

คุณสมบัติในการเป็นสารยึดเกาะของแป้งโซเดียมคาร์บอกซีเมทิล

นางสาวทัศนีย์ พิทักษ์สุธีพงศ์

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**TABLET BINDER PROPERTIES OF
SODIUM CARBOXYMETHYL STARCH**

Miss Tasana Pituksutheepong

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science in Pharmacy

Department of Manufacturing Pharmacy

Graduate School


Chulalongkorn University

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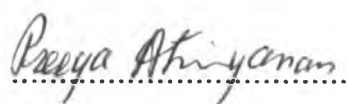
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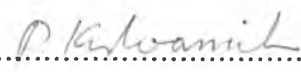
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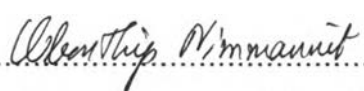
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พิมพ์ต้นฉบับบทคัดย่อวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

ทัศนาศึกษา พิกักษ์สุธีพงศ์ : คุณสมบัติในการเป็นสารยึดเกาะของแป้งโซเดียมคาร์บอกซีเมทิล
(TABLET BINDER PROPERTIES OF SODIUM CARBOXYMETHYL STARCH) อ.ที่ปรึกษา :
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ทำการเตรียมแป้งโซเดียมคาร์บอกซีเมทิลจากแห้งธรรมชาติ 5 ชนิด (แป้งข้าวเจ้า, แป้งข้าวเหนียว, แป้งข้าวโพด, แป้งมันสำปะหลัง และ แป้งมันฝรั่ง) ให้มีระดับการแทนที่ (degree of substitution) อยู่ในช่วงที่เหมาะสม 3 ระดับ เพื่อนำมาประเมินคุณสมบัติในการใช้เป็นสารยึดเกาะในสูตรตำรับยาเม็ดซึ่งมีพาราเซตามอลเป็นตัวยาสำคัญโดยเปรียบเทียบกับแป้งธรรมชาติ พบว่าแป้งโซเดียมคาร์บอกซีเมทิลที่ดัดแปรจากแป้งต่างชนิดกัน จะให้คุณสมบัติของยาเม็ดแตกต่างกัน และต่างจากยาเม็ดที่เตรียมโดยใช้แป้งธรรมชาติเป็นสารยึดเกาะ กล่าวคือ ยาเม็ดที่เตรียมโดยใช้แป้งดัดแปรเป็นสารยึดเกาะ มีความแข็งแรงสูงกว่า และความกร่อนน้อยกว่ายาเม็ดที่เตรียมโดยใช้แป้งธรรมชาติเป็นสารยึดเกาะ และระยะเวลาการแตกกระจายตัวยังคงอยู่ในมาตรฐานเภสัชตำรับ นอกจากนี้ยังพบว่า การเติมแป้งดัดแปรในสูตรตำรับยาเม็ดโดยวิธีการเติมในรูปแป้งเปียก (solution incorporation method) จะให้ยาเม็ดที่มีคุณสมบัติดีกว่าการเติมในรูปผงแห้ง (dry incorporation method)

จากการเปรียบเทียบคุณสมบัติในการเป็นสารยึดเกาะของแป้งดัดแปรทั้งหมดพบว่าแป้งข้าวเหนียวดัดแปรที่มีระดับการแทนที่ 0.35 มีคุณสมบัติในการเป็นสารยึดเกาะที่ดีที่สุด โดยให้ความแข็งแรงมากที่สุด และการแตกกระจายตัวเร็ว เมื่อนำแป้งข้าวเหนียวดัดแปรนี้มาเปรียบเทียบกับโพลีไวนิลไพโรลิโดน เค30 และแป้งข้าวเจ้าดัดแปรที่มีจำหน่ายในท้องตลาด พบว่าแป้งข้าวเหนียวดัดแปรตัวใหม่นี้มีคุณสมบัติในการเป็นสารยึดเกาะใกล้เคียงกับโพลีไวนิลไพโรลิโดน เค30 และดีกว่าแป้งข้าวเจ้าดัดแปรอื่นที่มีจำหน่ายในท้องตลาด ดังนั้นจึงสรุปได้ว่าแป้งข้าวเหนียวดัดแปรตัวใหม่ที่มีระดับการแทนที่ 0.35 เป็นสารยึดเกาะที่เหมาะสมสำหรับสูตรตำรับยาเม็ดพาราเซตามอล

