Thai Herbal Pharmacopoeia 2021

SUPPLEMENT 2023

กระทรวงสาธารณสุข
MINISTRY OF PUBLIC HEALTH

กรมวิทยาศาสตร์การแพทย์
DEPARTMENT OF MEDICAL SCIENCES

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Thai Herbal Pharmacopoeia 2021
SUPPLEMENT 2023

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PREFACE

Although modern medicine is now more available in Thailand compared to that in the past, the popularity of Thai herbal medicine has never declined. Its roles have become even more prominent in recent decades as herbal medicine has been integrated into the national healthcare system.

As quality, safety and efficacy of the drugs are of major concerns when using herbal drugs and herbal drug preparations, in 1989, the Department of Medical Sciences, Ministry of Public Health established the Thai Herbal Pharmacopoeia (THP) to set standards for quality control of herbal drugs and herbal drug preparations available in the market. The first volume was published in 1995 and the work has been carried out continuously since then. Throughout times, the THP has added more monographs and made some changes to its content and format, aiming at being the most effective and feasible tool for quality assurance of the drugs. In 2018, the THP started its digital version in parallel with the printed one for more convenient access.

The preparation of the current publication has been carried out by six Subcommittees under the supervision of the Thai Pharmacopoeia Committee, namely the Subcommittee on Establishment of the Thai Herbal Pharmacopoeia, the Subcommittee on Pharmacognostic and Botanic Specifications for the Thai Herbal Monographs, the Subcommittee on Physico-Chemical Specifications and Safety for the Thai Herbal Monographs, the Subcommittee on Standards for Thai Herbal Drug Preparations, the Subcommittee on Standards and Analytical Methods, and the Subcommittee on Editorial Style.

The Subcommittees and the Department of Medical Sciences humbly express their appreciation and gratitude to contributors, government agencies, academic institutions, and other organizations, as well as those individuals providing comments and advice and sharing their time and expertise. The publication would never have been successfully produced without their kind assistance and support.

(Mr. Anutin Charnvirakul)
Deputy Prime Minister
and Minister of Public Health

INTRODUCTION

In 1989, the Thai Pharmacopoeia Committee appointed the Subcommittee on Establishment of the Thai Herbal Pharmacopoeia with the mission of establishing the Thai Herbal Pharmacopoeia, a companion publication to the existing Thai Pharmacopoeia. The Subcommittee's responsibilities are:

1. selecting appropriate herbal drugs and herbal drug preparations based on public health and industrial demand for further consideration by the Thai Pharmacopoeia Committee;
2. establishing specifications for herbal drugs and herbal drug preparations selected by the Thai Pharmacopoeia Committee and compiling the corresponding monographs;
3. publishing the Thai Herbal Pharmacopoeia;
4. attending to all matters related to the preparation of the Thai Herbal Pharmacopoeia.

In 2010, the Thai Pharmacopoeia Committee appointed three specialized subcommittees to provide the existing subcommittee with data on specific fields in order to facilitate the work of the Subcommittee on Establishment of the Thai Herbal Pharmacopoeia. The responsibilities of each Subcommittee are as described below.

1. Subcommittee on Pharmacognostic and Botanic Specifications for Thai Herbal Monographs:

1.1 producing drafts of the pharmacognostic and botanic specifications of the Thai herbal monographs, i.e., nomenclature, definitions, plant descriptions, macroscopical and microscopical descriptions, and other related information;

1.2 submitting the drafts to the Subcommittee on the Establishment of the Thai Herbal Pharmacopoeia for approval;

1.3 attending to all matters related to the preparation of pharmacognostic and botanic specifications.

2. Subcommittee on Physico-Chemical Specifications and Safety for Thai Herbal Monographs:

2.1 producing drafts of the physico-chemical specifications of the Thai herbal monograph, i.e., constituents, packaging and storage, identification, assay, ashes, extractives, and other related information;

2.2 producing draft information on the safety of the Thai herbal monographs, i.e., categories, contra-indications, warnings, precautions, additional information, dosage, and other related information;

2.3 submitting the drafts to the Subcommittee on the Establishment of the Thai Herbal Pharmacopoeia for approval;

2.4 attending to all matters related to the preparation of the physico-chemical and safety specifications.

3. Subcommittee on Standards for Thai Herbal Drug Preparations:

3.1 producing draft specifications for Thai herbal drug preparations preselected by the Thai Pharmacopoeia Committee and compiling these specifications in monographs in the Thai Herbal Pharmacopoeia;

3.2 submitting the drafts to the Subcommittee on the Establishment of the Thai Herbal Pharmacopoeia for approval;

3.3 attending to all matters related to establishing the specifications for Thai herbal drug preparations;

3.4 preparing appendices of the tests related to the Thai herbal monographs.

It is worth mentioning here that the above tasks cannot be completed without the support of the following additional subcommittees.

1. **Subcommittee on Editorial Style:**
   - 1.1 designing the format and style for printing;
   - 1.2 editing the text;
   - 1.3 keeping conformity of the molecular formulae, chemical names, molecular weights, and expressions of the symbols of units throughout the text;
   - 1.4 attending to all matters related to editing the Pharmacopoeia.
2. **Subcommittee on Standards and Analytical Methods**
   - 2.1 selecting drugs to be included in or excluded from the Thai Pharmacopoeia;
   - 2.2 preparing draft specifications, including analytical procedure, for drug monographs in the Thai Pharmacopoeia;
   - 2.3 preparing the appendices regarding testing methods and reagents;
   - 2.4 performing any other assigned tasks.

Starting from the THP 2021 Supplement 2022, the Subcommittee on Establishment of the Thai Herbal Pharmacopoeia and its associates have made some changes by omitting non-essential data such as the table of hR_f values and replacing most line drawings of microscopical characters of herbal drugs with photomicrographs to streamline the content of the monographs. Minor changes of General Notices are made in this publication.

The Subcommittees appreciate all comments and suggestions from the readers/users. They will be incorporated as appropriate into the next revised monographs.

Reference to the previously established monographs

For the previously established monographs, please refer to THP 2021 (Volumes I and II) and THP 2021 Supplement 2022, or visit the BDN website at: http://bdn.go.th/thp/home. The "Thai Herbal Pharmacopoeia" application is also downloadble from Google Play Store and App Store.

THAI PHARMACOPOEIA COMMITTEE (1979-)

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Vimol **Notananda** (deceased), M.D., M.P.H. T.M. (1979)
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[1]Effective from October 2002 (formerly Drug Analysis Division)

[2]Effective from October 2002 (formerly Thai Pharmacopoeia Section)

[3]Effective from April 2005 (formerly Thai Pharmacopoeia and Reference Substances Section)

[4]Effective from October 2007 (formerly Thai Pharmacopoeia Section)

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Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm., *Representative*
Wilawan **Rattanathitakul**, B.Sc., M.Sc., *Representative*
Sopidawan **Wichenkun,** B.S., *Representative*
Director, Bureau of Drug and Narcotic (2014-)
Suratchanee **Savetsila**, B.Sc. in Pharm., M.Sc. in Pharm.
Somsak **Sunthornphanich**, B.Sc. in Pharm., M. Chem.
Supanee **Duangteerapreecha**, B.Sc. in Pharm., M.S., Ph.D., *Representative*
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm., *Representative*
Chief, Phytochemistry Section, Medicinal Plant Research Institute, Department of Medical Sciences (2000-2015)

Thidarat **Boonruad**, B.Sc., M.Sc. in Pharm.
Yenchit **Techadamrongsin**, B.Sc., B.S. Phar., Post. Cert.
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D., *Representative*

Chief, Pharmacognosy Section, Medicinal Plant Research Institute, Department of Medical Sciences (2000-2015)
Pranom **Dechwisisakul**, B.Sc., M.Sc. in Pharm.
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.

Chief, Herbal Quality Assurance Center, Medicinal Plant Research Institute, Department of Medical Sciences (2004-)
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Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Nawarat **Chadchen**, B. Pharm., M.Sc. in Pharm., *Representative*
Jiranuch **Mingmuang**, B. Pharm., M.Sc. in Pharm., *Representative*
Duangpen **Pattamadilok**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D., *Representative*
Puritat **Ratanasiri**, B.Sc. in Pharm., *Representative*
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Chief, Pharmaceutical Chemistry Laboratory, Medicinal Plant Research Institute, Department of Medical Sciences (2012-2015)
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.

Jaree **Bansiddhi**, B.Sc., M.Sc. (2010-)
Phichet **Banyati**, M.D., B.TTM, MPH, (2021-)
Rapepol **Bavovada**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (1993-2006)
Chitra **Chaiyawat**, B. Pharm. (2010-2014)
Kongkanda **Chayamarit**, B.Sc., M.Sc., D.Sc. (2013-)
Thaweephol **Dechatiwongse Na Ayudhya**, B.Sc. in Pharm. (1989-)
Supatra **Im-erb**, B.Sc. in Pharm., M.Sc. (Pharm. Chem.) (1990-1991, 2009-)
Panida **Kanchanapee** (deceased), B.Sc. in Pharm. (1993-2000)
Surapong **Kengtong**, B.Sc. in Pharm., M.Sc. in Pharm (2014-)
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L. (2014-)
Kaisee **Limprasert**, Cert. in TTM (2021-)
Wantana **Ngamwat**, B.Sc. in Pharm., M.Sc. (1989-1993)
Yupadee **Payakkapan**, B.Sc. in Pharm., M.Sc. in Pharmaceutical Analysis (1991-2021)
Thatree **Phadungcharoen**, B.Sc. in Pharm., M.Sc. in Pharm. (1989-)
Kalaya **Pharadai**, B.Sc. in Pharm., M.Eng. (1989-)
Chamlong **Phengklai**, B.S. (Forestry), Hon. D.Sc. in Forestry (KU), FRI (2000-2002)
Chayan **Picheansoonthon**, B.S. in Pharm., Ph.D., FRI (1995-)
Kamol **Sawasdimongkol**, B.Sc. in Pharm., M.S. (1995-2004)
Sawanee **Sathornviriyapong**, B.S. (Agriculture), M.S. (Horticulture), Ph.D. (2002-)
Chantra **Shaipanich**, B.Sc. in Pharm., M.S., Ph.D. (1989-1994)
Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2008-)
Taweesak **Suntorntanasat**, B.Sc. in Pharm., M.Sc. in Pharm. (2000-)
Khanit **Suwanborirux**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (1993-2021)
Yenchit **Techadamrongsin**, B.Sc., B.S. Phar., Post. Cert. (2008-)

Kanokwan **Watanayothin**, B.S. (Agriculture), M.S. (Agriculture), Ph.D. (2000-2009)
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2021-)

Secretaries:
Sasiwan **Aim-ot**, B.Sc. in Pharm. (2003-2004)
Chitra **Chaiyawat**, B. Pharm. (1996-2010)
Buussayamas **Charoensuk**, B. Pharm. (1999-2000)
Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D. (1998-1999, 2001-2003, 2008-)
Supanee **Duangteerapreecha**, B.Sc. in Pharm., M.S., Ph.D. (1989-1991)
Supatra **Im-erb**, B.Sc. in Pharm., M.Sc. (1989-1990)
Anuwat **Ittirittanon**, B.Sc. in Pharm. (1991-1992)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm. (2010-2015)
Wichuda **Jariyaphun**, B.Sc., M.Sc. (1989-1990)
Sarunyaporn **Kongchira**, B.S. in Pharm., M.S. (1993-1996)
Sarinee **Lenapun**, B.S. Pharm., M.Sc. in Pharm. (2004-2008)
Santi **Nimnoi**, B.S. in Pharm. (2017-)
Sasiwimon **Patasema**, B. Pharm., M.Sc. in Pharm. (2009, 2015-)
Thanita **Patthamajinda**, B.S. in Pharm., M.A. MS in Regulatory Affairs and Health Policy (2009-2015)
Supattra **Phongsri**, B.Sc. (Pharm.) (2000-2001)
Thanyarat **Putta**, B.Sc. in Pharm., M.Sc. in Pharm. (1996-1998)
Nantana **Sittichai**, B.Sc. in Pharm., M.S. (1990-2008)
Panit **Somhom**, B.Sc. in Pharm., M.Sc. in Pharm. (1991-1992)
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (1990-1991, 1993-1996)

This subcommittee is responsible for:

1.1 selecting the appropriate herbal drugs and herbal drug preparations based on public health and industrial demands for further consideration by the Thai Pharmacopoeia Committee;

1.2 establishing the specifications of herbal drugs and herbal drug preparations selected by the Thai Pharmacopoeia Committee and compiling the corresponding monographs;

1.3 publishing the Thai Herbal Pharmacopoeia;

1.4 attending to all matters related to the preparation of the Thai Herbal Pharmacopoeia.

2. SUBCOMMITTEE ON PHARMACOGNOSTIC AND BOTANIC SPECIFICATIONS FOR THAI HERBAL MONOGRAPHS (2010-)

Chairperson: Chayan **Picheansoonthon**, B.S. in Pharm., Ph.D., FRI (2010-)

Vice-chairperson: Thatree **Phadungcharoen**, B.Sc. in Pharm., M.Sc. in Pharm. (2010-2015)

Advisors: (2010-2015)
Chirayupin **Chandraprasong** (deceased), B.Sc., M.Sc., Hon. Ph.D., FRI
Kongkanda **Chayamarit**, B.Sc., M.Sc., D.Sc. (2010-2015)

Members: Chief, Pharmacognosy Section, Medicinal Plant Research Institute, Department of Medical Sciences (2010-)

Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Wilawan **Rattanathirakul**, B.Sc., M.Sc., *Representative*
Jaree **Bansiddhi**, B.Sc., M.Sc. (2010-)
Bhanubong **Bongcheewin**, B. Pharm., M.Sc., Ph.D. (2014-)
Kongkanda **Chayamarit**, B.Sc., M.Sc. D.Sc. (2015-)
Pranom **Dechwisissakul**, B.Sc., M.Sc. in Pharm. (2010-)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm. (2010-2015, 2017-)
Ornusa **Khamsuk**, B.S., M.S., Ph.D. (2014-)
Thatree **Phadungcharoen**, B.Sc. in Pharm., M.Sc. in Pharm. (2015-)
Kalaya **Pharadai**, B.Sc. in Pharm., M.Eng. (2010-)
Sawanee **Sathornviriyapong**, B.S. (Agriculture), M.S. (Horticulture), Ph.D. (2010-)
Anitthan **Srinual**, B.Sc. in Biology, M.Sc. in Biology, Ph.D. in Biology (2019-)

Secretaries: Sasiphimol **Boontavee**, Pharm. D., LL.B., (2017-2018)
Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D. (2010-)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm. (2015-2017)
Sasiwimon **Patasema**, B. Pharm., M.Sc. in Pharm. (2015-)
Thanita **Patthamajinda**, B.S. in Pharm., M.A. MS in Regulatory Affairs and Health Policy (2010-2015, 2018-)

This subcommittee is responsible for:

2.1 producing drafts of the pharmacognostic and botanic specifications for Thai herbal monographs, i.e., nomenclature, definitions, plant descriptions, macroscopical and microscopical descriptions, and other related information;

2.2 submitting the drafts to the Subcommittee on the Establishment of the Thai Herbal Pharmacopoeia for approval;

2.3 attending to all matters related to the preparation of pharmacognostic and botanic specifications.

3. SUBCOMMITTEE ON PHYSICO-CHEMICAL SPECIFICATIONS AND SAFETY FOR THAI HERBAL MONOGRAPHS (2010-)

Chairperson: Khanit **Suwanborirux**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2010-2021)
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2021-)

Vice-chairperson: Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2010-2015)

Advisor: Yupadee **Payakkapan**, B.Sc. in Pharm., M.Sc. in Pharmaceutical Analysis (2010-2015)

Members: Chief, Herbal Quality Assurance Center, Medicinal Plant Research Institute, Department of Medical Sciences (2010-2013, 2015-)
Somchit **Niumsakul**, B.Sc., M.Sc.
Nawarat **Chadchen**, B. Pharm., M.Sc. in Pharm., *Representative*
Jiranuch **Mingmuang**, B. Pharm., M.Sc. in Pharm., *Representative*
Apirak **Sakpetch**, B.S. Pharm., *Representative*
Chitra **Chaiyawat**, B. Pharm. (2010-2014)
Veena **Nukoolkarn**, B.S. in Pharm., Ph.D. (2014-)

Yupadee **Payakkapan**, B.Sc. in Pharm., M.Sc. in Pharmaceutical Analysis (2015-2021)
Chada **Phisalapong**, B.Sc. in Pharm., M.Sc., Ph.D. (2010-)
Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2015-)
Uthai **Sotanaphun**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2014-)
Taweesak **Suntorntanasat**, B.Sc. in Pharm., M.Sc. in Pharm. (2010-)
Witchuda **Thanakijcharoenpath**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2014-)
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2011-2021)

Secretaries: Sasiphimol **Boontavee**, Pharm. D., LL.B. (2017-)
Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D. (2010-2014)
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L. (2014-)
Santi **Nimnoi**, B.S. in Pharm. (2015-)

This subcommittee is responsible for:

3.1 producing drafts of the physico-chemical specifications for Thai herbal monograph, i.e., constituents, packaging and storage, identification, assay, ashes, extractives, and other related information;

3.2 producing draft information on the safety for Thai herbal monographs, i.e., categories, contra-indications, warnings, precautions, additional information, dosage, and other related information;

3.3 submitting the drafts to the Subcommittee on the Establishment of the Thai Herbal Pharmacopoeia for approval;

3.4 attending to all matters related to the preparation of the physico-chemical and safety specifications.

4. SUBCOMMITTEE ON STANDARDS FOR HERBAL DRUG PREPARATIONS (2010-)*

Chairperson: Yupadee **Payakkapan**, B.Sc. in Pharm., M.Sc. in Pharmaceutical Analysis (2010-2021)
Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2021-)

Members: Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D. (2015-)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.SC. in Pharm. (2017-)
Piyaporn **Prayakprom**, B.Sc. in Pharm., Ph.D. (2017-)
Nidapan **Ruangrittinon**, B.Sc. in Pharm., M.Sc. in Pharm. (2010-)
Churairat **Rakwatin**, B.Sc. in Pharm. (2010-)
Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2010-2021)
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2010-)
Sasida **Yoosuk**, B.Sc. in Pharm., M.Sc. in Pharm. (2017-)

Secretaries: Sasiphimol **Boontavee**, Pharm. D., LL.B. (2017-)
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L. (2010-)
Sarinee **Lenapun**, B.S. Pharm., M.Sc. in Pharm. (2010-2015)
Santi **Nimnoi**, B.S. in Pharm. (2015-)

*Effective from June 2017 (formerly The Ad Hoc Subcommittee on Standards of the Thai Herbal Drug Preparations)

This subcommittee is responsible for:

4.1 producing draft specifications for Thai herbal drug preparations preselected by the Thai Pharmacopoeia Committee and compiling these specifications in monographs in the Thai Herbal Pharmacopoeia;

4.2 attending to all matters related to establishing the specifications for Thai herbal drug preparations;

4.3 preparing appendices of the tests related to the Thai herbal monographs.

5. SUBCOMMITTEE ON EDITORIAL STYLE (1980-)

Chairpersons:

Komol **Pengsritong** (deceased), M.D., M.S., Ph.D., Hon. D.Sc. in Pharm. (1980-1988)
Nadhirat **Sangkawibha** (deceased), M.D., M.P.H. (1989-1997)
Sumana **Vardhanabhuti** (deceased), B.Sc. in Pharm., M.Sc. in Pharm., M.P.H., Cert. in Immunol. (WHO) (1997-2010)
Boonchua **Dhorranintra**, M.D., Dr.med (magna cum laude) (Freiburg U.), FRCP(T) (2010-)

Advisors:

Prachaksvich **Lebnak**, M.D. (2000-2003)
Komol **Pengsritong** (deceased), M.D., M.S., Ph.D., Hon. D.Sc. in Pharm. (CU) (1988-1991)
Rachanee **Pinthaworn**, B.Sc. in Pharm. (2003-2005, 2009-2010)
Manat **Pohmakotr**, B.Sc., M.Sc., Dr. rer. nat. (2005-2013)
Kamphol **Raksrivong**, B.Sc. in Pharm. (2000-2013)
Nadhirat **Sangkawibha** (deceased), M.D., M.P.H. (1997-2009)
Suntana **Sutadarat**, B.Ed. (Hons.), M.A., Ph.D. (1997)
Prakorb **Tuchinda** (deceased), M.D., Hon. D.Sc. in Med. (MU) (1988-1991)
Sumana **Vardhanabhuti** (deceased), B.Sc. in Pharm., M.Sc. in Pharm., M.P.H., Cert. in Immunol. (WHO) (2010-2015)
M.L. Pranod **Xumsaeng** (deceased), Ph.G., B.Sc. in Pharm. (1991-1997)

Members:

Director, Bureau of Drug and Narcotic (2015-)
Suratchanee **Savetsila**, B.Sc. in Pharm., M.Sc. in Pharm (2015-2021)
Somsak **Sunthornphanich**, B.Sc. in Pharm., M.chem. (2021-)
Supong **Akesiripong**, B. Pharm. (Hons.), Ph.D. (2000-2021)
Chantana **Aromdee**, B.Sc. in Pharm., M.Sc. (1986-1989)
Manas **Attawish**, B.S. (Pharm.) (2013-2015, 2017-)
Rapepol **Bavovada**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D. (2006-2008)
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Vichiara A. **Jirawongse** (deceased), B.Sc. in Pharm., Ph.D., Hon. D.Sc. in Pharm. (CU), Hon. Ph.D. (KKU) (1989-2006)
Than Phuying Preeya **Kashemsant Na Ayudhya**, B.Sc. in Pharm., M.Sc., Hon. D.Sc. in Pharm.(CU) (1989-1992)
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L. (2009-)
Prachaksvich **Lebnak**, M.D. (1997-2000)
Wantana **Ngamwat**, B.Sc., B.Sc. in Pharm., M.Sc. (1989-2015)

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Churairat **Rakwatin**, B.Sc. in Pharm. (2006-)
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Secretaries:
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Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D. (1997-1999, 2003)
Sarinee **Lenapun**, B. Pharm., M.Sc. in Pharm. (2005-2013)
Santi **Nimnoi**, B.S. in Pharm. (2013-)
Sasiwimon **Patasema**, B.Pharm., M.Sc. in Pharm. (2003-)
Thanita **Patthamajinda**, B.S. in Pharm., M.A, MS in Regulatory Affairs and Health Policy (2010-2015, 2018-)
Yupadee **Payakkapan**, B.Sc. in Pharm., M.Sc. in Pharmaceutical Analytical Analysis (1980-1991)
Thomayant **Prueksaritanont**, B.Sc. in Pharm., Ph.D. (1989-1991)
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Nantana **Sittichai**, B.Sc. in Pharm., M.S. (1980-2005)
Panit **Somhom**, B.Sc. in Pharm., M.Sc. in Pharm. (1991-1993)
Wanida **Suchonwanit**, B.Sc. in Pharm. (1997-2000)

This subcommittee is responsible for:

5.1 designing the format and style for printing;

5.2 editing the text;

5.3 keeping conformity of the molecular formulae, chemical names, molecular weights, and expressions of the symbols of units throughout the text;

5.4 organizing the information compiled by all subcommittees into a pharmacopoeial form and completing the final draft of the Pharmacopoeia;

5.5 attending to all matters related to editing the Pharmacopoeia.

