

A Report on the Manufacturing Process of Korean Herbal Acupuncture Prepared with KGMP

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I . Introduction

Herbal acupuncture therapy is a new type of acupuncture treatment method that incorporates existing acupuncture and herbal medication to stimulate the acupuncture point.^{1,2)}

In other words, herbs are processed and extracted to make injectable fluid and small amount of this extract is injected on the acupuncture point believed to be effective to achieve both efficacies of acupuncture and herbal medicine. People have been using herbal

chemical stimulation on the body points for many centuries^{3,4)} but injection of the extract dates back to 1960's. Excellent benefits and safeness of the herbal acupuncture have been known for quite some time now, but with lack of systemic findings, research results, and objectivity, the herbal acupuncture therapy still faces problems of safe소 and promoting superior effects to the public.

Therefore, to confirm the safeness of herbal extracts, this experiment was conducted with existing manufacturing procedures. This study was done in the

clean room (meeting the standard of KGMP : Korea Good Manufacturing Practice) of Korean Institute of Herbal Acupuncture for microbiological examination and achieved significant results.

II. Experiment

1. Sample preparation

1) Components of Herbal Extract (BU, BUM)

Fel Ursi, *Calculus Bovis*, and *Moschus Moschiferi* were purchased through Korean Trade Union

2) Lubricants (CF,JsD,CC,CFC) and Eight Principle Herbal Extract

These herbs were purchased at the local stores.

3) Bee Venom Herbal Extract

Bee venom extracted from the worker bee (*Apis mellifera*⁶⁾) using electromagnetic stimulation was processed and used for this experiment.

4) *Placenta Hominis* Herbal Extract

Raw material was purchased from the Hwasung Pharmaceuticals, Inc.

2. Manufacturing of Sample

1) Components of Herbal Extract (BU, BUM)

In the clean room, herbs were mixed and ground into fine powder, and carried out 90%, 80%, and 70% alcohol extraction.

At each stage, the components were decompressed and freeze-dried. (Fig. 1)

Final distilled water for diluting was at the pH balance of 7.3, and density was matched to that of the saline solution and sterilized at high pressure.

2) Lubricants of the herbal acupuncture extract (CF, JsD, CFC, CC)

Indian *Carthamus Flori* (CF) and Korean walnut (JsD) were extracted to obtain oil.

Extracted oil was placed in the fixed tank and precipitated in the refrigerator for 72 hours and the top layer was gathered and filtered three times in the clean room. Filtered oil was placed in the disinfected vial and to prevent oxidation, it was sealed with nitrogen gas, and randomly sampled. (Fig.2)

Siberian *Cervi Parvum* (CFC) was sliced upper 10% of the antler and processed with alcohol extraction and

magnetic circulation to yield the herbal extract. This extract was mixed with CF oil and decompressed. Filtered oil was placed in the disinfected vial and to prevent oxidation, it was sealed with nitrogen gas, and randomly sampled. (Fig.2)

CC is Siberian *Cervi Parvum* sliced upper 10% of the antler and processed with alcohol extraction and magnetic circulation to yield the herbal extract. This extract was mixed with distilled water and decompressed and freeze-dried.

Final distillation water had the pH balance of 7.3 and density was matched to that of the saline solution and sterilized at high pressure, and randomly sampled. (Fig.3)

3. Bee Venom Herbal Acupuncture

Bee venom powder collected with BV collector¹⁾ was filtered and freeze-dried, and mixed with the distilled water. Final distillation water had the pH balance of 7.3 and density was matched to that of the saline solution and sterilized at high pressure, and randomly sampled. (Fig.4)

BV Partner was prepared by decocting *Mori Albae* and filtered and decompressed in the clean room. It was

mixed with the bee venom at specific ratio and prepared. Final distillation water had the pH balance of 7.3 and density was matched to that of the saline solution and sterilized at high pressure, and randomly sampled. (Fig.5)

4. Eight Principles Herbal Acupuncture Extract

Carefully selected herbs were rinsed in the distilled water, and after soaked in the distilled water, they were decocted and cooled to gather the solution. After several steps of filtration and disinfection, the pH balance was adjusted and randomly sampled. (Fig.6)

5. *Placenta Homonis* herbal acupuncture extract

Raw sample from the Hwasung Pharmaceutical, Inc. was filtered and disinfected in the clean room, and randomly sampled.

