

การเตรียมและการประเมินคุณสมบัติการเป็นสารช่วยแขวนตะกอน

ของแป้งโซเดียมคาร์บอกซีเมทิล

นางสาวอรอนงค์ สุวรรณภากุล



วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต

ภาควิชาเภสัชอุตสาหกรรม

บัณฑิตวิทยาลัย จุฬาลงกรณ์มหาวิทยาลัย

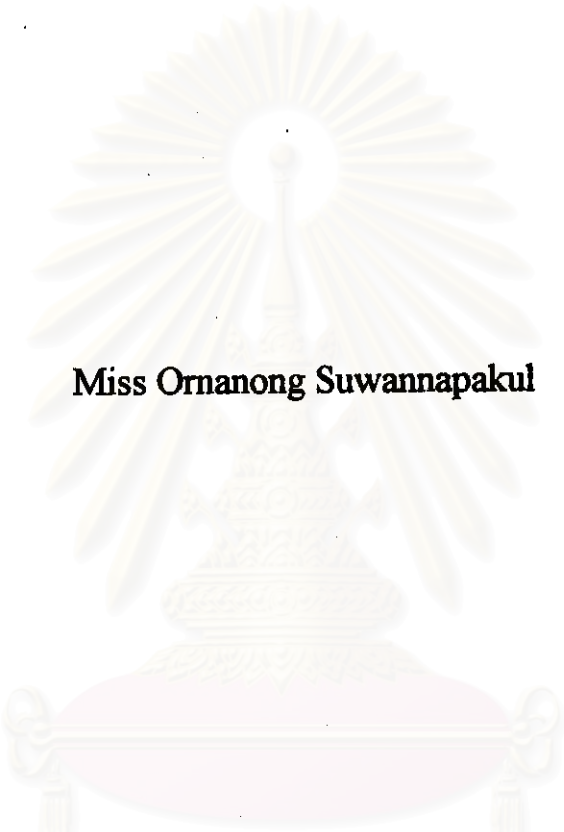
พ.ศ. 2539

ISBN 974-635-207-5

ลิขสิทธิ์ของบัณฑิตวิทยาลัย จุฬาลงกรณ์มหาวิทยาลัย

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**PREPARATION AND EVALUATION OF SODIUM
CARBOXYMETHYL STARCH AS SUSPENDING AGENT**



Miss Ornanong Suwannapakul

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science in Pharmacy

Department of Manufacturing Pharmacy

Graduate School

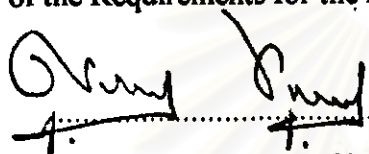
Chulalongkorn University

1996

ISBN 974-635-207-5

Thesis Title Preparation and Evaluation of Sodium Carboxymethyl Starch as
 Suspending Agent
By Miss Ornanong Suwannapakul
Department Manufacturing Pharmacy
Thesis Advisor Associate Professor Poj Kulvanich, Ph.D.

Accepted by the Graduate School, Chulalongkorn University in Partial
Fulfillment of the Requirements for the Master's Degree

 Acting Dean of Graduate School
(Professor Supawat Chutivongse, M.D.)

Thesis Committee

 Chairman
(Assistant Professor Wichein Thanindrataru, M.Sc.)

 Thesis Advisor
(Associate Professor Poj Kulvanich, Ph.D.)

 Member
(Associate Professor Parunee Thanomkiat, M.Pharm.St.)

 Member
(Associate Professor Suchada Prasertvithayakarn, M.Sc.)

พิมพ์ต้นฉบับบทคัดย่อวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

อรอนงค์ สุวรรณภากุล : การเตรียมและการประเมินคุณสมบัติการเป็นสารช่วยแขวนตะกอนของ แป้งโซเดียมคาร์บอกซีเมทิล (Preparation and Evaluation of Sodium Carboxymethyl Starch as Suspending Agent) อาจารย์ที่ปรึกษา : รศ.ดร.พจน์ กุลวานิช, 185 หน้า. ISBN 974-635-207-5