6. SUBCOMMITTEE ON STANDARDS AND ANALYTICAL METHODS (2019-)

Chairperson: Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2019-)

Members:
Director, Bureau of Drug and Narcotic
Suratchanee **Savetsila**, B.Sc. in Pharm., M.Sc. in Pharm. (2019-2021)
Somsak **Sunthornphanich**, B.Sc. in Pharm., M. Chem., (2021-)
Boontarika **Boonyapiwat**, B.Sc. in Pharm., M.Sc. in Biopharm., Ph.D. in Biopharm, *Representative*
Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D., *Representative*
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm., *Representative*
Maytinee **Limsiriwong**, B.Sc. in Pharm., M.Sc. in Pharm., *Representative*
Ladda **Poolsawat**, B.Sc. in Pharm., *Representative*
Sasida **Yoosuk**, B.Sc. in Pharm., M.Sc. in Pharm., *Representative*
Director, Medicinal Plant Research Institute, Department of Medical Sciences (2019-)
Nawarat **Chadchen**, B. Pharm., M.Sc. in Pharm., *Representative*
Warunee **Jirawattanapong**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D., *Representative*
Jiranuch **Mingmuang**, B. Pharm., M.Sc. in Pharm., *Representative*
Puritat **Rattanasiri**, B.Sc. in Pharm., *Representative*
Head, Physical and Chemical Testing Section, Bureau of Drug and Narcotic
Sasida **Yoosuk**, B.Sc. in Pharm., M.Sc. in Pharm. (2019-2021)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm. (2021-)
Wicharanee **Tongsima**, B.Sc. in Pharm., M.Sc. in Pharm. (Pharmaceutics), *Representative*
Tharntip **Wachirasakwong**, B. Pharm., M.Sc. in Pharm., *Representative*
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Churairat **Rakwatin**, B.Sc. in Pharm. (2019-)
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Yaowalak **Wattanapisit**, B.Sc. in Pharm., M.Sc. in Pharm. (2019-)

Secretaries:
Sasiphimol **Boontavee**, Pharm.D., LL.B. (2019-)
Sasiwimon **Patasema**, B.Pharm., M.Sc. in Pharm. (2019-)
Thanita **Patthamajinda**, B.S. in Pharm., M.A., MS in Regulatory Affairs and Health Policy (2019-)

This subcommittee is responsible for:

6.1 selecting drugs to be included in or excluded from the Thai Pharmacopoeia;

6.2 preparing draft specifications, including analytical procedures, for drug monographs in the Thai Pharmacopoeia;

6.3 preparing the appendices regarding testing methods and reagents;

6.4 performing any other assigned tasks.

7. WORKING GROUP ON PRINTING THE THAI HERBAL PHARMACOPOEIA (1989-1995)

Chairperson: Director, Drug Analysis Division, Department of Medical Sciences, Ministry of Public Health
Chongdee **Wongpinairat**, B.Sc. in Pharm., M.Sc., Ph.D.

Members: Chief, Herbal Quality Assurance Center, Medicinal Plant Research
Manas **Attawish**, B.S. (Pharm.)
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Kamphol **Raksrivong**, B.Sc. in Pharm.
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Nantana **Sittichai**, B.Sc. in Pharm., M.S.
Wanida **Suchonwanit**, B.Sc. in Pharm.
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.

***Contributors*:**

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Arom **Phichitkanka**, B.Sc.
Chada **Phisalaphong**, B.Sc. in Pharm., M.Sc., Ph.D.
Vansiri **Rimsamut**, Cert.A.
Amporn **Ruangchan**, B.Sc. in Pharm., M.Sc.
Weena **Sathianpokkasap**, B.Sc. in Pharm.
Kamol **Sawasdimongkol**, B.Sc. in Pharm., M.S.
Panit **Somhom**, B.Sc. in Pharm., M.Sc. in Pharm.
Suntana **Sutadarat**, B.Ed. (Hons.), M.A., Ph.D.
Yenchit **Techadamrongsin**, B.S., B.S. Phar., Post. Cert.
Parkpoom **Tengamnuay**, B. Pharm., Ph.D.
Thawatchai **Thawonying** (deceased), B.Sc. in Pharm.

The following individuals were engaged in the production of THP Volume II (1995-2000):

Jaree **Bansiddhi**, B.Sc., M.Sc.
Nuchattra **Chansuvanich**, B.Sc., M.S.
Vanida **Chantaratheptawan**, B.Sc. in Pharm., M.Sc. in Pharm.
Pranom **Dechwisissakul**, B.Sc., M.Sc. in Pharm.
Warunee **Jirawattanapong**, B.Sc. in Pharm., M.Sc. in Pharm.
Tathaporn **Maison**, B.Sc.
Narumole **Mongkolchaipak**, B. Pharm., M.Sc.
Arom **Phichitkanka**, B.Sc.
Proramate **Sansongsak**, B.Sc. (Pharm.)
Yenchit **Techadamrongsin**, B.Sc., B.S. Phar., Post. Cert.
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Rawat **Tiasakul**, B.Sc. (Pharm.)
Suppachai **Tiyaworanant**, B.Sc. (Pharm.), M.Sc. in Pharm.

The following individuals were engaged in the production of Supplement to THP (2000-2004):

Nuchattra **Chansuvanich**, B.Sc., M.S.
Tanwarat **Kajsongkram**, B.S., M.S. (Chemistry)
Pichitra **Maekprayoon**, B.Sc.
Tathaporn **Maison**, B.Sc.
Jiranuch **Mingmuang**, B.Sc. in Pharm.
Piya **Mokkamul**, B.S. (Forestry)
Narumole **Mongkolchaipak**, B. Pharm., M.Sc.
Thanawat **Thongchin**, B.S.
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Rawat **Tiasakul**, B.Sc. (Pharm.)

The following individuals were engaged in the production of THP Volume III (2004-2009):

Juthamas **Bhura**, B.Sc. in Pharm., M.Sc. in Pharm.
Chalermchoke **Boonchit**, B.F.A.
Nuchattra **Chansuvanich**, B.Sc., M.S.
Supanee **Duangteraprecha**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Pajaree **Inthachub**, B.Sc., M.Sc.
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm.
Tanwarat **Kajsongkram**, B.S., M.S.
Supachai **Koonterm**, B.Sc.
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L.
Sumanee **Lertakanokkun**, B.Sc. (Pharm.)
Pichitra **Maekprayoon**, B.Sc.
Duangpen **Pattamadilok**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Wittaya **Pongamornkul**, B.Sc., M.S.
Sununta **Srisopon**, B. Pharm., M. Pharm.
Thanawat **Thongchin**, B.S.
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Niran **Vipunngeun**, B.Sc., M.Sc.
Wimonwan **Warinpramote**, B. Pharm., Pg Dip Sc (Biotech.), M.Sc.
Sopidawan **Wichienkul**, B.S.

The following individuals were engaged in the production of Supplement to THP 2011:

Sasima **Juntryam**, B.Sc.
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L.
Areerat **Surathanjanya**, B.S., M.S.
Akekmol **Suttisun**, Cert. in Medical Science Technology
Parkpoom **Tengamnuay**, B. Pharm., Ph.D.

The following individuals were engaged in the production of THP Volume IV (2011-2014):

Chalermchoke **Boonchit**, B.F.A. (Visual Arts)
Kamthorn **Intharapichai**, B.Sc. (TTM.)
Pornpimon **Wongsuwan**, B.Sc., M.Sc.

The following individuals were engaged in the production of THP 2016-2017:

Sasiphimol **Boontavee**, Pharm. D., LL.B.
Jankana **Burana-osot**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Tasamaporn **Sukwattanasinit**, B. Pharm., Ph.D.

The following individuals were engaged in the production of THP 2018:

Sudarat **Homhual**, B.Pharm, M.Sc. in Pharm, Ph.D.
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm.
Jiranuch **Mingmuang**, B. Pharm., M.Sc. in Pharm.
Duangpen **Pattamadilok**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Thanita **Patthamajinda**, B.S. in Pharm., M.A., MS in Regulatory Affairs and Health Policy.
Thatree **Phadungcharoen**, B.Sc. in Pharm., M.Sc. in Pharm.
Wilawan **Rattanathirakul**, B.Sc., M.Sc.
Paweena **Sakhee**, B.S.
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Pratom **Thongsrirak**, B.Sc. (Agriculture)
Suppachai **Tiyaworanant**, B.Sc. (Pharm.), M.Sc. in Pharm.
Sopidawan **Wichienkul**, B.S.

The following individuals were engaged in the production of THP 2019:

Kanokporn **Atisook**, B.Sc.
Jaree **Bansiddhi**, B.Sc., M.Sc.
Pajaree **Inthachub**, B.Sc., M.Sc.
Warunee **Jirawattanapong**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Sakwichai **Ontong**, B.Sc. (Biology)
Duangpen **Pattamadilok**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Thatree **Phadungcharoen**, B.Sc. in Pharm., M.Sc. in Pharm.
Suphan **Phattaraporncharoen**, B.Sc. (Chemistry)
Nithida **Phonkot**, B.Sc. in Pharm., M.Sc. in Pharm.
Puritat **Rattanasiri**, B.Sc. in Pharm.
Wilawan **Rattanathirakul**, B.Sc., M.Sc.
Yenchit **Techadamrongsin**, B.Sc., B.S. Phar., Post. Cert.
Thanawat **Thongchin**, B.S. (Science)
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Pratom **Thongsrirak**, B.Sc. (Agriculture)

The following individuals were engaged in the production of THP 2020:

Nawarat **Chadchen**, B.Pharm., M.Sc. in Pharm.
Nuchattra **Chansuyanich**, B.Sc. (Biology), M.S.
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm.
Warunee **Jirawattanapong**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Somchit **Niumsakul**, B.Sc., M.Sc.
Sakwichai **Ontong**, B.Sc. (Biology)
Nithida **Phonkot**, B.Sc. in Pharm., M.Sc. in Pharm.
Puritat **Rattanasiri**, B.Sc. in Pharm.
Paweena **Sakhee**, B.S.
Apirak **Sakpetch**, B.S. Pharm.
Kwansri **Sarunkawin**, B.Sc. in Pharm.
Sirikarn **Thana-ariyaroj**, B.S. (Chemistry)
Pat **Tharapaisal**, B.S. Pharm.
Thanawat **Thongchin**, B.S. (Chemistry)
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Pratom **Thongsrirak**, B.Sc. (Agriculture)
Sopidawan **Wichienkul**, B.S.
Prapai **Wongsinkongman**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.

The following individuals were engaged in the production of THP 2021:

Jiranuch **Jamtaweekul**, B.Sc. in Pharm, M.Sc. in Pharm.
Warunee **Jirawattanapong**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Wareerat **Kanjananuch**, B.S. (Botany)
Sorrapetch **Marsud**, B.Sc. in Plant, M.Sc. in Horticultural
Sakwichai **Ontong**, B.Sc. (Biology)
Suphan **Phattarapornchaiwat**, B.Sc. (Chemistry)
Nithida **Phonkot**, B.Sc.in Pharm., M.Sc. in Pharm.
Puritat **Rattanasiri**, B.Sc. in Pharm.
Wilawan **Rattanathirakul**, B.Sc., M.Sc.
Apirak **Sakpetch**, B.S. Pharm.
Koravit **Somkid**, B.Sc. Health Education, M.Sc. in Toxicology
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Sopidawan **Wichienkul**, B.S.

The following individuals were engaged in the production of THP 2021 Supplement 2022:

Vilailuk **Chuennangchee**, B.S. (Chemistry)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm, M.Sc. in Pharm.
Warunee **Jirawattanapong**, B.Sc. in Pharm, M.Sc. in Pharm., Ph.D.
Wareerat **Kanjananuch**, B.S. (Botany)
Sorrapetch **Marsud**, B.Sc. in Plant, M.Sc. in Horticultural
Sakwichai **Ontong**, B.Sc. (Biology)
Duangpen **Pattamadilok**, B.Sc. in Pharm, M.Sc. in Pharm, Ph.D.
Suphan **Phattarapornchaiwat**, B.Sc. (Chemistry)
Nithida **Phonkot**, B.Sc. in Pharm., M.Sc. in Pharm.
Puritat **Rattanasiri**, B.Sc. in Pharm.
Paweena **Sakhee**, B.S.
Apirak **Sakpetch**, B.S. Pharm.

Koravit **Somkid**, B.Sc. Health Education, M.Sc. in Toxicology
Sirikarn **Thana-ari yaroj**, B.S. (Chemistry)
Peradhama **Thiemthieprat**, B.S. (Chemistry)
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.

The following individuals were engaged in the production of THP 2021 Supplement 2023:

Pimollada **Chairat**, B. Pharm.
Warunee **Jirawattanapong**, B.Sc. in Pharm., M.Sc. in Pharm., Ph.D.
Thaweesak **Juengwatanatrakul**, B. Pharm., M.Sc. in Pharm., Ph.D.
Wareerat **Kanjananuch**, B.S. (Botany)
Sorrapetch **Marsud**, B.Sc. in Plant, M.Sc. in Horticultural
Sakwichai **Ontong**, B.Sc. (Biology)
Suphan **Phattarapornchaiwat**, B.Sc. (Chemistry)
Nithida **Phonkot**, B.Sc. in Pharm., M.Sc. in Pharm.
Puritat **Rattanasiri**, B.Sc. in Pharm.
Koravit **Somkid**, B.Sc. Health Education, M.Sc. in Toxicology
Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.
Sopidawan **Wichienkul**, B.S.
Juraithip **Wungsintaweekul**, B.Sc. in Pharm., M.Sc. in Pharm., Dr.rer.nat. (Biochemistry)

***Photos*:**

Some photographs are courtesies of Bhanubong **Bongcheewin**, B. Pharm., M.Sc., Ph.D.; Kornvika **Charupant**, B.S. Pharm., M.Sc. in Pharm., Ph.D.; Thatree **Phadungcharoen**, B.Sc. in Pharm., M.Sc. in Pharm; Chayan **Picheansoonthon**, B.S. in Pharm., Ph.D., FRI.; and Pairin **Thongkhoom**, B.Sc., M.Sc. in Pharm.

GENERAL NOTICES

GENERAL NOTICES

The information given in the general notices provides the basic guidelines for the interpretation and applications of the standards, tests, assays and other specifications of the Thai Herbal Pharmacopoeia.

In the text of the Thai Herbal Pharmacopoeia the word "Pharmacopoeia" means the Thai Herbal Pharmacopoeia. The official abbreviation for the Thai Herbal Pharmacopoeia is THP. An herbal material is not of the pharmacopoeial quality unless it complies with all the requirements of the relevant monograph. The statements under the headings: Description, Solubility, Constituents, Packaging and storage, Contra-indication, Warning, Precaution, and Additional information are not to be regarded as analytical requirements. However, the macroscopic and microscopic descriptions under each monograph are important means for the identification of the drug and its corresponding origin.

Unless otherwise specified, the rules of the General Notices of the Thai Pharmacopoeia (TP) apply to the Thai Herbal Pharmacopoeia.

Monograph Nomenclature

A Thai name is adopted as the main title of each pharmacopoeial substance. It is transcribed to English following the Royal Institute's official transliteration system[1] and printed with capital letters. Subsidiary titles, where applicable, are other Thai name(s), Latin genitives of plants, English common name(s), and English synonym(s).

In the text, English common names are usually mentioned in place of the main titles. When the English common names are not available, the English names derived from the Latin genitives of plants will be used instead. All titles (main and/or subsidiary) and names (synonyms as well as botanical names) are listed in the index.

Reference Substances

Where a test or an assay calls for the use of a Reference Substance, the ASEAN Reference Substance or other recognized reference substances may be used. The ASEAN Reference Substances are available from the Bureau of Drug and Narcotic, the Department of Medical Sciences, Nonthaburi, Thailand.

Authenticated Reference Specimens

For the botanical evaluation of the crude drug samples, the herbarium specimen numbers of the corresponding plants provided in the text are taken from the Department of Medical Sciences Herbarium (DMSC), the Department of Medical Sciences, Nonthaburi, Thailand, or other recognized herbaria such as the Bangkok Herbarium (BK), the Department of Agriculture, Bangkok, Thailand; the Forest Herbarium (BKF),

[1] *Rules for Transcribing Foreign Words to Thai Script: English, French, German, Italian, Spanish, Russian, Japanese, Arabic, Malay* (The Royal Institute ed.), Bangkok: the Royal Institute, 1992.

the Department of National Parks, Wildlife and Plant Conservation, Bangkok, Thailand; the Herbarium of Queen Sirikit Botanic Garden (QSBG), Chiang Mai, Thailand. If not provided, the herbarium specimens could be compared to the existing named specimens at the above-mentioned herbaria.

For some plants non-native and not commercially cultivated in Thailand so that their herbarium specimens are not available at the above-mentioned herbaria, citation of the herbarium specimen numbers will be indicated under the Additional information of such monographs. If not indicated, it is suggested to investigate from other internationally-recognized herbaria.

The crude drug numbers (DMSc) are also cited. The reference crude drug specimens are authenticated by the Medicinal Plant Research Institute, the Department of Medical Sciences, Nonthaburi, Thailand.

Freshly and Recently Prepared

The direction that a preparation must be freshly prepared indicates that it must be made not more than 24 hours before it is issued for use. The direction that a preparation should be recently prepared indicates that deterioration is likely if the preparation is stored for longer than about 4 weeks at 15° to 25°.

Description

In addition to macroscopical and microscopical descriptions of crude drugs, the morphological and anatomical descriptions of plants are provided for the botanical identification of the samples. Colour photographs of the plants and crude drugs are also given.

Macroscopical descriptions in the monographs refer to features which can be seen by the unaided eyes or with the aid of a hand lens. Statements of the characteristic microscopical description of the whole drug are included in the monograph as a means for determining identity, quality, or purity. Most of the transverse sections of the plants are line drawn but some are photomicrographed and inserted to illustrate the authenticity of the cellular structures.

Identification

Thin-layer chromatography is used as one of the principal means of identification of herbal drugs. In some cases where isolated constituents of herbal drugs are available, chromatographically separated constituents are related to the known constituents used as markers[1]. For purposes of evaluation, an hR_f value is used in place of an R_f value in order to preclude the use of decimal fractions. The hR_f value is the R_f value multiplied by the factor 100, resulting in values of 0 to 100.

In the monograph, the hR_f values of known and unknown constituents are listed in the table, accompanied by the corresponding thin-layer chromatograms. The illustrations of thin-layer chromatograms are provided in colour photographs.

[1]Constituent(s) of a herbal material which is/are chemically defined and of interest for quality control purposes.

In cases where isolated constituents of herbal drugs are not readily available, a fingerprint of the separated constituents is obtained and the positions of major spots or bands in the chromatogram are described in relation to a non-constituent marker, in terms of their relative R_f values (RR_f). RR_f can be determined by the formula:

$$RR_f = a/b$$

where a = R_f value of a constituent of interest, and

b = R_f value of a non-constituent marker.

Due to variations in the levels of constituents in different samples of herbal drug, minor deviations from one chromatogram to another can be observed. A judgement by the analyst is needed as to the extent of deviation allowed before samples are considered incorrect or contaminated with foreign matter. Further investigations should be carried out in case of doubt.

Quantitative Determination

Unless otherwise specified, all quantitative determinations prescribed in the monographs are carried out on materials which have not been specially dried and calculations are made accordingly.