Fig.1 BU, BUM, CC Manufacturing Method

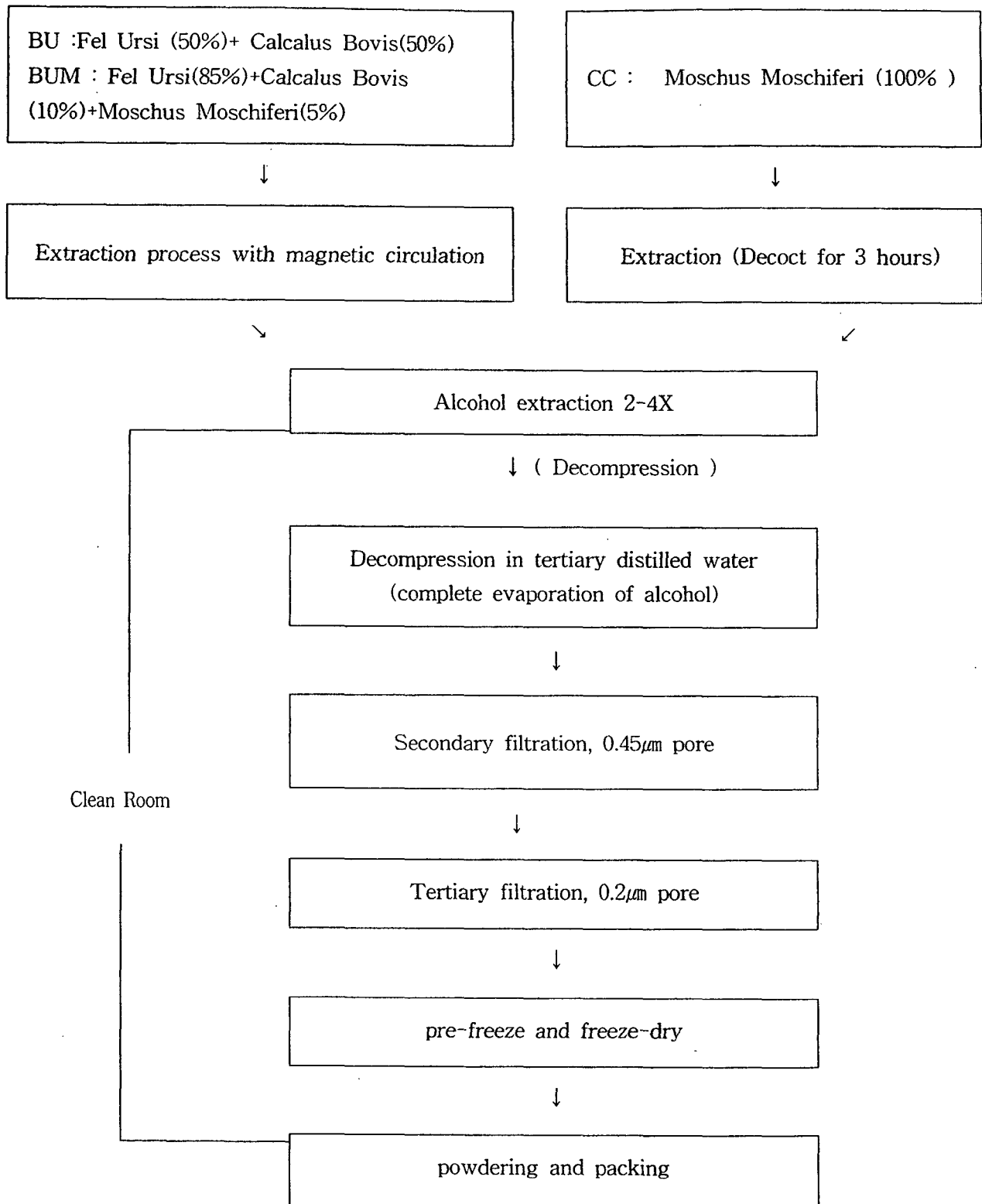


Fig.2 CF, JsD Manufacturing Method

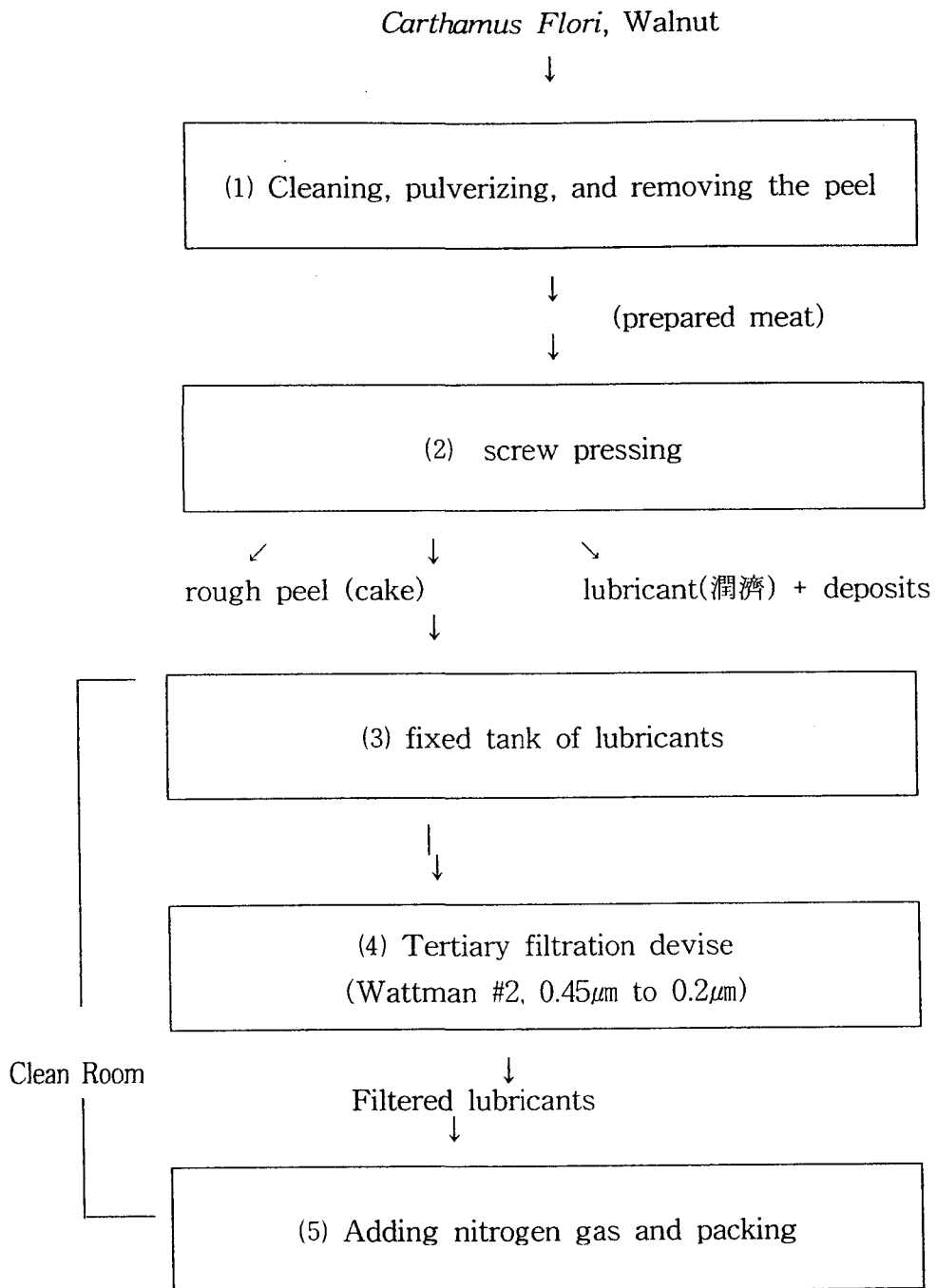