การศึกษานำแป้งมันสำปะหลัง แป้งข้าวเจ้า แป้งข้าวเหนียว และแป้งข้าวโพด มาดัดแปรทางเคมี และประเมินผลคุณสมบัติการเป็นสารช่วยแขวนตะกอน การเตรียมแป้งโซเดียมคาร์บอกซีเมทิลที่มีระดับการแทนที่ต่างกัน 3 ระดับ กระทำโดยปฏิกิริยาระหว่างแป้งธรรมชาติกับ monochloroacetic acid ภายใต้สภาวะที่เป็นต่างของโซเดียมไฮดรอกไซด์ แป้งดัดแปรที่เตรียมได้จะถูกนำไปทำการประเมินเบื้องต้นเพื่อคัดเลือกแป้งดัดแปรที่มีคุณสมบัติที่ดีที่สุดจากแป้งแต่ละชนิด โดยพิจารณาจากค่าความหนืดของแป้งดัดแปร และค่าการช่วยแขวนตะกอนและการกระจายตัวคิณรูปของตำรับยาแขวนตะกอนแคลเซียมคาร์บอเนตที่มีแป้งดัดแปรเป็นสารช่วยแขวนตะกอน แป้งดัดแปรที่ได้คัดเลือก ได้แก่ แป้งข้าวเหนียวดัดแปร แป้งข้าวเจ้าดัดแปร และแป้งมันสำปะหลังดัดแปร ที่มีระดับการแทนที่ 0.16, 0.26, และ 0.38 ตามลำดับ แป้งข้าวโพดดัดแปรไม่ได้นำมาศึกษาต่อไป เนื่องจากมีความหนืดต่ำ การแขวนตะกอนไม่ดี และการกระจายตัวคิณรูปทำได้ยาก นำแป้งดัดแปรที่คัดเลือกไปประเมินคุณสมบัติในการเป็นสารช่วยแขวนตะกอนในตำรับยาโอบูโพรเฟน เปรียบเทียบกับสารช่วยแขวนตะกอนที่ใช้กันทั่วไป 6 ชนิด คือ Xanthan gum (XG), Avicel® RC-591 (AV), Sodium Alginate (SA), Acacia (AC), Tragacanth (TG), และ Sodium carboxymethylcellulose (SCMC) การประเมินประกอบด้วยวิธีการช่วยแขวนตะกอน การประเมินการไหล การกระจายตัวคิณรูป และความสม่ำเสมอในการกระจายตัวยา ผลการศึกษาพบว่า แป้งข้าวเจ้าดัดแปร (MRS) และ แป้งมันสำปะหลังดัดแปร (MTS) มีคุณสมบัติในการเป็นสารช่วยแขวนตะกอนที่ดี โดยย่นำแขวนตะกอนที่ใช้แป้งทั้งสองชนิดเป็นสารช่วยแขวนตะกอนที่ความเข้มข้น 1% มีความหนืดสูง การแขวนตะกอนดี การกระจายตัวคิณรูปง่าย และการกระจายของตัวยาสม่ำเสมอ ซึ่งผลที่ได้เทียบอยู่ในระดับเดียวกับการใช้ XG และ SCMC และดีกว่าการใช้ AV, AC, SA หรือ TG เป็นสารช่วยแขวนตะกอน ในขณะที่แป้งข้าวเหนียวดัดแปรไม่สามารถนำมาใช้เป็นสารช่วยแขวนตะกอนได้ เนื่องจากเกิดความไม่เข้ากันกับสารลดแรงตึงผิว Tween® 80 ในตำรับยาเตรียม เป็นผลให้เกิดการตกตะกอนของตัวยารวดเร็ว ผลการศึกษานี้จะนำไปสู่การพัฒนาแป้งดัดแปรในการนำมาใช้เป็นสารช่วยแขวนตะกอน เนื่องจากมีการผลิตได้อย่างมากมายภายในประเทศ และราคาที่ถูก

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

ภาควิชา เภสัชอุตสาหกรรม
สาขาวิชา เภสัชอุตสาหกรรม
ปีการศึกษา 2539

ลายมือชื่อนิสิต
ลายมือชื่ออาจารย์ที่ปรึกษา
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม

##C775239 : MAJOR MANUFACTURING

KEY WORD: CARBOXYMETHYL STARCH / SUSPENDING AGENT / DEGREE OF SUBSTITUTION

Ornanong Suwannapakul : Preparation and Evaluation of Sodium Carboxymethyl starch as Suspending Agent. Thesis Advisor : Associate Professor Poj Kulvanich, Ph.D. 185 pp. ISBN 974-635-207-5