Arsenic and Heavy Metals

With regard to vegetable drugs, the toxic elements which may be present in sufficient quantity to pose potential risk vary from plant to plant. The amount of these elements depends on the location, the quality of the soil, or environmental pollution. Because of their toxic natures, arsenic and heavy metals are of major concern. Although not specifically required in the monograph, it is suggested that the maximum amounts of the toxic elements, based on the acceptable daily intake (ADI) values, in final dosage forms of plant materials be as follows:

Arsenic	4	ppm
Cadmium	0.3	ppm
Lead	10	ppm
Mercury	0.5	ppm

Unless otherwise indicated, the test procedures are provided in the "Limit Tests for Heavy Metals in Herbal Drugs and Herbal Drug Preparations" (Appendix 5.2).

Microbial Contamination

Although not specifically required in the monographs, possible microbial contamination should be controlled to such an extent that the preparations derived from them meet the requirements as described in the "Limits for Microbial Contamination" (Appendix 10.5).

Strength(s) Available

Strength(s) available is provided only as a guide and is not necessarily comprehensive. For Solid dosage forms such as Capsules, the strength is usually given as the amount of herbal drugs, in powder form, in each unit. For herbal drugs intended for oral aqueous preparations such as Herbal Teas, the strength is usually given as the amount of herbal drugs, in powder form, in each unit dose.

Contra-indication

This section specifies those conditions in which the drug should NOT be used.

Warning and Precaution

Under the heading "Warning", the possible risks of certain hazards from the use of a herbal drug are to be observed and taken care of before prescribing or administering it to a patient. Caution and careful consideration on the risk-benefit ratio of the drug should therefore be contemplated on an individual basis prior to the decision to use it.

On the other hand, important notes to be observed and carefully followed during and after the administration of a drug are described under the heading "Precaution".

Where there is a clear risk, the important warnings and precautions are selected and included under the headings "Warning" and "Precaution" in some monographs. However, it should not be assumed that the omission of a warning or a precaution in any particular monograph means that warning or precaution may not be of clinical significance for a specific patient.

Additional Information

Any personal observation of a particular drug and other special relevant information concerned are to be categorized under the heading "Additional information". It is not regarded as analytical requirements.

Category and Dose

The statements given under "Category" are provided only for information on the drug's main pharmacological actions, which are presumably based on its use in traditional medicine. It should not be assumed that the substance has no other actions or uses. Information on doses is also related to its traditional use and is intended only for general guidance. The dose of a drug specified in this Pharmacopoeia is the usual dose for adults; some adjustments may be necessary for individual patients, including children, depending on their conditions. Unless otherwise stated, the information is given for internal use.

Remark It is to be noted that the actions and doses stated in the Pharmacopoeia do not imply any regulatory acceptance for the purpose of licensing.

Packaging and Storage

The substances and preparations described in the Pharmacopoeia are stored in such a way as to prevent contamination and, as far as possible, deterioration. Precautions that should be taken in relation to the effects of the atmosphere, moisture, heat, and light are indicated, where appropriate, in the monographs.

CONTAINERS

The container is the device that holds the substance, either in the form of the raw material or of the finished dosage form. The closure of the container, including the stopper, the cap, the attached dropper, etc., is considered as a part of the container.

The *immediate container* is the one which is in direct contact with the substance.

The container should be cleaned before use, and no extraneous matter should be introduced into it or into the substance placed in it. It must, likewise, not interact physically or chemically with the substance which it holds so as to alter the latter's quality, purity, or therapeutic potency to a level below its Pharmacopoeial requirements.

Well-closed container

A well-closed container must protect the contents from extraneous matter or from loss of the substance under ordinary or customary conditions of handling, shipment, storage, or sale.

Tightly closed container

A tightly closed container must protect the contents from contamination by extraneous matter or moisture, from loss of the substance, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, or sale, and shall be capable of tight reclosure. Where a tightly closed container is specified, it may be replaced by a hermetically closed container for a single-dose of the substance.

STORAGE

The following expressions are used in monographs under Packaging and storage with the meaning shown.

Protected from light means that the product is to be stored either in a light-resistant container or in a container enclosed in an outer cover that provides such protection or stored in a place from which all such light is excluded.

Protected from moisture means that the product is to be stored in a tightly closed container. Care is to be taken when the container is opened in a damp atmosphere. A low moisture content may be maintained, if necessary, by the use of a desiccant in the container provided that direct contact with the product is avoided.

In a dry place means a place where its relative humidity should be between 40 and 60 per cent. If necessary, air conditioners and dehumidifiers should be installed.

STORAGE TEMPERATURES

When special conditions of storage are necessary, including limits of temperature, they are prescribed in the monograph. Where, in a monograph, the storage conditions are mentioned using the general expressions "at room temperature", "in a cold place", and the like, these terms are generally defined as follows.

Very cold temperature Any temperature above –10° but not higher than 8°. A *refrigerator* is a very cold place in which the temperature is maintained thermostatically between 2° and 8°.

Cool temperature Any temperature above 16° but not higher than 23°.

Room temperature Any temperature above 23° but not higher than 35°.

MONOGRAPHS

สารสกัดแห้งฟ้าทะลาย (FA THALAI DRY EXTRACT)

สารสกัดแห้งฟ้าทะลายโจร (FA THALAI CHON DRY EXTRACT)
Andrographis Dry Extract

Category Antipyretic, anti-inflammatory in laryngitis.

Andrographis Dry Extract is prepared from the powdered Andrographis Herb by extraction with *ethanol*. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of andrographolide ($C_{20}H_{30}O_5$); the labelled amount of andrographolide is not less than 4.5 per cent, calculated on the dried basis.

Description Brownish green powder.

Packaging and storage Andrographis Dry Extract shall be kept in tightly closed containers, protected from light, and stored in a cool and dry place.

Labelling The label on the container states (1) the amount of andrographolide; (2) the expiration date.

Identification The chromatogram of the Assay preparation shows several peaks, one of which corresponds to that of the Standard preparation, as obtained in the *Assay*.

Loss on drying Not more than 5.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15). Use 2.0 g.

Assay Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Mobile phase Prepare a mixture of equal volumes of *methanol* and *water*.

Standard preparation Transfer about 5 mg of Andrographolide RS, accurately weighed, to a 25-mL volumetric flask, add 2 mL of *methanol*, and sonicate for 5 minutes. Dissolve and dilute with *Mobile phase* to volume to obtain a stock solution having a known concentration of about 200 µg of andrographolide per mL. Dilute this solution quantitatively and stepwise with *Mobile phase* to obtain seven solutions having known concentrations of 10, 20, 40, 60, 80, 100, and 140 µg per mL. Filter through a nylon membrane having a 0.45-µm porosity.

Assay preparation Transfer an accurately weighed quantity of Andrographis Dry Extract, containing about 10 mg of andrographolide, to a 100-mL volumetric flask. Add 10 mL of *methanol* and sonicate for 5 minutes. Add 60 mL of *Mobile phase*, sonicate for 15 minutes, and stand for 30 minutes. Dilute with *Mobile phase* to volume, mix, and filter through a nylon membrane having a 0.45-µm porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (15 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (5 µm), equipped with a similarly packed guard column, (b) *Mobile phase* at a flow rate of 1.0 mL per minute, and (c) an ultraviolet photometer set at 224 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 60 µg per mL, and record the peak responses as directed under *Procedure*: the symmetry factor for the andrographolide peak is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure and **Calculation** Separately inject about 20 µL each of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Plot the readings and draw the standard curve of best fit. The curve shows the correlation coefficient of not less than 0.999. Inject about 20 µL of *Assay preparation* into the chromatograph, record the chromatograms, and measure the response for the major peak. By reference to the standard curve, calculate the content of andrographolide ($C_{20}H_{30}O_5$) in the portion of the Extract taken.

Other requirements Complies with the requirements described under "Extracts" (Appendix 1.16H).

ยาแคปซูลสารสกัดแห้งฟ้าทะลาย (FA THALAI DRY EXTRACT CAPSULES)

ยาแคปซูลสารสกัดแห้งฟ้าทะลายโจร (FA THALAI CHON DRY EXTRACT CAPSULES)
Andrographis Dry Extract Capsules

Category Antipyretic, anti-inflammatory in laryngitis, for alleviation of common cold symptoms.

Andrographis Dry Extract Capsules are prepared from Andrographis Dry Extract and contain not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of andrographolide ($C_{20}H_{30}O_5$), calculated on the dried basis.

Strengths available 200 to 400 mg (equivalent to 10 to 20 mg of andrographolide)

Dose Three to six capsules three times a day after meals or as directed by physicians.

Contra-indication It is contra-indicated in pregnant and nursing women and in patients with known allergy to plants of the Acanthaceae family.

Warning

1. It should not be used for more than 7 days as anti-inflammatory in laryngitis.
2. Concomitant use with anticoagulants, antiplatelets, and antihypertensives should be avoided.

Additional information Some clinical studies show the potential of andrographis paniculata-containing formulations for alleviating the symptoms of common cold and declining the severity of COVID-19 infection.

Packaging and storage Andrographis Dry Extract Capsules shall be kept in tightly closed containers, protected from light, and stored at a temperature not exceeding 30°.

Labelling The label on the container states (1) the amount of andrographolide; (2) the expiration date.

Identification The chromatogram of the Assay preparation shows several peaks, one of which corresponds to that of the Standard preparation, as obtained in the *Assay*.

Loss on drying Not more than 5.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15). Use 2.0 g.

Microbial limit Comply with the requirements for Category 1A in the "Limits for Microbial Contamination" (Appendix 10.5).

Assay Carry out the determination as described in the "Liquid Chromatography" Appendix 3.5).

Mobile phase Prepare a mixture of equal volumes of *methanol* and *water*.

Standard preparations Transfer about 5 mg of Andrographolide RS, accurately weighed, to a 25-mL volumetric flask, add 2 mL of *methanol*, and sonicate for 5 minutes. Dissolve and dilute with *Mobile phase* to volume to obtain a stock solution having a known concentration of about 200 µg of andrographolide per mL. Dilute this solution quantitatively and stepwise with *Mobile phase* to obtain seven solutions having known concentrations of 10, 20, 40, 60, 80, 100, and 140 µg per mL. Filter through a nylon membrane having a 0.45-µm porosity.

Assay preparation Weigh and mix the contents of not less than 20 Andrographis Dry Extract Capsules. Transfer an accurately weighed portion of the capsule contents, containing about 10 mg of andrographolide, to a 100-mL volumetric flask. Add 10 mL of *methanol* and sonicate for 5 minutes. Add 60 mL of *Mobile phase*, sonicate for 15 minutes, and stand for 30 minutes. Dilute with *Mobile phase* to volume and mix. Pass a portion of the clear solution through a filter having a 0.45-µm or finer porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (15 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (5 µm), equipped with a similarly packed guard column, (b) *Mobile phase* at a flow rate of 1.0 mL per minute, and (c) an ultraviolet photometer set at 224 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 60 µg per mL, and record the peak responses as directed under *Procedure*: the symmetry factor for the andrographolide peak is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure and **Calculation** Separately inject about 20 µL each of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Plot the readings and draw the standard curve of best fit. The curve shows the correlation coefficient of not less than 0.999. Inject about 20 µL of *Assay preparation* into the chromatograph, record the chromatograms, and measure the response for the major peak. By reference to the standard curve, calculate the content of andrographolide ($C_{20}H_{30}O_5$) in the portion of the Capsules taken.

Other requirements Comply with the requirements described under "Capsules" (Appendix 1.16H).

ยาเม็ดสารสกัดแห้งฟ้าทะลาย (FA THALAI DRY EXTRACT TABLETS)

ยาเม็ดสารสกัดแห้งฟ้าทะลายโจร (FA THALAI CHON DRY EXTRACT TABLETS)
Andrographis Dry Extract Tablets

Category Antipyretic, anti-inflammatory in laryngitis, for alleviation of common cold symptoms.

Andrographis Dry Extract Tablets are prepared from Andrographis Dry Extract and contain not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of andrographolide ($C_{20}H_{30}O_5$), calculated on the dried basis.

Strength available 250 mg (equivalent to 20 mg of andrographolide)

Dose One to two tablets three times a day after meals or as directed by physicians.

Contra-indication It is contra-indicated in pregnant and nursing women and in patients with known allergy to plants of the Acanthaceae family.

Warning

1. It should not be used for more than 7 days as anti-inflammatory in laryngitis.
2. Concomitant use with anticoagulants, antiplatelets, and antihypertensives should be avoided.

Additional information Some clinical studies show the potential of andrographis paniculata-containing formulations for alleviating the symptoms of common cold and declining the severity of COVID-19 infection.

Packaging and storage Andrographis Dry Extract Tablets shall be kept in tightly closed containers, protected from light, and stored at a temperature not exceeding 30°.

Labelling The label on the container states (1) the amount of andrographolide; (2) the expiration date.

Identification The chromatogram of the Assay preparation shows several peaks, one of which corresponds to that of the Standard preparation, as obtained in the *Assay*.

Loss on drying Not more than 5.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15). Use 2.0 g.

Microbial limit Comply with the requirements for Category 1A in the "Limits for Microbial Contamination" (Appendix 10.5).

Assay Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Mobile phase Prepare a mixture of equal volumes of *methanol* and *water*.

Standard preparations Transfer about 5 mg of Andrographolide RS, accurately weighed, to a 25-mL volumetric flask, add 2 mL of *methanol*, and sonicate for 5 minutes. Dissolve and dilute with *Mobile phase* to volume to obtain a stock solution having a known concentration of about 200 µg of andrographolide per mL. Dilute this solution quantitatively and stepwise with *Mobile phase* to obtain seven solutions having known concentrations of 10, 20, 40, 60, 80, 100, and 140 µg per mL. Filter through a nylon membrane having a 0.45-µm porosity.

Assay preparation Weigh and finely powder not less than 20 Andrographis Dry Extract Tablets. Transfer an accurately weighed portion of the powder, containing about 10 mg of andrographolide, to a 100-mL volumetric flask. Add 10 mL of *methanol* and sonicate for 5 minutes. Add 60 mL of *Mobile phase*, sonicate for 15 minutes, and stand for 30 minutes. Dilute with *Mobile phase* to volume and mix. Pass a portion of the clear solution through a filter having a 0.45-µm or finer porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (15 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (5 µm), equipped with a similarly packed guard column, (b) *Mobile phase* at a flow rate of 1.0 mL per minute, and (c) an ultraviolet photometer set at 224 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 60 µg per mL, and record the peak responses as directed under *Procedure*: the symmetry factor for the andrographolide peak is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure and **Calculation** Separately inject about 20 µL each of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Plot the readings and draw the standard curve of best fit. The curve shows the correlation coefficient of not less than 0.999. Inject about 20 µL of *Assay preparation* into the chromatograph, record the chromatograms, and measure the response for the major peak. By reference to the standard curve, calculate the content of andrographolide ($C_{20}H_{30}O_5$) in the portion of the Tablets taken.

Other requirements Comply with the requirements described under "Tablets" (Appendix 1.16H).

กำลังเสือโคร่ง (KAMLANG SUEA KHRONG)

กำลังพญาเสือโคร่ง (KAMLANG PHAYA SUEA KHRONG)
Betalae Alnoides Cortex
Himalayan Birch Bark

Synonym Indian Birch Bark

Category Anti-inflammatory, stomachic, tonic.

Himalayan Birch Bark is the dried stem bark of *Betula alnoides* Buch.-Ham. ex D. Don [*B. affinis* (Spach) Endl., *B. nitida* D. Don] (Family Betulaceae), Herbarium Specimen Number: DMSC 5332, Crude Drug Number: DMSc 1226.

Constituents Himalayan Birch Bark contains triterpenoids (e.g., betulin, betulinic acid, lupeol, oleanolic acid, and ursolic acid). It also contains phenolics such as methyl salicylate and arbutin.

Description of the plant (Fig. 1) Tree up to 35 m tall, monoecious; bark red-brown or silvery grey, with large oblong lenticels, exfoliating into thin slices; inner bark strongly aromatic; branchlet densely white villous, with resinous glands. Leaves simple, spirally arranged, ovate-lanceolate, ovate-elliptic, to ovate-oblong, 4 to 14 cm long, 2.5 to 5.5 cm wide, apex acuminate or caudate-acuminate, base cuneate to broadly cuneate or subrounded, rarely subcordate, margin serrate, papery, abaxially densely glandular punctate, sparsely villous along veins, bearded in axils of lateral veins, adaxially glabrous, lateral veins 8 to 13 on each side of midvein; petiole 1.5 to 4 cm long, densely white villous, with resinous glands. Inflorescence terminal or axillary pendulous catkins, cylindrical; pedunculate. Flower tiny, greenish, perianth minute. Staminate inflorescence up to 20 cm long, about 4 mm wide; bracts numerous, overlapping, each bract subtending 2 bracteoles and 3 flowers; staminate flowers: stamens 2, anthers 2-loculed, thecae connate, apex pubescent or glabrous. Pistillate inflorescence 5 to 10 cm long, 4 to 6 mm wide, in group of 2 to 5; peduncle 2 to 3 mm long, densely yellow villous; bract about 3 mm long, densely pubescent and ciliolate, becoming spongy at base, 3-lobed, middle lobe oblong or obtuse, lateral lobes reduced, auriculate, each bract subtending 3 ovaries at base; pistillate flowers: ovary, 2-loculed, each locule with 2 ovules, styles 2, persistent. Fruit a nutlet, with membranous wings; nutlet obovate, about 4 mm long (wings included), apex sparsely pubescent, flattened, with membranous wings twice as wide as nutlet.

Description Odour, slightly methyl salicylate-like; taste, slightly pungent.

Macroscopical (Fig. 1) Curved stem bark, 1.0 to 3.5 cm thick. Outer surface whitish brown to reddish brown, slightly rough, with parts of exfoliated yellowish brown of remained periderm, phellem slightly with scattered long horizontal whitish shallow groove of lenticels. Inner surface smooth, reddish brown.

Microscopical (Figs. 2a, 2b) Transverse section of the stem bark shows outer bark and inner bark. Outer bark: several layers of cork, some containing brown or red substance and groups of sclereids, some containing brown or red substance. Inner bark: groups of sclereids, phloem ray, phloem fibres, and phloem parenchyma, some containing starch grains, prismatic crystals, rosette aggregate crystals or brown substance.

Himalayan Birch Bark in powder possesses the diagnostic microscopical character of the unground drug. Groups of thick-walled sclereids with brown or red substance and thick-walled parenchyma containing brown substance are characteristic.

