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Development of a Peel-Off Facial Mask Formula Containing Crude Extracts of Andrographis Paniculata

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Abstract

Introduction: The use of facial masks provides a viable alternative to the use of cold poultice in traditional medicine. However, with regard to the use of Andrographis paniculata in Thai traditional medicine, previous studies have not described an appropriate formula for such facial masks and their associated properties. The objective of this study is to describe the chemical and physical properties and contaminants found in six peel-off facial mask formulas containing Andrographis paniculata extracts.

Methods: Investigators developed six formulas of facial masks containing Andrographis paniculata with varying amounts of PVA and HPMC but fixed proportion of crude Andrographis extract. Investigators then selected the formula with the most suitable properties for additional assessments regarding changes in their physical and chemical properties after a 3-month incubation period at varying temperatures, as well as chemical and microbial contaminations.

Results: The most appropriate formula contained 2.5% HPMC (vol/vol) and 10% PVA (vol/vol). After incubation, formula at higher incubation temperature had lower andrographolite than formula at lower incubation temperature. The pH, colour, and thickness had little variations by incubation temperatures. Chemical and microbial contaminations were all according to standards.

Discussion and Conclusion: The findings of the study had implications for stakeholders in pharmaceutical sciences and traditional medicine. However, limitations regarding the sample size and lack of generalizability should be considered in the interpretation of the study findings.

Keywords: Peel-off facial masks; Formula; Andrographis paniculate

1. Introduction

Thai traditional medicine includes the use of herbal extracts for various ailments and remedies in the form of ingested extracts as well as cold poultice (Wathanawekhin, 2010). One of the most commonly used herb in cold poultice recipes is Andrographis paniculata, which contains 4 types of lactone substances that with a viscous cooling effect (Department of Mental Health, 2021) and an active ingredient, andrographolide, that reduces inflammation and pain. Cold poultice requires fresh preparation and does not enable long-term storage, and also has the undesirable characteristics of staining clothing items, and the thick and adhesive nature, all of which creates inconvenience for use (Wetchakun, Phuaphermphulsiri, & Silaorn, 2015).

Facial masks are a prepared form of medicine for transdermal delivery of active ingredients in the form of a flexible sheet that sticks well to the skin (United States Patent No. US20030175333A1, 2003). Thus, the use of facial masks has the potential to become a viable alternative for delivery of andrographolide compared to the use of cold poultice. There has been no previous studies on the development of medications from Andrographis paniculata has not found the appropriate formula for face masks containing extracts of Andrographis Furthermore, data are also scarce regarding the changes to the chemical and physical properties of face masks containing Andrographis extracts when stored at various temperatures, as well as the chemical and microbial contaminations found in such products. Such findings have implications for stakeholders in pharmaceutical sciences and traditional medicine. Thus, the objective of this study is to describe the chemical and physical properties and contaminants found in six peel-off facial mask formulas containing Andrographis paniculata extracts.

2. Methods

2.1 Study design and setting

This is a laboratory-based study conducted at the Faculty of Thai Traditional Medicine. Prince of Songkla University.

2.2 Development of the Facial Mask Formulas

Investigators contacted a GMP and Thai Herbal Pharmacopoeia Volume 1 (1995) certified distributor (Kaew Mangkorn Pharmacy Co., Ltd.) to purchase crude Andrographic paniculata extract. The investigators then developed six formulas of peel-off facial mask with varying levels of PVA and HPMC, and fixed levels of glycerin, methylparaben, propylparaben, and crude Andrographis paniculata extract (Table 1). Investigators mixed PVA with distilled water (80 degrees Celsius) using a mechanical stirrer with continuously stirring. Investigators then added HPMC and stirred until reaching uniformity. Investigators then dissolved the crude extracts of Andrographis paniculata, methylparaben and propylparaben were in glycerin before adding to the PVA and HPMC. Investigators then mixed the mixture until reaching a uniform consistency (Depkes, 1995; Mappa, Edy, & Kojong, 2013;Rahmawanty, Yulianti , & Fitriana, 2015).

