表4 半夏厚朴湯処方のエキス収量と構成生薬エキス収量の総和の比較

	半夏厚朴湯一日量中の分量 [g]		A社	B社	C社	D社	E社	平均	[f]変動係数 [%]
厚朴	3	[a]理論値 [g]	0.366	0.316	0.276	0.284	0.340	0.316	10.7
生姜	1	[a]理論値 [g]	0.104	0.100	0.048	0.112	0.076	0.088	26.5
蘇葉	2	[a]理論値 [g]	0.292	0.331	0.304	0.251	0.461	0.328	21.8
半夏	6	[a]理論値 [g]	0.575	0.803	0.565	0.384	0.415	0.548	27.1
茯苓	5	[a]理論値 [g]	0.067	0.069	0.033	0.044	0.043	0.051	28.0
半夏厚朴湯処方		[b]理論値 [g]	1.404	1.619	1.225	1.075	1.335	1.332	13.6
		[c]測定値(1回目) [g]	1.190	1.540	1.190	0.860	1.280	1.212	18.0
		[c]測定値(2回目) [g]	1.160	1.500	1.140	1.020	1.170	1.198	13.4
		[c]測定値(3回目) [g]	1.220	1.240	1.210	0.850	1.080	1.120	13.1
		[d]測定値の平均値 [g]	1.190	1.427	1.180	0.910	1.177	1.177	13.9
		[e]変動係数 [%]	2.06	9.32	2.49	8.56	6.95	3.44	–
		理論値/測定値	1.18	1.13	1.04	1.18	1.13	1.13	4.6

a それぞれの生薬の単位エキス収量(表3)に、葛根湯一日量中の分量を乗じて算出した、一日量中のエキス量の理論値

b それぞれの構成生薬の一日量中のエキス量理論値の総和

c 半夏厚朴湯一日量(厚朴3 g、生姜1 g、蘇葉2 g、半夏6 g、茯苓5 g)を400 mLの水で半量まで煎じ、凍結乾燥させたエキスの重量(3回独立に煎出して測定)

d 3回の測定値の平均

e 3回の測定値の変動係数

f 5社の理論値、測定値あるいは平均値の変動係数

厚生労働科学研究費補助金（医薬品・医療機器等レギュラトリーサイエンス総合研究事業）
分担研究報告書

分担研究課題　生薬及び漢方処方の国際調和に関する研究

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第5回 Forum for the Harmonization of Herbal Medicines（FHH）国際会議に関する報告

第5回 FHH Standing Committee 会議がソウル、セジョンホテルで開催された。本会議では各地域の現状に関する報告並びに Nomenclature and Standardization、Quality Assurance and Information 及び Adverse Drug Reaction に関する3つの Sub-Committee の活動報告がなされた。特に日本が主催する Sub-Committee I (Nomenclature and Standardization) では、前回の本会議においてクリーンアナリシスを念頭に国際調和を推進する観点から、TLC を用いた確認試験で使用される有害試薬の排除を目的とした各国共同の比較試験が提案し、今回、日本のみ検討結果の報告を行ったが、他国では検討が終了していなかったため、その結果について次回の第6回 FHH Standing Committee において、各国が報告することとなった。また、FHH 設立以来の活動内容をまとめた FHH technical reports の作成について提案がなされ、各 Sub-Committee のメンバーを中心にレポートを作成することとされた。

A. 研究目的

2002 年3月に北京において「生薬・薬用植物に関する国際調和のための西太平洋地区討論会」（FHH : Western Pacific Region Forum for the Harmonization of Herbal Medicines）設立のための国際会議が開催され、日本はその下部組織である Nomenclature and Standardization に関する Sub-Committee 会議を主催することを受諾し、2002 年5月、東京で、Sub-Committee I 会議が開催され、本会議において以下の5つの専門部会（Expert working group）が設立された。

1）Nomenclature

2）Testing Method in Monographs

3）List of Chemical Reference Standards (CRS) and Reference of Medicinal Plant Materials (RMPM)

4）List of Analytically Validated Method

5）Information on General Test

これらの専門部会では、それぞれの分野における各国薬局方の比較表を作成することが課題事項として議決された。

これらの課題事項の進捗状況に関しては 2003 年 11 月に中国・昆明で開催された第1回 FHH Standing Committee、2004 年9月に中国・上海で開催された第2回 FHH Standing Committee、2005 年6月に東京で開催された第3回 FHH Standing Committee 及び 2006 年 11 月に東京で開催された第4回 FHH Standing Committee において報告がなされ、比較表の完成に向けて継続的な活動を行うことが了承された。主任研究者並びに本分担研究者は、本 Sub-Committee I の実質的な運営者であり、本報告書では、第5回 FHH Standing Committee 会議の内容を中心に、次の報告書では、Sub-Committee I Expert working group 5 の活動を中心に報告する。

B. 研究方法

本会議は平成19年10月8日、韓国、ソウル、セジョンホテルで開催された。日本側の参加者は合田幸広、川原信夫（国立医薬食品衛生研究所）、木内文之（基盤研筑波）、佐竹元吉（お茶の水女子大）、山本芳邦（日本香料協会）の5名で、諸外国からの参加者はWPROよりDr. Choi Seung-Hoon、中国よりProf. Jin Shaohong、Dr. Zhang Wei、Dr. Chen Yi-xin、Dr. Lin Ruichao、香港よりMs.Choi Koon-kay、Mr. Law Kwonk-wai、Dr. Zhao Zhong-zhen、Dr. Chiu Pui-yin (Amy)、Mr. Chan Linng-fung (Frank)、韓国よりProf. Il-Moo Chang、Dr. Chang Seung-yeup、シンガポールよりMr. Yee Shen Kuan、Ms. Chu Swee-seng、Mr. Victor Wong、オーストラリアよりDr. David Briggs、カナダよりMs. Julie Robert、モンゴルよりMr. Sharav Bold、Mr. Jigjid Togtokhbayarの総勢25名のメンバーで行われた。なお、諸般の事情により本会議にベトナムは参加することができなかった。今回の会議のスケジュールを別紙に示す。

C. 研究結果、考察

第5回FHH Standing Committee会議の概要10月8日午前

1．オープニングセレモニー

KFDAのDr. Chang Seung-yeupより開催の祝辞が述べられた。また、WPROのDr. Choi Seung-Hoonより今回Dr. Chang Seung-yeup並びに彼らのチームにより会議が滞りなく運営されていることに対し感謝する旨、挨拶が述べられた。全体写真の撮影後、座長のDr. Chang Seung-yeupより本会議の暫定的なプログラムの説明がなされ、本プログラムに沿って審議を行うことが了承された。午前中の会議では合田部長とMr. Yee Shen Kuanが座長を務め、Dr. Chiu Pui-yin (Amy)とProf. Jin ShaohongがSub-committee II及びIIIの座長を務めることが了承された。また、午後の会議ではDr. David BriggsとProf. Il-Moo Changが座長を務め、Mr. Victor Wong及びMr. Chan Linng-fung (Frank)がレポーターを務めることが了承された。

2．Sub-committee Iに関する報告（合田幸広、国立衛研生薬部長）

国立衛研、合田生薬部長よりSub-committee Iの全般的な活動内容について説明がなされた。なお、本報告は時間の関係上、10月7日の夕方、午後6時30分ー7時30分に行われた。昨年の第4回FHH Standing Committee会議において、クリーンアナリシスを念頭に国際調和を推進する観点から、各国局方のTLCによる生薬の確認試験において、有害溶媒を用いる展開溶媒条件と有害溶媒を用いない展開溶媒条件がある場合、有害溶媒を用いる条件を既定している国は、自国の生薬で有害溶媒を用いない他国の条件を検討することが承認された。本会議ではその検討内容について報告がなされた。また、各国薬局方の比較表に関する冊子の改訂版"Comparative Studies on Pharmacopoeial Definitions, Requirements and Information for Crude Drugs among FHH Member Countries in 2007"が出版され、その内容について報告がなされた。

1）クリーンアナリシスを指向したTLCによる確認試験法の検討

国立衛研、川原生薬部室長よりFHH諸国の局方での共通生薬におけるTLCを用いた確認試験法について、各種展開溶媒並びに試験法の検討結果について説明がなされた。本検討では、3ヵ国以上の局方に収載された共通生薬15種を選定し、TLCによる確認試験における有害試薬の使用の有無を調査した。次いで、JPに記載された試料調製法により試料を調製し、TLCの結果の比較を行った。この結果、15種の共通生薬のうち、サンシュユ、コウボク、キクカは指標成分が異なった。それ以外の生薬では、すべて有害試薬を使用しない方法でも同一の指標成分が確認可能であることが示された。特にサイコでは、JP/KPでクロロホルムを使用する一方、CP/VPでは有害溶媒を使用しておらず、CP/VP法でも国内流通生薬の確認が可能であることが明らかとなった。

2）"Comparative Studies on Pharmacopoeial Definitions, Requirements and Information for Crude Drugs among FHH Member Countries in 2007"の概要

川原室長より今回出版された冊子について説明がなされた。前回出版した冊子の内容をリニューアルし、特に前回以降に出版されたベトナム薬局方 2005 年版、中華人民共和国薬典 2005 年版、第 15 改正日本薬局方の内容を反映させ、新規収載された部分並びに変更点について解説を行った。

3）Sub-committee I の今後の方針

EWG1、2 及び 5 の task は、ほぼ終了しており、新しい情報が入手次第更新を行う。EWG3 に関しては CP の CRS 及び RMPM のデータを入手し、比較表を作成並びに更新を行う。EWG4 に関しては関連情報がある場合、引き続き情報を提供する。

以上各 EWG で作成した比較表等は順次 FHH のウエブサイトに収載する。

引き続きクリーンアナリシスを念頭に国際調和を推進する観点から、各国局方の TLC による生薬の確認試験において、有害溶媒を用いる展開溶媒条件と有害溶媒を用いない展開溶媒条件がある場合、有害溶媒を用いる条件を既定している国は、自国の生薬で有害溶媒を用いない他国の条件を検討し、その成果について第 6 回 FHH Sub-Committee 会議において報告を行う。さらに試験において良好な結果が得られた場合、有害溶媒を用いない TLC 条件について国際調和を図る様、自国で検討する。