Fig. 3 CFC Manufacturing Method

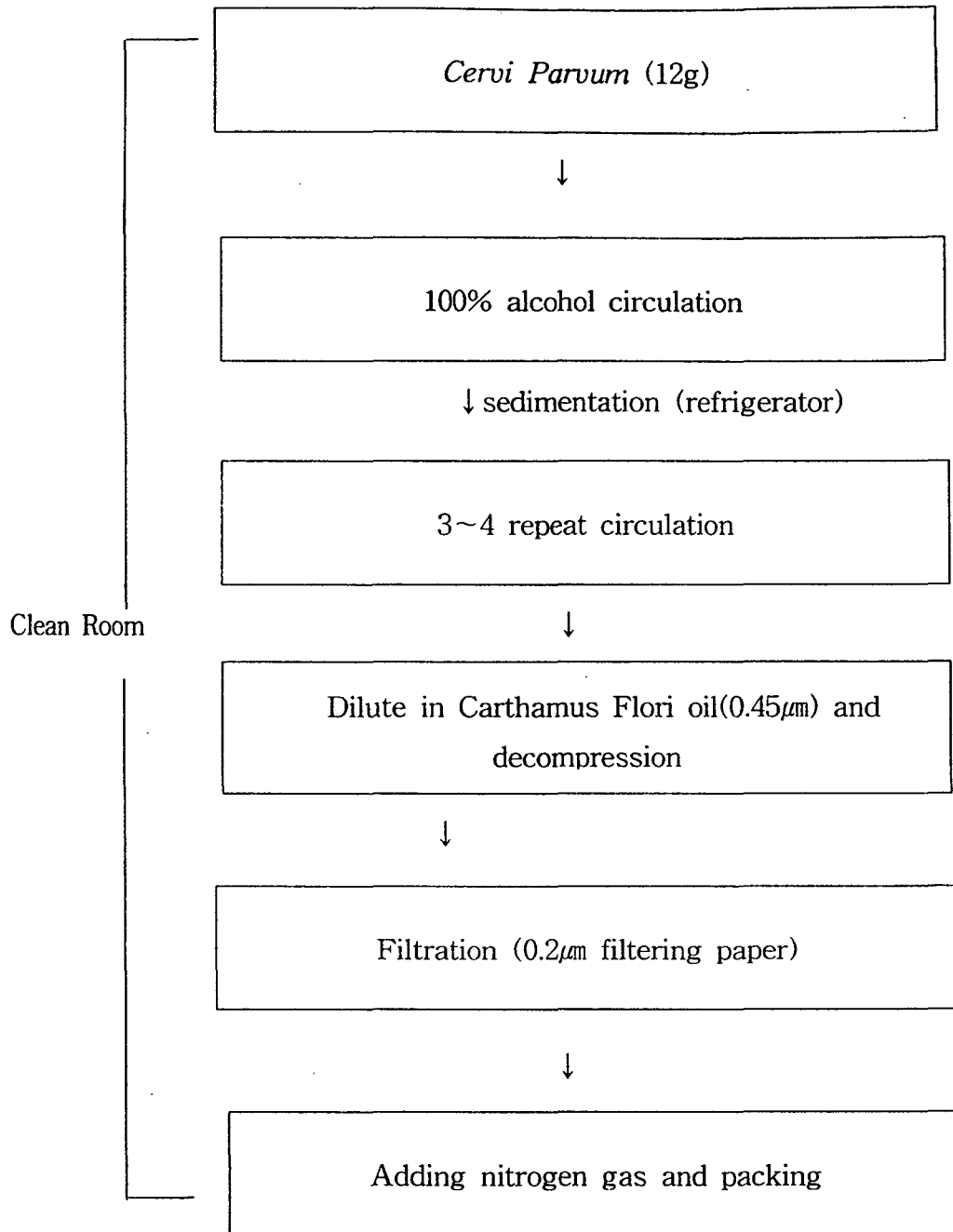


Fig.4 Bee Venom Extract Manufacturing Method

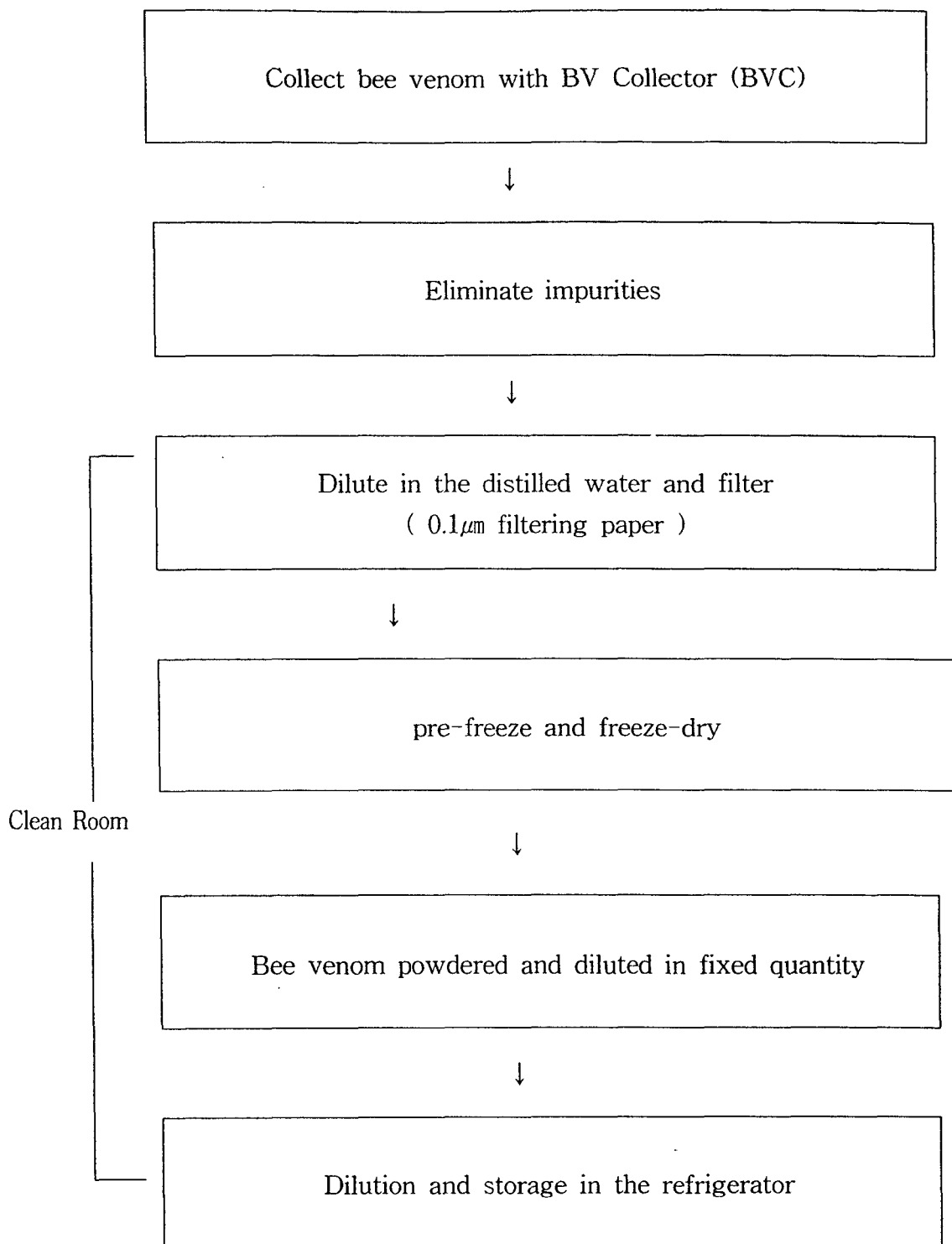