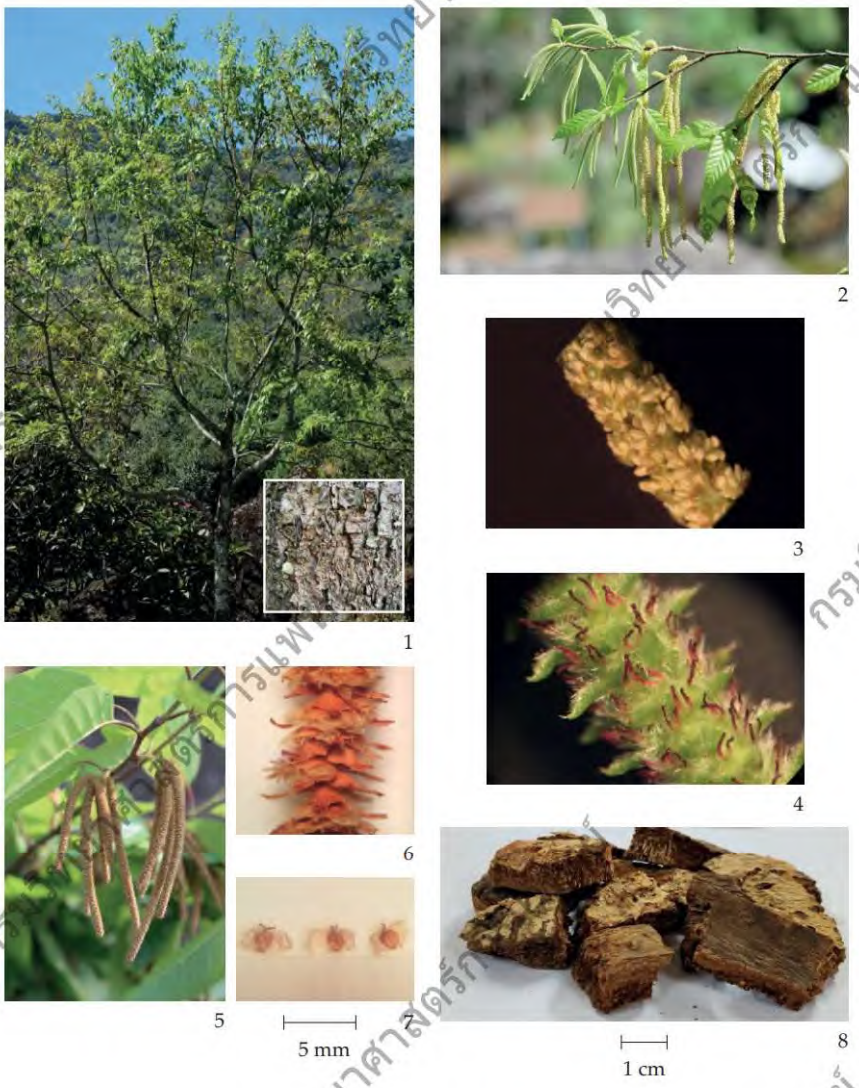


Fig. 1 *Betula alnoides* Buch.-Ham. ex D. Don
1. habit and bark 2. male and female inflorescences
3. part of male inflorescences 4. part of female inflorescences 5. infructescences
6. part of infructescences 7. nutlets 8. crude drug

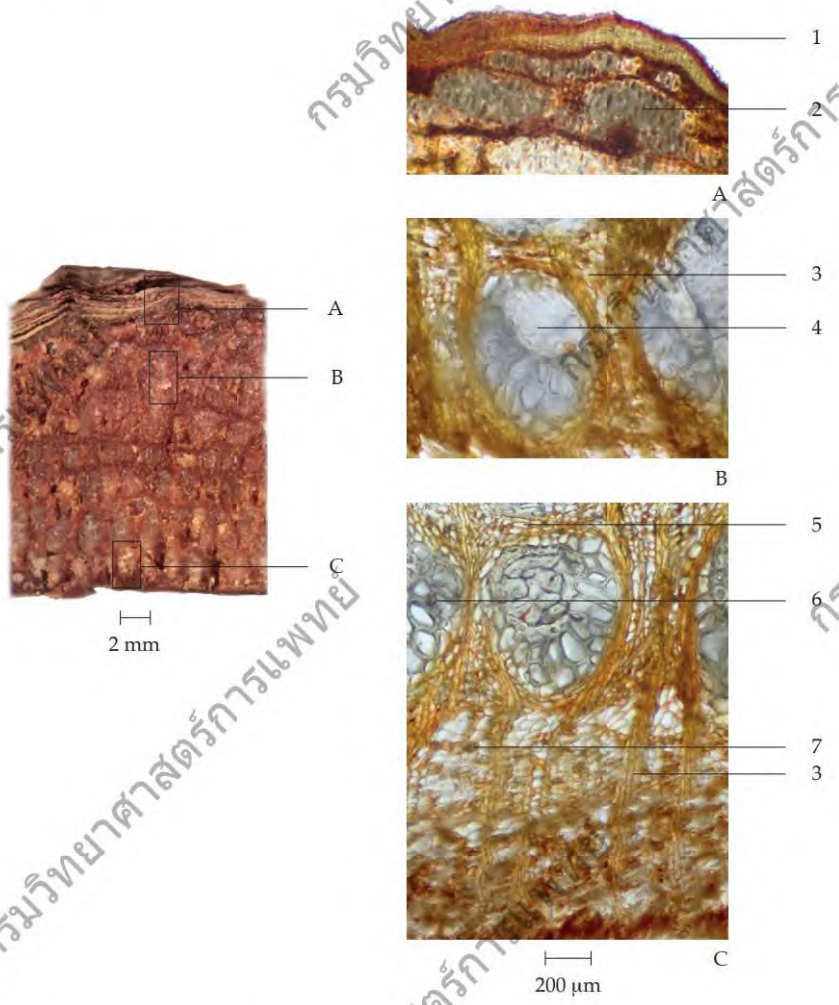


Fig. 2a Photomicrographs of Transverse Sections of the Stem Bark of *Betula alnoides* Buch.-Ham. ex D. Don
A. Outer and Inner Bark
B. and C. Inner Bark

1. cork
2. sclereid with brown substance
3. phloem ray
4. group of sclereids
5. phloem parenchyma
6. prismatic crystal
7. rosette aggregate crystal

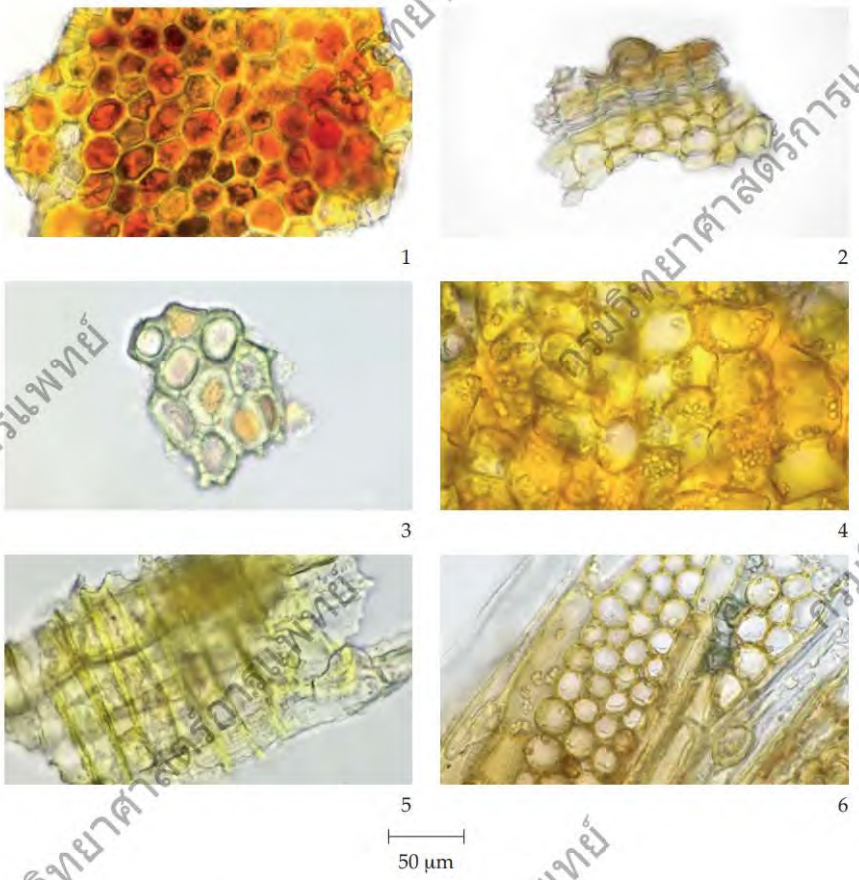


Fig. 2b Photomicrographs of Powdered Drug of the Stem Barks of *Betula alnoides* Buch.-Ham. ex D. Don

1. cork cells in surface view, some containing brown or red substance
2. cork cells in sectional view, some containing brown substance
3. thick-walled parenchyma, some containing brown substance
4. parenchyma, containing brown substance and starch grains
5. medullary ray in radial longitudinal view
6. medullary ray in tangential longitudinal view

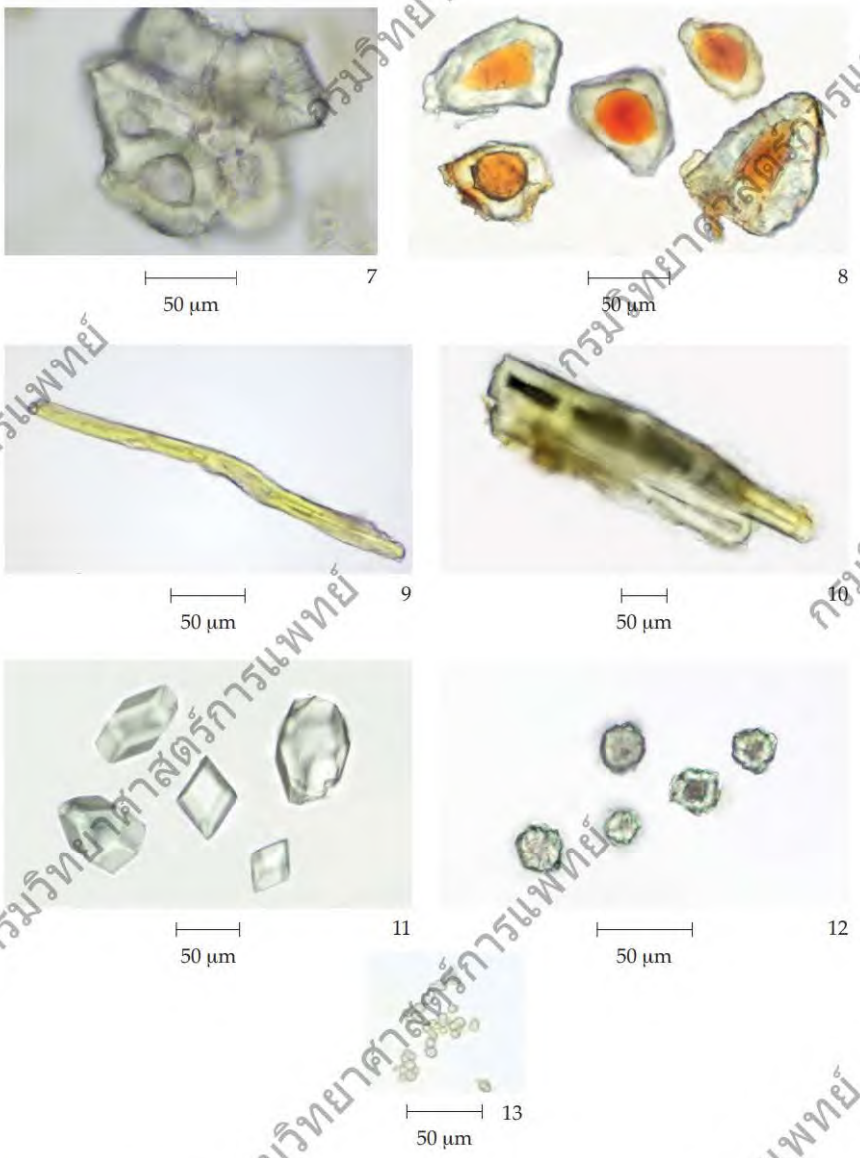


Fig. 2b (continued)

7. group of sclereids
8. sclereids containing brown or red substance
9. phloem fibre
10. phloem fibres and sclereids
11. prismatic crystals
12. rosette aggregate crystals
13. starch grains

Packaging and storage Himalayan Birch Bark shall be kept in well-closed containers, protected from light, and stored in a cool and dry place.

Identification

A. To 1 g of the sample, in *No. 250 powder*, add 30 mL of *water* and heat on a water-bath for 20 minutes. Immediately filter through a plug of cotton wool and allow the filtrate to cool. Shake 5 mL of the filtrate with 2 mL of *chloroform* for 2 minutes. Separate the chloroform layer and transfer 1 mL of this layer to a test-tube, slowly add a few drops of *sulfuric acid* to form a layer: a reddish brown ring forms at the zone of contact.

B. Boil 1 g of the sample, in *No. 250 powder*, with 20 mL of *water*, cool and filter. To 1 mL of the filtrate, add 5 mL of *water*, mix and then add a few drops of *iron(III) chloride TS*: a dark blue precipitate develops.

C. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel GF254* as the coating substance and *chloroform* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply separately to the plate as bands of 5 mm, 4 µL each of solutions A and B. Prepare solution (A) by refluxing 2 g of the sample, in *No. 250 powder*, with 30 mL of *ethyl acetate* for 15 minutes and filtering. Evaporate the filtrate to dryness, dissolve the residue in 2 mL of *methanol*. For solution (B), dissolve 1 mg of *lupeol* in 1 mL of *methanol*. After removal of the plate, allow it to dry in air. Spray the plate with *anisaldehyde TS* and heat at 105° for 5 minutes and examine under daylight; the band corresponding to lupeol is purple (hR_f value 62 to 67). Nine purple bands are also observed. Subsequently examine the same plate under ultraviolet light (366 nm); the band due to lupeol shows purple fluorescence; two yellow and seven blue fluorescent bands are also observed (Fig. 3).

Loss on drying Not more than 9.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Total ash Not more than 3.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 12.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 8.0 per cent w/w (Appendix 7.12).

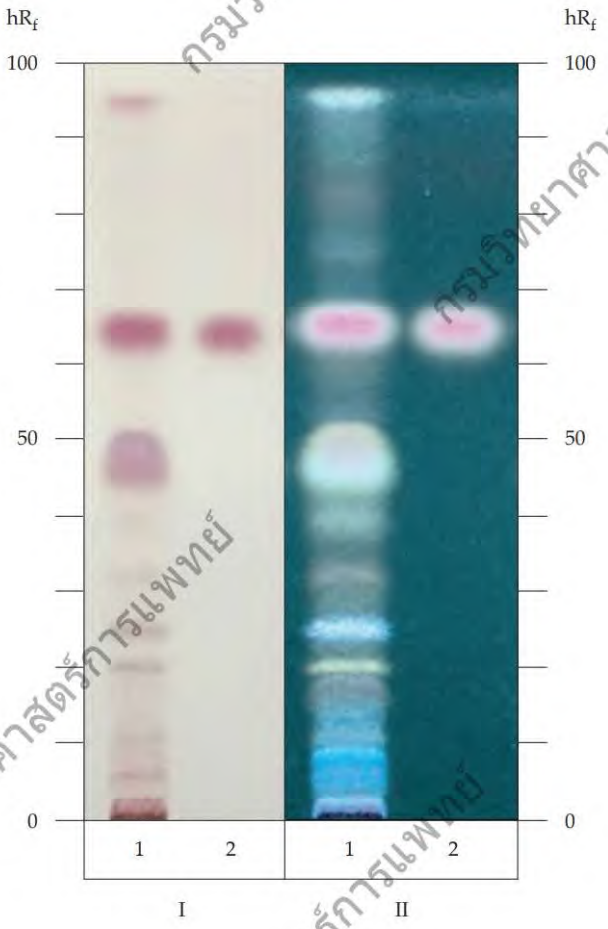


Fig. 3 Thin-Layer Chromatogram of Ethyl Acetate Extract of the Stem Barks of *Betula alnoides* Buch.-Ham. ex D. Don

1 = solution (A)
2 = solution (B)
I = detection under daylight after spraying with *anisaldehyde TS*
II = detection under UV light (366 nm) after spraying with *anisaldehyde TS*

กัญชา, ราก (KANCHA, RAK)

Cannabis Sativae Radix
Cannabis Sativa Root

Synonym Cannabis Root

Category Anti-inflammatory.

Cannabis Sativa Root is the dried root of *Cannabis sativa* L. [*C. indica* Lam., *C. ruderalis* Janisch., *C. ruderalis* (Janisch.) S. Z. Liou, *C. sativa* L. subsp. *indica* (Lam.) E. Small & Cronquist, *C. sativa* L. var. *indica* (Lam.) Wehmer] (Family Cannabaceae), Herbarium Specimen Number: DMSC 5268, Crude Drug Number: DMSc 1213.

Constituents Cannabis Sativa Root contains triterpenoids (e.g., epifriedelinol and friedelin). It also contains sterols, alkaloids, polyphenols, etc.

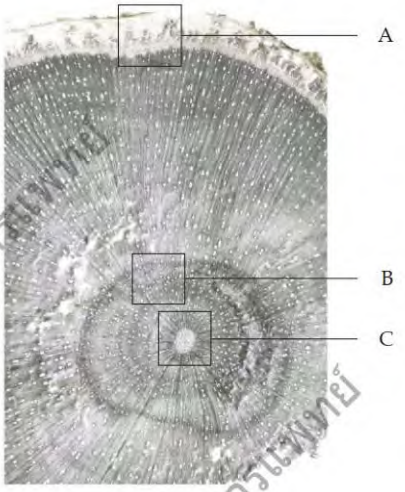
Description of the plant (Fig. 1) Herbaceous plant, dioecious, occasionally monoecious, 0.2 to 6 m tall; stem and branches angular, erect, covered with rather short stiff hairs. Leaves palmately compound, opposite near base, spirally arranged upwards; petiole up to 10 cm long, pubescent; stipule erect, linear or narrowly subulate, 4 to 6 mm long, persistent; leaflets (3–)5 to 11, narrowly lanceolate, linear to linear-lanceolate, 2 to 15 cm long, 0.2 to 2 cm wide, apex acuminate-caudate, base narrowly cuneate, margin coarsely serrate, upper surface dark green, scabrous, lower surface whitish green with scattered brownish resinous dots, densely pubescent with appressed hairs, nerves 8 to 20 pairs; sessile. Flowering top numerous inflorescences, terminal or axillary; male inflorescence diffused and paniculate, bracts small; female inflorescence crowded among foliaceous bracts, 1 to 5 cm long. Flower small; male flower yellowish green, tepals 5, free, elliptic or oblong, 3 to 5 mm long, 1.5 to 2 mm wide, apex acute, margin entire, finely pubescent; stamens 5, opposite tepals, filament slender, 0.5 to 1 mm long, anther basifixed, oblong, 2-celled, dehiscing by apical pore; female flower greenish, subsessile, enveloped by perigonal bract, membranous spathe-like, dark green, with glandular hairs; tepals fused into thin-textured tube adnate to ovary, in some cultivars, merely a ring at base of ovary; ovary superior, subglobose, 1 to 2 mm in diameter, 1-loculed, style short divided into 2 stigmatic slender arms, brown, pubescent, caducous. Fruit an achene, ovoid or ellipsoid, 2 to 5 mm long, 3 to 4 mm wide, somewhat compressed, minutely pilose to glabrous, shiny, yellowish brown to white or greenish, mottled with purple pericarp crustaceous, finely reticulate. Seed 1.

Description Odourless; taste, bland.

Macroscopical (Fig. 1) Tap root cylindrical, up to 5 cm in diameter, whitish to pale brown, various lengths. Secondary roots numerous, varied in length, slender, whitish to pale brown, up to 1.5 mm in diameter.

Microscopical (Figs. 2a, 2b) Transverse section of the root shows cork, cortex, vascular tissue, and pith. Cork: several layers of thin-walled rectangular cells. Cortex: polygonal and rectangular parenchyma cells. Vascular tissue: phloem, small thin-walled round parenchyma, phloem ray, and phloem fibres; xylem, vessels, xylem ray, some containing starch grains, and xylem fibres. Pith: thick-walled round parenchyma, some containing rosette aggregate crystals.

Fig. 1 *Cannabis sativa* L.
1. habit 2. male inflorescence 3. female flowers 4. female inflorescence 5. fresh roots 6. crude drug



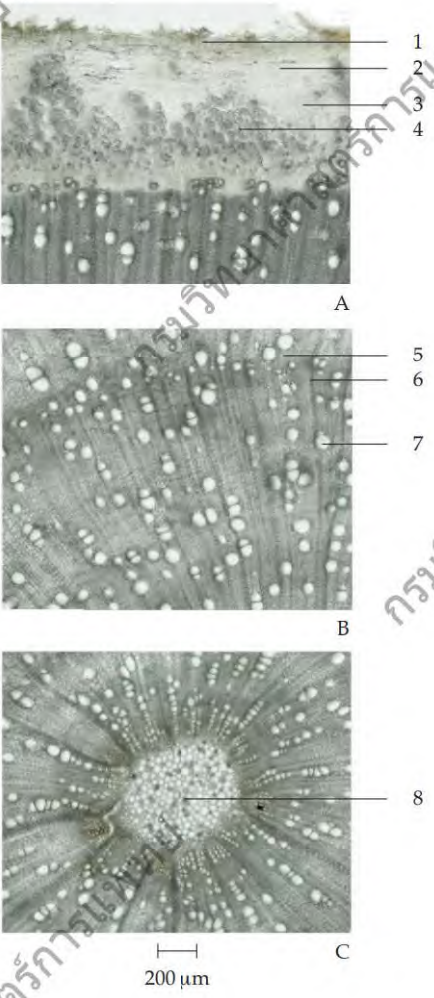


Fig. 2a Photomicrographs of Transverse Sections of the Root of *Cannabis sativa* L.

A. Bark and Part of Wood
B. Part of Wood
C. Part of Wood and Pith

1. cork
2. parenchyma
3. phloem ray
4. phloem fibre
5. xylem fibre
6. xylem ray
7. vessel
8. parenchyma containing rosette aggregate crystals

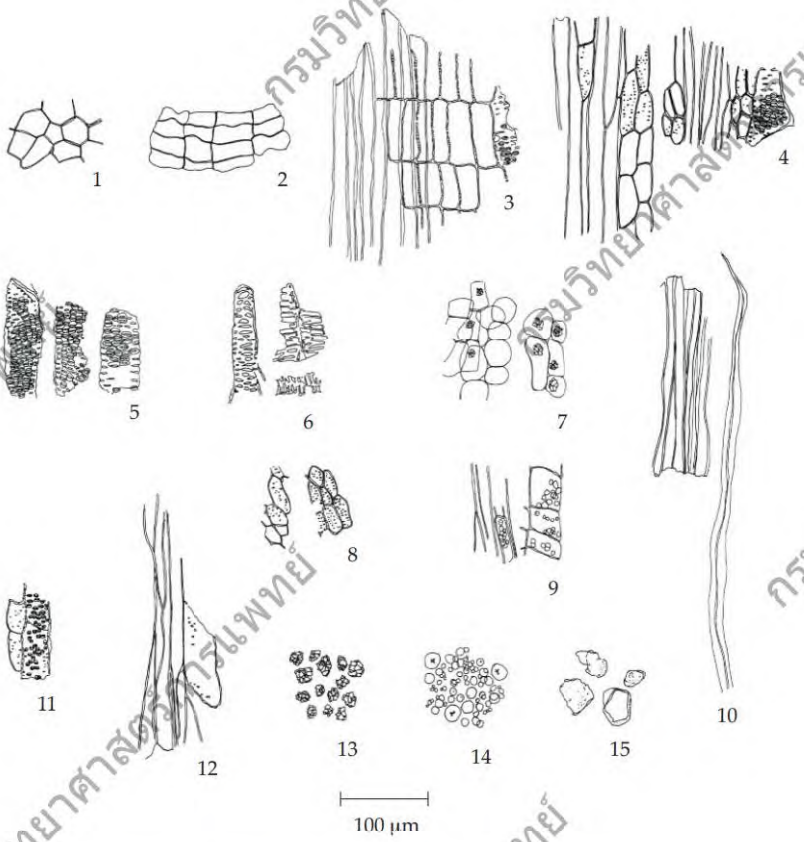


Fig. 2b Line Drawings of Powdered Drug of the Roots of *Cannabis sativa* L.

