

คุณสมบัติทางเคมีกายภาพและเชิงกล และการควบคุมการปลดปล่อยในเฟลลทเคลือบ
ของฟิล์มผสมระหว่างเอริลเซสลูโลส และแอมโมนิโอเมธาคริเลต โคโพลิเมอร์
ทั้งในระบบตัวทำละลายอินทรีย์ และในระบบชนิดกระจายตัวในน้ำ

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**PHYSICO-CHEMICAL AND MECHANICAL PROPERTIES
AND CONTROLLED RELEASE IN COATED PELLETS OF MIXING FILMS
BETWEEN ETHYLCELLULOSE AND AMMONIO METHACRYLATE
COPOLYMER IN ORGANIC AND AQUEOUS DISPERSION SYSTEMS**

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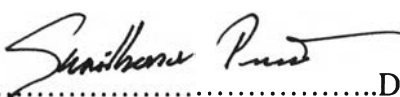
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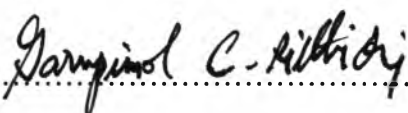
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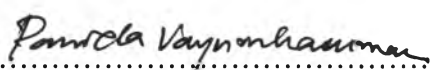
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ในเพลลทเคลือบของฟิล์มผสมระหว่างเอซิลเซลลูโลส แอมโมนิโอเมทาคริเลต โคโพลิเมอร์ทั้งใน
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ศึกษาคุณสมบัติของฟิล์มเดี่ยวและฟิล์มผสมระหว่างเอซิลเซลลูโลสและแอมโมนิโอเมทาคริเลต โค
โพลิเมอร์ ชนิด บี ในระบบตัวทำละลายอินทรีย์ (เอซิลเซลลูโลส กับ ยูตราจิต อาร์ เอส 100) และในระบบชนิด
กระจายตัวในน้ำ (ซัวร์ลีส กับ ยูตราจิต อาร์ เอส 30 ดี) รวมทั้งอิทธิพลของชนิดและปริมาณของพลาสติกไซ
เซอร์ต่อคุณสมบัติทางเคมีกายภาพและเชิงกลของฟิล์ม และผลต่อลักษณะการปลดปล่อยตัวยาจากโพรพรา
โนลอลไฮโดรคลอไรด์เพลลทที่เคลือบด้วยฟิล์มเดี่ยวและฟิล์มผสมเหล่านี้ เตรียมโพรพารโนลอลไฮโดรคลอไรด์
เพลลทโดยใช้เทคนิคเอ็กซ์ทูรชัน-สเฟียไรเซชันโรโนซ์เซชัน แล้วนำมาเคลือบฟิล์มโดยใช้เทคนิคการเคลือบแบบฟลู
อิดไดซ์เบดชนิดพ่นจากด้านล่าง พบว่าชนิดและปริมาณที่แตกต่างกันของพลาสติกไซเซอร์มีอิทธิพลต่อลักษณะ
พื้นผิวและคุณสมบัติเชิงกลของฟิล์มเดี่ยวและฟิล์มผสม ในระบบตัวทำละลายอินทรีย์ ได้บิวทิล ทาลททำให้
ฟิล์มของเอซิลเซลลูโลสและฟิล์มผสมที่มีสัดส่วนของเอซิลเซลลูโลสอยู่มากกว่ามีลักษณะพื้นผิวและคุณสมบัติ
เชิงกลที่ดี ในขณะที่ไตรเอซิล ซิเทรททำให้ฟิล์มของยูตราจิต อาร์ เอส 100 และฟิล์มที่มีสัดส่วนของยูตราจิต
อาร์ เอส 100 อยู่มากกว่ามีลักษณะพื้นผิวและคุณสมบัติเชิงกลที่ดี ส่วนฟิล์มผสมทั้งหมดที่เตรียมจากระบบชนิด
กระจายตัวในน้ำ และมีไตรเอซิล ซิเทรทเป็นพลาสติกไซเซอร์สามารถทำให้เกิดฟิล์มที่นุ่มและยืดหยุ่นได้ดี รวม
ทั้งทำให้ฟิล์มมีลักษณะเรียบมากขึ้น ในการเพิ่มปริมาณของพลาสติกไซเซอร์ สามารถทำให้เกิดลักษณะพื้นผิว
และคุณสมบัติเชิงกลที่ดีขึ้น นอกจากนี้ชนิดและปริมาณที่แตกต่างกันของพลาสติกไซเซอร์ยังสามารถปรับเปลี่ยน
ลักษณะและอัตราเร็วของการปลดปล่อยยา การเติมยูตราจิต อาร์ เอส 100 ลงในฟิล์มผสมจะทำให้พื้นผิวมี
ลักษณะที่เรียบขึ้น แต่การเติมยูตราจิต อาร์ เอส 30 ดีในฟิล์มผสมไม่ได้ช่วยทำให้เกิดลักษณะพื้นผิวที่ดีขึ้น
อย่างไรก็ตามฟิล์มผสมที่ได้อยู่ระหว่างโพลิเมอร์ 2 ชนิดทั้งในระบบตัวทำละลายอินทรีย์ และในระบบชนิดกระจาย
ตัวในน้ำสามารถทำให้อัตราการปลดปล่อยของยาช้าลงเมื่อเปรียบเทียบกับฟิล์มเดี่ยวๆ ที่เตรียมจากยูตราจิต อาร์
เอส (แอมโมนิโอเมทาคริเลต โคโพลิเมอร์ ชนิด บี) ผลจากอินฟราเรดสเปคตรัมแสดงให้เห็นว่าเกิดปฏิกิริยา
ระหว่างโพลิเมอร์ 2 ชนิดนี้เตรียมจากระบบชนิดกระจายตัวในน้ำ แต่จากลักษณะของเอ็กซ์เรย์ดิฟแฟรคไท
แกรมไม่สามารถตรวจสอบการเกิดปฏิกิริยาใดๆ ระหว่างโพลิเมอร์ 2 ชนิดในระบบชนิดกระจายตัวในน้ำ