3. Sub-committee II (Quality Assurance and Information) に関する報告（Prof. Il-Moo Chang）

Prof. Il-Moo Chang より Sub-committee II の進捗状況に関する全般的な説明がなされた。

1）Information に関する現状報告（Prof. Il-Moo Chang）

FHH website の現状に関する説明がなされた。FHH 会議も今回で第 5 回を迎え、過去 5 年間の成果に関する情報を整理し、FHH website に掲載してはいかがかとの提案がなされた。

2）GMP EWG の現状報告（Prof. Il-Moo Chang）

2007 年 5 月に韓国で行われた Sub-committee II 会議の概要に関して説明がなされた。詳細に関して香港の Dr. Zhao Zhong-zhen より報告がなされた。生薬の修治は中国の明の時代より始まり現代に到っており、修治法の標準化並びに研究は非常に重要であるとの報告がなされた。さらに、Prof. Il-Moo Chang は 2007 年 12 月を目途に Sub-committee II の活動内容について website にアップロードする旨、報告がなされた。

4．Sub-committee III (Adverse Drug Reaction (ADR)) に関する報告（Prof. Jin Shaohong）

Prof. Jin Shaohong より Sub-committee III の設立に至るまでの経緯が説明された。また、現在までに報告されている生薬類の安全性問題に関して情報交換された 40 事例の主要な問題は、西洋薬、微生物並びに有害な重金属等の不純物混入であるとの報告がなされた。また ADR 情報は FHH website に掲載されていないため、本会議において掲載を承認してもらいたい旨、説明がなされた。さらに今後の活動予定として、さらなる ADR モニタリングの強化と薬事監視への拡大、生薬類の安全性情報交換の強化、生薬類の安全性ガイドラインの作成、生薬類の ADR に関連するセミナーの開催等の必要性に関する説明がなされた。

5．地域レポート

1）WPRO（Dr. Choi Seung-Hoon）

伝統薬関連の近年における WHO の取り組みについて説明がなされた。特に伝統薬の規格化については西太平洋エリアの国々が牽引役を担っているとの見解が示された。

2）韓国（Dr. Chang Seung-yeup）

韓国における 3 つのトピックについて説明がなされた。第一に韓国生薬局方の第 9 版の改正について報告がなされ、第二に各種有害物質（重金属、二酸化硫黄、アフラトキシン）の限度値の改正について説明がなされ、最後に各種生薬のガイドブックの出版についての説明がなされた。

3）オーストラリア（Dr. David Briggs）

オーストラリアにおける補完医療薬の規制の現状、改正点について説明がなされた。改正点については、新たに医薬品のリストに収載された物質の使用法について、ブラックコホシュを含有する医薬品のラベル表示について、最終製品の不純物や異物の規制について、補完医療薬の研究に関して政府が国立研究所の設立を含めた予算化を行っていること等の報告がなされた。また、オーストラリアとニュージーランド政府との間で医薬品の規制に関する調和が延期となった旨、説明がなされた。

4）中国（Dr. Zhang Wei）

中国における医薬品審査、研究及び流通市場の現状について報告がなされた。2007 年 10 月 1 日よりすべての Traditional Chinese Medicines (TCM) の審査基準がより厳格になるとの説明がなされた。また、TCM に関して、2006 年 3 月 15 日より薬局や製品ラベルのための新たな規制が開始された旨、報告がなされた。

5）香港（Dr. Chiu Pui-yin、Mr. Law Kwonk-wai）

香港特別行政区における中薬の規制、安全性及び品質評価の概要について報告がなされた。現在香港において進行中である Hong Kong Chinese Materia Medica Standards (HKCMMS)プロジェクトは、香港行政区保健部において 60 品目の繁用生薬について香港標準中薬としての規格化を目標としている。Phase 1 の 8 品目は、規格化が終了し、2005 年 8 月に出版され、Phase 2 の 24 品目は、近々規格化が終了し、出版される予定である。さらに Phase 3 の 28 品目は、現在規格化に向けた研究を継続中であるとの説明がなされた。

10 月 8 日午後

6）日本（合田幸広、国立衛研生薬部長）

2006 年から 2007 年における日本の生薬関連トピックについて報告がなされた。2007 年 10 月に第 15 改正日本薬局方第一追補が施行された旨、報告がなされた。内容的には新たに生薬 7 品目（サンザシ、ゼンコ、ドクカツ、ビャクゴウ、ヤクモソウ、ウコン末、エンゴサク末）と医療用漢方エキス 2 品目（ケイシブクリョウガンエキス、ハンゲコウボクトウエキス）が収載された。また、38 品目の生薬について重金属限度値（10 ppm）が新規設定され、59 品目の生薬にヒ素限度値（5 ppm）が新規設定された。さらに参考情報として遺伝子情報を利用する生薬の純度試験が収載されることとなった旨、説明がなされた。

7）シンガポール（Mr. Yee Shen Kuan）

2006 年 12 月から 2007 年 9 月までのシンガポールにおける伝統薬の規制に関する動向について説明がなされた。2007 年 2 月に“Health Products”に関する法律が制定され、伝統薬並びに健康補助食品等の標準化と品質管理が行われることになった旨、報告がなされた。また、ASEAN 諸国における伝統薬と健康補助食品の標準化と品質管理に関する調和を目的として、ASEAN Traditional Medicines and Health Supplements Products Working Group (TMHS PWG) 会議がベトナム（第 6 回）とブルネイ（第 7 回）で行われ、シンガポールは第 7 回会議においてワークショップを開催した旨、報告がなされた。

8）モンゴル（Mr. Sharav Bold）

今回初めて FHH Standing Committee 会議に参加できたことを感謝すると共に、モンゴルにおける医薬行政の現状について説明がなされた。

9）カナダ（Ms. Julie Robert）

カナダにおける自然健康食品の規制に関する現状と目的について説明がなされた。2006 年に Health Canada では食品並びに健康食品類の規制を目的としたシステムの再構築が開始されたとの説明がなされた。今後もさらなる国際共同研究を通じて情報を共有し、カナダにおける食品並びに健康食品類の規制システムの確立に向けて活動を継続する旨、方針が示された。

6．今後の Standing Committee 及び Sub-committee の運営における確認事項について

1）FHH technical reports の作成

Prof. Il-Moo Chang より FHH 設立以来の活動内容

をまとめたFHH technical reportsの作成について提案がなされた。他のメンバーもFHHが設立されてから既に5年以上経過しているため、報告書の作成に関して異存はなく、了承された。審議の結果、Sub-Committee の活動に関するFHH technical reportsの作成担当は、以下のメンバーとすることが承認された。Sub-committee I（合田部長、川原室長及び佐竹教授）、Sub-committee II (Prof. Il-Moo Chang)、Sub-committee III (Prof. Jin Shaohong 及び Dr. Chen Yi-xin)。さらに報告書の各分野の取りまとめの責任者は以下のメンバーとすることが承認された。前文と概要（シンガポール及びオーストラリア）、Sub-committee I（合田部長）、Sub-committee II (Prof. Il-Moo Chang)、Sub-committee III (Prof. Jin Shaohong 及び Dr. Chen Yi-xin)。また、それぞれの国々における生薬並びに生薬製剤の審査及び登録の現状に関する概要報告について以下のメンバーが担当することとされた。日本（合田部長及び佐竹教授）、オーストラリア(Dr. David Briggs)、中国 (Dr. Zhang Wei 及び Dr. Lin Ruichao)、香港 (Dr. Chiu Pui-yin 及び Mr. Chan Linng-fung)、韓国 (Prof. Il-Moo Chang)、シンガポール (Mr. Yee Shen Kuan)。

2）第3回 FHH Symposium について

韓国側より 2008年11月に第3回FHH Symposiumを予定しているとの説明がなされた。シンポジウムの内容に関して、GAP 並びに生薬の修治等、品質評価に関する事例を中心にプログラムを作成すべきとの提案がなされ、了承された。また、シンポジウム開催に当たり、実行委員会を組織し、そのメンバーは各 Sub-committee の代表者が就任することとされた。さらにProf. Il-Moo Changを責任者として技術委員会を組織し、各国の担当者は、発表者を推薦することとされた。なお、本シンポジウムの運営費用は韓国が負担する旨、報告がなされ、各国より謝意が表明された。

3）次回の FHH Standing Committee Meeting について

Dr. Chang Seung-yeup より次回の本会議の日程に関して提案がなされた。次回は 2008 年 11 月を予定している旨、説明がなされた。

7．閉会の辞

Dr. Chang Seung-yeup 及び WPRO の Dr. Choi Seung-Hoon より閉会の辞が述べられた。FHH の今後の発展を祈念して会議を終了した。

D. 結論

第5回 FHH Standing Committee 会議がソウル、セジョンホテルで開催された。本会議では各地域の現状に関する報告並びに Nomenclature and Standardization、Quality Assurance and Information 及び Adverse Drug Reaction に関する3つの Sub-Committee の活動報告がなされた。特に日本が主催する Sub-Committee I (Nomenclature and Standardization) では、前回の本会議においてクリーンアナリシスを念頭に国際調和を推進する観点から、TLC を用いた確認試験で使用される有害試薬の排除を目的とした各国共同の比較試験が提案し、今回、日本のみ検討結果の報告を行ったが、他国では検討が終了していなかったため、その結果について次回の第 6 回 FHH Standing Committee において、各国が報告することとなった。また、FHH 設立以来の活動内容をまとめたFHH technical reportsの作成について提案がなされ、各 Sub-Committee のメンバーを中心にレポートを作成することとされた。

E. 健康危険情報

本研究において健康に危険を及ぼすような情報はない。

F. 研究発表

1．論文発表

1）川原信夫，糸数七重，佐竹元吉，合田幸広：西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方収載生薬の各種試験法並びに規格値の比較に関する研究（第３報）生薬関連一般試験法の比較．生薬学雑誌, 61 (1), 44-57 (2007).

