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และการปลดปล่อยนาน

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วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาเภสัชศาสตรดุษฎีบัณฑิต

สาขาเภสัชกรรม ภาควิชาเภสัชกรรมและเภสัชอุตสาหกรรม

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FILM-COATING OF CHITOSAN ONTO PROPRANOLOL HYDROCHLORIDE
TABLETS: APPROACH TO FAST AND EXTENDED DRUG RELEASES

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แผ่นฟิล์มโคโตนอะซิเตต, ซิเตรต, ฟอ์เมต, โกลโคเลต, แลคเตต, มาเลต และโพรพิโอเนตที่มีอัตราส่วนโดยโมลของกรดต่อกลูโคซามีน 1.2:1 เตรียมได้จากภาวะแห้งตัวทำลาย จากการศึกษาด้วย FT-IR spectrometry, DSC และ solid state ¹³C NMR พบว่ามีหลักฐานการเกิดเอไมด์และเอสเทอร์ของฟิล์มโคโตนภายหลังการสัมผัสความร้อนขึ้นที่ 60°ซ 75%RH และความร้อนแห้งที่ 130°ซ ตามลำดับ การลดลงของหมู่ที่ชอบน้ำภายหลังการเกิดเอไมด์และเอสเทอร์นำไปสู่การลดการดูดซับน้ำและการละลายของฟิล์ม ฟิล์มโคโตนอะซิเตตและโพรพิโอเนตภายหลังสัมผัสความร้อนขึ้นมีการดูดซับน้ำและการละลายที่ต่ำกว่าขณะที่ค่าเหล่านี้ของโคโตนซิเตรตและมาเลตยังคงสูงอยู่ ดังนั้นฟิล์มสองชนิดแรกได้ถูกเลือกเพื่อใช้เป็นสารเคลือบสำหรับยาเม็ดชนิดออกฤทธิ์นานและฟิล์มสองชนิดหลังสำหรับยาเม็ดชนิดออกฤทธิ์เร็ว โปรปราโนลอล ไฮโดรคลอไรด์ซึ่งบรรจุในยาเม็ดแกนถูกใช้เป็นยาโมเดล

อิทธิพลของพลาสติกไซเซอร์ ซี และ สารทึบแสงชนิดต่างๆต่อการเข้ากันได้กับสารละลายโคโตนหรือคุณสมบัติเชิงกลและการยึดติดได้รับการทดสอบ โพรไฟลีน โกลคอล, บริลเลียน บลู และทัลคัมในความเข้มข้น 25, 0.5 และ 15% โดยน้ำหนักตามลำดับมีความเหมาะสมในการเป็นพลาสติกไซเซอร์ ซี และ สารทึบแสงสำหรับฟิล์มโคโตนซิเตรตเนื่องจากคุณสมบัติการละลายน้ำ การยึดติดที่ดี และมีความคงตัวภายหลังการเก็บเป็นเวลานาน ทำให้มีความเป็นไปได้ในการนำโคโตนซิเตรตเพื่อใช้เป็นสารเคลือบซึ่งนำไปสู่การปลดปล่อยเร็ว บริลเลียน บลูมีผลต่อการปลดปล่อยยาน้อยกว่า กรีน เอฟเอสและให้ความเข้มข้นของสีที่เพียงพอต่อการแต่งสี การเติมโพรไฟลีน โกลคอล 25% และทัลคัมในปริมาณต่ำสามารถเพิ่มคุณสมบัติเชิงกลและทัลคัมมีแนวโน้มลดการดูดซับความชื้นและทำให้โคโตนซิเตรตมีความมันเงา

ความร้อนขึ้นที่ 60°ซ 75%RH มีประสิทธิภาพมากกว่าความร้อนขึ้นที่ 45°ซ 75%RH และความร้อนแห้งที่ 60°ซ ในการยึดการปลดปล่อยยาให้นานขึ้นของยาเม็ดที่เคลือบด้วยฟิล์มโคโตนอะซิเตตซึ่งประกอบด้วยแมกนีเซียมสเตียเรต ทัลคัม หรือ ไทเทเนียม ไดออกไซด์ จากการศึกษาด้วย FT-IR spectrometry, powder X-ray diffraction และ DSC พบว่าโมเลกุลสเตียเรตจากแมกนีเซียมสเตียเรตสามารถทำปฏิกิริยากับหมู่เอมิโนซึ่งมีการโปรโตเนชันของโคโตนและภายหลังสัมผัสความร้อนขึ้นมีการเกิดเอไมด์ในฟิล์มโคโตน ดังนั้นการเติมแมกนีเซียมสเตียเรตมีประสิทธิภาพในการยึดการปลดปล่อยยามากกว่า ทัลคัม และ ไทเทเนียม ไดออกไซด์ การเติมน้ำมันละหุ่งมีผลเพิ่มประสิทธิภาพการยึดการปลดปล่อยด้วยยา ยูเรียที่ความเข้มข้น 5% สามารถลด lag time และเพิ่มปริมาณยาที่ถูกปลดปล่อย ยาเม็ดที่ได้มีความคงตัวดีและมีการปลดปล่อยยาผ่านข้อกำหนดของยาโปรปราโนลอล ไฮโดรคลอไรด์ชนิดออกฤทธิ์นาน 24 ชั่วโมงที่กำหนดใน USP XXIII