ภาควิชา.....เภสัชอุตสาหกรรม.....
สาขาวิชา.....เภสัชอุตสาหกรรม.....
ปีการศึกษา.....2542.....

ลายมือชื่อผู้ผลิต.....
ลายมือชื่ออาจารย์ที่ปรึกษา.....
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The properties of single film and mixed film of ethylcellulose and ammonio methacrylate copolymer type B prepared in organic system (ethylcellulose and Eudragit[®] RS100) and aqueous dispersion system (Surelease and Eudragit[®] RS30D) were investigated. The effect of type and amount of plasticizers on their physico-chemical and mechanical properties of film as well as on the release of the drug from propranolol hydrochloride pellets coated with these single film and blended films were observed. The propranolol hydrochloride pellets were prepared by extrusion-spheronization technique and were coated by a Wurster type fluidized bed technique. The surface appearances and the mechanical properties of single polymer and polymer blends were affected by the various types and amounts of plasticizers. For the organic system, dibutyl phthalate could improve appearances and mechanical properties of ethylcellulose and the polymer blends with higher portion of ethylcellulose while triethyl citrate could improve appearances and mechanical properties of Eudragit[®] RS100 and the polymer blends with higher portion of Eudragit[®] RS100. All of the triethyl citrate-plasticized films prepared from aqueous dispersion system produced soft and tough films with smooth surface. An increase in amount of plasticizers could produce good properties of both surface appearances and mechanical properties. The different type and amount of plasticizers could also modify the drug release characteristics. The incorporation of Eudragit[®] RS100 in the blended films improved the smoothness of the coating surface but the incorporation of Eudragit[®] RS30D did not improve the surface appearances of the blended films. Nevertheless, the mixtures of two polymers in both systems could retard drug release characteristics when compared to the pure films of Eudragit[®] RS type. The interaction between two polymers prepared from aqueous dispersion system was revealed by the IR spectra whereas the X-ray diffractograms could not detect any interaction of two polymers in aqueous dispersion system.

ภาควิชา.....เภสัชอุตสาหกรรม.....

สาขาวิชา.....เภสัชอุตสาหกรรม.....

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LIST OF ABBREVIATIONS

bar	kg/cm ²
°C	degree celcius (centigrade)
cm	centimeter (s)
bp	boiling point
DBP	dibutyl phthalate
DSC	differential scanning calorimetry
EC	ethylcellulose
EuRS100	Eudragit [®] RS100
EuRS30D	Eudragit [®] RS30D
e.g.	exempli gratia, for example
et al.	et alli, and others
etc.	et cetera (and so on)
gm	gram (s)
hr	hour (s)
i.e.	id est, that is
IR	infrared
MFT	minimum film-forming temperature
MPa	millipascal
M.W.	molecular weight
mg	milligram (s)
min	minute (s)
ml	millimeter (s)
mp	melting point
No.	number
nm	nanometer (s)

PEG	polyethylene glycol
pH	the negative logarithm of the hydrogen ion concentration
pKa	the negative logarithm of the dissociation constant
q.s.	make to volume
r^2	coefficient of determination
rpm	revolutions per minute
SD	standard deviation
SEM	scanning electron microscopy
SR	Surelease [®]
Tg	glass transition temperature
TEC	triethyl citrate
TRC	triacetin
USP	The United States Pharmacopoeia
UV	ultraviolet
w/w	weight by weight
μg	microgram (s)
μm	micrometer (s), micron (s)
%	percentage
°	degree