2．学会発表

1） 川原信夫、井戸淑惠、川崎武志、酒井英二、合田幸広：FHH 各国局方生薬における生薬の試験法と規格値（5）．日本薬学会第 128 年会、横浜（2008．3）

G．知的所有権の取得状況

特になし

Program of Standing Committee
October 7-8, Seoul, Korea

October 7 (Sun): at Sejong Hotel

16:30 ~ 17:00:

- Registration (name card must be submitted)

17:00 ~ 19:00: at Sejong Hotel

- Report of Subcommittee 1 (Convener: Dr. Y. GODA)

19:20: at Sejong Hotel

- Dinner invited by Chairman

October 8 (Mon)

09:00 ~ 09:30: at Sejong Hotel

- Opening and Registration (Convener, Dr. S. Y. CHANG)
- Election of Chairpersons and Reporter (3 chairpersons and 2 reporters)

09:30 ~ 10:30:

- Continuation of Subcommittee Reports (II and III)

10:30 ~ 12:50: Country Reports

- Progress and News from W.H.O.WPRO (Dr. S. H. CHOI)
- Australia
- China
- Hong Kong
- Japan
- Korea
- Singapore
- Vietnam
- Observers' Expression (New regulatory affairs for Herbal Medicines, etc)
  - Canada and Mongolia

13:00 ~ 14: 30: Lunch

14:30 ~ 16: 30: Issues and Discussion

- Agenda 1: Collection and Evaluation of Five-year's Works
  - Current sources from e-documents on website
  - Review and editorial committee
  - Publication: monograph-typed hard copies
- Agenda 2: Next year's Plan
  - Date of the Standing Committee

- Theme of Symposium
  - Selection of Candidate Speakers

■ Agenda 3: Other issues

16:30 ~ 17:00:

■ Closing

18:00 ~ 20:00:

■ Dinner Invited by Chairman

Agenda for Standing Committee

8th of October 2007

1. Compiling Achievements Produced by Each Subcommittee's Activities
   - Formation of Editorial Team
     ① Chairman of each subcommittee and designated persons by memb er country
     ② Selection of items for compiling
   - Formation of Proof-reading team (AU, HK, Singapore and WHO)
   - Electronic files and Hard copy
     ① Financial support by WHO
     ② Support by KFDA
     ③ Others?
   - Final date of release: Before next standing committee meeting
2. Next Standing Committee Meetings
   - Theme of Symposium
   - Date
3. Other issues

Standing Committee Meeting Attendee (Oct. 7th - 8th)

Nationality	Designation	Name	e-Mail	Address	Phone/Fax	Position
China	Prof.	JIN Shaohong	jinshh@nicpbp.org.cn	Temple of Heaven, No.2 Tiantan Xili, Beijing, P. R. China 100045	Tel: 8610-67095258 Fax: 8610-67018715	General Director, Center for Drug Reevaluation, SFDA, National Center for ADR Monitoring, China
	Prof.	LIN Rui-chao	linrch307@sina.com	2 Tiantan Xili, Beijing 100050, P R China	Tel: 86-10-67095307 Fax: 86-10-67023650	Director, Division of Chinese Materia Medica and Natural Products, National Institute for the Control of Pharmaceutical and Biological Products, State Food and Drug Administration
	Mr.	ZHANG Wei	zhangwei@sfda.gov.cn	A38, Beilishilu, Xicheng District, Beijing 100810, People's Republic of China	Tel: 86-10-88331210 Fax: 86-10-68330853	Director General, Department of Drug Registration State Food and Drug Administration
	Dr.	Chen Yixin	yix_chen@263.net	Building 6, No.3 Yard, San Li He Yi Qu, Xicheng District, Beijing, P. R.China, Postcode: 100045	Tel: 86-10-68586031 Fax: 86-10-68586295	Director, Division of ADR Monitoring, National Center for Drug Reevaluation, SFDA
Australia	Dr.	David Briggs	david.briggs@health.gov.au	PO Box 100, Woden Act 2606, Australia	Tel: 61-2-62328439 Fax: 61-2-62328913	Australian Therapeutic Goods Administration / Director
Singapore	Mr.	YEE Shen Kuan	yee_shen_kuan@hsa.gov.sg	11 Biopolis Way #11-03 Helios Singapore 138667	Tel: 65-68663403 Fax: 65-64789037	Senior Deputy Director Centre for Drug Administration Health Products Regulation Group Health Sciences Authority Singapore
	Ms.	CHU Swee Seng	chu_swee_seng@hsa.gov.sg	11 Biopolis Way #11-03 Helios Singapore 138667	Tel: 65-68663451 Fax: 65-64789037	Head (Chinese Proprietary Medicines) Centre for Drug Administration Health Products Regulation Group Health Sciences Authority, Singapore
	Mr.	Victor WONG	victor_wong@hsa.gov.sg	11 Biopolis Way #11-03 Helios Singapore 138667	Tel: 65-68663452 Fax: 65-64789037	Deputy Head (Chinese Proprietary Medicines) Centre for Drug Administration Health Products Regulation Group Health Sciences Authority Singapore
Japan	Dr.	Yukihiro GODA	goda@nihs.go.jp	1-18-1 Kamiyoga, Setagaya-ku, Tokyo, 158-8501, Japan	Tel: 81-3-3700-9154 Fax: 81-3-3700-9165	Head, Division of Pharmacognosy, Phytochemistry and Narcotics, National Institute of Health Sciences
	Prof.	Motoyoshi SATAKE	satake.motoyoshi@ocha.ac.jp	2-1-1 Ohtsuka, Bunkyo-ku, Tokyo, 112-8610, Japan	Tel: 81-3-5978-5806 Fax: 81-3-5978-5805	Guest Professor, Institute of Environmental Science for Human Life, Ochanomiza University
	Dr.	Fumiyuki KIUCHI	kiuchi@nibio.go.jp	1-2 Hachiman-dai, Tsukuba, Ibaragi, 305-0843, Japan	Tel: 81-029-838-0571 Fax: 81-029-838-0575	Director, Research Center for Medicinal Plant Resources, National Institute of Biomedical Innovation
	Dr.	Yoshikuni YAMAMOTO	ypcyy01@gold.ocn.ne.jp	3-6, 1-chome, Kitakyuhoji-machi, Chuo-ku, Osaka, Japan	Tel: 81-6-6261-5801 Fax: 81-6-6261-5803	Executive, Japan Perfumery & Flavoring Association
	Dr.	Nobuo KAWAHARA	kawahara@nihs.go.jp	1-18-1, Kamiyoga, Setagaya-ku, Tokyo 158-8501, Japan	Tel: 81-3-3700-9165 Fax: 81-3-3700-9165	Section Chief, Division of Pharmacognosy, Phytochemistry and Narcotics, National Institute of Health Sciences

Nationality	Designation	Name	e-Mail	Address	Phone/Fax	Position
W.H.O.	Dr.	Choi Seung-Hoon	chois@wpro.who.int	PO Box 2932(United Nations Avenue) 1000 Manila, Philippines	Tel: 632-5289844 Fax: 632-521-1036	Regional Adviser, World Health Organization, West Pacific Regional Office
HongKong	Mr.	Koon-kay CHOI	kkchoi@govtlab.gov.hk	7/F, 88 Chung Hau Street, Homantin Government Offices, Hong Kong	Tel: (852) 2762 3879 Fax: (852) 2714 4083	Chief Chemist, Hongkong Government Laboratory
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	Prof.	Zhongzhen ZHAO	zzzhao@hkbu.edu.hk	School of Chinese Medicine, Hong Kong Baptist University, Kowloon Tong, Hong Kong	Tel: (852) 3411 2424 Fax: (852) 3411 2461	Professor, Hong Kong Baptist University
	Dr.	Pui Yin(Amy) CHIU	amy_py_chiu@dh.gov.hk	32/F, Wu Chung House, 213 Queen's Road East, Wan Chai, Hong Kong	Tel: (852) 2126 5100 Fax: (852)2123 9566	Assistant Director, Traditional Chinese Medicine Division, Department of Health, Hong Kong
	Mr.	CHAN Ling-fung	pharm_tcm1@dh.gov.hk	2/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, Hong Kong	Tel: (852) 2209 9449 Fax: (852) 2319 2664	Chinese Medicine Division, Department of Health
Mongolia	Mr.	Sharav Bold	shrvbold@yahoo.com	22-2, 6 micro district, 5th khoroo,Chingeltei District.	Tel: 976-11-680563 Mobile: 976-9911-1418	President, the Mongolian Oriental Medicine Association "Uvidasiin Dalai"
	Mr.	Jigjid Togtokhbayar	togtokhbayar@minister.com	The state specialized inspection agency, Builder's square, 211238, Mongolia	Tel: 976-51-261426, Mobile: 976-9908-5285	Senior Inspector, Department of Mongolian Medicine, The State Specialized Inspection Agency, Mongolia
Korea	Dr.	CHANG Seung-yeup	cys8569@kfda.go.kr	194 Tongilro, Eunpyung-Gu, Seoul, 122-704, Korea	Tel: 82-2-380-1728 Fax: 82-2-385-0297	Director, Department of herbal medicines evaluation, KFDA
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Canada	Ms.	Julie Robert	julie_robert@hc-sc.gc.ca	Qualicum Tower A, AL: 3300B 2936 Baseline Road, Ottawa, Ontario CANADA K1A 0K9	Tel: 1-613-948-2016 Fax: 1-613-954-2877	Natural Health Products Directorate Health Products and Food Branch Health Canada

厚生労働科学研究費補助金（医薬品・医療機器レギュラトリーサイエンス総合研究事業）
分担研究報告書

分担研究課題
生薬及び漢方処方の国際調和に関する研究

分担研究者　川原　信夫　国立医薬品食品衛生研究所生薬部室長

西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方に収載された生薬関連一般試験法の比較に関する研究

FHH (Western Pacific Regional Forum for the Harmonization of Herbal Medicines)、Sub-committee I Expert working group 5 (Information on General Test) では，各国の薬局方について共通点と相違点を認識することを目的として，特に日本，中国，韓国，ベトナム４カ国の薬局方に収載された生薬関連一般試験法について比較表の作成を試みた．この結果，試料の採取，異物，乾燥減量，灰分，酸不溶性灰分，エキス含量，精油含量，重金属，ヒ素等の設定及びその内容に関して共通点が多く認められたが，CP 及び VP では鏡検の方法，特にスライド作成法や観察方法の詳細な記載及びその内容に関して，相違点が認められた．

A．研究目的

近年，代替医療として漢方薬あるいは生薬への関心が高まる中で，名称の類似，同名異物等の問題が表面化してきている．生薬の安全性を確保し，有効利用を考える上で，生薬の正しい認識と理解が必須であり，各国で使用されている生薬に関する情報を収集，整理し，共通認識を得ることは生薬，薬用植物の国際調和の観点からも非常に重要と考えられる．このような背景から 2002 年３月に北京において「生薬・薬用植物に関する国際調和のための西太平洋地区討論会」（FHH : Western Pacific Region Forum for the Harmonization of Herbal Medicines）設立のための国際会議が開催された．本フォーラムでは，西太平洋地区の６カ国７地域（日本，中国，韓国，ベトナム，シンガポール，オーストラリア，香港）の生薬・薬用植物の規制に関する関係者が一堂に会し，生薬・薬用植物の安全性，有効性及び品質に関する技術的な記録とコンセンサスを提供することが目的に掲げられた．日本はその下部組織である Nomenclature and Standardization に関する Sub-Committee 会議を主催することを受諾し，2002 年５月，FHH 東京会議が開催された．本会議において以下の５つの専門部会（Expert working group, EWG）が設立された．