Table 1: Recipe for formulas of peel-off facial mask containing coarsely extracted Andrographis paniculata

Material	Formula #1	Formula #2	Formula #3	Formula #4	Formula #5	Formula #6
PVA (% vol/vol)	7	9	10	7	9	10
HPMC (% vol/vol)	2	2	2	2.5	2.5	2.5
Glycerin (% vol/vol)	10	10	10	10	10	10
Methylparaben (% vol/vol)	0.18	0.18	0.18	0.18	0.18	0.18
Propylparaben (% vol/vol)	0.02	0.02	0.02	0.02	0.02	0.02
Crude Andrographis extract (% vol/vol)	2.5	2.5	2.5	2.5	2.5	2.5
Aquadest Ad (mL)	100	100	100	100	100	100

Note: Each formula was repeated three times.

2.3 Assessment of Physical and Chemical Properties of Developed Facial Mask Formulas

The investigators then assessed the physical and chemical properties of the six formulas with regards to: 1) Color and clarity (Hunter Lab model Color Quest); 2) Acidity (pH meter); 3) Viscosity before pouring the marker base into the template (using a viscometer); 4) Tensile strength, percent elongation at break, and peeling force (Texture analyzer model AT. XT. plus); 5) Mask thickness (Digital Thickness Gauge machine); 6) Drying time, by pouring 3 grams of the mask formula onto a smooth surface measuring 10 cm x 10 cm and placing the formula in a temperature-controlled water bath at 35 ± 2 degrees Celsius, then measuring the time from placement until the sample can be peeled off into sheets. The investigators then chose the formula with the lowest viscosity, shortest drying time, highest tensile strength, higher percent elongation at break, and highest peeling force (or a combination thereof) as the most suitable formula of facial mask for further investigations.

2.4 Assessments of Changes in Chemical and Physical Properties during Incubation at Various Temperatures

Investigators packed the most suitable formula in three separate, tightly closed containers, and store each container at 4, 25 and 40 degrees Celsius with 75% relative humidity for 3 months. Investigators then measured the physical and chemical properties of the facial mask products including the pH, drying time, color, thickness and amount of key active ingredient (i.e., Andrographolide).

2.5 Assessment of Chemical and Microbial Contaminations of Developed Facial Masks

Investigators followed the procedures for basic contamination testing (Prasertwaree, Mingmuang, Thongdee, Onthong, & Chansuwanich, 2015) and checked for chemical contaminants, including lead, mercury, arsenic, cadmium and common microbial organisms that contaminate facial masks, including *Staphylococcus Aureus*, *Pseudomonas aeruginosa*, and *Clostridium spp*. (Bureau of Scientific Equipment and Testing, Prince of Songkla University).

2.6 Data Management and Analysis

Investigators entered the study data into a spreadsheet software and analyzed the study data using descriptive statistics, stratified by formula of the facial mask where applicable.

3. Results

Assessment of chemical and physical properties of the six formulas of peel-off facial mask showed that Formula #6 with 2.5% HPMC (vol/vol) and 10% PVA (vol/vol) had the lowest viscosity, shortest drying time, highest tensile strength, highest percent elongation at break, and highest required peeling force out of all the assessed formulae (Table 2). Thus, the investigators deemed Formula #6 to be the most suitable for further investigation. The colour of the Formula #6 facial mask changed during the 3-month incubation period (Table 3). The amount of andrographolite varied by incubation temperature but remained above the standard level at all incubation temperatures. However, the pH, colour, and thickness had little variations by incubation temperatures.

