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FORMULATION OF FAST DISSOLVING ORAL STRIPS CONTAINING GARCINIA MANGOSTANA HUSK EXTRACT

Miss Nittaya Ruamkittham

A Thesis Submitted Partial Fulfillment of the Requirements
for the Degree of Master of Science in Pharmacy Program in Pharmaceutics

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Garcinia mangostana husk extract

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การศึกษานี้มีวัตถุประสงค์เพื่อพัฒนาตำรับแผ่นอมชนิคละลายเร็วในช่องปากของสารสกัด จากเปลือกผลมังคุดเพื่อยับยั้งแบคทีเรียในช่องปาก โดยใช้สารก่อฟิล์มชนิดละลายน้ำที่มีความหนืด ้ ต่ำได้แก่ ไฮครอกซิโพรพิลเมทิลเซลลูโลส (เอชพีเอ็มซี) และ ไฮครอกซีโพรพิลเซลลูโลส (เอชพีซี) และประกอบด้วยสารปรุงแต่งอื่นๆในตำรับเช่น สารให้ความหวานคือ อะซิซัลเฟมโพแทสเซียม สารแต่งกลิ่นรส คือ เมนทอลและน้ำมันยูคาลิปตัส โดยศึกษาถึงผลของสารก่อฟิล์มต่อคุณสมบัติ ทางกายภาพ คุณสมบัติเชิงกลและเวลาในการละลายของแผ่นอม เปรียบเทียบกับผลิตภัณฑ์ทางการ ค้ารูปแบบฟิล์ม เอ ซึ่งเป็นแผ่นอมชนิดละลายเร็วที่มีขายในท้องตลาด จากการศึกษาเวลาในการ ละลายพบว่าแผ่นอมเปล่าที่มีสารก่อฟิล์มผสมระหว่างเอชพีเอ็มซี 3 ซีพีเอส และเอชพีซี แอลวี ใน สัคส่วน 2:1 3:1 4:1 และ 5:1 มีค่าไม่แตกต่างกับผลิตภัณฑ์ทางการค้ารูปแบบฟิล์ม เอ อย่างมี นัยสำคัญทางสถิติ (p>0.05) จากการศึกษาสแกนนิงอิเล็กตรอนไมโครสโคปี พบว่าแผ่นอมที่มีสาร สกัดจากเปลือกผลมังคุดมีพื้นผิวเป็นรูพรุน การปลดปล่อยยารวดเร็วมากกว่า 80 เปอร์เซ็นต์ ภายใน เวลา 3-7 นาที โดยสูตรที่มีการปลดปล่อยยาเร็วที่สุดคือ สูตรผสมระหว่างเอชพีเอ็มซี 3 ซีพีเอส และ เอชพีซี แอลวี ในสัดส่วน 5:1 ผลจากติฟเฟอเรนเชียลสแกนนิงแคลอรีเมทรีแสดงให้เห็นว่าสารสกัด จากเปลือกผลมังคุดและสารปรุงแต่งอื่นๆในตำรับไม่อยู่ในรูปผลึก การศึกษาฤทธิ์ต้านจุลินทรีย์ใน หลอดทดลองของแผ่นอบที่มีสารสกัดพบว่าสามารถด้านแบคทีเรียในช่องปากและฟัน ได้แก่ *สแตป* ฟิโลคอกคัส ออเรียส เอทีซีซี 25923 และ สเตรปโตคอกคัส มิวแตนส์ เอทีซีซี เคพีเอสเค, ใน การศึกษาความคงตัวภายใต้สภาวะเค้นที่อุณหภูมิ 40 องศาเซลเซียส ความชื้นสัมพัทธ์ เปอร์เซ็นต์ พบว่าแผ่นอมมีความคงตัวคื

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ลายมือชื่อนิสิต ขึ้วมกิจธรรง ลายมือชื่ออาจารย์ที่ปรึกษา วามกิจธรรง ลายมือชื่ออาจารย์ที่ปรึกษาร่วม การไฟ กองโดมา # # 4676573533 : MAJOR PHARMACY

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KEY WORD: GARCINIA MANGOSTANA / FAST DISSOLVING ORAL STRIPS /
NITTAYA RUAMKITTHAM: FORMULATION OF FAST DISSOLVING ORAL
STRIPS CONTAINING GARCINIA MANGOSTANA HUSK EXTRACT.
THESIS ADVISOR: ASSOC. PROF. SUCHADA CHUTIMA WORAPAN, Ph.D.,
THESIS CO-ADVISOR: ASSOC. PROF. AREERAT LAORPAKSA, M. Sc. in

The purpose of this study was to develop fast dissolving oral strips containing Garcinia mangostana husk extract. The films consisted of low viscosity hydrophilic polymers such as hydroxypropyl methylcellulose and hydroxypropylcellulose, acesulfame potassium as sweetener, and menthol and eucalyptus oil as flavoring agents. The physical and mechanical properties and dissolution time of film bases were compared with commercial product strips A. From the dissolution time data, it was found that the film prepared from mixed polymer between HPMC 3 cps and HPC LV at ratios 2:1, 3:1, 4:1 and 5:1 were not significantly different from commercial product strips A (p>0.05). The films containing extract were light yellow and had porous surface based on observation from scanning electron microscopy. The dissolution profiles of all formulations showed the rapid release more than 80 percent of mangostin from films within 3-7 minutes and the fastest release was from formulation of HPMC 3 cps and HPC LV at ratio 5:1. Differential scanning calorimetry results exhibited that the Garcinia mangostana extract and additives were not in crystalline form in the films. The fast dissolving oral strips containing Garcinia mangostana husk extract showed in vitro antimicrobial activity against oro-dental bacteria, namely, Staphylococcus aureus ATCC 25923 and Streptococcus mutans ATCC KPSK₂. Under stress conditions at 40 degree Celcius and 75 percent relative humidity, the strips showed a good stability.

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LIST OF ABBREVIATIONS

ANOVA = analysis of variance

°C = degree Celcius

cm = centimeter

cm² = square centimeter

conc = concentration

cps = centipoises

CV = coefficient of variation

df = degree of freedom

E hydroxypropyl methylcellulose

et al. = and others

g = gram hr = hour

HPLC = high performance liquid chromatography

HPMC = hydroxypropyl methylcellulose

HPC LV = hydroxypropyl cellulose low viscosity

k = release rate constant

MBC = minimal bactericidal concentration

mg = milligram

MIC = minimal inhibitory concentration

min = minute ml = milliliter

mm = millimeter

mm² = square millimeter

mPas = millipascal.second

N = Newton

No. = number

nm = nanometer

R² = coefficient of determination

RH = relative humidity

rpm = revolution per minute

RSD = Relative standard deviation

sec = second

SD = standard deviation

SS = sum of square

TLC = thin layer chromatography

UV = ultraviolet

VR = variance ratio

v/v = volume by volume

w/w = weight by weight

 $mcg, \mu g$ = microgram μl = microliter

 $\mu m = micrometer$