1) Nomenclature
2) Testing Method in Monographs
3) List of Chemical Reference Standards (CRS) and Reference of Medicinal Plant Materials (RMPM)
4) List of Analytically Validated Method
5) Information on General Test

これらの専門部会では，将来的な国際調和を踏まえ，各国の薬局方収載生薬について共通点と相違点を認識すること目的として，それぞれの分野における各国薬局方の比較表を作成することが課題事項として議決された．EWG2 (Testing Method in Monographs) の責任者となった分担研究者は試験法及び規格値に関する比較表の作成について担当し，日本，中国，韓国，ベトナム４カ国の薬局方に収載された生薬の試験法，特に確認試験法における TLC 条件並びに定量法（成分含量測定法）における分析条件の詳細につ

いて比較表を作成し，比較検討を行った．

本研究ではEWG 5 (Information on General Tests) の課題事項である日本，中国，韓国，ベトナム4カ国の薬局方に収載された生薬関連一般試験法の詳細について比較表を作成し，比較検討を行った．

なお，本報告では各国の局方に収載されている一般試験法の中で，特に生薬を規定するために必要な試験法を「生薬関連一般試験法」として比較検討の対象とした．

B．研究方法

本研究ではFHH参加国及び地域のうち，独自の薬局方を保有している日本，中国，韓国，ベトナムの4カ国の生薬に関する一般試験法を精査し，各国の試験法（試料の採取，異物，分析用試料の作成，乾燥減量，灰分，酸不溶性灰分，エキス含量，精油含量，鏡検，重金属，ヒ素等）の各項目について試験法の設定の有無，試験方法について比較表を作成した．本比較表の作成に使用した各国薬局方をTable 1に示す．尚，本研究において動物由来試料を用いた実験は行わず，倫理面で大きな支障となる問題は無いと考えられる．

Table 1 Pharmacopoeias Used in Preparation of Comparative Table

日本薬局方 (JP)	第 14 改正日本語版，英語版 第 14 改正第一追補日本語版，英語版 第 14 改正第二追補日本語版 第 15 改正日本語版 日本薬局方外生薬規格1989年日本語版
中華人民共和国薬典 (CP)	2000 年版中国語版，英語版 2005 年版中国語版
大韓民国薬局方 (KP)	1997 年第 7 版英語版 2002 年第 8 版韓国語版，英語版
ベトナム薬局方 (VP)	2002 年第 3 版ベトナム語版 2005 年第 3 版英語版

C．研究結果

作成した比較表をTable 2. に示す．この結果，日本薬局方（JP）と大韓民国薬局方（KP）の一般試験法における試験項目，記載内容は，重金属試験法においてJPでは第1法ー第4法が記載されているのに対し，KP では第 5 法まで記載されている以外はほぼ同一であった．他方，中華人民共和国薬典（CP）とベトナム薬局方 (VP) の一般試験法における試験項目，記載内容はほぼ同一であった．また，CP 及び VP において，分析用試料の作成の項目は認められないが，生薬の品質評価法，生薬の調製・加工，タンニン量及びシネオール量についての項目が収載されていた．エキス含量の項においては，JP 及び KP では希エタノールエキス，水製エキス及びエーテルエキス定量法が収載されているのに対し，CP 及び VP ではエーテルエキス定量法は収載されていなかった．さらに VP では硫酸処理灰分及び水不溶性灰分の項目設定がなされていた．

一方，鏡検に関してJP及びKPでは装置，鏡検用プレパラートの作成及び性状の項の各要素の観察の各小項目で比較的簡単に記載されているのに対し，CP及びVPでは崩壊した組織のスライド作成法，花粉や胞子のスライド作成法，細胞や細胞内容物の測定法，細胞壁及び細胞内容物の観察方法等，詳細な記載が認められた．

D．考察

今回の比較表作成より，東アジア地区4カ国の薬局方における生薬関連一般試験法の共通点，相違点が明らかとなった．特にJPとKP，CPとVPについては一般試験法における試験項目，記載内容がほぼ同一であり，これは局方英語版作成に当り，KP はJPを，CP は VP をそれぞれ参考にして作成されているためこのような結果が得られたものと推測された．また鏡検に関してCP 及び VP では小項目ごとに具体的かつ詳細な記載がなされており，鏡検による生薬の鑑別が現在においても重要視されていることが示唆された．さらに生薬の品質評価法，生薬の調製・加工等，CP及びVPにのみに収載されている項目も多く認められており，興味深い．

E．結論

昨年度に引き続き，将来的な国際調和を踏まえ，各国の薬局方について共通点と相違点を認識することを目的として，各国の薬局方について共通点と相違点を認識することを目的として，特に日本，中国，韓国，ベトナム4カ国の薬局方に収載された生薬関連一般試験法について比較表の作成を試みた．この結果，試料の採取，異物，乾燥減量，灰分，酸不溶性灰分，エキス含量，精油含量，重金属，ヒ素等の設定及びその内容に関して共通点が多く認められたが，CP及びVPでは鏡検の方法，特にスライド作成法や観察方法の詳細な記載及びその内容に関して，相違点が認められた．

第4回 FHH Standing Committee Meeting では，クリーンアナリシスの国際調和の観点から，我が国も含め有害試薬を使用している国は，他国の有害試薬を使用しない試験法を参考にして自国の試験法を変更する努力を行うことが重要であるとの提案がなされた．本提案に基づき，TLC を用いた確認試験で使用される有害試薬について，各国で比較試験を行うことが承認された．今後は，共通生薬 15 種の TLC を用いた確認試験法について，各種展開溶媒並びに試験法の詳細な検討を行い，比較実験を行う予定である．

F．参考文献

1) 川原信夫，酒井英二，糸数七重，佐竹元吉，合田幸広：西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方収載生薬の各種試験法並びに規格値の比較に関する研究．生薬学雑誌，**60** (1), 39-50 (2006).
2) 川原信夫，酒井英二，糸数七重，佐竹元吉，合田幸広：西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方収載生薬の各種試験法並びに規格値の比較に関する研究（第２報）生薬学雑誌，60 (2), 73-85 (2006).
3) 合田幸広：厚生労働科学研究費補助金特別研究事業　平成 14 年度総括・分担研究報告書 生薬規格の国際調和に関する研究 (H-14-特別-005), 国立医薬品食品衛生研究所，pp. 22-30, (2003).
4) 第十五改正日本薬局方作成基本方針及び原案作成要領：http:/moldb.nihs.go.jp/jp/jp15.htm

G．健康危険情報

本研究において健康に危険を及ぼすような情報はない。

H．研究発表

１．論文発表

1) 川原信夫，糸数七重，佐竹元吉，合田幸広：西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方収載生薬の各種試験法並びに規格値の比較に関する研究（第３報）生薬学雑誌，61 (1), 44-57 (2007).

２．学会発表

1) 川原信夫、糸数七重、佐竹元吉、合田幸広：FHH 各国薬局方における試験法と規格値（４）．日本薬学会第 127 年会、富山（2007．3）
2) 川原信夫、井戸淑惠、川崎武志、酒井英二、合田幸広：FHH 各国薬局方における試験法と規格値（５）．日本薬学会第 128 年会、横浜（2008．3）

I．知的所有権の取得状況

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Table 2 Comparative Table on General Testing Methods for Crude Drugs in JP, KP, CP and VP