Table 2: Chemical and physical properties of six formulas of peel-off facial mask containing Andrographis paniculata extracts

Formula	Colour	pH	Viscosity (PA)	Thickness (mm)	Drying Time	Tensile strength (g)	Percent elongation at break (mm)	Peeling force (N/mm^2)
Formula#1 (n=3 samples)	L* : 82.58±0.28 a* : -2.53±0.01 b* : 23.75±0.10	4.67 ± 0.00	1722.00 ± 0.00	0.34 ± 0.01	30 Hrs.	394.36 ± 4.20	123.39 ± 7.66	0.02 ± 0.01
Formula#2 (n=3 samples)	L* : 61.24±0.07 a* : 0.55±0.02 b* : 33.49±0.28	4.71 ± 0.00	1430.33 ± 0.58	0.23 ± 0.00	30 Hrs.	344.85 ± 27.60	56.82 ± 4.65	0.02 ± 0.00
Formula#3 (n=3 samples)	L* : 66.44±0.16 a* : 1.13±0.01 b* : 43.63±0.18	4.96 ± 0.01	2740.67 ± 0.58	0.21 ± 0.01	30 Hrs.	607.69 ± 34.36	81.81 ± 4.88	0.04 ± 0.01
Formula#4 (n=3 samples)	L* : 76.07±0.03 a* : -0.75±0.02 b* : 36.50±0.08	4.76 ± 0.00	179.27 ± 0.23	0.22 ± 0.00	30 Hrs.	843.80 ± 32.11	142.15 ± 6.53	0.05 ± 0.01
Formula#5 (n=3 samples)	L* : 81.40±0.15 a* : -2.70±0.03 b* : 26.74±0.11	4.83 ± 0.00	2084.67 ± 0.58	0.22 ± 0.00	29 Hrs.	650.28 ± 38.15	103.88 ± 8.58	0.05 ± 0.00
Formula#6 (n=3 samples)	L* : 69.24±0.16 a* : 1.50±0.14 b* : 45.19±0.17	4.72 ± 0.00	1220.00 ± 1.00	0.25 ± 0.01	28 Hrs.	1149.29 ± 39.54	165.70 ± 2.23	0.06 ± 0.01

Legend
L*: clear color value (out of 100 percent); a*: Color tone (positive = pink or purple; negative = green); b*: Color tone (positive = yellow; negative = blue)

Table 3: PH value, color, thickness, andrographolide amount at various time and incubation temperature for peel-off facial mask Formula #6

Time and incubation temperature	PH at the end of the measurement period	Colour			Thickness (mm)	Andrographolide Amount (mg/g)*
		L*	a*	b*		
0 month at 29 °C (n=3 samples)	4.72 ± 0.00	69.24 ± 0.16	1.50 ± 0.14	45.19 ± 0.17	0.25 ± 0.01	17.63 ± 0.09
3 month at 4 °C (n=3 samples)	6.01 ± 0.01	24.57 ± 0.19	0.12 ± 0.05	5.66 ± 0.08	0.22 ± 0.01	16.39 ± 0.32
3 month at 25°C (n=3 samples)	6.19 ± 0.01	28.63 ± 0.15	0.15 ± 0.12	5.40 ± 0.58	0.22 ± 0.01	15.54 ± 0.59
3 month at 40°C (n=3 samples)	6.00 ± 0.01	24.60 ± 0.12	0.15 ± 0.10	5.30 ± 0.67	0.22 ± 0.01	12.24 ± 0.09

L*: clear color value (out of 100 percent); a*: Color tone (positive = pink or purple; negative = green); b*: Color tone (positive = yellow; negative = blue); Standard andrographolide amount should be above 11 mg/g.

With regard to detection of chemical and biological contaminants (Table 4), the investigators found no trace of lead, mercury, and cadmium. The level of arsenic contaminant in the facial mask Formula #6 was below the Ministry of Public Health's threshold. The investigators also found no contamination by *Staphylococcus aureus*, *Pseudomonas aeruginosa*, or *Clostridium perfringers*.