1. cork in surface view
2. cork in sectional view
3. xylem in radial longitudinal view showing fibres, xylem ray, and bordered-pitted vessel
4. fibres, xylem ray, uniseriate and biseriate, and bordered-pitted vessel in tangential longitudinal view
5. bordered-pitted vessels
6. reticulate vessels
7. parenchyma, some containing rosette aggregate crystals
8. xylem parenchyma
9. parenchyma containing starch grains
10. fibres
11. xylem parenchyma associated with bordered-pitted vessel
12. xylem fibres associated with vessel
13. rosette aggregate crystals
14. starch grains
15. brownish substance

Cannabis Sativa Root in powder possesses the diagnostic microscopical characters of the unground drug. The combination of thin-walled cork, uniseriate and biseriate medullary rays in tangential view, and various sizes of starch grains should be characteristic.

Additional information

1. It is commonly used with other herbal drugs in Thai traditional herbal preparations.
2. It is to be noted that traces of cannabinoids may be found in cannabis roots.

Packaging and storage Cannabis Sativa Root shall be kept in well-closed containers, protected from light, and stored in a dry place.

Identification

A. Macerate 500 mg of the sample, in powder, with 5 mL of *chloroform* for 15 minutes and filter. Evaporate 1 mL of the filtrate to dryness. Dissolve the residue in 1 mL of *acetic anhydride*, shake well, and slowly add 1 mL of *sulfuric acid* to form a layer: a brown colour develops at the zone of contact and the upper layer is bluish green.

B. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using a high-performance plate with *silica gel 60F254* as the coating substance and a mixture of 90 volumes of n-*hexane* and 10 volumes of *ethyl acetate* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply separately to the plate, as bands of 8 mm, 10 µL of solution (A) and 5 µL of solution (B). Prepare solution (A) by macerating 1 g of the sample, in powder, with 5 mL of *chloroform*, shaking for 10 minutes and filtering. For solution (B), dissolve 1 mg of *friedelin* in 1 mL of *chloroform*. After removal of the plate, allow it to dry in air. Spray the plate with *anisaldehyde TS* and heat at 105° for 5 minutes. The chromatogram obtained from solution (A) shows a yellow band (hR_f value 46 to 49), corresponding to the friedelin band obtained from solution (B). Two purple and two violet bands are also observed (Fig. 3).

Loss on drying Not more than 8.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 1.5 per cent w/w (Appendix 7.6).

Total ash Not more than 8.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 2.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 4.0 per cent w/w (Appendix 7.12).

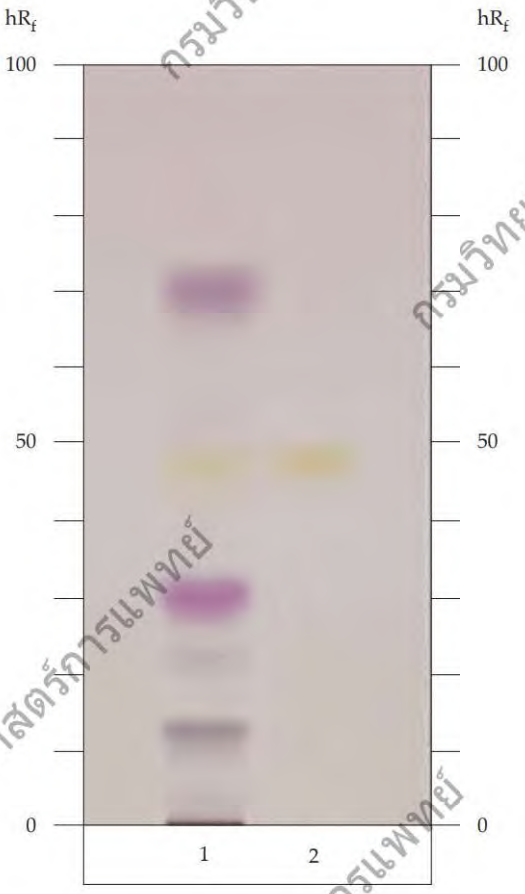


Fig. 3 Thin-Layer Chromatogram of Chloroform Extract of the Roots of *Cannabis sativa* L., Detected With *Anisaldehyde TS*
1 = solution (A)
2 = solution (B)

คำฝอย (KHAM FOI)

ดอกคำ (DOK KHAM), **โกฐกุสุมภ์** (KOT KUSUM)
Carthami Tinctorii Flos
Safflower

Synonyms Fake Saffron, False Saffron

Category Blood tonic.

Safflower is the dried florets of *Carthamus tinctorius* L. [*Calcitrapa tinctoria* (L.) Röhl., *Carduus tinctorius* (L.) Falk, *Carthamus glaber* Burm. f., *C. tinctorius* var. *spinosus* Kitam., *Centaurea carthamus* E. H. L. Krause] (Family Compositae), Herbarium Specimen Number: DMSC 5251, Crude Drug Number: DMSc 1227.

Constituents Safflower contains quinochalcones (e.g., carthamin, hydroxysafflor yellow A, and safflor yellow A and B) and flavonoids and its derivatives (e.g., kaempferol, quercetin, and rutin).

Description of the plant (Fig. 1) Annual herb 0.4 to 1.3 m tall; stem erect, ribbed, glabrous, apically branched. Leaves simple, spirally arranged, oblong, oblong-lanceolate, or ovate-oblong, 3 to 15 cm long, 1 to 6 cm wide, apex acicular or obtuse, base semiamplexicaul, margin spinosely toothed or entire, rigidly-coriaceous, glabrous on both surfaces; petiole sessile. Inflorescence in terminal head, ovoid-globose; involucre ovoid, about 2.5 cm in diameter, phyllaries in about 5 rows, outer phyllaries leaflike, ovate-lanceolate. Flower yellow to orange, turning orange-red; corolla tube 1.5 to 2 cm long, thin, deeply 5-partite lobes; stamens 5, anther sagittate; ovary inferior, stigma 2-armed. Fruit an achene, ovoid to ellipsoid, 6 to 8 mm long, apex truncate, 4-angled; pappus about 5 mm long, consisting of unequal scales.

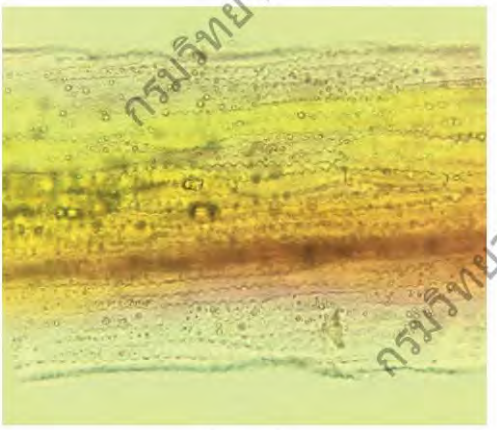
Description Odour, slightly aromatic; taste, slightly bitter.

Macroscopical (Fig. 1) Florets orange to red, 1 to 1.5 cm long, consisting of corolla tube, 5 mm long, slender, apex 5-lobed, each lobe linear, 5 mm long, deep red; stamen yellowish; style and stigma yellowish.

Microscopical (Figs. 2a, 2b, 2c, 2d) Transverse section of the corolla tube through the style shows upper epidermis, mesophyll, vascular tissue, and lower epidermis. Upper epidermis: a layer of thick-walled rectangular cells, some with papillae. Mesophyll: thin-walled parenchyma. Vascular tissue: vascular bundles of petals in the lower part of corolla tube and vascular bundles of filaments adnate to the corolla lobes. Lower epidermis: a layer of thick-walled rectangular cells. Style: a layer of epidermis, ground parenchyma cells, 2 vascular bundles, and a group of angular collenchyma in the centre.

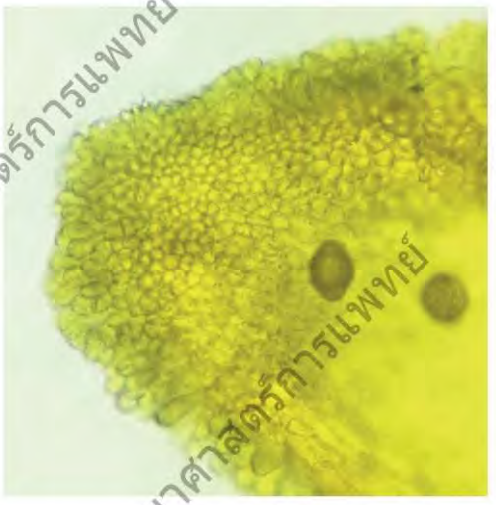
Safflower in powder possesses the diagnostic microscopical characters of the unground drug. Pollen grains with tricolporate and echinate sculpturing, finger-like papillae of stigma, laticiferous ducts of corolla lobe, and papillae of corolla tips are characteristic.

Fig. 1 *Carthamus tinctorius* L.
1. habit 2. inflorescence 3. inflorescence with bracts and calyx removed 4. floret with calyx removed showing ovary, corolla tube, corolla lobes, syngenesious anthers, style, and stigma 5. floret, showing free filaments and syngenesious anthers 6. crude drug



10 µm

Surface View of Corolla Lobe



10 µm

Surface View of Tip of Corolla Lobe Showing Papillae

Fig. 2a Photomicrographs of Surface Views of the Corolla Lobe and the Tip of Corolla Lobe of *Carthamus tinctorius* L.

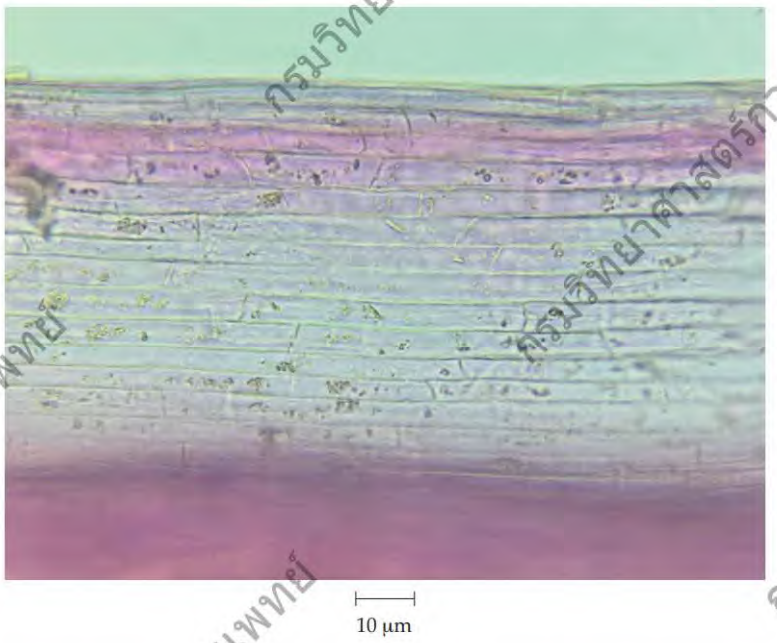


Fig. 2b Photomicrograph of Surface View of the Corolla Tube of *Carthamus tinctorius* L.

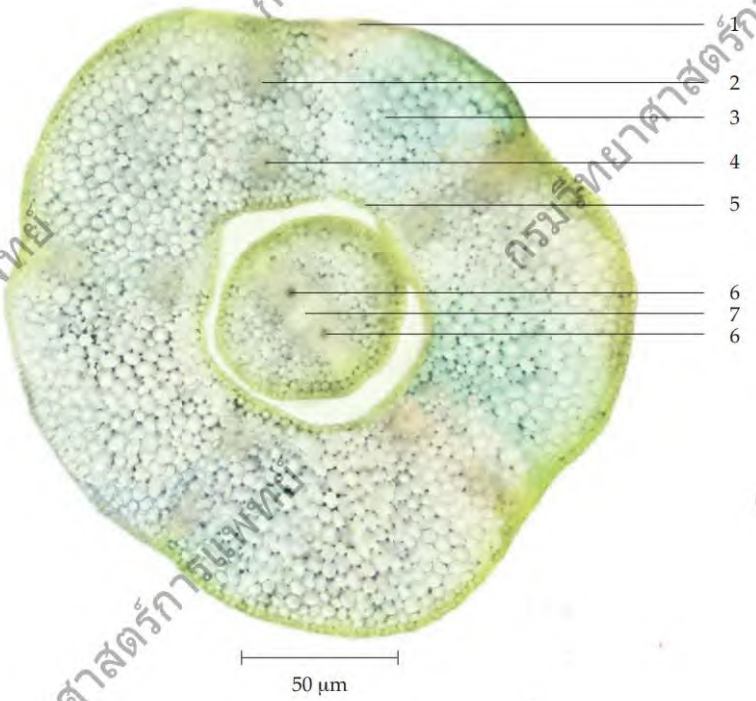


Fig. 2c Photomicrograph of Transverse Section of the Corolla Tube and the Style of *Carthamus tinctorius* L.

1. lower epidermis
2. vascular bundle of corolla tube
3. parenchyma
4. vascular bundle of stamen
5. upper epidermis
6. vascular bundle of style
7. collenchyma

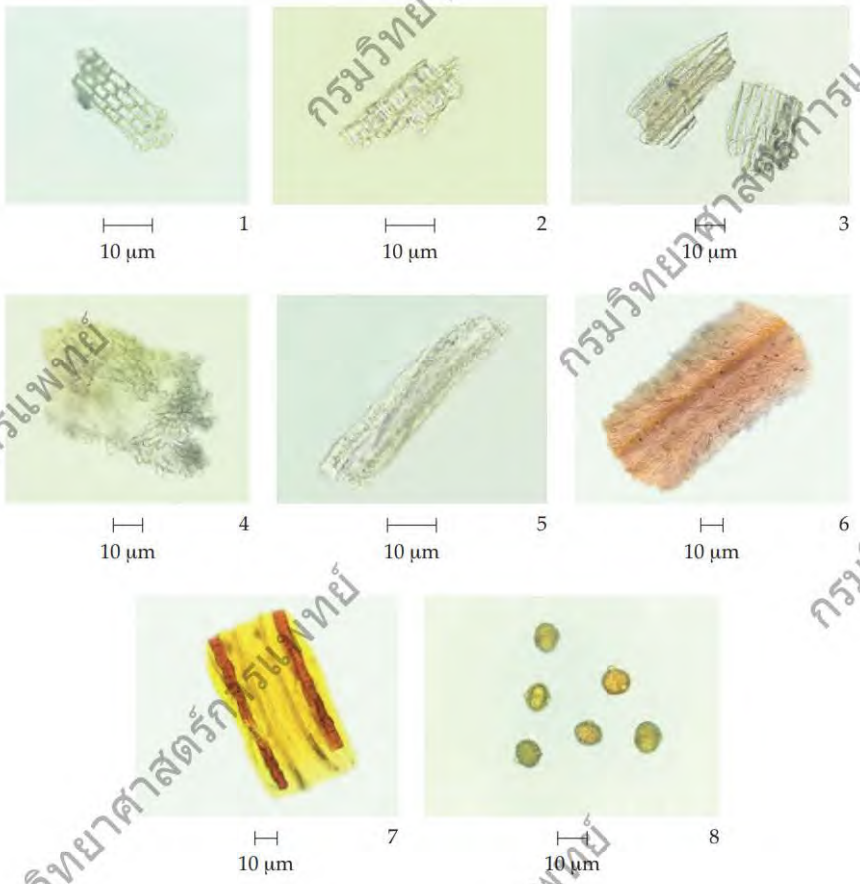


Fig. 2d Photomicrographs of Powdered Drug of the Florets of *Carthamus tinctorius* L.

1. endothecium in surface view
2. endothecium in sectional view
3. epidermis of corolla
4. corolla tip in surface view, showing papillae
5. fragment of corolla in surface view, showing spiral vessels
6. fragment of stigma with finger-like papillae
7. fragment of corolla showing laticiferous ducts and spiral vessels
8. pollen grains

Packaging and storage Safflower shall be kept in well-closed containers, protected from light, and stored in a cool and dry place.

Identification

A. Sonicate 400 mg of the sample, in powder, with 4 mL of *methanol* for 30 minutes or until a yellowish orange solution is obtained and filter or centrifuge. To 2 mL of the filtrate or supernatant, add a few drops of *iron(III) chloride TS*: a dark green colour develops.

B. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel F254* as the coating substance and a mixture of 80 volumes of *ethyl acetate*, 20 volumes of *methanol*, and 10 volumes of *water* as the mobile phase and allowing the solvent front to ascend 9 cm above the line of application. Apply to the plate as a band of 6 mm, 15 µL of the test solution, prepared by sonicating 100 mg of the sample, in powder, with 5 mL of *ethanol* for 15 minutes, filtering or centrifuging, and using the filtrate or supernatant. After removal of the plate, allow it to dry in air. Examine under ultraviolet light (254 nm), marking the quenching bands. Subsequently examine the plate under ultraviolet light (366 nm); one yellow and two brown fluorescent bands are observed. Spray the plate with a 20 per cent v/v solution of *sulfuric acid* and heat at 105° for 5 minutes. One purple and two yellow bands are also observed (Fig. 3).

Loss on drying Not more than 14.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 5.0 per cent w/w (Appendix 7.6).

Total ash Not more than 15.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 11.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 27.0 per cent w/w (Appendix 7.12).

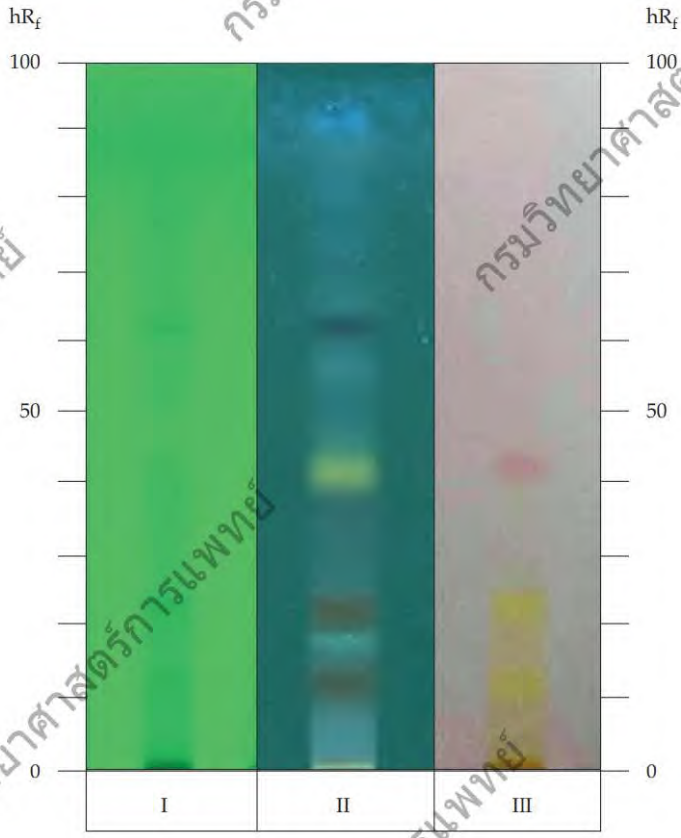


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Florets of *Carthamus tinctorius* L.
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with a 20 per cent v/v solution of *sulfuric acid*

กระท่อม (KRATHOM)

ใบกระท่อม (BAI KRATHOM), ใบท่อม (BAI THOM), ท่อม (THOM), กระท่อมก้านแดง (KRATHOM KAN DAENG)
Mitragynae Speciosae Folium
Krathom

Category Analgesic, antidiarrheal.

Krathom is the dried leaf of *Mitragyna speciosa* (Korth.) Havil. (Family Rubiaceae), Herbarium Specimen Number: DMSC 5333, Crude Drug Number: DMSc 1228.

Constituents Krathom contains indole alkaloids (e.g., corynantheidine, 7-hydroxymitragynine, mitragynine, paynantheine, speciociliatine, and speciogynine). It also contains flavonoids, triterpenoids, etc.