Fig.5 BVP Manufacturing Method

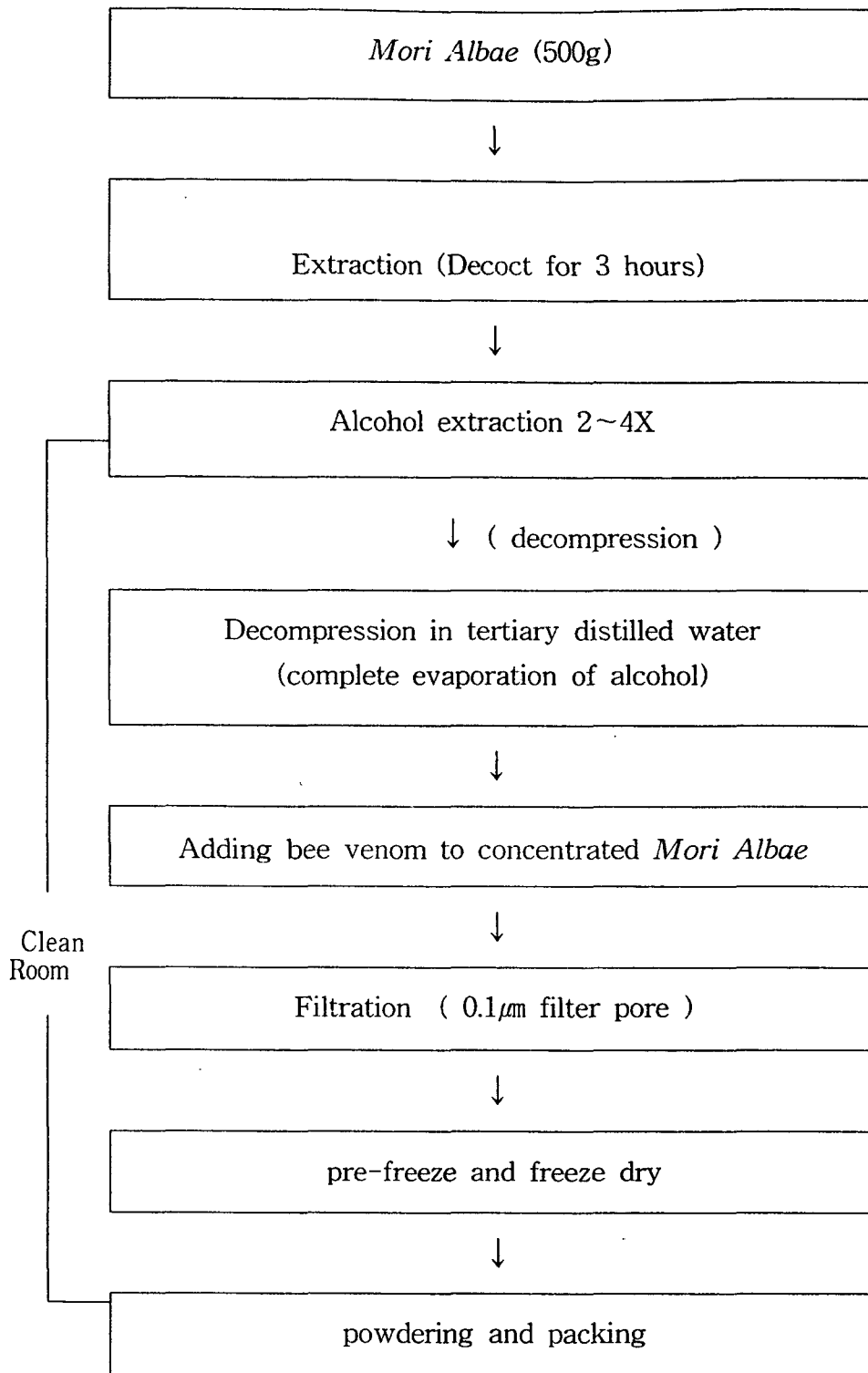
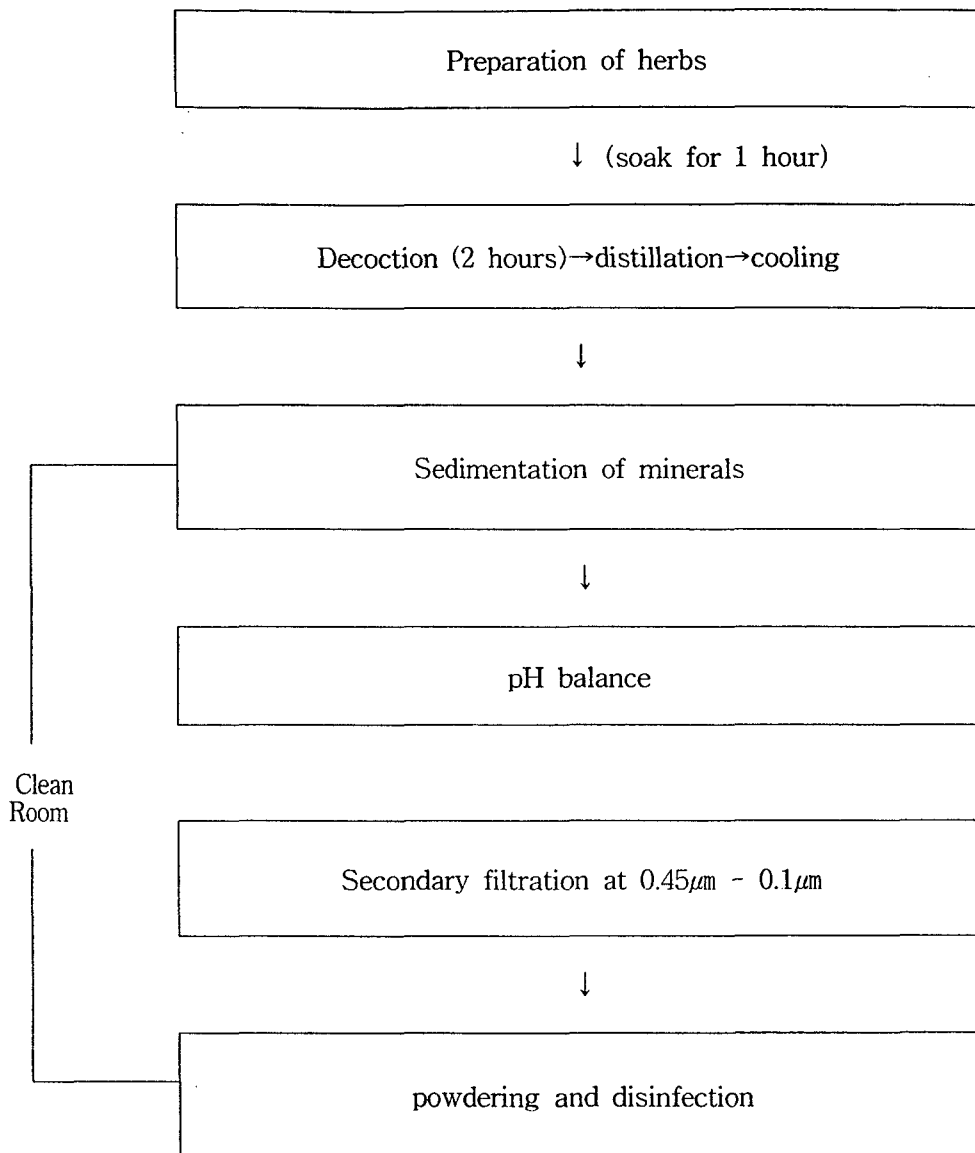


Fig.6 Eight Principles herbal extract Manufacturing Method



3. Microbiological examination of processed samples

1. Microorganism standard culture medium

For culturing the microorganism, Thioglycollate Broth and Trypticase Soy Broth were used, and BAP (Blood Agar Plate, KOMED) and Mac (MacConkey Agar Plate, KOMED) were used for the secondary culturing.