JP	KP	CP	VP
Sampling	Sampling	Sampling of Crude Drugs	SAMPLING OF CRUDE DRUGS
Unless Otherwise specified, sample should be taken by the following methods. If necessary, preserve the samples in tight containers. (1) When crude drugs to be sampled are small-sized, cut or powdered, 50 to 250 g of sample should be taken after mixing thoroughly. (2) When crude drugs to be sampled are large-sized, 250 to 500 g of sample should be taken after mixing thoroughly. (3) When the mass of each single piece of the crude drugs is not less than 100 g, not less than 5 pieces should be taken for a sample, or not less than 500 g of the sample should be taken after cutting to a suitable size and mixing thoroughly.	Unless Otherwise specified, sample should be taken by the following methods. If necessary, preserve the samples in tight containers. (1) When crude drugs to be sampled are small-sized, cut or powdered, 50 to 250 g of sample should be taken after mixing thoroughly. (2) When crude drugs to be sampled are large-sized, 250 to 500 g of sample should be taken after mixing thoroughly. (3) When the mass of each single piece of the crude drugs is not less than 100 g, not less than 5 piecee should be taken for a sample, or not less than 500 g of the sample should be taken after cutting to a suitable size and mixing thoroughly.	Sampling of Crude Drugs refers to the method used to sort the crude drugs for examination. The validity of sampling affects directly the precision and accuracy of the examination. The procedure for sampling should be followed in details. 1. Examine the confirmation of the name, source of material, specification and package form of the cargo before sampling. Examine the intactness cleanliness of package and contamination of moulds and foreign matter, make notes in detail. The abnormal packages should be examined separately. 2. The general requirements for sampling of crude drugs in a consignment are as follows: when the total number of package less than 5, the packages are sampled one by one. 5-99 packages, 5 packages are sampled at random; 100-1000 packages, 5% are sampled; more than 1000 packages, 1% of the part in excess of 1000 packages are sampled; Precious crude drugs are sampled one by one, regardless of the number of packages. 3. If the material is in crushed or powdered form or in pieces of less than 1 cm in size, at least 2-3 portions of sample are taken by suitable means from different parts in each package. If volume of package is large, samples taken should be 10 cm in depth below the surface from different parts. The quantity of samples taken is defined as follows: Common druge: 100-500 g Powdered drugs: 25 g Precious druge: 5-10 g As for the druge of large size or large number, representative samples can be taken on the basis of real situation. 4. Mix the samples thoroughly, i. e. the total quality of samples taken. If the total quantity of samples taken is several times that required for the testing, take an avarage sample by quartering, until sufficient quantity of sample is obtained for testing and retention. 5. The quantity or average sample taken should be not less than 3 times of that required for the testing, using one third for analysis, another one third for verification and the remaining as aretention which should be kept.	Sampling of clude druge refers to the method used to sort the crude drugs for examination. The representativeness of samples affects directly the prescision and accuracy of the examination. Attention should be paied to the following points while sampling: a) Valify the name, source of the material, specifications and forms of packages before sampling. Examine the intactness, cleanliness of the packagem the contamination of modules and foreign matter, make notes in details. Abnormal packages should be eamined more carefully. b) The general requirements for sampling of crude drugs are as follows: For a number of packages: less tha 5, every package is sampled; less than 100, 5 packages are sampled; from 100 to 1000, 5% of packages are sampled; over 1000, 50 packages and 1% of the number in excess of 1000 packages are sampled. For precious crude druge every package is sampled, regardless of the number of packages. c) If the material is in scraps or powder form or in pieces of less than 1 cm in size, at least 2-3 portions of sample are taken by suitable means from different places in each package. If the number of packages is small, the amount of sample taken shoule be not less than 3 times the quantity required for testing. If the number of packages is large, the amount of sample taken is as follows: Common druge: 100-500 g Powdered druge: 25 g Precious druge: 5-10 g (unless otherwis specified) For the drugs in large size, a representative sample can be taken from different places of a package (at 10 cm in depth below the surface for large package). d) Mix the samples taken as required for the test sample. If the sample size of drug is small, take an aberage sample by quartering method as follows: Spread the samples (after mixing throughly) in a square, then divide the sample into 4 equal parts by diagonals; take two opposite parts and mix again. With the mixture obtained, repeat the quartering in the wame way until a sufficient amount of sample is obtained for testing and retention. In the case of large size druge, the avarage samples can be obtained with any appropriate methods. The amount of an average sample should not less than 3 times of that required for testing, using one third for analysis, another for verification and the remaining as retained sample which should be kept at least for one year.
Foreign matter	Foreign matter	Determination of Foreign Matter	DETERMINATION OF FOREIGN MATTER IN CRUDE DRUGS
Unless otherwise specified, weigh 25 to 500 g of the sample, spread out in a thin layer, and separate the foreign matter by inspecting with the naked eye or with the use of a magnifying glass of 10 magnifications. Weigh, and determine the percentage of foreign matter.	Unless otherwise specified, weigh 25 to 500 g of the sample, spread out in a thin layer, and separate the foreign matter by inspecting with the naked eye or with the use of a magnifying glass of 10 magnifications. Weigh, and determine the percentage of foreign matter.	Foreign mater consists of any or all of the following: 1. The biological origin of which is the same as that specified in the monograph concerned but the appearance or botanical parts is different. 2. The biological origin of which differs from that specified in the monograph concerned. 3. Foreign mineral matters such as stones. sand. lumps of soil. Method (1) Weight a quantity of the drug as specified in the monograph and spread out in a thin layer. Detect the foreign matter by inspection with naked eye or with a lens (5-10 X), or by the use of a suitable sieve, if necessary, to separate the foreign matter. (2) Weight separately each kind of foreign matter and calculate the percentage content.	Foreign matter in herbal drugs consists of any or all of the following: Foreign mineral mannter such as stons, sand, lumps of soil. Other herbs and other parts of the plant that are not specified as clude drugs. Remains of insects. Method: Weigh a quantity of the crude drug as specified in the monograph and spread out in a thin layer. Detect the foreign matter by inspection with naked eye or with a lens or by use of a suitable sieve. If necessary, to separate the foreign matter. Weigh the foreign matter and calculate the percentage, using the expression: X% = a/p x 100 where: a: Mass of foreign matter (g), p: Mass of test sample being examined (g)
Preparation of the test sample for analysis	Preparation of the test sample for analysis		
Preparations are to be made by mixing the sample well. Powdered drugs should be used as they are, and in the case of unpowdered drugs, unless otherwise specified, grind the sample into powder. If the sample cannot be ground into powder, reduce it as finely as possible, spread it out in a thin layer, and withdraw a typical portion for analysis. If necessary, preserve the test sample in a tight container.	Preparations are to be made by mixing the sample well. Powdered drugs should be used as they are, and in the case of unpowdered drugs, unless otherwise specified, grind the sample into powder. If the sample cannot be ground into powder, reduce it as finely as possible, spread it out in a thin layer, and withdraw a typical portion for analysis. If necessary, preserve the test sample in a tight container.		
Loss on drying	Loss on drying	Determination of Loss on Drying	DETERMINAITON OF LOSS ON DRYING
Unless otherwise specified, transfer 2 to 6 g of the test sample for analysis to a tared weighing bottle, and weigh accurately. Dry at 105℃ for 5 hours, allow to cool in a desiccator (silica gel), and weigh accurately. Continue the drying at 105℃, and weigh accurately at 1-hour intervals.	Unless otherwise specified, transfer 2 to 6 g of the test sample for analysis to a tared weighing bottle, and weigh accurately. Dry at 105℃ for 5 hours, allow to cool in a desiccator (silica gel), and weigh accurately. Continue the drying at 105℃, and weigh accurately at 1-hour intervals.	Mix the substance being examined thoroughly, if it is in the form of large crystals, reduce them to a size of about 2 mm by crushing. Place 1 g or the amount specified under individual monographs of the substance being examined in a tarred, shallow weighing bottle, previously dried to constant weight under the conditions specified in individual monographs, unless otherwise directed. The substance being	Loss on drying is the loss of mass, expressed as percentage (m/m), of the test sample being dried under conditions specified in the individual monograph. The loss of mass after during represents the loss of the absorbed water, one part or the whole water of crystallisation and other volatile substances present in the sample being examined. The determination of loss of drying should not affect basic physico-

JP	KP	CP	VP
Loss on drying	Loss on drying	Determination of Loss on Drying	DETERMINAITON OF LOSS ON DRYING
When the mass of the sample becomes constant, the loss of mass represents the percentage of loss on drying (%). When the period of time for drying is specified, weigh accurately after drying for the period of time specified, and determine the loss on drying (%).	When the mass of the sample becomes constant, the loss of mass represents the percentage of loss on drying (%). When the period of time for drying is specified, weigh accurately after drying for the period of time specified, and determine the loss on drying (%).	examined should be evenly distributed to form a layer of not more than 5 mm in thickness, or not more than 10 mm in the case of bulky material. When the loaded bottle is placed in the chamber of desiccator, remove the stopper and put in beside the bottle, or leave it on the bottle in half open position. Upon the opening of the drying chamber or desiccator, the bottle should be closed promptly. If the substance is dried by heating, allow it to cool to room temperature in a desiccator before weighing. If the substance melts at a lower temperature than the specified drying temperature, maintain the bottle with its content below the melting temperature until most of water is removed, then dry it under the specified conditions. If a vacuum desiccator or constant temperature vacuum desiccator is to be used, a pressure of 2.67 kPa (20 mm Hg) or less should be maintained unless otherwise directed. The desiccants used in a desiccator are usually anhydrous calcium chloride, silica gel or phosphorus pentoxide. Phosphorus pentoxide is often used in a constant temperature vacuum desiccataor. The desiccants should be kept fully effective.	chemical properties of the substance being examined; so in each individual monograph the drying method is specified and selected among the following methods: Method 1: drying in an oven under atmospheric pressure Method 2: drying under reduced pressure Method 3: drying in a desiccator over a strong desiccant such as concentrated sulfuric aciem phosphorus pent oxide, anhydrous calcium chloride, silica gel, etc... For each method, detailed specific conditions are prescribed in the individual monograph for the substance being examined. When prescribed in the monograph: "Not exceed 1% (1 g, 105℃, 4 hours)", it means method 1 used: one gram of the sample being examined is dried in an oven at 105℃ for 4 hours and the loss mass should not exceed 10 mg. "Not exceed 0.5% (1 g, phosphorous pent oxide, 24 hours)" means method 2 is used: one gram of the substance being examined is dried in a drying device for 24 hours under reduced pressure (2 kPa) with the presence of phosphorus pent oxide as desiccant and the loss of mass should not exceed 5mg. Not exceed 0.2% (1 g, silica gel, 24 hours) means method 3 is used: one gram of the substance being examined is dried in a drying device for 24 hours under reduced pressure (2kPa) with the presence of desiccant silica gel and the loss of mass should not exceed 2 mg. When the drying time is not specified in the monograph, the sample should be dried to constant weight (this means two consecutive weightings should not differ by more than 0.5 milligram, the second weighing being made after an additional period of drying (1 hour in an oven or 6 hours in a desiccator). Method The container used in weightings ca be a Petri dish or a weighing bottle which is dried for 30 minutes following the method and conditions specified in the monograph, and then the container is weighed to determine its mass. Place immediately a quantity of the substance being examined (the quantity prescribed in the monograph, with a deviation of ±10%) in the container and weigh it accurately. Unless otherwise stated in the monograph, the sample being examined is evenly spread to form a layer of a thickness not more than 5 mm. If the sample being examined contains large pieces, it should be quickly ground to obtain particles of size under 2 mm before weighing. Dry the sample under the conditions prescribed in the monograph using the same drying device as that has been used for drying the container. When drying in an oven, the temperature in the oven used should not differ by more than ±2℃ from the specified temperature. After drying, the sample is allowed to cool in a desiccator. over silica gel as desiccant, down to room temperature, then weighed immediately. If the substance being examined melts at a temperature lower than the specified temperature, it should be kept for 1 to 2 hours at a temperature 5℃ to 10℃ lower than its melting point before heating up to the described temperature. For sample in the form of capsules or draggers, the shells should be discarded and the sample being examined is quickly ground to form a powder of 2 mm particles, and amount of powder equivalent to at least 4 draggers or capsules is taken for testing. For materia medica, unless otherwise prescribed, method 1 is applied. The sample is ground into pieces not larger than 3 mm in diameter, then an amount of 2 g to 5 g is taken and evenly spread to form a layer of a thickness not more than 5 mm (or not more than 10 mm when the sample is porous material). The sample is dried as described in the monograph at the specified temperature for the prescribed period of time.
Total ash	Total ash	Determination of Ash (Total ash)	DETERMINATION OF ASH
Ignite previously a crucible of platinum, quartz or porcelain between 500℃ and 550℃ for 1 hour. Cool, and weigh accurately the crucible. Unless otherwise specified, weigh accurately 2 to 4 g of the test sample for analysis in this crucible, take off the lid or keep it open a little if necessary, heat the crucible at a low temperature at first, then gradually heat to a temperature between 500℃ and 550℃, ignite to incinerate the residue for more than 4 hours until no carbonized substance remains in the ash, cool, and weigh accurately the ash. Incinerate repeatedly to	Ignite previously a crucible of platinum, quartz or porcelain between 500℃ and 550℃ for 1 hour. Cool, and weigh accurately the crucible. Unless otherwise specified, weigh accurately 2 to 4 g of the test sample for analysis in this crucible, take off the lid or keep it open a little if necessary, heat the crucible at a low temperature at first, then gradually heat to a temperature between 500℃ and 550℃, ignite to incinerate the residue for more than 4 hours until no carbonized substance remains in the ash, cool, and weigh accurately the ash. Incinerate repeatedly to	Pulverize the material being examine, pass through No.2 sieve, mix well. Place 2—3 g (3—5 g for the determination of acid-insoluble ash) of powdered drug in a tarred crucible, weigh accurately (to nearest 0.01 g), ignite slowly till the sample is completely carbonized, keep it from burning with care, raise the temperature gradually to 500—600℃, incinerate to constant weight and the ash is carbon-free. Calculate the percentage of ash with reference to the air-dried drug. If carbon-free ash cannot be obtained in this way, cool the crucible and moisten the residue with hot water or 2 ml of 10% ammonium nitrate solution. Evaporate to dryness on a water bath, ignite the residue as above until carbonfree ash is obtained.	Use method 1 unless otherwise directed in the monograph. Method 1: For vegetable drugs: incinerate 2 to 3 of the ground drug in a tarred platinum or silica crucible at a temperature not exceed 450℃ until free from carbon, cool and weigh. If a carbon-free ash cannot be obtained in this way, exhaust the charred mass with hot water, stair with glass rod, filter through an ashless filter paper. Wash the glass rod and filter paper, combine the washings and the filtrate. Place the filter paper and the residue in a crucible and ignite until a white or almost white ash obtained. Add the filtrate to residue in the crucible, evaporate to dryness, and ignite at a temperature not exceeding 450℃ to constant mass. Calculate the percentage of ash with reference to air dried drug. For other substances: Carry out the above method using 1g, unless