Description of the plant (Fig. 1) Briefly deciduous or evergreen tree, up to 33 m tall, sometimes buttressed; bark grey to greyish brown, smooth or scaly. Leaves simple, decussate, elliptic to ovate or obovate, 9 to 24 cm long, 3.5 to 12.5 cm wide, apex acuminate or acute, base mostly rounded to cordate, rarely cuneate or truncate, margin undulate, sometimes distally unevenly dentate with 1 to 5 teeth on each side, chartaceous to subcoriaceous, glabrous on both surfaces or glabrescent on veins below, midrib and secondary veins red, reddish green or pale green, raised below, secondary veins 10 to 17 pairs, pale hairy domatia in vein axils, tertiary veins scalariform; petiole red, reddish green or pale green, 2 to 4.5 cm long, glabrescent, shallowly grooved above; stipule interpetiolar, reddish green or green, elliptic, 3.5 to 6.5 cm long, 1 to 2.5 cm wide, keeled, glabrescent. Inflorescence terminal globose head, 3 to 4 cm in diameter, many-flowered, simple or compound dichasium-like; peduncle 0.3 to 1.3 cm long, glabrous; receptacle hairy; bract leaf-like, elliptic, 2.3 to 8(–15) cm long, 1 to 6.8 cm wide; interfloral bracteole spathulate, 5 to 6 mm long, 0.3 to 2 mm wide. Flower 5-merous; calyx pale green, tubular, 1 to 1.5 mm long, 2.5 to 3 mm in diameter, glabrous, lobe triangular, 0.3 to 0.7 mm long, 1 to 1.5 mm wide, apex acute, margin ciliate; corolla creamy white to pale yellow, becoming darker when aged, narrowly hypocrateriform, 5 to 6 mm long, 2 to 3 mm wide, lobe narrowly elliptic, 3 to 4.5 mm long, 1 to 2 mm wide, outside glabrous, inside densely long-hairy; stamens 5, protruding from corolla throat, filament 0.3 to 0.5 mm long, anther 1.7 to 2.2 mm long, protruding from corolla throat; ovary obovoid, 2 to 2.2 mm long, 1.5 to 2.2 mm, style slender, 0.9 to 1.3 cm long, glabrous, stigma mitriform, 2.2 to 3 mm long, 1 to 1.5 mm wide, style and stigma protruding from corolla throat. Fruiting head 1.5 to 2.7 cm in diameter; stalk 0.4 to 1.5 cm long, glabrous; fruit obovoid or turbinate, 0.5 to 1 cm long, 2 to 5 mm in diameter, green or dark green, becoming brown or blackish brown when dry, glabrous, with persistent calyx. Seeds numerous, narrowly elliptic, 3 to 4 mm long, 0.3 to 0.6 mm in diameter (including wings), brown, flattened, winged at both ends, sometimes lower wing bifid.

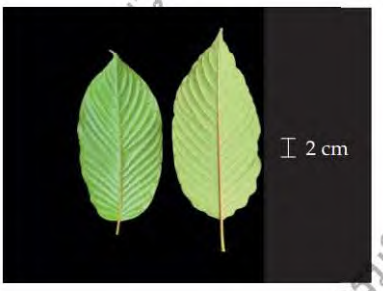
Description Odour, mild; taste, bitter and astringent.

Macroscopical (Fig. 1) Whole leaves and broken leaves. Whole leaves folded, mostly with petiole, petiole reddish, 1.6 to 3.5 cm long, lower leaf surface with reddish midrib and veins. Broken leaves, irregularly shaped and sized.

Microscopical (Figs. 2a, 2b, 2c, 2d, 2e) Transverse section of the leaf through the midrib shows upper epidermis, mesophyll, vascular tissue, and lower epidermis. Upper epidermis: a layer of rectangular cells, covered with cuticle layer; and unicellular trichomes, rarely 2- to 3-cellular trichomes. Mesophyll: layers of cylindrical palisade cells; some of which containing rosette aggregate crystals; spongy cells, irregularly shaped, loosely arranged, some of

1

2



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4

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6

Fig. 1 *Mitragyna speciosa* (Korth.) Havil.
1. habit 2. part of twig showing interpetiolar stipules and reddish petioles, midribs and veins 3. leaves with reddish petioles 4. inflorescence 5. fruiting heads: mature (a), dry (b) 6. crude drug

Upper Epidermis of the Lamina

Lower Epidermis of the Lamina

Fig. 2a Photomicrographs of Epidermises of the Leaf of *Mitragyna speciosa* (Korth.) Havil.
1. epidermal cell
2. unicellular trichome
3. stoma
4. veinlet

Transverse Section of the Midrib

Transverse Section of the Lamina

Fig. 2b Photomicrographs of Transverse Sections of the Leaf of *Mitragyna speciosa* (Korth.) Havil.

1. upper epidermis
2. trichome
3. collenchyma
4. phloem
5. parenchyma containing rosette aggregate crystal
6. reddish substance
7. vessel
8. parenchyma
9. lower epidermis
10. rosette aggregate crystal
11. palisade cell
12. spongy cell

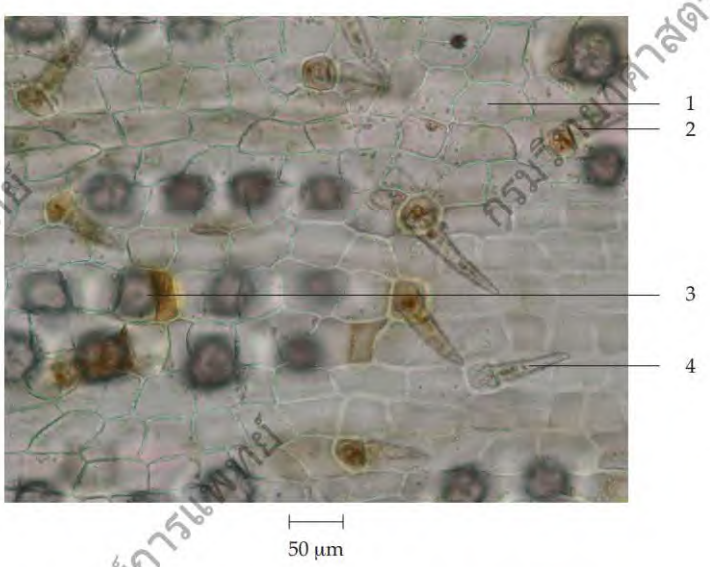


Fig. 2c Photomicrograph of Epidermis of the Petiole of *Mitragyna speciosa* (Korth.) Havil.
1. epidermal cell
2. unicellular trichome
3. rosette aggregate crystal
4. bicellular trichome

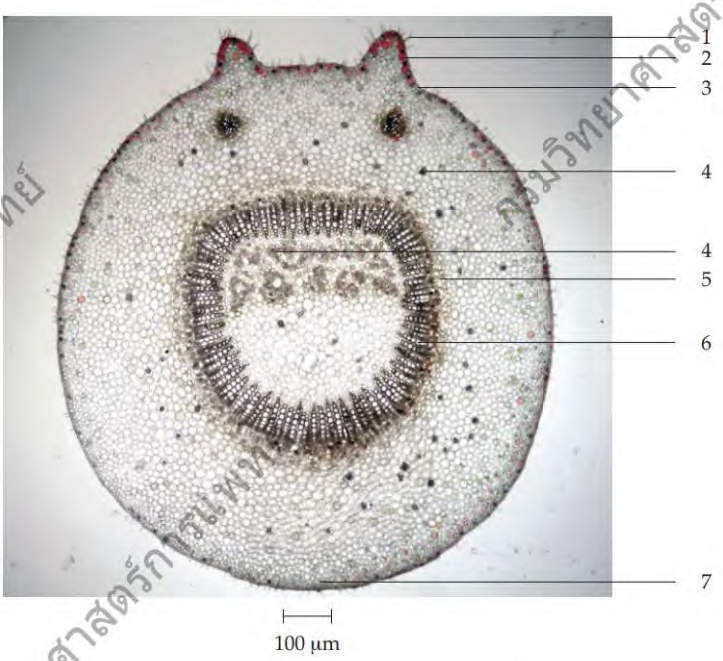


Fig. 2d Photomicrograph of Transverse Section of the Petiole of *Mitragyna speciosa* (Korth.) Havil.

1. trichome
2. reddish substance
3. epidermis
4. parenchyma containing rosette aggregate crystal
5. phloem
6. vessel
7. collenchyma

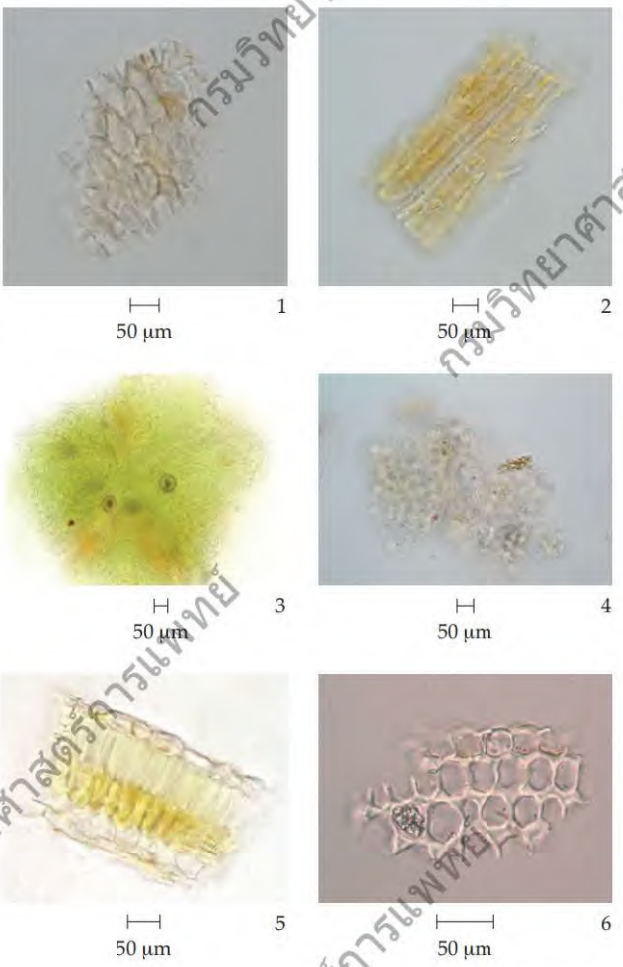


Fig. 2e Photomicrographs of Powdered Drug of the Leaves of *Mitragyna speciosa* (Korth.) Havil.

1. parenchyma
2. epidermis with trichomes, in surface view
3. upper epidermis with veinlet and globular shaped rosette aggregate crystals, with underlying mesophyll
4. lower epidermis of lamina, with paracytic stomata in surface view
5. sectional view of lamina showing epidermal layer, palisade, and spongy cells
6. collenchyma, some containing rosette aggregate crystal

Fig. 2e (continued)

7. fibres with part of a chain of rosette aggregate crystals
8. fibres
9. spiral and reticulate vessels
10. unicellular trichomes
11. rosette aggregate crystals, star-like shaped (a), and globular shaped (b)

which containing reddish substance; angular collenchyma and parenchyma, some of which containing rosette aggregate crystals, or reddish substance in the upper and lower parts of the midrib. Vascular bundle: phloem and xylem. Lower epidermis: a layer of rectangular cells, covered with cuticle layer and unicellular trichomes, rarely 2- to 3-cellular trichomes.

In surface view, the lamina shows upper epidermis and lower epidermis. Upper epidermis: irregularly shaped. Lower epidermis: wavy, paracytic and anomocytic stomata; and unicellular trichomes, rarely 2- to 3-cellular trichomes.

Transverse section of the petiole illustrates epidermis, cortex, and vascular tissue. Epidermis: a layer of rectangular cells covered with cuticle layer; and unicellular trichomes, rarely 2- to 3-cellular trichomes. Cortex: angular collenchyma and thin-walled parenchyma, some containing rosette aggregate crystals or reddish substance. Vascular tissue: phloem and xylem.

In surface view, the petiole shows rectangular epidermal cells; unicellular trichomes, rarely 2- to 3-cellular trichomes; and rosette aggregate crystals arranged in long chains.

Krathom in powder possesses the diagnostic microscopical characters of the unground drug. Two different types of rosette aggregate crystals, star-like shaped and globular shaped, and reddish substance in parenchyma cells are characteristic.

Packaging and storage Krathom shall be kept in well-closed containers, protected from light, and stored in a dry place.

Additional information

1. It may be highly addictive in some individuals. It may cause hyperpigmentation of the cheeks, tremor, anorexia, weight loss, and psychosis in those with long-term addiction.
2. It has been used traditionally as a sedative opium substitute, an aid to opium-use cessation, and as a stimulant to combat fatigue, depending on amount taken and individuals.
3. There are 3 strains of Krathom cultivated in Thailand, i.e., Kan Daeng, Taengkwa, and Yak Yai. Since the "Kan Daeng" strain is more popularly used, it is therefore employed in establishing this monograph.

Identification

A. Reflux 1 g of the sample, in powder, with 25 mL of *ethanol (80 per cent)* for 10 minutes, allow to cool and filter (solution 1). To 1 mL of solution 1, add a few drops of *iron(III) chloride TS*: a dark green colour develops.

B. Evaporate 1 mL of solution 1 to dryness. Dissolve the residue in 0.5 mL of a 10 per cent v/v solution of *sulfuric acid* and add a few drops of *modified Dragendorff TS2*: an orange precipitate is produced.

C. The chromatogram of the Sample preparation shows several peaks, one of which corresponds to the mitragynine peak of the Standard preparations, as obtained in the *Mitragynine content* (Fig. 3).

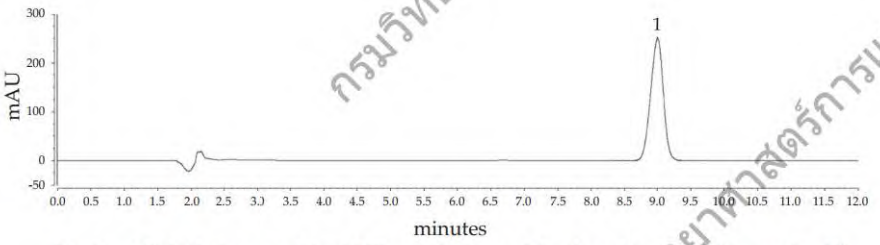


Fig. 3 High-Perfomance Liquid Chromatogram of Krathom Showing Mitragynine (1)

D. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel 60 F254* as the coating substance and a mixture of 50 volumes of *n hexane*, 50 volumes of *ethyl acetate*, and 7.5 volumes of *triethylamine* as the mobile phase and allowing the solvent front to ascend 9 cm above the line of application. Apply separately to the plate as bands of 8 mm, 5 µL each solutions (A) and (B). Prepare solution (A) by sonicating 100 mg of the sample, in powder, with 10 mL of *methanol* for 30 minutes and filtering. For solution (B), dissolve 1 mg of *mitragynine* in 1 mL of *methanol*. After removal of the plate, allow it to dry in air and examine the plate under ultraviolet light (254 nm), marking the quenching bands. The chromatogram obtained from solution (A) shows a quenching band (hR_f value 61 to 63), corresponding to the mitragynine band obtained from solution (B). Spray the plate with *modified Dragendorff TS2*; the band due to mitragynine is yellowish orange. Another yellowish orange band is also observed (Fig. 4).

Loss on drying Not more than 7.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Total ash Not more than 6.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 25.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 19.0 per cent w/w (Appendix 7.12).

Mitragynine content Not less than 1.0 per cent w/w of mitragynine ($C_{23}H_{30}N_2O_4$), calculated on the dried basis. Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Diluent Prepare a mixture of 8 volumes of *methanol* and 2 volumes of a 0.1 per cent v/v solution of *glacial acetic acid*.

Buffer solution Dissolve 1.54 g of *ammonium acetate* in 500 mL of *water*, adjust with *glacial acetic acid* to pH 6.0, and dilute to 1000.0 mL. Filter through a membrane having a 0.45-µm porosity.

Mobile phase Prepare a mixture of 65 volumes of *acetonitrile* and 35 volumes of *Buffer solution*. Filter through a membrane having a 0.45-µm porosity.

Standard preparations Dissolve a suitable quantity of Mitragynine RS in sufficient *Diluent* to obtain a stock solution having a known concentration of about 1 mg of mitragynine per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain five solutions having known concentrations of 10, 20, 40, 60, and 100 µg of mitragynine per mL. Filter through a membrane having a 0.45-µm porosity.

Sample preparation Transfer about 50 mg of Krathom, in *fine powder* and accurately weighed, to a 10-mL volumetric flask and add 7 mL of *Diluent*. Sonicate for 30 minutes, allow to cool to room temperature, and adjust to volume with the same solvent. Centrifuge the resulting solution at 3000 × *g* for 5 minutes. Transfer 5.0 mL of the supernatant to a 10-mL volumetric flask, dilute with *Dilent* to volume, and filter through a membrane having a 0.45-µm porosity.

Chromatographic procedure The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (5 µm), (b) *Mobile phase* at a flow rate of 1.0 mL per minute, and (c) an ultraviolet photometer set at 225 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 40 µg per mL, and record the peak response as directed under *Procedure* and *Calculation*: the relative standard deviation for replicate injections is not more than 2.0 per cent. The symmetry factor for mitragynine peak is not more than 1.5.

Procedure and **Calculation** Separately inject about 20 µL of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for the mitragynine peaks. Plot the readings and draw the standard curve of best fit: the curve shows the correlation coefficient of not less than 0.999. Inject about 10 µL of *Sample preparation* into the chromatograph, record the chromatogram and measure the response for mitragynine peak. By reference to the standard curve, calculate the content of mitragynine ($C_{23}H_{30}N_2O_4$) in the portion of the Krathom taken.

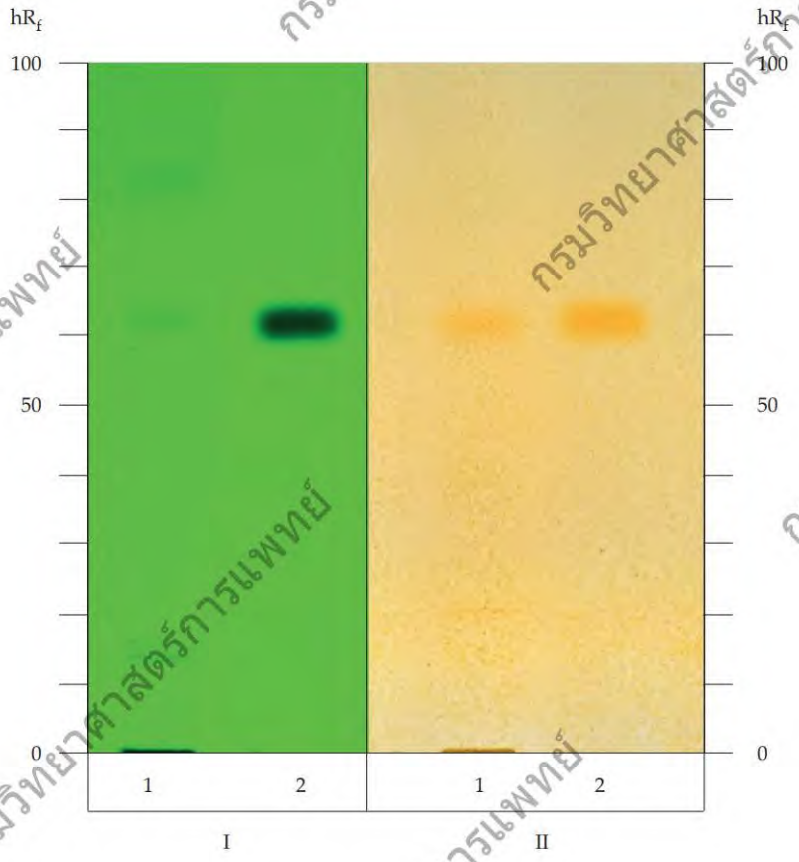


Fig. 4 Thin-Layer Chromatogram of Methanolic Extract of the Leaves of *Mitragyna speciosa* (Korth.) Havil.

1 = solution A
2 = solution B
I = detection under UV light (254 nm)
II = detection with *modified Dragendorff TS2*

โพคาน (PHO KHAN)

Malloti Repandi Caulis
Mallotus Repandus Stem

Category Analgesic, anti-inflammatory.

Mallotus Repandus Stem is the dried stem of *Mallotus repandus* (Rottler) Müll. Arg. [*Croton rhombifolius* Willd., *Mallotus scandens* (Span.) Müll. Arg., *Rottlera scabrifolia* A. Juss.] (Family Euphorbiaceae), Herbarium Specimen Number: DMSC 5264, Crude Drug Number: DMSc 1229.

Constituents Mallotus Repandus Stem contains phenolics such as bergenin. It also contains terpenoids, sterols, etc.

Description of the plant (Fig. 1) Scandent shrub or woody climber 2 to 10 m tall; dioecious; branchlet, petiole and inflorescence covered with yellowish to brownish simple and stellate hairs; glandular scale orange; stipule triangular, about 1 mm long, persistent or caducous. Leaves simple, alternate, ovate, triangular ovate to oblong-ovate, 2.2 to 11.4 cm long, 1.5 to 9 cm wide, apex acute or acuminate, base round to truncate, margin entire to somewhat denticulate with few glandular teeth, upper surface glabrescent, mainly hairy on nerves, with 2 to 4 extrafloral nectaries per side, lower surface light green, stellate-pubescent, with scattered yellowish granular glands, venation triplinerved, lateral veins 4 to 6 per side, ending to margin; petiole up to 8 cm long. Inflorescence terminal and axillary, solitary to groups of up to 4, sometimes branching; bract triangular, 1 to 1.6 mm long, about 1 mm wide. Male inflorescence up to 20 cm long; flowers in group up to 6 per node; male flower yellowish white to yellow; pedicel 3 to 3.5 mm long; sepals 3 or 4, elliptic, 2.8 to 3.2 mm long, 1 to 2 mm wide; stamens many, filament 1.8 to 2.2 mm long, anther about 0.6 mm long. Female inflorescence up to 12 cm long; female flower yellow; pedicel 1 to 2 mm long; calyx 3- or 4-lobed, about 3 mm long, lobe ovate, 2.3 to 2.8 mm long, 1 to 1.5 mm wide; ovary superior, dull light greenish, 2-loculed, densely hairy, glabrous, style brown, 0.3 to 0.4 mm long, stigma 3 to 4 mm long. Fruit a capsule, lobed, 6 to 8 mm long, about 1 cm wide, densely hairy. Seed subglobose, about 5 mm in diameter.