สมการ KGT2 ได้สร้างขึ้นเพื่ออธิบายลักษณะกราฟการปลดปล่อยยาจากตำรับที่เคลือบด้วยฟิล์มชนิดละลายได้ และมีตัวแปรจูนในสารแกน สมการนี้สามารถประยุกต์กับการปลดปล่อยยาจากยาเม็ดเคลือบฟิล์มชนิดออกฤทธิ์เร็วและใช้คาดการณ์ถึงเวลาและอัตราการละลายของฟิล์มและอัตราการปลดปล่อยยาจากยาเม็ดแกนภายหลังการละลายของฟิล์ม สมการ KGT3 ถูกพัฒนาต่อมาจากสมการ KGT1 ภายใต้สมมติฐานว่าฟิล์มได้เปลี่ยนเป็นชนิดไม่ละลายโดยความร้อน สมการ first order และ KGT3 สามารถถูกพิตได้เป็นอย่างดีกับเส้นกราฟส่วนมากของการปลดปล่อยยาชนิดออกฤทธิ์นานของเม็ดยาที่เคลือบด้วยฟิล์มโคโตนอะซิเตตที่ปรับปรุงแล้วภายหลังสัมผัสความร้อนขึ้น กลไกการปลดปล่อยยามีลักษณะผสมระหว่างการควบคุมจากการแพร่และแรงดันออสโมติก

ภาควิชา.....เภสัชกรรม-เภสัชอุตสาหกรรม
สาขาวิชา.....เภสัชกรรม
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ลายมือชื่อนิสิต..... รัชชัย แพชมัด
ลายมือชื่ออาจารย์ที่ปรึกษา.....
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Cast films of chitosan acetate, citrate, formate, glycolate, lactate, malate and propionate containing acid : glucosamine unit at mole ratio of 1.2 : 1 were fabricated by solvent evaporation. From FT-IR, DSC and solid state ^{13}C NMR studies, there was an evidence of amide formation and esterification in chitosan salt films after moist heat treatment at 60°C 75%RH and dry heat treatment at 130°C respectively. The decrease in hydrophilic groups after amide formation and esterification led to the decrease in water sorption and dissolution of heat treated films. Water sorption and dissolution of chitosan acetate and propionate films after moist heat treatment were very low whereas those of chitosan citrate and malate films were still quite high. Thus the former two films after heat treatment were chosen to apply as coating material for extended release coated tablet and the latter two films for fast release coated tablet. Propranolol HCl encapsulated in core tablet was used as model drug.

Effect of various plasticizers, colorants and opaquants on compatibility with chitosan solutions or mechanical and adhesion properties of chitosan film was investigated. Propylene glycol, brilliant blue or green FS and talcum at concentration of 25, 0.5 and 15% w/w respectively were proved as a suitable plasticizer, colorant and pigment for the chitosan citrate film. Owing to aqueous soluble and rapidly disintegrating properties, good adhesion and long term aging stability, chitosan citrate seemed potentially to be utilized for the film coating approaching to fast release. Brilliant blue affected drug release behavior less than green FS and could provide enough tinctorial strength for coloring. Addition of propylene glycol 25% and low amount of talcum could improve mechanical properties. Talcum could potentially reduce moisture sorption and provide desired glossiness of film coat.

Moist heat treatment at 60°C 75%RH was more effective than that at 45°C 75%RH and dry heat treatment at 60°C to prolong drug release of tablets coated with chitosan acetate film containing magnesium stearate, talcum or titanium dioxide. From FT-IR, powder X-ray diffraction and DSC studies, stearate molecules liberated from magnesium stearate could react with protonated amino groups of chitosan and further there was amide formation after moist heat treatment in chitosan film, thus incorporation of magnesium stearate was more effective than talcum and titanium dioxide to prolong drug release. An addition of castor oil into film containing magnesium stearate increased the effectiveness to prolonging drug release. Urea at concentration of 5% could shorten the lag time and enhance the amount of drug release. The stability of this coated tablet was good and the drug release complied with the USP XXIII for 24 hours propranolol HCl extended release product.

The mathematical expression, KGT2, was derived to describe the characteristic of drug release from soluble film coated preparation which the drug was in core material. This model expression could apply for the drug release from soluble chitosan film coated tablets and could predict the film dissolution time and rate and also the release rate of remained core tablet after film dissolution. KGT3 equation was sequentially developed from KGT1 by assuming that the film was altered to insoluble film by moist heat treatment. First order and KGT3 equations could be successfully fitted with most of sustained drug release profiles from tablets coated with modified chitosan acetate films after moist heat treatment. The release mechanism of encapsulated drug appeared concomitantly the diffusion controlled and osmotically driven force.

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LIST OF ABBREVIATIONS

%	percentage
%RH	percentage of relative humidity
β	beta
α	alpha
$^{\circ}\text{C}$	degree celsius (centigrade)
$\mu\text{m.}$	micrometre
AVG	average
cm.	centrimetre
cps.	centripoise
DSC	differential scanning calorimetry
e.g.	exempli gratia, for example
et al.	et alii, and others
FTIR	Fourier transform infrared spectroscopy
g.	gram
HCl	hydrochloric acid
HPLC	high performance liquid chromatography
HPMC	hydroxypropyl methyl cellulose
hr.	hour
i.e.	id est, that is
IR	infrared
Kp.	kilo pound
min.	minute
ml.	millilitre
N	normality
NaOH	sodium hydroxide
NF	The National Formulary
nm.	nanometre
NMR	nuclear magnetic resonance
no.	number
pH	the negative logarithm of the hydrogen ion concentration
pKa	the negative logarithm of the dissociation constant
rpm	revolution per minute
RT	room temperature
SD	standard deviation
SEM	scanning electron microscopy
USP	The United States Pharmacopeia
UV-vis	ultraviolet visible
w/v	weight/volume
w/w	weight/weight