนินการดัดแปลงแป้งโดยทางเคมีกายภาพ และศึกษาความสามารถในการดอกอัดเป็นเม็ดแป้งดัดแปลงที่ได้ทำการพัฒนานี้มีความสามารถในการดอกอัดเป็นเม็ดสูง เมื่อเปรียบเทียบกับแป้งดัดแปลงอื่นที่มีจำหน่ายในท้องตลาด*

**กุญแจคำ :** แป้ง, ดัดแปลงทางเคมีกายภาพ , ความสามารถในการดอกอัด