JP	KP	CP	VP
Total ash	Total ash	Determination of Ash (Total ash)	DETERMINATION OF ASH
constant mass, cool, weigh accurately, and determine the amount (%) of total ash. If a carbonized substance remains and constant mass cannot be obtained in the above-mentioned method, extract the charred mass with hot water, collect the insoluble residue on filter paper for assay, and incinerate the resi-due and filter paper until no carbonized substance remain in the ash. Then add the filtrate, evaporate it to dryness, and incinerate. Cool, weigh accurately, and determine the mass (%) of the total ash. If a carbon-free ash cannot be obtained even in this way, moisten the ash with a small amount of ethanol (95), break up the ash with a glass rod, wash the rod with a small amount of ethanol (95), evaporate carefully, and determine the mass of the total ash as described above. A desiccator (silica gel) is used for cooling.	constant mass, cool, weigh accurately, and determine the amount (%) of total ash. If a carbonized substance remains and constant mass cannot be obtained in the above-mentioned method, extract the charred mass with hot water, collect the insoluble residue on filter paper for assay, and incinerate the resi-due and filter paper until no carbonized substance remain in the ash. Then add the filtrate, evaporate it to dryness, and incinerate. Cool, weigh accurately, and determine the mass (%) of the total ash. If a carbon-free ash cannot be obtained even in this way, moisten the ash with a small amount of ethanol (95), break up the ash with a glass rod, wash the rod with a small amount of ethanol (95), evaporate carefully, and determine the mass of the total ash as described above. A desiccator (silica gel) is used for cooling.		otherwise directed in the monograph. Calculate the percentage of ash. Method 2: Heat a porcelain or platinum crucible to red heat for 30 minutes, allow to cool in a desiccator and weigh. Unless otherwise specified in the monograph, evenly distribute 1 g of the substance being examined in the crucible, dry at 100℃ to 150℃ for 1 hour and ignite to constant weight in a muffle furnace at 575℃ to 625℃. Allow the crucible to cool in a desiccator and weigh after each ignition. Flames should not be produced at any time during the procedure. If after prolonged ignition a carbon-free ash cannot be obtained, take up with hot water, filter through an ashless filter paper and ignite again the residue and the filter paper. Combine the filtrate with the ash, carefully evaporate to dryness and ignite to constant weight. Calculate the percentage of ash with reference to the air-dried drug.
Acid-insoluble ash	Acid-insoluble ash	Determination of Ash (Acid-insoluble ash)	DETERMINATION OF ACID INSOLUBLE ASH
Add carefully 25 mL of dilute hydrochloric acid to the total ash, boil gently for 5 minutes, collect the insoluble matter on filter paper for assay, and wash thoroughly with hot water. Dry the residue together with the filter paper, and ignite to incinerate in a tared crucible of platinum, quartz or porcelain for 3 hours. Cool in a desiccator (silica gel), weigh, and determine the amount (%) of acid-insoluble ash. When the amount determined exceeds the limit specified, incinerate repeatedly to constant mass.	Add carefully 25 mL of dilute hydrochloric acid to the total ash, boil gently for 5 minutes, collect the insoluble matter on filter paper for assay, and wash thoroughly with hot water. Dry the residue together with the filter paper, and ignite to incinerate in a tared crucible of platinum, quartz or porcelain for 3 hours. Cool in a desiccator (silica gel), weigh, and determine the amount (%) of acid-insoluble ash. When the amount determined exceeds the limit specified, incinerate repeatedly to constant mass.	Place the obtained in the determination of total ash in crucible, add 10 ml of dilute hydrochloric acid with great care, cover with a watch glass, heat on a water bath for 10 minutes. Rinse the watch glass, with 5 ml of hot water and add the rinsings to the crucible, filter with an ashless filter paper, transfer the residue to the filter paper with water, wash till the filtrate yields no reactions of chlorides. Transfer the filter paper together with the residue to the original crucible, dry and ignite to constant weight. Calculate the percentage of acid-insoluble ash with reference to the air-dried drug.	Use method 1 unless otherwise directed in the monograph. Method 1: Boil the ash for 5 minutes with 25 ml of 2 M hydrochloric acid R, filter, collect the insoluble matter in a previously weighed sintered-glass crucible or on an ashless filter paper, wash with hot water and ignite. Calculate the percentage of acid-insoluble ash with reference to the air-dried drug. Method 2: Place the ash or the sulphated ash, as specified in the mono-graph, in a crucible, add 15 ml of water and 10 ml of hydrochloric acid R, cover with a watch glass, boil gently for 10 minutes and allow to cool. Wash the watch glass with 5ml of hot water, collect the washings in the crucible. Collect the insoluble matter in a previously weighed sintered-glass funnel or on ashless filter paper, wash with hot water until the filtrate is neutral. Dry, ignite to dull redness, allow to cool in a desiccator and weigh. Repeat until the difference between tow successive weightings is not more than 1 mg. Calculate the percentage of acid-insoluble ash with reference to air-dried drug.
			DETERMINATION OF SULPHATED ASH
			Use method 1 unless otherwise directed in the monograph. Method 1: Heat a porcelain or platinum crucible to redness for 10 minutes, allow to cool in a desiccator and weigh. Unless otherwise specified in the monograph, place 1 g of the substance being examined in the crucible, moisten with sulphuric acid R, ignite gently, again moisten with sulphuric acid and ignite at about 800℃. Cool, weigh again, ignite for 15 minutes and cool, weigh again. Repeat this procedure until tow successive weightings do not differ by more than 0.5 mg. If the residue is reserved for the test of heavy metals, ignition should be carried out at 500℃ to 600℃. Method 2: Heat a porcelain or platinum crucible to redness for 10 minu-tes, allow to cool in a desiccator and weigh. Place a suitable quantity of the substance being examined in the crucible, add 2 ml of 1 M sulphuric acid R and heat, first on a water bath, then cautiously over a flameand then progressively to about 600℃. Continue incineration until all black particles have disappeared and then allow to cool. Add a few drops of 1 M sulphuric acid R, incinerate as before and allow to cool. Add a few drops of a 15.8 % m/v solution of ammonium carbonate R, evaporate to dryness. Incinerate carefully, allow to cool, weigh. Incinerate for 15 minutes and repeat this procedure to constant mass.
			DETERMINATION OF WATER-SOLUBLE ASH
			Boil the ash (Appends 7.6) for 5 minutes with 25 ml of water. Collect the insoluble matter in a previously weighed sintered-glass funnel or filter crucible or on an ashless filter paper, wash with hot water and ignite for 15 minutes at a temperature not exceeding 450℃. Allow to cool in a desiccator and weigh to determine the quantity of water insoluble residue. The difference between the weight of ash add the weight of water-insoluble residue is the mass of water-soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.
Extract content	Extract content	Determination of Extractives	DETERMINATION OF EXTRACTIVES IN HERBAL DRUGS
The test for the extract content in crude is performed as directed in the following methods: (1) Dilute ethanol-soluble extract-Unless	The test for the extract content in crude is performed as directed in the following methods: (1) Dilute ethanol-soluble extract-Unless	1. Determination of Water-soluble Extractives Pulverize the material being examined, pass through No.2 sieve, mix well. Cold maceration method Place 4 g of the powdered material,	Determination of water-soluble extractives Cold maceration method: Unless otherwise specified in the monograph, place about 4.000 g of the moderately coarse powdered

