

DEVELOPMENT OF TERBUTALINE SULPHATE SUSTAINED RELEASE PELLETS
USING WATER INSOLUBLE POLYMER AS A MEMBRANE SYSTEM



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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

1995

ISBN 974-631-157-3

Thesis Title DEVELOPMENT OF TERBUTALINE SULPHATE SUSTAINED
RELEASE PELLET USING WATER INSOLUBLE POLYMER AS A
MEMBRANE SYSTEM

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พิมพ์ต้นฉบับบทคัดย่อวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

ผดุงขวัญ จิตโรภาส : การพัฒนาเทอร์บูทาลีน ซัลเฟต เพลเลท ออกฤทธิ์นาน โดยใช้
พอลิเมอร์ชนิดไม่ละลายน้ำเป็นระบบเมมเบรน (DEVELOPMENT OF TERBUTALINE
SULPHATE SUSTAINED RELEASED PELLETT USING WATER INSOLUBLE POLYMER AS
A MEMBRANE SYSTEM) อ.ที่ปรึกษา : รศ.ดร.ไกรสิทธิ์ อัมพรายน, อ.ที่ปรึกษาร่วม :
นายสุวัฒน์ อามฤตขจร, 266 หน้า. ISBN 974-631-157-3

การศึกษาการเตรียมแลคโตส-อะริเซล พีเอช101 เพลเลทชนิดหลอก โดยใช้วิธีเอ็กทราซัน-
สเฟียร์โรโนเซชัน โดยศึกษาถึง อิทธิพลของตัวแปรต่าง ๆ ในกระบวนการที่มีต่อคุณสมบัติทางกายภาพ
ของเพลเลท ตัวแปรที่นำมาศึกษา คือ ความเร็วในการหมุนของสเฟียร์โรโนเซอร์ เวลาที่ใช้ในกระบวนการ
สเฟียร์โรโนเซชัน ชนิดของสารยึดเกาะ ความเข้มข้นของสารยึดเกาะ และปริมาณน้ำ ตัวแปรต่าง ๆ ไม่มี
ผลต่อคุณสมบัติการไหล และความกร่อนของเพลเลทที่ผลิตได้โดยกระบวนการนี้ แต่ตัวแปรเหล่านี้มีผลต่อ
คุณสมบัติทางกายภาพอื่น ๆ ของเพลเลท การเพิ่มความเร็วในการหมุนของสเฟียร์โรโนเซอร์ทำให้
เพลเลทมีความกลมเพิ่มขึ้น เมื่อเพิ่มเวลาที่ใช้ในกระบวนการสเฟียร์โรโนเซชันทำให้ได้เพลเลทที่มีความ-
กลม พื้นผิวเรียบ และขนาดอนุภาคเฉลี่ยของเพลเลทเพิ่มขึ้น การเพิ่มความเข้มข้นของสารยึดเกาะทำให้
ขนาดอนุภาคเฉลี่ยของเพลเลท และอัตราการไหลเพิ่มขึ้น เพลเลทที่ใช้ไฮดรอกซีโพรพิลเซลลูโลสชนิด
ความหนืดปานกลาง เป็นสารยึดเกาะ ที่ความเร็วในการหมุนของสเฟียร์โรโนเซอร์สูง จะได้อนุภาค
ทรงกลม การกระจายขนาดแคบ มีคุณสมบัติการไหลที่ดี เมื่อเพิ่มความเข้มข้นของไฮดรอกซีโพรพิล-
เซลลูโลสชนิดความหนืดปานกลาง จะไม่มีผลต่อรูปร่าง และขนาดอนุภาคเฉลี่ยของเพลเลท การเพิ่มปริมาณ
น้ำมีผลต่อรูปร่าง อัตราการไหล และความหนาแน่น

เมื่อศึกษาคุณลักษณะการละลายของเทอร์บูทาลีนซัลเฟต เพลเลทชนิดออกฤทธิ์นาน เมื่อ เคลือบ
ด้วยเอซิลเซลลูโลส และไฮดรอกซีโพรพิลเซลลูโลสชนิดความหนืดปานกลางในสารละลายที่ใช้เคลือบ
ปริมาณต่าง ๆ กัน การเพิ่มปริมาณของเอซิลเซลลูโลส ทำให้การปลดปล่อยตัวยาสำคัญลดลง ในกรณีของ
ไฮดรอกซีโพรพิลเซลลูโลส การปลดปล่อยตัวยาสำคัญเพิ่มขึ้น เมื่อเพิ่มปริมาณในสารละลายที่ใช้เคลือบ
นอกจากนี้รูปแบบการละลายของเทอร์บูทาลีนซัลเฟต เพลเลทชนิดออกฤทธิ์นาน ที่เตรียมโดยกระบวนการนี้
ยังมีค่าใกล้เคียงกับบริคานิล ดูรูล กระบวนการนี้สามารถเตรียมซ้ำได้

