

ศึกษาการนำเปลือกหุ้มเมล็ดเทียนเกล็ดหอยมาใช้เป็นสารยึดเกาะ
ในการเตรียมยาเม็ด

นาย สรวุฒิ รุจิวิวัฒน์



วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาเภสัชศาสตรมหาบัณฑิต

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THE STUDIES OF ISPAGHULA HUSK AS BINDER FOR
TABLET PREPARATIONS

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พิมพ์ต้นฉบับบทความวิจัยวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว



สรุทธิ รุจิวิวัฒน์ : ศึกษาการนำเปลือกหุ้มเมล็ดเทียนเกล็ดหอยมาใช้เป็นสารยึดเกาะในการเตรียมยาเม็ด (THE STUDIES OF ISPAGHULA HUSK AS BINDER FOR TABLET PREPARATIONS) อ. ที่ปรึกษา : รศ. ดร. ไกรสิทธิ์ อัมพรายน , 157 หน้า. ISBN 974-633-247-3

เปลือกหุ้มเมล็ดชั้นนอกและชั้นติดกันที่แยกจากเมล็ดสุกที่แห้งของเทียนเกล็ดหอย (*Plantago ovata* Forsk.) มีผู้รายงานว่ามีความหนืดและเป็นสารยึดติดที่เป็นเมือก ในการศึกษานี้ได้ประเมินคุณสมบัติการยึดเกาะสำหรับการเตรียมยาเม็ดเปรียบเทียบกับสารช่วยยึดเกาะอื่นที่ใช้กันทั่วไป เช่น PVP K30, HPC type L, gelatin, corn starch และ Starch 1500^o การศึกษาใช้สองวิธี สารช่วยยึดเกาะใช้ระดับ 0.5, 1 และ 2% ของน้ำหนักแห้งสำหรับยาเม็ดพาราเซตามอล และ นิโคตินาไมด์ สำหรับการเตรียมโดยวิธี solution incorporation ส่วนการเตรียมโดยวิธี dry incorporation จะใช้สารช่วยยึดเกาะในปริมาณ 1, 2 และ 4% ของน้ำหนักแห้งของตำรับ คุณสมบัติช่วยยึดเกาะของสารต่างๆที่ใช้จะประเมินจากคุณสมบัติทางกายภาพของแกรนูล (เช่น ขนาดและการกระจายขนาดของแกรนูล การไหล ความกร่อนของแกรนูล) และเม็ดยา (เช่น ความกร่อน การแตกกระจายตัว การละลายและค่าดัชนีการยึดเกาะ) จากผลการทดลองค่าดัชนีการยึดเกาะที่ได้จากตัวยาทั้งสองชนิด แสดงให้เห็นว่า เปลือกหุ้มเมล็ดเทียนเกล็ดหอยมีคุณสมบัติช่วยยึดเกาะดีกว่า corn starch และ Starch 1500^o แต่ด้อยกว่า PVP K30, HPC type L, gelatin ในกรณีวิธี dry incorporation เปลือกหุ้มเมล็ดเทียนเกล็ดหอยให้คุณสมบัติช่วยยึดเกาะดีกว่า Starch 1500^o (ยกเว้น นิโคตินาไมด์ ที่ความเข้มข้นของสารช่วยยึดเกาะ 4% ของน้ำหนักแห้งของตำรับ ซึ่ง Starch 1500^o ดีกว่า) แต่ด้อยกว่า PVP K30 จากการศึกษานี้ ความเข้มข้นของเปลือกหุ้มเมล็ดเทียนเกล็ดหอยที่เหมาะสมจะใช้เป็นสารช่วยยึดเกาะที่มีประสิทธิภาพสำหรับทั้งสองวิธีกับยาทั้งสองชนิด ประมาณ 2% ของน้ำหนักแห้งของตำรับ นอกจากนี้ในกรณีของพาราเซตามอล แกรนูล และยาเม็ด พาราเซตามอล พบว่า การเตรียมโดยวิธี solution incorporation จะให้ค่าดัชนีการยึดเกาะสูงกว่าการเตรียมโดยวิธี dry incorporation ยิ่งกว่านั้น นิโคตินาไมด์แกรนูล และยาเม็ดยา นิโคตินาไมด์ ซึ่งเตรียมโดยทั้งสองวิธี จะให้ผลที่ใกล้เคียงกัน

ภาควิชา เกษัตริย์ศาสตร์
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ลายมือชื่ออาจารย์ที่ปรึกษาร่วม