JP	KP	CP	VP
Extract content	Extract content	Determination of Extractives	DETERMINATION OF EXTRACTIVES IN HERBAL DRUGS
otherwise specified, weigh accurately about 2.3 g of the sample for analysis, extract with 70 mL of dilute ethanol in a suitable flask with intermittent shaking for 5 hours, and allow to stand for 16 to 20 hours. Filter, and wash flask and residue with small portions of dilute ethanol until the filtrate measures 100 mL. Evaporate a 50 mL aliquot of filtrate to dryness, dry at 105℃ for 4 hours, and cool in a desiccator (silica gel). Weigh accurately the amount, multiply it by 2, and determine theamount of dilute ethanol-soluble extract. Calculate the extract content (%) with respect to the amount of the sample on the dried basis, obtained under the loss on drying. (2) Water-soluble extract-Proceed as directed in (1), using water instead of dilute ethanol, weigh accurately the amount, multiply by 2, and determine the amount of water-soluble extract. Calculate the extract content (%) with respect to amount of the sample on the dried basis, obtained under the loss on drying. (3) Diethyl ether-soluble extract-Unless otherwise specified, dry the sample for analysis in a desiccator (silica gel) for 48 hours, weigh accurately about 2 g of it, and place in a suitable flask. Add 70 mL of diethyl ether, attach a reflux condenser to the flask, and boil gently on a water bath for 4 hours. Cool, filter, and wash the flask and the residue with small portions of diethyl ether until the filtrate measures 100 mL. Evaporate a 50 mL aliquot of the filtrate to dryness on a water bath, dry in a desiccator (silica gel) for 24 hours, weigh accurately the amount, multiply it by 2, determine the amount of diethyl ether-soluble extract, and calculate the extract content (%).	otherwise specified, weigh accurately about 2.3 g of the sample for analysis, extract with 70 mL of dilute ethanol in a suitable flask with intermittent shaking for 5 hours, and allow to stand for 16 to 20 hours. Filter, and wash flask and residue with small portions of dilute ethanol until the filtrate measures 100 mL. Evaporate a 50 mL aliquot of filtrate to dryness, dry at 105℃ for 4 hours, and cool in a desiccator (silica gel). Weigh accurately the amount, multiply it by 2, and determine theamount of dilute ethanol-soluble extract. Calculate the extract content (%) with respect to the amount of the sample on the dried basis, obtained under the loss on drying. (2) Water-soluble extract-Proceed as directed in (1), using water instead of dilute ethanol, weigh accurately the amount, multiply by 2, and determine the amount of water-soluble extract. Calculate the extract content (%) with respect to amount of the sample on the dried basis, obtained under the loss on drying. (3) Diethyl ether-soluble extract-Unless otherwise specified, dry the sample for analysis in a desiccator (silica gel) for 48 hours, weigh accurately about 2 g of it, and place in a suitable flask. Add 70 mL of diethyl ether, attach a reflux condenser to the flask, and boil gently on a water bath for 4 hours. Cool, filter, and wash the flask and the residue with small portions of diethyl ether until the filtrate measures 100 mL. Evaporate a 50 mL aliquot of the filtrate to dryness on a water bath, dry in a desiccator (silica gel) for 24 hours, weigh accurately the amount, multiply it by 2, determine the amount of diethyl ether-soluble extract, and calculate the extract content (%).	accurately weight (to the nearest 0.01 g), in a 250~300 ml stoppered conical flash, add accurately 100 ml of water, stopper well. Macerate the drug with shaking for 6 hours and allow to stand for 18 hours. Filter rapidly through a dry filter, transfer accurately 20 ml of filtrate to an evaporating dish, previously dried to constant weight, and evaporate to dryness on a water bath. Dry at 150℃ for 3 hours and allow to cool for 30 minutes in a desiccator. Weigh rapidly and accurately, unless specified otherwise in the monograph, calculate the percentage of water-soluble extractives on the dried basis (%). Hot extraction method: Place 2~4 g of the powdered material, accurately weighted in a 100~250 ml stoppered conical flask, add a accurately 50~100 ml of water, stopper well and weigh, allow to stand for 1 hour. Boil gently under reflux for 1 hour. Allow to cool, take off the flask, stopper well and weigh, add water to restore its original weight, shake well and filter through a dry filter. Place 25 ml of the filter, accurately, in an evaporating dish, previously dried to constant weight, and evaporate to dryness on water bath. Dry at 105℃ for 3 hours and allow to cool for 30 minutes in a desiccator. Weigh rapidly accurately, unless specified otherwise in the monograph, calculate the percentage of water-soluble extractives on the dried basis (%). 2. Determination of Ethanol-soluble Extractives Proceed as directed under determination of water-soluble extractive (hot extraction method should be heating on a water bath), using ethanol or methanol of a strength specified in individual monograph as the solvent instead of water. 3. Determination of volatile ether extractives Place 2-5 g of the powdered material (through No. 4 sieve), accurately weighed, dry for 12 hours in a desiccator with P_2O_5. Place in a Soxhlet's extractor, add a quantity of ehter, boil under reflux for 8 hours, unless specified otherwise in the monograph. Place in a evaporate to dryness. Dry for 18 hours in a desiccator with P_2O_5, weigh accurately, heat to 105℃ slowly, dry at 105℃ to constant weight. The weight loss is the weight of volatile ether extractives.	material, accurately weighed, in a 250-300 ml stoppered conical flask. Add accurately 100.0 ml of water, close well, allow to macerate cold occasionally shaking for 6 hours, then allow to stand fro 18 hours. Filter through a dry filter into a suitable dry flask. Pipette 20 ml of the filtrate to a glass beaker, previously dried to constant mass, and evaporate to dryness in a water bath. Dry the residue at 105℃ for 3 hours and allow to cool for 30 minutes in a desiccator, weigh rapidly to determine the mass of the residue, calculate the percentage of water-soluble extractives with reference to the air-dried drug. Hot extraction method: Unless otherwise specified in the monograph, place about 2.000 g to 4.000 g of the moderately coarse powdered material, accurately weighed, in a 100 ml or 250 ml close conical flask. Add accurately 50.0 or 100.0 ml of water, close well and weigh, allow to stand for 1 hour, then heat under a reflux condenser in a water bath for 1hour, allow to cool, take off the flask, closes well and weigh, add water to restore its original mass, filter though a dry filter into a suitable dry flask. Pipette 25 ml of the filtrate to a glass beaker, previously dried to constant mass, and evaporate to dryness in a water bath. Dry the residue a 105℃ for 3 hours and allow to cool for 30 minutes in a desiccator, weigh rapidly to determine the mass of the residue, calculate the percentage of water-solbule extractives with reference to the air-dried drug. Detrmination of alcohol-soible extractives Process as directed under determination of water-soluble extractives, using ethanol or methanol of strength specified in individual monograph as extraction solvent instead of water.
Essential oil content	Essential oil content	Determination of Volatile Oil	DETERMINATION OF VOLATILE OIL IN DRUGS
The test of essential oil content in crude drugs is performed as directed in the following method: Essential oil determination: Weigh the quantity of the test sample for analysis directed in the monograph in a 1-L hard glass-stoppered flask, and add from 5 to 10 times as much water as the drug. Set up apparatus for essential oil determination in the upper mouth of it, and heat the content of the flask in an oil bath between 130℃ and 150℃ to boiling. The graduated tube of the apparatus is to be previously filled with water to the standard line, and 2.0 mL of xylene is added to the graduated tube. Unless otherwise specified, continue boiling for 5 hours, allow to stand for some time, and open the stopper of the apparatus. Draw off the water slowly until the surface of the oil layer corresponds to the preparation line, and allow it to stand for than 1 hour at ordinary temperature. Then lower the surface of the oil layer to the zero line. and read the volume (mL) of the oil at ordinary temperature. Subtract the volume (mL) of xylene from the volume of the total oil.	The test of essential oil content in crude drugs is performed as directed in the following method: Essential oil determination: Weigh the quantity of the test sample for analysis directed in the monograph in a 1-L hard glass-stoppered flask, and add from 5 to 10 times as much water as the drug. Set up apparatus for essential oil determination in the upper mouth of it, and heat the content of the flask in an oil bath between 130℃ and 150℃ to boiling. The graduated tube of the apparatus is to be previously filled with water to the standard line, and 2.0 mL of xylene is added to the graduated tube. Unless otherwise specified, continue boiling for 5 hours, allow to stand for some time, and open the stopper of the apparatus. Draw off the water slowly until the surface of the oil layer corresponds to the preparation line, and allow it to stand for than 1 hour at ordinary temperature. Then lower the surface of the oil layer to the zero line. and read the volume (mL) of the oil at ordinary temperature. Subtract the volume (mL) of xylene from the volume of the total oil.	The drug being examined should be pulverized to pass through No.2 or No.3 sieves and then mixed well, unless otherwise specified. Method 1 This method is used for determining volatile oil of which the relative density is less than 1.0. Weigh accurately to the nearest 0.01 g, a quantity of the substance being examined equivalent to 0.5~1.0 ml of volatile oil, into flask A. Add 300~500 ml of water and a few glass beads, shake and mix well. Connect flask A to volatile oil determination tube B and then connect B to reflux condenser C. Add water through the top of reflux condenser C until the graduated tube of B is filled and overflows to flask A. Heat the flask gently in an electric heating jacket or by other suitable means until boiling begins-continue heating for about 5 hours, until the volume of oil does not increase. Stop heating, allow to stand for a few minutes, and open the stopcock at the lower part of B, run off the water layer slowly until the oil layer is 5 mm above the zero mark. Allow to stand for at least 1 hours, open the stopcock again, run off the remaining water layer carefully until the oily layer is just on the zero mark. Read the volume of oil in the graduated portion of the tube and calculate the content of volatile oil, expressed as percentage (ml/g). Method 2 This method is used for determination volatile oils of which the relative density is more than 1.0. Transfer 300 ml of water and a few class beads to flask A. Connect flask A to volatile oil determination assembly B. Add water through the top of B until the graduated measuring tube of B is filled and water overflows to flask A. Add 1 ml of xylene with pipette andthen connect the reflux condenser C to B. Heat the flask until boiling begins and continue the distillation at a rate that will keep the middle part of the condenser cold. Stop heating after 30 minutes, allow to stand for at least 15 minutes. Read the volume of xylene in the graduate portion of the tube. Carry out the procedure described under Method I. Beginning at the words "Weigh accurately to the nearest 0.01 g...". Subtract the volume of xylene previously from the volume of the oil layer, Subtract the volume of xylene previously from the volume of the oil layer, the remainder is taken to the content of volatile oil in the drug being examined, expressed as percentage (ml/g).	The determination of volatile oil in drugs is carried out by steam distillation in the apparatus described in the Fig 9.2. The distillate is collected in a tube graduated into divisions of 0.05 ml and the aqueous phase is automatically recalculated into the distillation flask. The volume of volatile oil may be measured directly on the graduated tube or xylene may be used to take up the volatile oil to the graduated part of the tube (for the volatile oils the relative density of which is more than 1.0), and then total volume of the mixture of xylene and volatile oil is measured. The content of volatile oil is expressed as a percentage v/m. *Determination of the volatile oils the relative density of which is less than 1.0.* Weigh accurately the nearest 0.01 g, a quantity of the substance being examined passed through sieve No. 2000 equivalent to 0.5-1.0 ml of volatile oil in to the distillation flask. Add 300-500 ml of water and a few pieces of porous earthenware. Connect the distillation flask to the still head A of the apparatus. Add water through the funnel N until it is at the level B. Heat the flask until ebullition begins and adjust the distillation rate 2 to 3 ml per minute unless otherwise prescribed. Determine the rate of distillation by lowering the level of distillation liquid by means of the three-way tap M until the meniscus is level with the lower mark I, J, closing the tap M and simultaneously starting a stop watch. When the level reaches the mark H, stop the watch and note the time. Open the tap M and continue the distillation for 5 hours, unless otherwise prescribed, until the volume of volatile oil stops to increase. Stop heating and after at least 10 minutes read the volume of the oil collector in the graduated tube. *Determination of the volatile oils the relative density of which is more than 1.0.* Connect the distillation flask containing about 300-500 ml of water and a far small pieces of porous earthenware, to the still head A of the apparatus. Add water though the funnel N until it is at the level B. Introduce 1 ml of xylene R at K by means of a pipette (the tip of which is inserted the lower part of orifice K). Heat the flask until ebullition begins and adjust the distillation rate as the way described under the method for determination of the volatile oils relative density of which is less than 1.0. After 30 minutes discontinue heating and after at least a 10 minutes read the volume of xylene R collected in the graduated tube. Introduce the specified quantity of drug passed the through No. 2000

