

LIST OF CONTENTS

Chapter		Page
I	INTRODUCTION.....	1
	Rationale for study.....	1
	Objectives of the study.....	3
	Expected outputs.....	3
	Expected outcomes.....	4
II	REVIEWS OF RELATED LITERATURE AND RESEARCH.....	5
	Skin structure.....	5
	Epidermis.....	6
	Dermis.....	6
	Subcutaneous tissue.....	6
	Skin properties related with outcome measurement in this study.....	7
	Skin color.....	7
	Skin hydration or water content of skin.....	7
	Skin pH.....	8
	Skin elasticity.....	8
	Transepidermal water loss of skin.....	9
	Facial cleansing lotion.....	9
	The instruments for measuring skin properties.....	10
	Mexameter.....	10
	Cutometer.....	11
	Skin-pH-Meter.....	13
	Corneometer.....	13
	Tewameter.....	14
	Alpha-hydroxy acids.....	14
	General information of AHAs.....	14

LIST OF CONTENTS (CONT.)

Chapter	Page
The consequence of AHAs in each skin layer.....	16
Adverse effects of AHAs.....	16
Comparisons of synthetic- and natural AHA.....	17
Tamarind.....	17
Overview of tamarind.....	17
Clinical trial of product containing tamarind's fruit pulp extract....	18
Interventions or study products.....	19
Clinical research methodology.....	21
Overview of clinical trials/study.....	21
Type of clinical controlled trial designed.....	22
Randomization in clinical trial.....	24
Blinding or masking.....	27
Outcomes assessment.....	27
Adherence to the protocol.....	29
Patient safety.....	29
Statistical issues.....	30
Sample size calculation.....	30
Analysis result.....	30
Relevant studies of the efficacy and safety of facial cleansing product containing extract of tamarind's fruit pulp.....	31
Clinical trials for evaluation the efficacy and safety skin whitening products contain herbal extract.....	31
Measurement of skin color.....	31
The duration of study.....	32

LIST OF CONTENTS (CONT.)

Chapter	Page
III RESEACH METHODOLOGY.....	33
Overview of design.....	33
Setting.....	33
Recruitment of the participants.....	33
Participant eligibility criteria.....	34
Inclusion criteria.....	34
Exclusion criteria.....	34
Discontinuation criteria.....	35
Procedure to ensure the safety of participants.....	35
Subject enrollment procedures.....	35
Interventions.....	36
Description of interventions.....	36
The direction for use the product.....	36
Randomization and allocation concealment of interventions.....	36
The procedure of study.....	37
The method of study.....	37
The diagram of study procedures.....	37
The framework of the study.....	39
Outcome assessment	40
Measurement the skin properties.....	40
Measurement the adverse events.....	41
Measurement the satisfaction.....	41
Sample size determination and data analysis.....	41
Sample size determination.....	41
Data analysis.....	42
Quality assurance of study.....	42

LIST OF CONTENTS (CONT.)

Chapter	Page
Training the staffs.....	42
Training the participants.....	43
Compliance of protocol.....	43
Data processing and management.....	44
Data validity and reliability.....	44
Loss to follow up procedures.....	44
Handling missing data.....	45
The facilities.....	45
Budget.....	45
IV RESULTS.....	46
Characterization of test product and placebo product.....	46
Result of eligibility and demographic data of subjects.....	47
Efficacy of product.....	49
Skin parameters for efficacy assessment.....	49
The satisfaction of subjects.....	52
Safety of products.....	54
Skin parameters for irritation assessment:.....	54
Clinical evaluation of adverse events.....	55
Quality control of study.....	56
Compliance of subject.....	56
Other procedures to control the quality of study.....	56
V DISCUSSION AND CONCLUSION	58
REFERENCES.....	63

LIST OF CONTENTS (CONT.)

Chapter	Page
APPENDICES.....	73
A: Application form.....	74
B: Subject information sheet.....	76
C: Subject safety data sheet	85
D: Informed consent form.....	89
E: Diary	94
F: Case report form.....	96
G: Form for evaluation product use of subject.....	117
H: Example of evaluation form for content validity.....	119
I: Questionnaires for subject.....	121
J: Material safety data sheet.....	126
K: Result of randomization.....	138
L: Results of each skin parameter.....	140
M: Irritation test of facial product.....	164
BIOGRAPHY.....	175

LIST OF TABLES

Table		Page
1	The range of skin pH-value in women and men.....	13
2	The formula of each product and basic function of each ingredient.....	20
3	Stratified randomization with block size of four.....	26
4	The diagram of study procedures.....	38
5	The schedule and detail of measurement skin properties.....	40
6	The management of budget in this study.....	45
7	Physicochemical parameters of test and placebo products.....	46
8	Demographic data of subjects.....	48
9	Baseline skin characteristics of each group.....	49
10	Overall results at the middle and the end of study.....	50
11	Mean of satisfaction value.....	53
12	Each skin parameter at the middle and the end of study.....	54
13	Product weight and total amount of using product.....	56
14	Number of subjects use appropriate or inappropriate dose.....	57
15	Absolute mean difference between test and control group of each skin parameter (Based on value at measurement time value at baseline)....	141
16	Melanin values at baseline of each subject.....	142
17	Melanin values of each subject at week 4	144
18	Melanin values of each subject at week 8.....	145
19	Water content of each subject at baseline.....	147
20	Water content of each subject at week 4.....	148
21	Water content of each subject at week 8.....	150
22	Skin pH of each subject at baseline, week 4, and week 8.....	151
23	Skin elasticity of each subject at baseline.....	153
24	Skin elasticity of each subject at week 5.....	154
25	Skin elasticity of each subject at week 8.....	156

LIST OF TABLES (CONT.)

Table		Page
26	Absolute mean difference between test and control group of erythema, and TEWL values (Based on value at measurement time - value at baseline).	157
27	Erythema index of each subject at baseline.....	158
28	Erythema index of each subject at week 4.....	159
29	Erythema index of each subject at week 8.....	161
30	TEWL values of each subject at baseline, week 4, and week 8.....	162
31	Results of all measurement at baseline, day 5, and day 8.....	174



LIST OF FIGURES

Figure	Page
1 Skin structure.....	5
2 The instruments for measuring skin properties in this study.....	11
3 Time-curve of skin deformation obtained with cutometer.....	12
4 The structure of AHAs.....	15
5 The crossover design.....	22
6 The parallel design.....	23
7 The within person design.....	23
8 The example of block of four.....	26
9 Placebo and test products.....	46
10 Result of eligible process.....	47
11 The melanin values of each group.....	51
12 The skin hydration and skin pH of each group.....	51
13 The gross and net elasticity of skin of each group.....	52
14 The TEWL in each group.....	55
15 The erythema index in each group.....	55
16 Test areas of test product, placebo, and de-ionized water, respectively.....	174