2. Analysis equipment and Card

VITEK Senior 60 (bioMérieux, France) was used for analysis and, analysis cards were GNI (Gram Negative Identification) and GPI (Gram Positive Identification). For additional motility test, RapID One System, and RapID NF + System (REMEL Inc.) were employed.

3. Culturing requirement and examination method

Culturing was done in the incubator at $35\pm 2^{\circ}\text{C}$ for 7 days, and the samples showing positive reaction went through secondary culturing. Secondary culturing was done for 24 to 48 hours.

4. Analyzing process

After sample labelling using BAP and

MAC, the samples were collected with disinfected 1mL syringe and placed on the standard culture medium. Then this culture medium was incubated for 24-48 hours at $35\pm 2^{\circ}\text{C}$, and the sample from the individual colony was analyzed with VITEK Senior 60. Sample with multiple colonies were generated in succession and confirmed through additional tests.

Additional test were SIM (Hydrogen Sulfide Indole Motility), TSI (Hydrogen Sulfide : Glucose, Sucrose, Lactose) Oxidase test, and Oaltalace test.

5. Motility method of VITEK Senior

Kinetic reading was measured for 2-15 hours in each motility kit's (Card) 30 wells for biochemical reactions. Fresh microorganism was suspended in 0.45% of NaCl and inserted in the card. Then VITEK Senior 60 checked for optical density every 30 minutes and measured the motility.

III. Experiment result

date of request		12/13/2000			Experiment result	
No.	Name of extract	Date of Prep.	Form	Cultured result		
1	Ren 4	00.10.31	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		
2	KD yang deficiency	00.11.29	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		
3	CF 1	00.11.30	brownish lubricant	No growth after 7days * Gram stain : No bacteria are seen.		
4	CF 2	00.11.30	brownish lubricant	No growth after 7days * Gram stain : No bacteria are seen.		
5	JsD 1	00.11.17	brownish lubricant	No growth after 7days * Gram stain : No bacteria are seen.		
6	JsD 2	00.11.17	brownish lubricant	No growth after 7days * Gram stain : No bacteria are seen.		
7	CFC 1	00.12.08	brownish lubricant	No growth after 7days * Gram stain : No bacteria are seen.		
8	CFC 2	00.12.08	brownish lubricant	No growth after 7days * Gram stain : No bacteria are seen.		
9	CC 1	00.12.08	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		
10	CC 2	00.12.08	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		
11	BU 1	00.11.22	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		
12	BU 2	00.11.22	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		
13	BUM 1	00.11.23	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.		

date of request	12/13/2000	Experiment result
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No	name of extract	Date of prep	Form	Cultured result
14	BUM 2	00.11.23	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
15	PURE1-1	00.12.04	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
16	PURE1-2	00.12.04	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
17	PURE2-1	00.12.06	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
18	PURE2-2	00.12.06	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
19	BVP-1 #1	00.12.02	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
20	BVP-1 #2	00.12.02	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
21	BVP-2 #1	00.02.02	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
22	BVP-2 #2	00.02.02	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
23	<i>Placenta Hominis 1</i>	00.12.06	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
24	<i>Placenta Hominis 2</i>	00.12.06	brownish transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
25	Distilled water 1	00.12.08	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.
26	Distilled water 2	00.12.08	clear, transparent liquid	No growth after 7days * Gram stain : No bacteria are seen.

IV. Discussion

Herbal acupuncture therapy is a new type of acupuncture treatment method that incorporates existing acupuncture and herbal medication to stimulate the acupuncture point.¹⁾

Herbal acupuncture therapy incorporates knowledge of basic herbs and prepared with single or multiple herbs with diverse extraction methods of decoction, alcohol extraction, steam extraction, pressure extraction, to name a few. These extracts are selected depending on the body constitution type, severity and nature of diseases, climate factors, and others.

People have been using herbal chemical stimulation on the body points as early as 2,500 years ago⁴⁾ but injection of the extract dates back to 1960's^{2,5)}. Due to excellent clinical results, more and more researches are done these days.^{8,9,10)}

Since the experiment of "Shangshan injection extract"¹¹⁾ from 1960's, numerous researches on the animals and clinical reports have been accumulated. Despite Chinese herbal acupuncture is based on Oriental medicine, notable differences exist between Chinese and Korean herbal acupuncture.

Chinese tends to use herbal extract in mixture with the western drugs such as vitamins and Procaine. Korea has been developing unique theory in regards to the herbal acupuncture. Meridian theory^{5,13)} and steamed distillation²⁾ for extracting the extract are only found in Korea.