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Ispaghula husk (*Plantago ovata* Forsk.), the epidermis and the collapsed adjacent layers removed from dried ripe seeds, is reported to form viscous and adhesive mucilage. In this study, it was evaluated for binding properties in tablet preparation as comparing with commonly used binders such as PVP K30, HPC type L, gelatin, corn starch and Starch 1500. Two methods were studied. For solution incorporation, the binders were employed at 0.5, 1 and 2% w/w of paracetamol and nicotinamide tablets. In the case of dry incorporation method, the amount of binder used were 1, 2 and 4% w/w. The physical properties of granules (such as granule size, size distribution, flowability and granule friability) and tablets (such as hardness, friability, disintegration, dissolution and binder index) were evaluated for their binding efficacy. According to the results of binder index obtained from both drugs illuminated that in solution incorporation method, Ispaghula husk possessed binding properties superior to corn starch and Starch 1500 but inferior to PVP K30, HPC type L, gelatin. In the case of dry incorporation method, Ispaghula husk gave binding properties superior to Starch 1500 (except for nicotinamide at binder concentration 4% w/w, Starch 1500 was better) but inferior to PVP K30. From this study, suitable concentration of Ispaghula husk used as the effective binding agent for both methods with both drugs was \cong 2% w/w. In addition, in the case of paracetamol granules and tablets, it was found that solution incorporation method produced binder index higher than dry incorporation method. Furthermore, nicotinamide granules and tablets prepared by both methods gave comparable results

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CONTENTS

	PAGE
ABSTRACT (Thai).....	IV
ABSTRACT (English).....	V
ACKNOWLEDGMENTS.....	VI
CONTENTS.....	VII
LIST OF TABLES.....	VIII
LIST OF FIGURES.....	XII
LIST OF ABBREVIATIONS.....	XXI
CHAPTER	
I INTRODUCTION.....	1
LITERATURE REVIEW	2
PURPOSE OF THE STUDY.....	15
II EXPERIMENTAL.....	16
III RESULTS.....	31
IV DISSCUSSION AND CONCLUSION.....	91
REFERENCES.....	99
APPENDICES.....	104
VITAE.....	157

LIST OF TABLES

Table		Page
1	Characteristics of Plantago seeds from various species.....	3
2	Summaries some commonly used binders with the usual concentration range of their application , together with the granulating solvent.....	6
3	Formulation of paracetamol and nicotinamide tablets prepared by solution incorporation method.....	19
4	Formulation of paracetamol and nicotinamide tablets prepared by dry incorporation method.....	19
5	Particle size distribution of paracetamol granules prepared with various binders.....	41
6	Particle size distribution of nicotinamide granules prepared with various binders.....	43
7	Physical properties of paracetamol granules prepared with various binders and concentrations.....	58
8	Physical properties of nicotinamide granules prepared with various binders and concentrations.....	60
9	Physical properties of paracetamol tablets prepared with various binders and concentration.....	64
10	Physical properties of nicotinamide tablets prepared with various binders and concentration.....	66
11	Calibration data between strain and applied forces of strain guages bound on upper punch.....	108
12	Absorbance of paracetamol standard solution in phosphate buffer pH 5.8	109

Table	Page
13 Absorbance of nicotinamide standard solution in purified water	110
14 Dissolution data of paracetamol tablets prepared with Ispaghula husk by dry incorporation method.....	123
15 Dissolution data of paracetamol tablets prepared with pregelatinized starch by dry incorporation method.....	124
16 Dissolution data of paracetamol tablets prepared with polyvinylpyrrolidone by dry incorporation method.....	125
17 Dissolution data of paracetamol tablets prepared with corn starch by solution incorporation method.....	126
18 Dissolution data of paracetamol tablets prepared with gelatin by solution incorporation method.....	127
19 Dissolution data of paracetamol tablets prepared with polyvinylpyrrolidone by solution incorporation method.....	128
20 Dissolution data of paracetamol tablets prepared with pregelatinized starch by solution incorporation method.....	129
21 Dissolution data of paracetamol tablets prepared with Ispaghula husk by solution incorporation method.....	130
22 Dissolution data of paracetamol tablets prepared with hydroxypropyl cellulose by solution incorporation method.	131
23 Dissolution data of nicotinamide blank tablets	132
24 Dissolution data of nicotinamide tablets prepared with Ispaghula husk by dry incorporation method.....	133
25 Dissolution data of nicotinaamide tablets prepared with pregelatinized starch by dry incorporation method.....	134
26 Dissolution data of nicotinamide tablets prepared with polyvinylpyrrolidone by dry incorporation method.....	135