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จุฬาลงกรณ์มหาวิทยาลัย

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C575177 : MAJOR MANUFACTURING PHARMACY

KEY WORD: TERBUTALINE SULPHATE/ PELLET/ EXTRUSION-SPHERONIZATION

PADUNGKWAN CHITROPAS : DEVELOPMENT OF TERBUTALINE SULPHATE SUSTAINED RELEASE PELLET USING WATER INSOLUBLE POLYMER AS A MEMBRANE SYSTEM.

THESIS ADVISOR : ASSO. PROF. KAISRI UMPRAYN, Ph.D. THESIS CO-ADVISOR : Mr. SUKAVAT AMAREKAJORN, 266 pp. ISBN 974-631-157-3

Preparation of lactose-Avicel PH101^R placebo pellets using extrusion-spheronization process was studied. The influence of processing variables including the spheronizer speed, the spheronization time, the binder type, the binder concentration and the amount of water content on physical properties of the pellets. This process provided good flow property and low friability pellets which were not affected by variables used. But the other physical properties of the pellets were affected by the variables. The sphericity of pellets were increased with increasing spheronizer speed. When spheronization time was increased, increasing in sphericity, smooth surface and mean particle size of pellets were obtained. Increasing binder concentration, the pellets were increased in mean particle size and flow rate. Pellets using hydroxypropyl cellulose (HPC-M^R) as a binder at high spheronizer speed had sphere shape, narrow size distribution and good flow characteristic. Increasing hydroxypropyl cellulose (HPC-M^R) concentration had no effect on shape and mean particle size of pellets. The amount of water content had effect on shape, flow rate and density.

The dissolution characteristic of sustained release terbutaline sulphate pellets when coated with various amounts of ethylcellulose and hydroxypropyl cellulose (HPC-M^R) in coating solution were investigated. The release of the active drug decreased as the amount of ethylcellulose was increased. In the case of hydroxypropyl cellulose, the release of the active drug increased as the amount of it in coating solution was increased. In addition, dissolution profiles of sustained release terbutaline sulphate pellets prepared with this process were comparable to Bricanyl Durules^R. The process was also reproducible.

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ACKNOWLEDGEMENT



I would like to express my sincere gratitude to my thesis advisor, Associate Professor Dr. Kaisri Umprayn for his helpful advices, attention, encouragement throughout this study and deeply appreciate for his kindness and understanding.

My special grateful thanks to my co-advisor, Mr. Sukavat Amarekajorn, Managing Director of Pharmaceutical and Medical Supply Co.,Ltd.for his valuable advices and suggestions and his permission of using the extruder and spheronizer equipments and other facilities.

I also would like to thanks to Mr.Thawal Chuenkarndee,Managing Director of Siam Pharmaceutical Co.,Ltd. for his permission of using the fluidized bed equipment and other facilities.

I wish to appreciate to the thesis committee fortheir valuable suggestions and discussion.

I am indebted to Graduate School,Chulalongkorn University, for granting partial financial support to fulfill this project.

The special acknowledgement is given to every personnels in the Department of Manufacturing Pharmacy for their assistance and encouragement.

Finally, I would like to express my infinite thanksand deepest gratitude to my parents for their financial support, endless love, care, understanding and encouragement.

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ABBREVIATIONS

bar	Kg/cm ²
°C	degree celsius
cm	centimeter
EC	ethylcellulose
g	gram
HCl	hydrochloric acid
HPC	hydroxypropyl cellulose
HPLC	high performance liquid chromatography
HPMC	hydroxypropyl methylcellulose
hr	hour
LSR	least significant ranges
M	molar
MC	methylcellulose
mg	milligram
min	minute
ml	milliliter
mm	millimeter
nm	nanometer
N	normal
NaOH	sodium hydroxide
rpm	revolutions per minute
SEM	scanning electron microscope
SD	standard deviation
UV	ultraviolet

VS	versus
x	mean
w/v	weight by volume
w/w	weight by weight
ul	microliter



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