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Essential oil content	Essential oil content	Determination of Volatile Oil	DETERMINATION OF VOLATILE OIL IN DRUGS
			sieve equivalent to 0.5-1.0 ml of volatile oil into the distillation flask. Carry out the distillation at the distillation rate from 2 to 3 ml per minute for 5 hours, unless otherwise prescribed, until the volume of the volatile oil stops to increase. Stop heating and after at least 10 minutes read the volume of the mixture of xylene R and volatile oil. Subtract the volume of xylene R previously observed from the volume of the oily layer. The difference in volume and the quantity of drug are taken to be the content of volatile oil in the drug being examined.
Microscopic examination	Microscopic examination	Microscopical Identification for Crude Drugs and Patent Medicines	MICROSCOPICAL IDENTIFICATION FOR CRUDE DRUGS AND PATENT MEDICINES
(1) Apparatus Use an optical microscope with objective of 10 and 40 magnifications, and an ocular of 10 magnifications. (2) Preparation for microscopic examination (i) Section: To a section an a slide glass add 1 to 2 drops of a mounting agent, and put a cover glass in it, taking precaution against inclusion of bubbles. Usually use a section 10 to 20 mm in thickness. (ii) Powder: Place about 0.1 g of powdered sample in a watch glass containing 2 to 3 drops of a swelling agent, stir well with a small rod preventing inclusion of bubbles, and allow to stand for more than 10 minutes to swell the sample. Smear, using a small glass rod, the slide glass with a small amount of the swollen sample, add 1 drop of the mounting agent, and put a cover glass on it so that the tissue sections spread evenly without overlapping each other, taking precaution against inclusion of bubbles. Unless otherwise specified, use a mixture of glycerin and water (1:1) as mounting agent and swelling agent. (3) Observation of components in the description in each monograph, description is usually given of the outer portion and the inner portion of section in this order, followed by a specification of cell contents. Observation should be made in the same order. In the case of a powdered sample, description is given of a characteristic component or a matter present in large amount, rarely existing matter, and cell contents in this order. Observation should be made in the same order.	(1) Apparatus Use an optical microscope with objective of 10 and 40 magnifications, and an ocular of 10 magnifications. (2) Preparation for microscopic examination (i) Section: To a section an a slide glass add 1 to 2 drops of a mounting agent, and put a cover glass in it, taking precaution against inclusion of bubbles. Usually use a section 10 to 20 mm in thickness. (ii) Powder: Place about 0.1 g of powdered sample in a watch glass containing 2 to 3 drops of a swelling agent, stir well with a small rod preventing inclusion of bubbles, and allow to stand for more than 10 minutes to swell the sample. Smear, using a small glass rod, the slide glass with a small amount of the swollen sample, add 1 drop of the mounting agent, and put a cover glass on it so that the tissue sections spread evenly without overlapping each other, taking precaution against inclusion of bubbles. Unless otherwise specified, use a mixture of glycerin and water (1:1) as mounting agent and swelling agent. (3) Observation of components in the description in each monograph, description is usually given of the outer portion and the inner portion of section in this order, followed by a specification of cell contents. Observation should be made in the same order. In the case of a powdered sample, description is given of a characteristic component or a matter present in large amount, rarely existing matter, and cell contents in this order. Observation should be made in the same order.	Microscopical identification is method with the application of the microscope to identify the characters of tissues, cells or cell contents in sections, powders disintegrated tissues or surface slides of crude drugs and patent medicines. Representative to meet the requirements of identifications for each drugs. The slides of patent medicines are made after appropriate treatment with reference to their different dosage forms. 1. Microscopical slides of crude drugs (1) Transverse or Longitudinal Sections Select the observed part of the drug, cut into sections of 10-20 mm in thickness with a razor blade or using sliding microtome after softened. Material may be embedded in hard paraffin before cutting if necessary. Select a flat section on the glass slide, according to different phenomena, treate with glycerol-acetic acid TS, choral hydrate TS or other test solutions 1-2 drops, and cover the cover glass. If necessary, after treat chloral hydrate TS, heat until it is transparent, and then treat with glycerol-ethanol TS or diluent glycerol, cover the cover glass. (2) Slides of Powder Spread a small quantity of the powder, through a seive No. 4, on a slide, and examine after treated with glycerol-acetic acid TS, chloral hydrate TS, or other suitable test solutions, cover the cover glass. (3) Slides of Surface After moistening and softening the materials, cut two parts of about 4 mm² of the observed part, place on the glass slide (one for the obverse, the other for the opposite) or tear its epidermis, add suitable test solutions or heat until it is transparent, cover the cover glass. (4) Slides of Disintegrated Tissue The material should be cut into small strips of about 5 mm in length, 2 mm in diameter or pieces of about 1 mm thick before being disintegrated. Potassium hydroxide method can be used parenchyma makes most part of the material or the material with few or scattered woody tissues; chromic-nitric acids method or potassium chlorate method can be used if the material is hard, with the presence of more woody tissues or the woody grouped to lager bundles. ① Potassium Hydroxide Method ② Chromic-Nitric Acids Method ③ Potassium Chlorate Method (5) Slides of Pollen and Spore Grind Pollens, anthers (or small flowers) or sori (soften the dry material inglacial acetic acid) with a glass rod and filter into a centrifugal tube, centrifuge. To the precipitate add 1-3 ml of a freshly prepared mixture of acetic anhydride-sulfuric acid (9:1), heat on a water bath for 2-3 minutes, centrifuge. Wash the precipitate with water twice, place a little on the glass slide, treat with choral hydrate TS, cover the cover glass, or add 1-2 drops of 50% glycerin and 1% phenol, mount in fuchsin-glycerin gelatin. 2. Microscopical slides of preparations including druge powder 3. Identification of cell wall (1) Lignified cell wall (2) Suberized or Cuticularized Cell Wall (3) Cellulose Cell Wall (4) Siliceous Cell Wall 4. Identification of Cell Content (1) Starch (2) Aleurone (3) Fatty oil, Volatile Oil or Resin (4) Inulin (5) Mucilage (6) Calcium Oxalte Crystals (7) Calcium Carbonate (stalactile) (8) Silicum 5. Microscopical measure It refers to measure the size of cells and cell contents in the microscope	Microscopical identification is a method using a microscope to identify the characters of tissues, cells or cell contents in sections, powders, disintegrated tissues or surface slides of crude drugs and patent medicines. Representative samples are chosen to be identified and slides are prepared to meet the requirements of identification for each drug. The slide of patent medicines are after appropriate treatment with reference ton their different dosage forms. Transverse of longitudinal sections Select a suitable oar of the drug having enough required botanical characteristics as specified below: Stems and small roots: Take a piece with a full sartorial trance verse section. Stems, big roots: Take a piece with a spectral transeverse section (showing from the epidermis to the centre). Stem bark: Take a piece with a rectangular transeverse section (showing from cork to xylem). Leaves: Take a piece with central vein and part of the lobes on both of its side. Flowers: Take the epiderma or cut transversely every part of the flower. Small fruits and seeds: Take the whole fruit or seed. Big fruits and seeds: Take a part of fruit or seed so that a section of which shows all botanical characteristics. Cut into thin sections with razor bale or using sliding microtome after being softened. Material may be embedded in herd paraffin before cutting if necessary. The section is examined immediately under a microscope unless otherwise specified or after being treated by the following ways: Macerate the section in 5% solution of chloramines TR until it is white, thoroughly wash with water. Macerate the section in a 1% solution of acetic acid R for 2 minutes, thoroughly wash with water. Macerate the section in green iod solution R or methylene blue for 1-5 s. quickly wash with ethanol (60%) R then with water. Macerate the section in carmine 40 solution R until it is coloured, wash with water. Slides of powder Spread a small quantity of the powder on a slide, and examine under a microscope after being treated with either water, glycerol, chloral hydrate R, or other suitable test solutions. Slide of surface After moistening and softening the materials (when necessary) out a part or tear its epidermis, add suitable test solutions and examine. Slide of disintegrated tissue Potassium hydroxide method can be used if parenchyma makes most part of the material or the material with a few or scattered woody tissues; chromic-nitric acids method or potassium chlorate method can be used if the material is hard, with the presence of more woody tissues or the woody tissues propped into larger bundles. The material should be cut into small strips or pieces of about 2 mm wide or thick before being disintegrated. a. Potassium hydroside method b. Chromic-nitric acids method c. Potassium chlorate method Pollen and spore slides Grind pollens, anthers, small flowers or sore (soften the dry material in glacial acetic acid R) with a glass rod and filter into a centrifugal tube, centrifuge. To the precipitate add 1 - 3 ml of a freshly prepared mixture of acetic anhydride-sulfuric acid (9:1), heat on a water bath for 2-3 minutes, centrifuge. Wash the precipitate with water twice, add 3-4 drops of glycerine gelatine and examine. Chloral hydrate R may also be used as mount ant for the examination. Measurements of cells and cell contents To measure the sizes of cells and cell contents, etc, under the microscope, ocular micrometer can be used. Place the ocular micrometer in an eyepiece first, then calibrate with a stage micrometer. For the calibration, turn the eyepiece and move the stage micrometer to make the divisions on the two scales parallel and their left "O" lines