Table	Page	
27	Dissolution data of nicotinamide tablets prepared with corn starch by solution incorporation method.....	136
28	Dissolution data of nicotinamide tablets prepared with polyvinylpyrrolidone by solution incorporation method.....	137
29	Dissolution data of nicotinamide tablets prepared with gelatin by solution incorporation method.....	138
30	Dissolution data of nicotinamide tablets prepared with hydroxypropyl cellulose by solution incorporation method.	139
31	Dissolution data of nicotinaamide tablets prepared with pregelatinized starch by solution incorporation method.....	140
32	Dissolution data of nicotinamide tablets prepared with Ispaghula husk by solution incorporation method.....	141
33	Analysis of variance and LSD analysis for hardness of paracetamol tablets prepared with various binders at 1 % w/w by dry incorporation method.....	145
34	Analysis of variance and LSD analysis for hardness of paracetamol tablets prepared with various binders at 2 % w/w by dry incorporation method.....	146
35	Analysis of variance and LSD analysis for hardness of paracetamol tablets prepared with various binders at 4 % w/w by dry incorporation method.....	147
36	Analysis of variance and LSD analysis for hardness of paracetamol tablets prepared with various binders at 0.5 % w/w by solution incorporation method.....	148
37	Analysis of variance and LSD analysis for hardness of paracetamol tablets prepared with various binders at 1 % w/w by solution incorporation method.....	149
39	Analysis of variance and LSD analysis for hardness of nicotinamide tablets prepared with various binders at 1 % w/w by dry incorporation method.....	151

Table	Page
40 Analysis of variance and LSD analysis for hardness of nicotinamide tablets prepared with various binders at 2 % w/w by dry incorporation method.....	152
41 Analysis of variance and LSD analysis for hardness of nicotinamide tablets prepared with various binders at 4 % w/w by dry incorporation method.....	153
42 Analysis of variance and LSD analysis for hardness of nicotinamide tablets prepared with various binders at 0.5 % w/w by solution incorporation method.....	154
43 Analysis of variance and LSD analysis for hardness of nicotinamide tablets prepared with various binders at 1 % w/w by solution incorporation method.....	155
44 Analysis of variance and LSD analysis for hardness of nicotinamide tablets prepared with various binders at 2 % w/w by dry incorporation method.....	156

LIST OF FIGURES

Figure		Page
1	Stage in the development of moist granules as the proportion of liquid is increased in wet granulation process.....	8
2	Function block diagram of press and associated measuring system.....	23
3	Calibration curve between strain and applied forces of gaugee bound on instrumented upper punch.....	24
4	Fractured tablets after diametral compression	26
5	Standard curve of paracetamol in phosphate buffer pH 5.8 at 249 nm	29
6	Standard curve of nicotinamide in purified water at 262 nm ..	29
7	Diagram of procedure for assay the quantity of paracetamol tablets.....	30
8	Diagram of procedure for assay the quantity of nicotinamide tablets.....	30
9	Photomicrographs of original paracetamol powders.....	32
10	Photomicrographs of lactose powders.....	32
11	Photomicrographs of paracetamol granules prepared without binder.....	32
12	Photomicrographs of paracetamol granules prepared with 2 % Starch 1500 [®] by dry incorporation method	33
13	Photomicrographs of paracetamol granules prepared with 2 % PVP K30 by dry incorporation method	33
14	Photomicrographs of paracetamol granules prepared with 2 % Ispaghula husk by dry incorporation method.....	33

Figure		Page
15	Photomicrographs of paracetamol granules prepared with 2% gelatin by solution incorporation method	34
16	Photomicrographs of paracetamol granules prepared with 2% HPC type L by solution incorporation method	34
17	Photomicrographs of paracetamol granules prepared with 2% corn starch by solution incorporation method	34
18	Photomicrographs of paracetamol granules prepared with 2% Starch 1500 [®] by solution incorporation method	35
19	Photomicrographs of paracetamol granules prepared with 2% PVP K30 by solution incorporation method	35
20	Photomicrographs of paracetamol granules prepared with 2% Ispaghula husk by solution incorporation method	35
21	Photomicrographs of original nicotinamide powders.....	36
22	Photomicrographs of nicotinamide granules prepared without binder.....	36
23	Photomicrographs of nicotinamide granules prepared with 2% Starch 1500 [®] by dry incorporation method	36
24	Photomicrographs of nicotinamide granules prepared with 2% PVP K30 by dry incorporation method	37
25	Photomicrographs of nicotinamide granules prepared with 2% Ispaghula husk by dry incorporation method	37
26	Photomicrographs of nicotinamide granules prepared with 2% gelatin by solution incorporation method	37
27	Photomicrographs of nicotinamide granules prepared with 2% HPC type L by solution incorporation method.....	38
28	Photomicrographs of nicotinamide granules prepared with 2% corn starch by solution incorporation method	38