Despite it's superb efficacy and safeness for 30 years, the treatment form is close to muscle injection and careful management of the herbs is strictly required. Most of the studies made for the herbal acupuncture were limited to the efficacy of herbs and experiments for safeness of the herbal acupuncture were available until recent times.^{14,15,16,17)}

Even the Department of Health and Social Welfare requires attachment of safety test for all the medications, the procedure is too vague to follow and current situation doesn't permit proper enforcement.

For the herbal acupuncture therapy to represent Korean medicine to the world, many obstacles must be solved. And thanks to continuous efforts made by the practitioners, the herbal acupuncture therapy is honored by the medical insurance²⁰⁾ and acknowledged as legitimate treatment method.

No one can deny that the herbal acupuncture will enjoy more popularity and concrete preparation is necessary.

1) standardized manufacturing process should be outlined, 2) efficacy and field of treatment must be established, 3) acute and chronic toxicity test in the animals, 4) accumulation of basic safety tests, and 5) toxicity and safety in the clinical surrounding must be reported.

As part of this procedure, this study was done in the clean room (meeting the standard of KGMP : Korea Good Manufacturing Practice) of Korean Institute of Herbal Acupuncture for microbiological examination and consigned analysis at Green Cross, Inc.

According to the analysis, none of the extracts made in the clean room contained microorganisms. From this result, the herbal extracts made with the current manufacturing method in the clean room is determined safe to use. Since keeping the clean room aseptic for a long time is a difficult task, tests must be done periodically to reconfirm the safeness.

V. Conclusion

This study was done in the clean room (meeting the standard of KGMP : Korea Good Manufacturing Practice) of Korean Institute of Herbal Acupuncture for microbiological examination to confirm safeness of the herbal extracts.

The following results were obtained:

1. There was no precipitated floating matter in the blood culture (Thioglycollate Broth, Trypticase Soy Broth).

2. There was no change in the turbidity of culturing ground, suggesting no signs of microorganisms. All the results were negative, meaning state of no bacterias.

3. There was no formation of colonies in the culturing ground, stating the herbal extract was microorganism free.

Bibliography

1. 대한약침학회. 약침요법 시술지침서, 대한약침학회, 13, 186, 1999.
2. 김정언. 기적의 약침요법, 금강출판사, 15, 1987.

3. 전국한외과대학 경혈·침구학교실, 침구학(하), 집문당, 1059, 1056, 1988.
4. 인창식, 고행균 : 봉독요법에 대한 한의학 최초의 문헌기록: 마왕퇴의서의 봉독요법 2례, 대한침구학회지, Vol 15, No1, p143, 1998.
5. 남상천. 경락, 세명출판사, 1988.
6. 최승윤. 양봉, 꿀벌과 벌통, 오성출판사, 117,118, 1987.
7. 이진선, 권기록, 최호영. HPLC를 이용한 봉약침의 주요성분 분석, 대한침구학회지, Vol.17. No.4, 2000
8. 강성길. 대극수침이 진통 및 수은 중독에 미치는 영향, 경희대학교 논문집, Vol.5 1-18, 1982
9. 김갑성. 초롱담수침이 슬관절 염증성 부종에 미치는 영향, 경희대학교 논문집, 1987.
10. 김재규. Ethanol 중독에 대한 침, 구 및 인삼수침이 해독효과에 미치는 영향, 경희대학교 논문집, Vol.9 1-17, 1986.
11. 曹春林. 中藥製劑準編, 人民衛生出版社, 66, 173, 1978.
12. 손인철, 이문호. 藥鍼療法, 一中社, 17-34, 1999.
13. 남상천. 면역의학, 경락의학사, 19-22, 1997.
14. 김현수, 이윤호, 최용태. 약침용 단삼추출액의 피부자극시험, 피하 및 근육자극시험 및 항원성 시험에 관한 연구, 대한침구학회지, Vol.11, No.1, 25, 1994.
15. 이종석, 고행균, 김창환. 약침용 봉독액의 급성 독성에 관한 연구, 대한침구학회지, Vol.11, No.1, 177, 1994.
16. 문성호, 최도영, 안병철. 약침용 유향추출액의 안정성 시험을 위한 문헌적 연구, 대한침구학회지, Vol.11, No.1, 131, 1994.
17. 최민섭, 김창환, 고행균. 약침용 황기추출액의 급성 독성에 관한 연구, 대한침구학회지, Vol.12, No.1, 179, 1994.
18. 채동규, 약사관련법규집, 보건법규사, 657, 1999.
19. 중화인민공화국 위생부. 신약심비변법 1992.
20. 민족의학신문사. 민족의학신문 2001 1.8, 1 2001.