ผลจากการศึกษานี้แสดงให้เห็นการประยุกต์ใช้ผลิตภัณฑ์แป้งไปทางเภสัชกรรมอีกแนวทางหนึ่ง แป้งข้าวเหนียวดัดแปรที่มีคุณสมบัติที่ดีที่สุดในบรรดาแป้งดัดแปรชนิดอื่น ๆ ที่ได้นำมาศึกษา โดยที่แป้งข้าวเหนียวดัดแปรสามารถใช้เป็นสารยึดเกาะในสูตรตำรับยาเม็ด โดยการนำมาละลายได้โดยตรงในน้ำเย็น พร้อมทั้งจะนำมาใช้ได้ทันที ซึ่งถ้าสามารถนำไปสู่การผลิตทางการค้าได้แล้วจะเป็นผลดีในการเพิ่มมูลค่าของผลิตภัณฑ์ทางการเกษตรกรรมของประเทศ

ภาควิชา เภสัชอุตสาหกรรม
สาขาวิชา
ปีการศึกษา 2538

ลายมือชื่อนิติ ทัศนาศึกษา พิกักษ์สุธีพงศ์
ลายมือชื่ออาจารย์ที่ปรึกษา
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม

#C675186 : MAJOR MANUFACTURING PHARMACY

KEY WORD: CARBOXYMETHYL STARCH/ DEGREE OF SUBSTITUTION/ TABLET BINDER

TASANA PITUKSUTHEEPONG : TABLET BINDER PROPERTIES OF SODIUM CARBOXYMETHYL STARCH. THESIS ADVISOR : ASSIST. PROF. POJ KULVANICH, Ph.D.
202 pp. ISBN 974-632-598-1

Sodium carboxymethyl starches were prepared from five native starches (rice, glutinous rice, corn, tapioca and potato starches) to have three different degrees of substitution. They were evaluated for their binding properties in tablet formulations using paracetamol as a model drug in comparison with the unmodified starches. It was found that various sodium carboxymethyl starches provided tablets having different physical properties. The tablets prepared with modified starches were harder and less friable than those prepared with native starches and the disintegration time met the requirement of pharmacopoeia. Moreover, the addition of the modified starches in the formulations by solution incorporation method provided better physical property tablets than when they were added by dry incorporation method.

Among various types and degrees of substitution of modified starches, modified glutinous rice starch at 0.35 degree of substitution was the best binder. It imparted the hardest tablets with short disintegration time. Furthermore, this modified glutinous rice starch was compared with polyvinylpyrrolidone K30 (PVP K30) and other modified rice starches commercially available and it was found that the modified glutinous rice starch was comparable with PVP K30 and had better properties than other modified rice starches commercially available. So, it was concluded that the new product of modified glutinous rice starch at 0.35 degree of substitution was suitable for use as a binder in paracetamol tablet formulation.

The findings emerged from this work is another breakthrough in pharmaceutical application of starch. Modified glutinous rice starch have shown the most interesting property among the modified starches derived from different native starch. It could be used as the binder in tablet formulation by directly dispersing in cold water to form ready for use paste. If this starch product could introduced commercially, it would be beneficial by adding more value to agricultural products of the country.

ภาควิชา เกษษอุตสาหกรรม.....

ลายมือชื่อนิสิต..... กัตนา พัทธ์นัสศิริพงษ์

สาขาวิชา.....

ลายมือชื่ออาจารย์ที่ปรึกษา.....

ปีการศึกษา 2538.....

ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

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ABBREVIATIONS

M (R,G,C,T,P) S	modified (R,G,C,T,P) starch
R	rice starch
G, GLU	glutinous rice starch
C	corn starch
T	tapioca starch
P	potato starch
M()S 1	modified () starch produced by method 1
M()S 2	”-----” 2
M()S 3	”-----” 3
D.S.	degree of substitution
BU	Brabender unit
Avg.	average
°C	degree celsius
ml.	millilitre
min.	minute
gm.	gram
mg.	milligram
mm.	millimetre
um.	micrometre
N	normality
kp.	kilopound
PVP K30	polyvinyl pyrrolidone K30, crospovidone
LSR	least significant range