Figure		Page
29	Photomicrographs of nicotinamide granules prepared with 2% Starch 1500 [®] by solution incorporation method.....	38
30	Photomicrographs of nicotinamide granules prepared with 2% PVP K30 by solution incorporation method	39
31	Photomicrographs of nicotinamide granules prepared with 2% Ispaghula husk by solution incorporation method.....	39
32	Effect of binder types and concentrations on average size of nicotinamide granules prepared by dry incorporation method.....	42
33	Effect of binder types and concentrations on average size of nicotinamide granules prepared by solution incorporation method.....	42
34	Effect of binder types and concentrations on average size of paracetamol granules prepared by dry incorporation method.....	44
35	Effect of binder types and concentrations on average size of paracetamol granules prepared by solution incorporation method.....	44
36	Compressibility of paracetamol granules prepared by dry incorporation method.....	46
37	Compressibility of paracetamol granules prepared by solution incorporation method.....	46
38	Compressibility of nicotinamide granules prepared by dry incorporation method.....	47
39	Compressibility of nicotinamide granules prepared by solution incorporation method.....	47
40	Flowability of paracetamol granules prepared by dry incorporation method.....	50

Figure		Page
41	Flowability of paracetamol granules prepared by solution incorporation method.....	50
42	Flowability of nicotinamide granules prepared by dry incorporation method.....	51
43	Flowability of nicotinamide granules prepared by solution incorporation method.....	51
44	Percent fine of paracetamol granules prepared by dry incorporation method.....	52
45	Percent fine of paracetamol granules prepared by solution incorporation method.....	52
46	Percent fine of nicotinamide granules prepared by dry incorporation method.....	53
47	Percent fine of nicotinamide granules prepared by solution incorporation method.....	53
48	Friability of paracetamol granules prepared by dry incorporation method.....	56
49	Friability of paracetamol granules prepared by solution incorporation method.....	56
50	Friability of nicotinamide granules prepared by dry incorporation method.....	57
51	Friability of nicotinamide granules prepared by solution incorporation method.....	57
52	Effect of various binder and concentrations on hardness of paracetamol tablets.....	68
53	Effect of various binder and concentrations on hardness of nicotinamide tablets.....	68
54	Effect of various binder and concentrations on tensile strength of paracetamol tablets.....	69

Figure		Page
55	Effect of various binder and concentrations on tensile strength of nicotinamide tablets.....	69
56	Effect of various binder and concentrations on friability of paracetamol tablets.....	71
57	Effect of various binder and concentrations on friability of nicotinamide tablets.....	71
58	Effect of various binder and concentrations on porosity of paracetamol tablets.....	73
59	Effect of various binder and concentrations on porosity of nicotinamide tablets.....	73
60	Effect of various binder and concentrations on disintegration time of paracetamol tablets.....	75
61	Effect of various binder and concentrations on disintegration time of nicotinamide tablets.....	75
62	Dissolution rate profiles of paracetamol tablets prepared with Ispaghula husk by dry incorporation method.....	77
63	Dissolution rate profiles of paracetamol tablets prepared with pregelatinized starch by dry incorporation method.....	77
64	Dissolution rate profiles of paracetamol tablets prepared with PVP K30 by dry incorporation method.....	78
65	Dissolution rate profiles of paracetamol tablets prepared with corn starch by solution incorporation method.....	78
66	Dissolution rate profiles of paracetamol tablets prepared with gelatin by solution incorporation method.....	79
67	Dissolution rate profiles of paracetamol tablets prepared with PVP K30 by solution incorporation method.....	79
68	Dissolution rate profiles of paracetamol tablets prepared with pregelatinized starch by solution incorporation method	80