Description Odour, indistinct; tasteless.

Macroscopical (Fig. 1) Transverse or oblique pieces, 2 to 5 cm long, 1 to 4 cm in diameter; externally brown, longitudinally wrinkled and with numerous warty lenticels; internally off-white, light yellow or light brown.

Microscopical (Figs. 2a, 2b) Transverse section of the stem shows periderm, phloem tissue, xylem tissue, and pith. Periderm: numerous layers of rectangular cork cells, some containing brown substance. Phloem tissue: phloem ray, phloem parenchyma, and phloem fibres. Xylem tissue: xylem ray, vessels, xylem fibres, and primary xylem. Pith: parenchyma, some containing yellow substance or rosette aggregate crystals.

Mallotus Repandus Stem in powder possesses the diagnostic microscopical characters of the unground drug. Fibres and cork cells with brown substance are frequently seen.

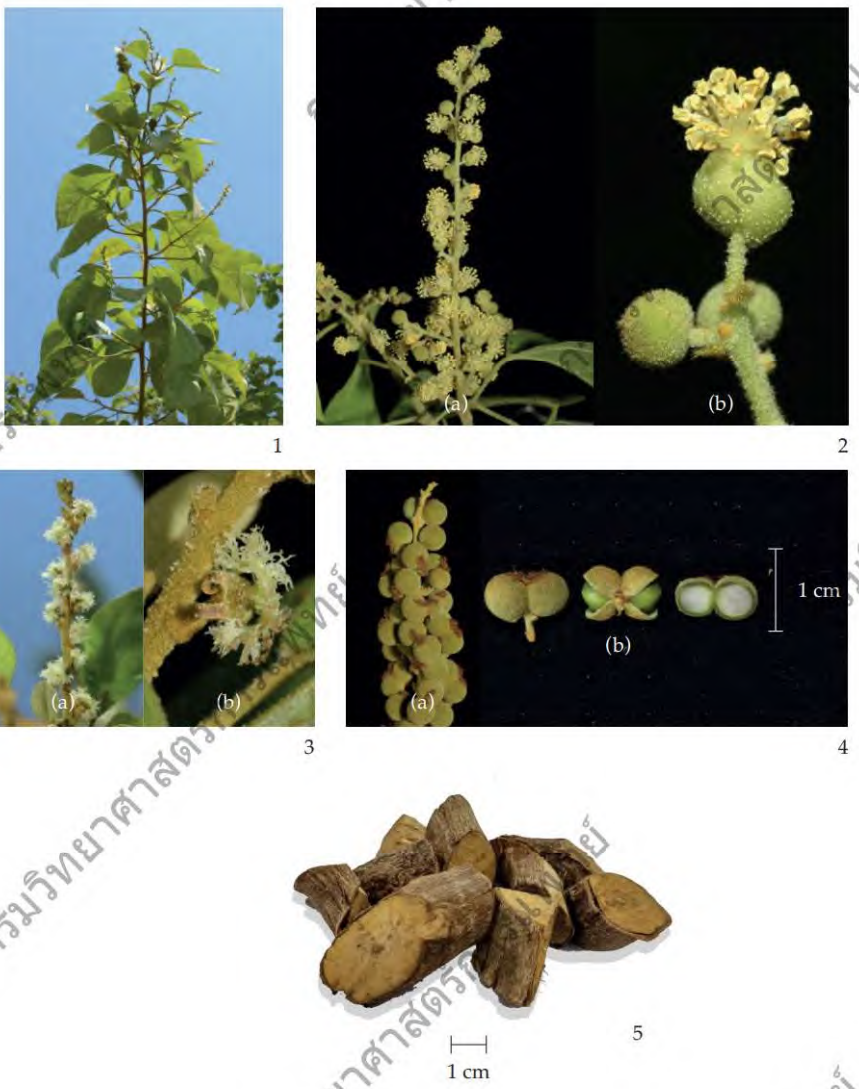


Fig. 1 *Mallotus repandus* (Rottler) Müll. Arg.
1. habit 2. male inflorescence (a) and male flowers (b) 3. female inflorescence (a) and female flowers (b) 4. infructescence (a) and fruits (b) 5. crude drug

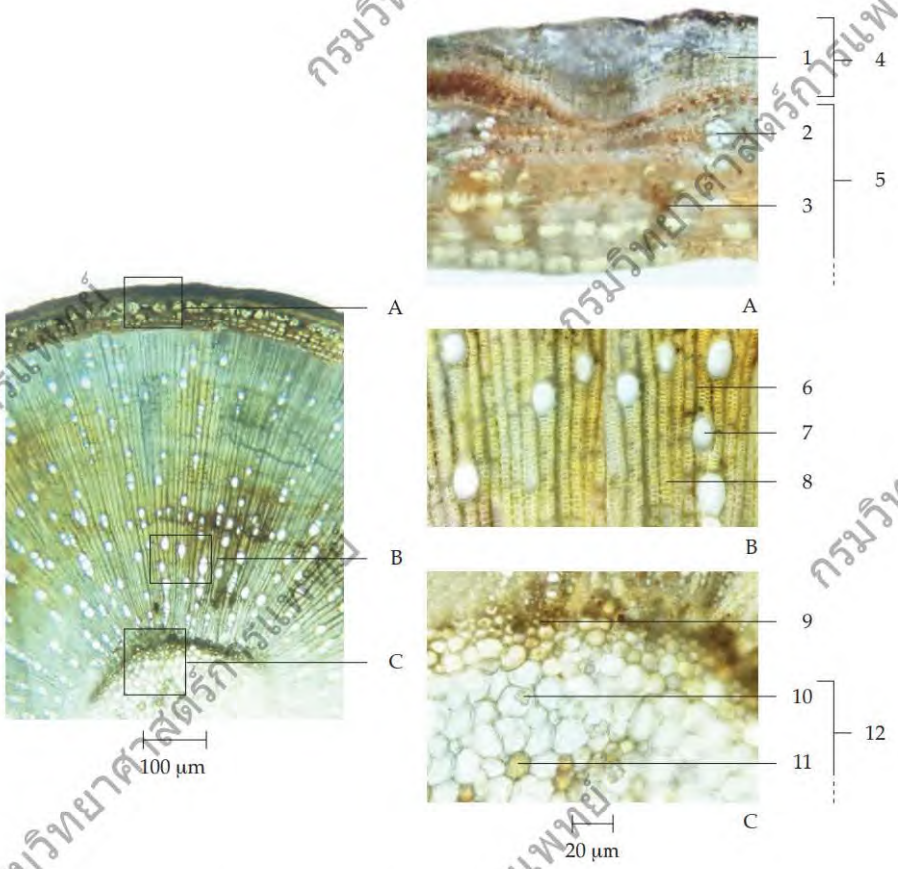


Fig. 2a Photomicrographs of Transverse Sections of the Stem of *Mallotus repandus* (Rottler) Müll. Arg.
A. Outer Part
B. and C. Inner Part

1. cork
2. phloem fibre
3. phloem ray
4. periderm
5. phloem
6. xylem ray
7. vessel
8. xylem fibre
9. primary xylem
10. rosette aggregate crystal
11. parenchyma containing yellow substance
12. pith

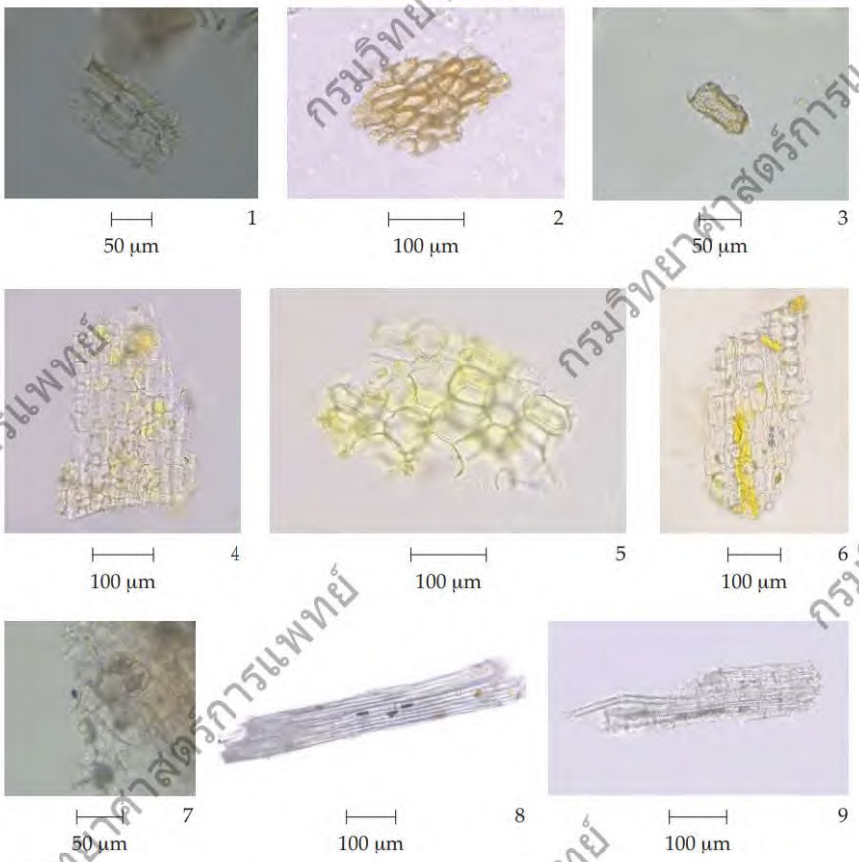


Fig. 2b Photomicrographs of Powdered Drug of the Stems of *Mallotus repandus* (Rottler) Müll. Arg.

1. cork in sectional view
2. cork in surface view
3. sclereid
4. parenchyma in longitudinal view, stained with aniline sulfate
5. parenchyma, stained with aniline sulfate
6. parenchyma, some containing rosette aggregate crystals and medullary ray, in tangential longitudinal view, stained with aniline sulfate
7. parenchyma, some containing rosette aggregate crystals
8. fibres
9. fibre and medullary ray in radial longitudinal view

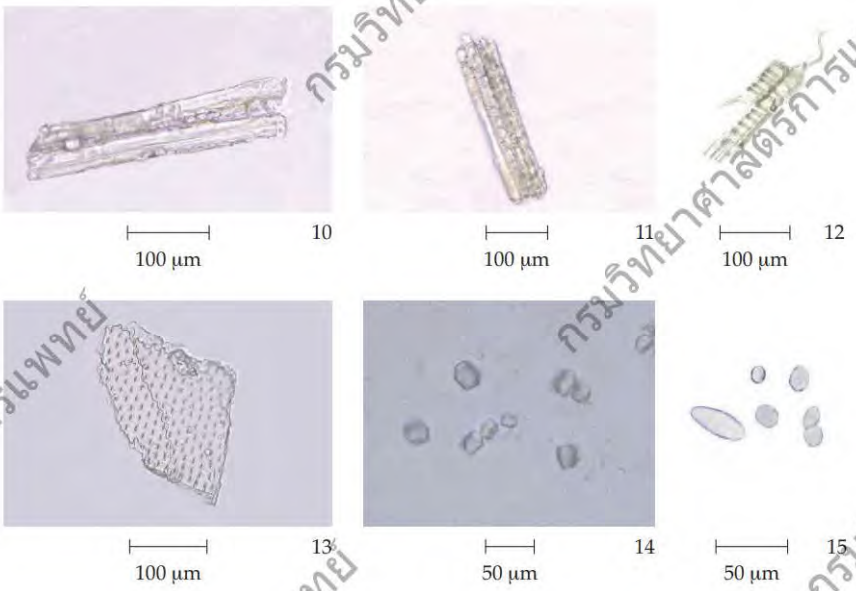


Fig. 2b (continued)

10. fibres and medullary ray in tangential longitudinal view with prismatic crystals
11. fibres and prismatic sheath
12. spiral vessels
13. bordered-pitted vessel
14. prismatic crystals
15. starch grains

Packaging and storage Mallotus Repandus Stem shall be kept in well-closed containers, protected from light, and stored in a dry place.

Identification

A. Heat 500 mg of the sample, in *coarse powder*, with 5 mL of *ethanol* on a water-bath for 10 minutes, allow to cool and filter. Place a few drops of the filtrate to a filter paper, allow the filter paper to dry, add 1 to 2 drops of a 20 per cent w/v solution of *sodium hydroxide*, and examine under ultraviolet light (366 nm): a blue fluorescence is detected.

B. Heat 500 mg of the sample, in *coarse powder*, with 10 mL of *water* on a water-bath for 10 minutes, allow to cool and filter. To 1 mL of the filtrate, add a few drops of a 1 per cent w/v solution of *iron(III) chloride*: a blue colour is produced.

C. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel F254* as the coating substance and a mixture of 70 volumes of *dichloromethane* and 30 volumes of *methanol* as the mobile phase. Apply separately to the plate as bands of 10 mm, 40 µL each of solutions (A) and (B). Prepare solution (A) by macerating 1 g of the sample, in *coarse powder*, with 3 mL of *methanol* for 1 hour and filtering. For solution (B), dissolve 1 mg of *bergenin* in 1 mL of *methanol*. After removal of the plate, allow it to dry in air and examine under ultraviolet light (254 nm), marking the quenching bands. The chromatogram obtained from solution (A) shows a quenching band (hR_f value 73 to 78) corresponding to the bergenin band from solution (B). Subsequently examine the plate under ultraviolet light (366 nm) through the cut-off filter; the band due to bergenin shows a light blue fluorescence; other one intense blue and two green fluorescent bands appear. Spray the plate with a 10 per cent w/v solution of *phosphomolybdic acid* in *ethanol* and heat at 105° for 10 minutes; the band corresponding to bergenin is brown and other two blue bands are observed (Fig. 3).

Loss on drying Not more than 9.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 1.0 per cent w/w (Appendix 7.6).

Total ash Not more than 8.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 3.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 5.0 per cent w/w (Appendix 7.12).

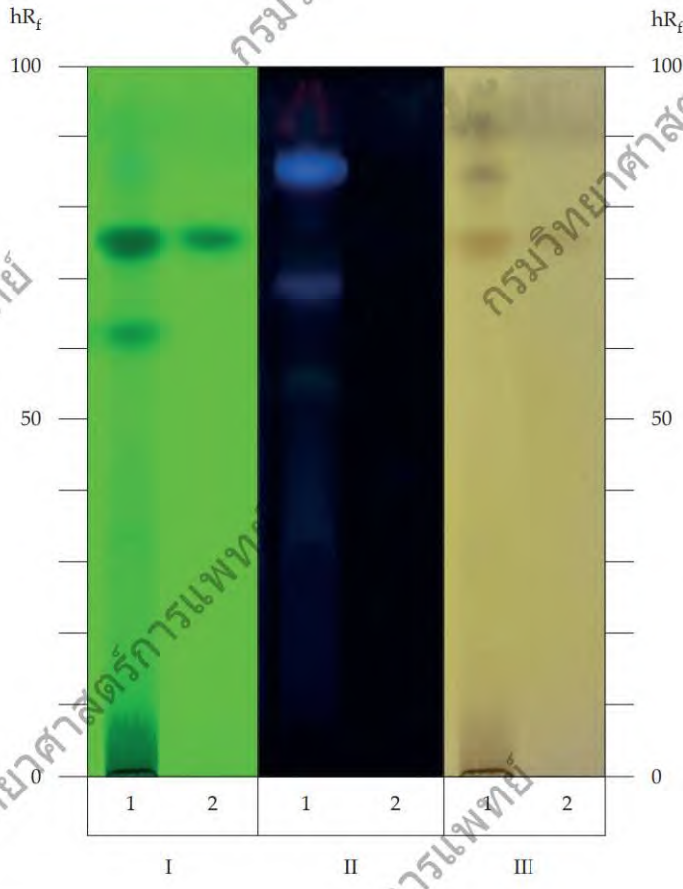


Fig. 3 Thin-Layer Chromatogram of Methanolic Extract of the Stems of *Mallotus repandus* (Rottler) Müll. Arg.

1 = solution (A)
2 = solution (B)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with a 10 per cent w/v solution of *phosphomolybdic acid* in *ethanol*

สะเดา, ใบ (SADAO, BAI)

เดา, ใบ (DAO, BAI); กะเดา, ใบ (KADAO, BAI); สะเลียม, ใบ (SALIAM, BAI)
Azadirachtae Siamensis Folium
Siamese Neem Leaf

Synonym Siamese Nim Leaf

Category Bitter tonic.

Siamese Neem Leaf is the dried leaflets of *Azadirachta indica* A. Juss. var. *siamensis* Valeton (Family Meliaceae), Herbarium Specimen Number: DMSC 5336, BK 070190, Crude Drug Number: DMSc 1230.

Constituents Siamese Neem Leaf contains tetranortriterpenoids (e.g., azadirachtin) and flavonoids (e.g., quercetin and rutin).

Description of plant (Fig. 1) Evergreen tree, up to 20 m tall; bark greyish brown, vertically striated. Leaves pinnately compound, spirally arranged, young leaves usually reddish; exstipulate; rachis 20 to 40 cm long; petiole 6 to 14 cm long, slender, swollen at base; leaflets 6 to 12 pairs, opposite or subopposite, leaflet at tip sometimes reduced; exstipellate; petiolule 4 to 7 mm long, slender, glabrous; lamina oblanceolate or broadly falcate, 6.5 to 12.5 cm long, 2.1 to 5.2 cm wide, apex acuminate, base oblique, margin serrate or serrate-undulate, coriaceous, glabrous, lateral nerves 8 to 13 pairs, slender, prominent, veinlets reticulate, fainted. Inflorescence panicle, axillary or terminal, up to 30 cm long, appearing before leaves. Flower white, bisexual, 1 to 1.5 cm in diameter; bracteole scaly; pedicel about 2 mm long; sepals 5, free, ovate; petals 5, free, obovate-oblong, hairy, imbricate in bud; stamens 10, connated into cylindrical staminal tube, about 6 mm long, terminally 10-lobed, glabrous outside, inside pubescent, anthers 10, attached at base of lobes inside, slightly exserted; ovary superior, globose, 3-loculed, ovules 2 per locule, placentation axile, style slender, elongate, stigma slightly 3-lobed. Fruit a drupe, oblong-ovoid, 1.5 to 2 cm long, 0.5 to 1 cm wide, green when young, yellow when ripe, shiny. Seeds 1 or 2.

Description Odour, green, characteristic; taste, bitter

Macroscopical (Fig. 1) A mixture of entire and broken, greenish brown to brown leaflets, without petiole and rachis. Complete leaflet, greenish to brown, oblanceolate or broad falcate, apex acuminate, base oblique, margin serrate or serrate-undulate, glabrous; petiolule 4 to 7 mm long, slender, glabrous.

Microscopical (Figs. 2a, 2b, 2c) Transverse section of the leaflet through midrib and lamina shows upper epidermis, mesophyll, vascular bundle, and lower epidermis. Upper epidermis: 1 to 2 layers of slightly thick-walled rectangular cells, idioblasts, some containing brownish yellow substance, rosette aggregate crystals, covered with cuticle layer. Mesophyll: palisade cells, 1 to 3 layers, cylindrical, some containing rosette aggregate crystals; spongy cells, irregularly shaped, loosely arranged, varied in size, some containing rosette aggregate crystals; angular collenchyma and parenchyma, some containing rosette aggregate crystals or starch grains, in the upper and lower parts of the midrib. Vascular bundle: xylem and phloem, found in midrib and mesophyll. Lower epidermis: 1 to 2 layers of rectangular cells, some containing rosette aggregate crystals, slightly raised stomata, and glandular trichomes, covered with cuticle layer.