Table 4: Contaminants detection results for peel-off facial mask Formula #6 (n=3 samples)

Contaminants tested	Standard	Result
Lead (*µg*/kg)	Not found	Not found
Mercury (*µg*/kg)	Not found	Not found
Arsenic (*µg*/kg)	< 5000	< 41.67
Cadmium (*µg*/kg)	Not found	Not found
Staphylococcus Aureus (*number/g*)	Not found	Not found
Pseudomonas aeruginosa (*number/g*)	Not found	Not found
Clostridium perfringers (*number/g*)	Not found	Not found

Source regarding the standard: Announcement of the Ministry of Public Health, 2016

4. Discussion

In this laboratory study, we described the chemical and physical properties of six formulas of peel-off facial mask containing Andrographis paniculata extracts. We also reported changes in physical and chemical properties over a 3-month incubation period at varying incubation temperature, and chemical and microbial contaminations of the formula that we deemed to be the most suitable candidate for drug

development. The selected formula met the existing standards with regard to chemical and physical properties and contaminations.

In the selected Formula #6, the HPMC:PVA ratio was 1:4, which might have enabled a smoother surface for the facial mask from a higher tensile strength and a greater percent elongation at break. The findings of a previous study (Bianchi et al., 2011) supports this notion, as the study found that HPMC:PVA ratio of lower than 1:3 caused incompatility and resulting in facial masks without a smooth surface. Increasing the amount of PVA or other polymers can make the mask more viscous (Beringhs, Rosa, Stulzer, Budal, & Sonaglio, 2013), whereas increasing HPMC can enhance the tensile strength and achieve better skin adhesion (Rowe, Sheskey, & Quinn, 2009). These considerations should be taken into account in the future development of additional formulas.

With regard to changes in the chemical and physical properties, we found that the acidity of the facial mask became weaker over time. This was consistent with previous research which found that Andrographis paniculata extract when baked Dry will have a mild acidity at pH 6.50 (Charoen, 2009), and would be less likely to induce skin irritation. The slight reduction in thickness was likely due to evaporated moisture. The color did not extensively change because the natural color of the crude extract of Andrographis paniculata was dark greenish-yellow, although the clarity and yellowness faded. The amount of andrographolide, the key active ingredient, decreased at higher incubation temperature, which suggested that refrigeration may be required for long-term storage (Dechatiwongse Na Ayudhya, Techadamrongsin, & Jirawattanapong, 1993; Prasertwaree, Mingmuang, Thongdee, Onthong, & Chansuwanich, 2015)

The formula that we reported in this study did not contain contaminations exceeding the standards for facial masks in Thailand (Ministry of Public Health, 2016) However, the investigators developed the formula using Andrographis paniculata extract purchased from a distributor who was certified in GMP and Thai Herbal Pharmacopia 1998. In the development of the formula en masse or by other producers, chemical and biological contaminations could have occurred at various stages of the production process (Irfan, et al., 2022) The probability of such contaminations should be considered in subsequent stages of drug development and production.

The strength of this study was the rigor applied in the development of the formulas, which enabled testing of chemical and physical properties without the effects of chemical or biological contaminations. However, a number of limitations should be considered in the interpretation of the study findings. Firstly, due to budgetary constraints, the investigators could not conduct the study with greater sample size. Thus, chance could not be ruled out as the best explanation of the observed findings. Secondly, the use of ready-made extracts precluded the investigators from reporting the physical and chemical properties and contaminations in the real-world production process, which limited the ability to generalize the study findings.

5. Conclusion

We developed six formulas of peel-off facial mask containing Andrographis paniculata extracts, chose one formula with the most suitable characteristics for further development, and described changes in chemical and physical properties and contaminations. The study findings have implications for future development of drugs and cosmetics containing Andrographis paniculata extracts. However, limitations regarding the sample size and lack of generalizability should be considered in the interpretation of the study findings.

6. Conflict of Interest

The authors declare that there is no conflict of interest.

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