Figure		Page
69	Dissolution rate profiles of paracetamol tablets prepared with Ispaghula husk by solution incorporation method.....	80
70	Dissolution rate profiles of paracetamol tablets prepared with HPC type L by solution incorporation method.....	81
71	Dissolution rate profiles of nicotinamide tablets prepared without binder.....	81
72	Dissolution rate profiles of nicotinamide tablets prepared with Ispaghula husk by dry incorporation method.....	82
73	Dissolution rate profiles of nicotinamide tablets prepared with pregelatinized starch by dry incorporation method.....	82
74	Dissolution rate profiles of nicotinamide tablets prepared with PVP K30 by dry incorporation method.....	83
75	Dissolution rate profiles of nicotinamide tablets prepared with corn starch by solution incorporation method.....	83
76	Dissolution rate profiles of nicotinamide tablets prepared with PVP K30 by solution incorporation method.....	84
77	Dissolution rate profiles of nicotinamide tablets prepared with gelatin by solution incorporation method.....	84
78	Dissolution rate profiles of nicotinamide tablets prepared with HPC type L by solution incorporation method.....	85
79	Dissolution rate profiles of nicotinamide tablets prepared with pregelatinized starch by solution incorporation method.	85
80	Dissolution rate profiles of nicotinamide tablets prepared with Ispaghula husk by solution incorporation method.....	86
81	Effect of various binder and concentrations on median dissolution time of paracetamol tablets.....	87
82	Effect of various binder and concentrations on median dissolution time of nicotinamide tablets.....	87

Figure		Page
83	Effect of various binder and concentrations on binder index of paracetamol tablets.....	90
84	Effect of various binder and concentrations on binder index of nicotinamide tablets.....	90
85	The cumulative percent undersize of paracetamol granules prepared without binder.....	112
86	Effect of PVP K30 concentration on the cumulative percent undersize of paracetamol granules prepared by dry incorporation method.....	112
87	Effect of Ispaghula husk concentration on the cumulative percent undersize of paracetamol granules prepared by dry incorporation method.....	113
88	Effect of pregelatinized starch concentration on the cumulative percent undersize of paracetamol granules prepared by dry incorporation method.....	113
89	Effect of Ispaghula husk concentration on the cumulative percent undersize of paracetamol granules prepared by solution incorporation method.....	114
90	Effect of pregelatinized starch concentration on the cumulative percent undersize of paracetamol granules prepared by solution incorporation method.....	114
91	Effect of HPC type L concentration on the cumulative percent undersize of paracetamol granules prepared by solution incorporation method.....	115
92	Effect of PVP K30 concentration on the cumulative percent undersize of paracetamol granules prepared by solution incorporation method.....	115
93	Effect of corn starch concentration on the cumulative percent undersize of paracetamol granules prepared by solution incorporation method.....	116

Figure		Page
94	Effect of gelatin concentration on the cumulative percent undersize of paracetamol granules prepared by solution incorporation method.....	116
95	The cumulative percent undersize of nicotinamide granules prepared without binder.....	117
96	Effect of PVP K30 concentration on the cumulative percent undersize of nicotinamide granules prepared by dry incorporation method.....	117
97	Effect of Ispaghula husk concentration on the cumulative percent undersize of nicotinamide granules prepared by dry incorporation method.....	118
98	Effect of pregelatinized starch concentration on the cumulative percent undersize of nicotinamide granules prepared by dry incorporation method.....	118
99	Effect of corn starch concentration on the cumulative percent undersize of nicotinamide granules prepared by solution incorporation method.....	119
100	Effect of HPC type L concentration on the cumulative percent undersize of nicotinamide granules prepared by solution incorporation method.....	119
101	Effect of pregelatinized starch concentration on the cumulative percent undersize of nicotinamide granules prepared by solution incorporation method.....	120
102	Effect of Ispaghula husk concentration on the cumulative percent undersize of nicotinamide granules prepared by solution incorporation method.....	120
103	Effect of PVP K30 concentration on the cumulative percent undersize of nicotinamide granules prepared by solution incorporation method.....	121

Figure	Page
104 Effect of gelatin concentration on the cumulative percent undersize of nicotinamide granules prepared by solution incorporation method.....	53

LIST OF ABBREVIATIONS

μm	=	micrometer
avg	=	average
cm	=	centimeter
g	=	gram
kg	=	kilogram
kp	=	kilopound
m	=	meter
mg	=	milligram
min	=	minute
ml	=	milliliter
q.s.	=	make to quantity
r.p.m.	=	revolution per minute
S.D.	=	standard deviation
sec	=	second
SEM	=	scanning electron photomicrograph
$^{\circ}\text{C}$	=	degree Celcius