Four domestically available starches, including tapioca starch, rice starch, glutinous rice starch, and corn starch, were chemically modified and evaluated for their properties as suspending agent. Sodium Carboxymethyl starches with three different degrees of substitution (DS) were prepared from the reaction between native starches and monochloroacetic acid in NaOH. The prepared modified starches were subjected to the preliminary selection for the best modified starch from each type. The selection was made based on the viscosity of dispersion of modified starch and on the sedimentation volume (SV) and the redispersibility of calcium carbonate suspension containing modified starches. Modified starches being selected were modified glutinous rice starch (MGS), modified rice starch (MRS), and modified tapioca starch (MTS) with DS of 0.16, 0.26, and 0.38, respectively. Modified corn starch (MCS) was excluded from the study after preliminary evaluations due to its poor viscosity, sedimentation volume, and redispersibility. Selected modified starches were then evaluated for their suspending property in ibuprofen suspension, in comparison with six commonly used suspending agents - Xanthan Gum (XG), Avicel® RC-591 (AV), Sodium Alginate (SA), Acacia (AC), Tragacanth (TG), and Sodium Carboxymethylcellulose (SCMC). The evaluation parameters included SV, rheology, redispersibility, and uniformity of drug dispersion during storage. The results suggested that MRS and MTS were promising suspending agent. Suspensions containing as low as 1% MRS and MTS possessed high viscosity and sedimentation volume, good redispersibility and uniformity of drug dispersion during storage. The results are comparable to those of XG and SCMC and are much better than those of AV, AC, SA, and TG. The use of MGS as suspending agent was limited by its incompatibility with a component in the formulation, Tween® 80, which resulted in rapid sedimentation of suspension. Considering the amounts of rice starch and tapioca starch produced in Thailand annually, MRS and MTS are good candidates for the development as new, low-cost suspending agents.

สถาบันวิทยบริการ

จุฬาลงกรณ์มหาวิทยาลัย

ภาควิชา..... เกษษัตริศาสตร์

ลายมือชื่อนิสิต..... *Ornanong Suwannapakul*

สาขาวิชา..... เกษษัตริศาสตร์

ลายมือชื่ออาจารย์ที่ปรึกษา..... *Poj Kulvanich*

ปีการศึกษา..... 2539

ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....



ACKNOWLEDGEMENTS

I am deeply indebted to many people for their intellectual contributions, support, and encouragement in making this thesis possible.

I would like to express my sincere gratitude to my research advisor, Associate Professor Dr.Poj Kulvanich, who has tirelessly supervised my Master thesis. He reserved so many hours to guide me throughout the research. His encouragement, generosity, and advices have been both challenging and inspirational.

I am deeply grateful to Assistant Professor Wichien Thanindratan whose countless insight, technical guidance, and consistent encouragement were invaluable in all phases of this research.

I gratefully acknowledge innumerable and invaluable comments from Associate Professor Suchada Prasertvithayakarn and Associate Professor Parunee Thanomkiat who served on my thesis committee. Their comments have been extremely precise and constructive.

I would like to extend my hearty appreciation to Associate Professor Dr. Jaratbhan Sanguansermisri, Assistant Professor Dr.Puckprink Sangdee, Associate Professor Dr.Aranya Manosroi, and Assistant Professor Pramote Tipduangta, all from Faculty of Pharmacy, Chiangmai University, for their thoughtful advices, supports, and generous guidances during my masters program years.

Special thanks to Tasana Pitaksuteepong and Wallop Weecharangsarn for thier advices on the modification of starches.

For their encouragement, assistance, and goodwill, I am indebted to my graduate colleagues, Neeranuch Phuwakul, Indira Kuwanichwong, and Sutasinee Pichayavasin. Thanks also are due to the University Developing Council (UDC) and the Graduate School of Chulalongkorn University for the scholarship and financial support in form of teaching assistantship, and to the UNIDO people, who helped me on transparency and presentation preparation.

Last but not least, the most special acknowledgement is reserved for my parents and my sister, Suleeporn Suwannapakul. Their loves and patience made this work possible.

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LIST OF ABBREVIATIONS

AC	=	Acacia
AV	=	Avicel [®] RC-591
°c	=	Degree Celcius
DS	=	Degree of Substitution
FT	=	Freeze-Thaw Cycle
g	=	Gram
IR	=	Infrared Spectrometry
mPa	=	MilliPascal
mg	=	Mlligram
min	=	Minute
mL	=	Millilitre
MS	=	Modified Starch
MCS	=	Modified Corn Starch
MRS	=	Modified Rice Starch
MGS	=	Modified Glutinous Rice Starch
MTS	=	Modified Tapioca Starch
PAA	=	
PEG	=	Polyethylene Glycol
SA	=	Sodium Alginate
SCMC	=	Sodium Carboxymethylcellulose
SV	=	Sedimentation Volume
TG	=	Tragacanth
qs	=	quantium sufficiat = sufficient quantity
μL	=	Microlitre
UV	=	Ultraviolet Spectrometry
XG	=	Xanthan Gum