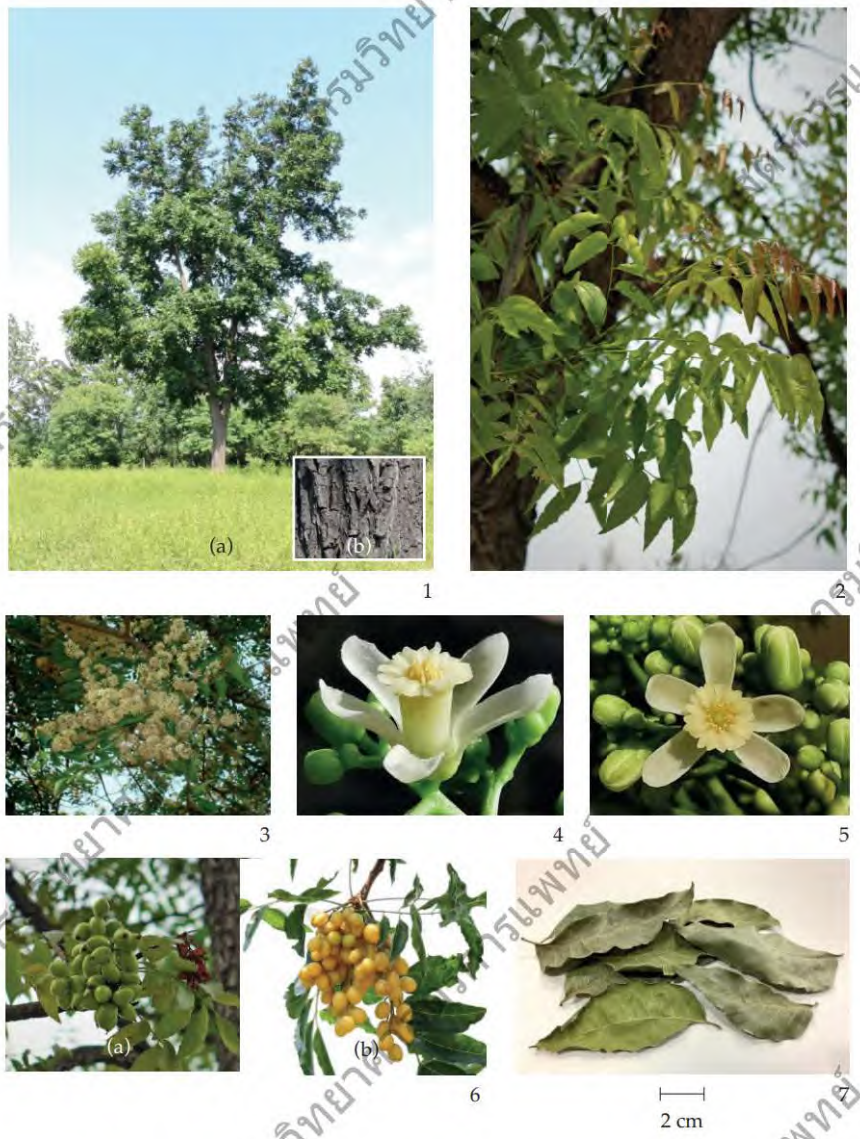
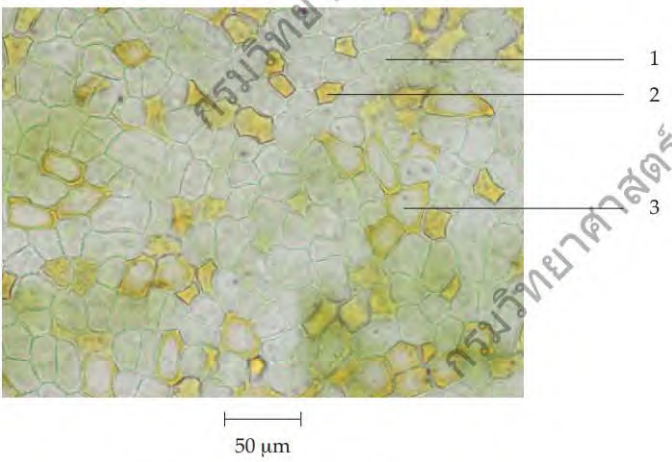
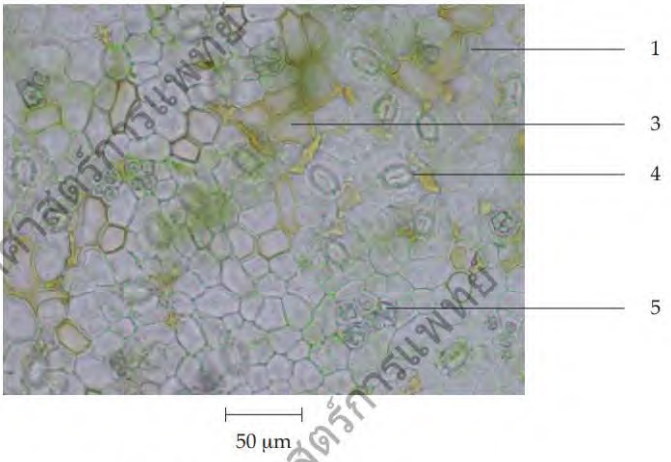


Fig. 1 *Azadirachta indica* A. Juss. var. *siamensis* Valeton
1. habit (a), bark (b) 2. stem and leaves 3. inflorescences 4. flower (side view) 5. flower (top view) 6. fruits, unripe (a), ripe (b) 7. crude drug



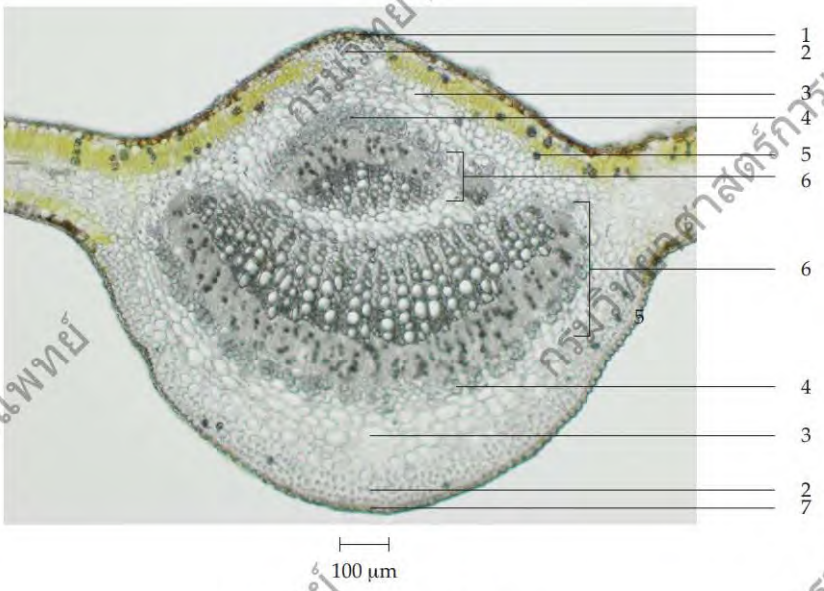
Upper Epidermis of the Lamina



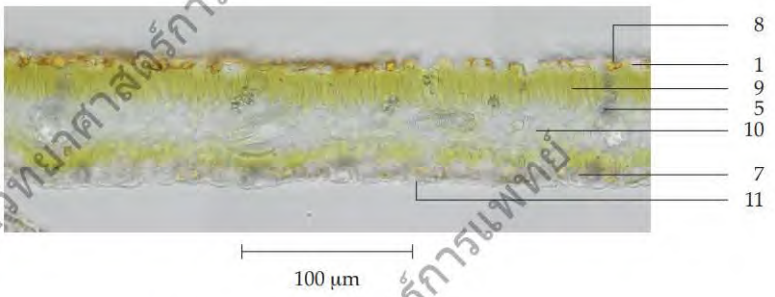
Lower Epidermis of the Lamina

Fig. 2a Photomicrographs of Epidermises of the Leaflet of *Azadirachta indica* A. Juss. var. *siamensis* Valeton

1. epidermal cell
2. brown substance
3. idioblast
4. stoma
5. rosette aggregate crystal



Transverse Section of the Midrib



Transverse Section of the Lamina

Fig. 2b Photomicrographs of Transverse Sections of the Leaflet of *Azadirachta indica* A. Juss. var. *siamensis* Valeton

1. upper epidermis
2. collenchyma
3. parenchyma
4. fibre
5. rosette aggregate crystal
6. vascular bundle
7. lower epidermis
8. brown substance
9. palisade cell
10. spongy cell
11. stoma

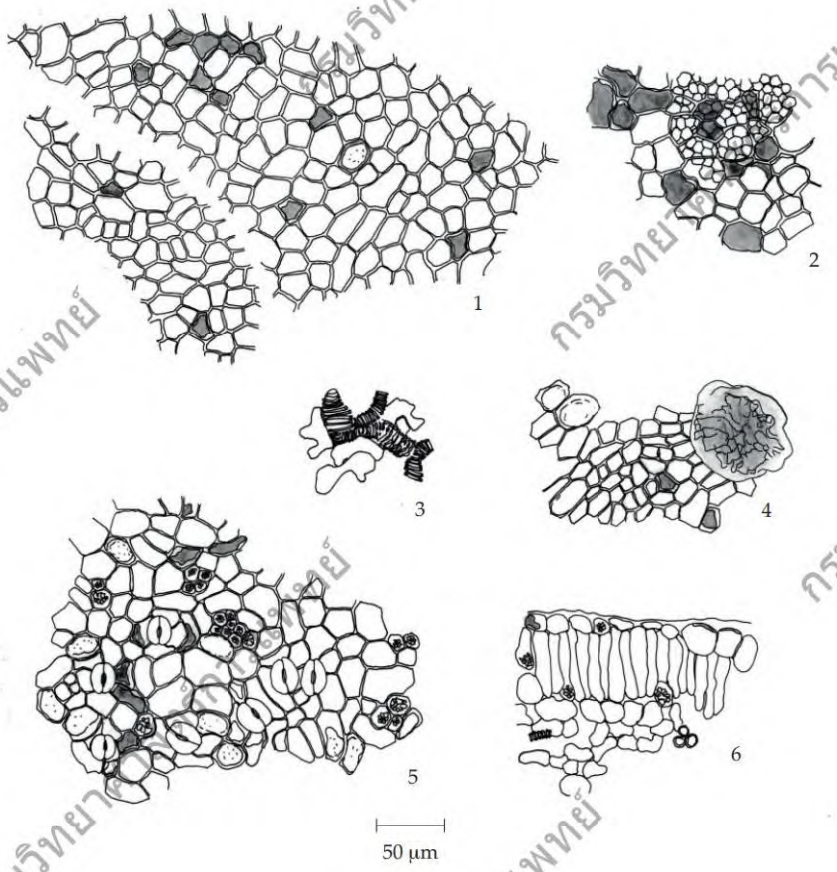


Fig. 2c Line Drawings of Powdered Drug of the Leaflets of *Azadirachta indica* A. Juss. var. *siamensis* Valeton

1. upper epidermis and idioblast, some containing brown substance
2. upper epidermis and idioblast, some containing brown substance and underlying palisade cells
3. spiral vessels associated with spongy cells
4. lower epidermis and idioblast, some containing brown substance, and glandular trichome
5. lower epidermis and idioblast, some containing brown substance or rosette aggregate crystals; and stomata
6. lamina in sectional view

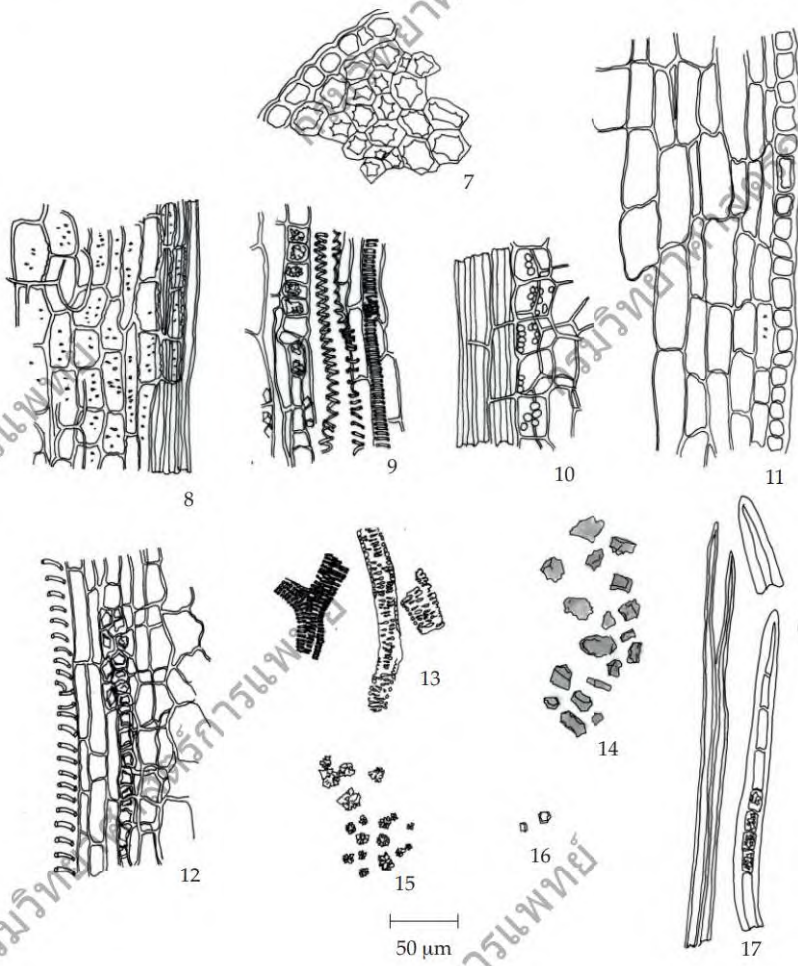


Fig. 2c (continued)

7. epidermis and collenchyma in sectional view
8. parenchyma associated with fibres in longitudinal view
9. parenchyma, some containing prismatic or rosette aggregate crystals, associated with spiral vessels and fibres in longitudinal view
10. parenchyma, some containing starch grains, associated with fibres in longitudinal view
11. epidermis and parenchyma of petiolule in longitudinal view
12. parenchyma, some containing prismatic crystals, associated with spiral vessel
13. spiral and pitted vessels
14. brown substances
15. rosette aggregate crystals
16. prismatic crystals
17. fibres

In surface view, upper and lower epidermises of the lamina show polygonal cells, some containing brown substance, idioblasts; stomata with 5 to 7 surrounding cells, some containing rosette aggregate crystals and glandular trichomes in the lower epidermis.

Siamese Neem Leaf in powder possesses the diagnostic microscopical characters of the unground drug. Both upper and lower epidermises with idioblast, some containing rosette aggregate crystals, and glandular trichome are characteristic.

Packaging and storage Siamese Neem Leaf shall be kept in well-closed containers, protected from light, and stored in a dry place.

Identification

A. Sonicate 5 g of the sample, in powder, with 30 mL of *acetone* for 30 minutes. Filter, discard the filtrate, and keep the marc. Extract the marc with the same solvent and procedure twice more. Further extract the marc with a mixture of 1 volume of a 1 per cent v/v solution of *sulfuric acid* and 100 volumes of a 40 per cent v/v solution of *absolute ethanol* by sonicating for 30 minutes and filter. Repeat the marc extraction two more times. Combine the resulting extracts (solution 1). To 1 mL of solution 1, add 1 piece of *magnesium ribbon*, shake well, and mix with 2 drops of *hydrochloric acid*: a faint pink colour develops.

B. To 200 mg of the sample, in powder, add 10 mL of *water*, heat in a water-bath for 10 minutes, and filter. To 2 mL of the filtrate, add a few drops of *iron(III) chloride TS*: a greenish blue colour is produced.

C. To 2.5 g of the sample, in powder, add 20 mL of *ethanol*, boil in a water-bath for 10 minutes and filter. To the filtrate, add 1 g of *decolorizing charcoal*, stir, and filter. Evaporate 3 mL of the filtrate to dryness, add 2 drops of a 2 per cent w/v solution of *3,5-dinitrobenzoic acid* in *methanol* and 2 drops of a 5.7 per cent w/v solution of *potassium hydroxide* in *methanol*: a purplish red colour develops.

D. To 500 mg of the sample, in powder, add 10 mL of *water*, heat in a water-bath for 10 minutes and filter. To 2 mL of the filtrate, add a few drops of a 1 per cent w/v solution of *gelatin* in a 10 per cent w/v solution of *sodium chloride*: a white precipitate is produced.

E. Shake vigorously 500 mg of the sample, in powder, with 10 mL of *water*: a long lasting foam is produced.

F. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel GF254* as the coating substance and a mixture of 40 volumes of *ethyl acetate*, 20 volumes of *dichloromethane*, 20 volumes of *methanol*, and 2 volumes of *formic acid* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply separately to the plate as bands of 8 mm, 10 µL of solution (A) and 5 µL of solution (B). For solution (A), use solution 1 as described in Identification A. For solution (B), dissolve 300 µg of *rutin* in 1 mL of *methanol*. After removal of the plate, allow it to dry in air, and examine the plate under ultraviolet light (254 nm), marking the quenching bands. The chromatogram obtained from solution (A) shows a quenching band (hR_f value 32 to 33), corresponding to the rutin band from solution (B). Examine the plate under ultraviolet light (366 nm); the band due to rutin is blue and other six blue fluorescent bands are also observed. Heat the plate at 80° for at least 10 minutes and spray the plate with *natural products (NP) TS* while the plate is still warm. Subsequently spray the plate with *polyethyleneglycol (PEG) TS* and observe the colours of the bands under ultraviolet light (366 nm) within 5 to 15 minutes; the band due to rutin is orange and other four orange bands are also observed. Examine the plate under ultraviolet light (366 nm); the band due to rutin shows orange fluorescence. Other four orange and four blue fluorescent bands are also observed (Fig. 3).

Loss on drying Not more than 11.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 1.0 per cent w/w (Appendix 7.6).

Total ash Not more than 12.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 5.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 20.0 per cent w/w (Appendix 7.12).

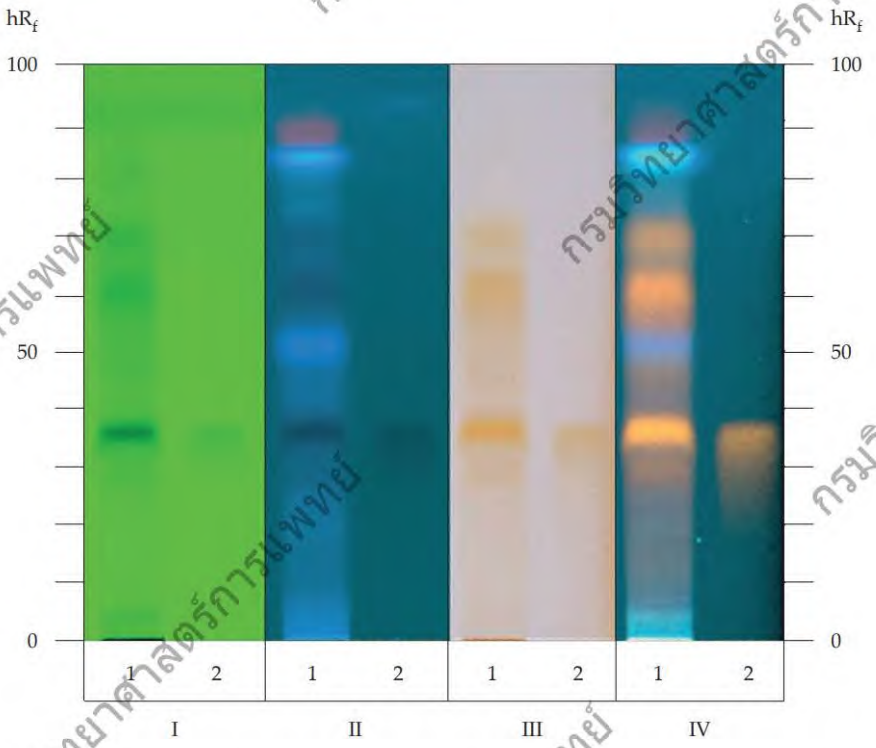


Fig. 3 Thin-Layer Chromatogram of the Extract of the Leaves of *Azadirachta indica* A. Juss. var. *siamensis* Valeton

1 = solution (A)
2 = solution (B)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with *NP/PEG TS*
IV = detection under UV light (366 nm) after spraying with *NP/PEG TS*

สะเดา, เปลือกต้น (SADAO, PLUEAK TON)

เดา, เปลือกต้น (DAO, PLUEAK TON); กะเดา, เปลือกต้น (KADAO, PLUEAK TON); สะเลียม, เปลือกต้น (SALIAM, PLUEAK TON)
Azadirachtae Siamensis Cortex
Siamese Neem Bark

Synonym Siamese Nim Bark

Category Antipyretic, anti-dysentery.

Siamese Neem Bark is the dried stem bark of *Azadirachta indica* A. Juss. var. *siamensis* Valeton (Family Meliaceae), Herbarium Specimen Number: DMSC 5311, Crude Drug Number: DMSc 1231.

Constituents Siamese Neem Bark contains tetranortriterpenoids (e.g., nimbin and 6-deacetylnimbin) and phenolics (e.g., catechin and epicatechin).

Description of the plant (Fig. 1) Evergreen tree, up to 20 m tall; bark greyish brown, vertically striated. Leaves pinnately compound, spirally arranged, young leaves usually reddish; exstipulate; rachis 20 to 40 cm long; petiole 6 to 14 cm long, slender, swollen at base; leaflets 6 to 12 pairs, opposite or subopposite, leaflet at tip sometimes reduced; exstipellate; petiolule 4 to 7 mm long, slender, glabrous; lamina oblanceolate or broadly falcate, 6.5 to 12.5 cm long, 2.1 to 5.2 cm wide, apex acuminate, base oblique, margin serrate or serrate-undulate, coriaceous, glabrous, lateral nerves 8 to 13 pairs, slender, prominent, veinlets reticulate, fainted. Inflorescence panicle, axillary or terminal, up to 30 cm long, appear before leaves. Flower white, bisexual, 1 to 1.5 cm in diameter; bracteole scaly; pedicel about 2 mm long; sepals 5, free, ovate; petals 5, free, obovate-oblong, hairy, imbricate in bud; stamens 10, connated into cylindrical staminal tube, about 6 mm long, terminally 10-lobed, glabrous outside, inside pubescent, anthers 10, attached at base of lobes inside, slightly exserted; ovary superior, globose, 3-loculed, ovules 2 per locule, placentation axile, style slender, elongate, stigma slightly 3-lobed. Fruit a drupe, oblong-ovoid, 1.5 to 2 cm long, 0.5 to 1 cm wide, green when young, yellow when ripe, shiny. Seeds 1 or 2.

Description Odour, unpleasantly characteristic; taste, bitter.

Macroscopical (Fig. 1) Irregular pieces of stem bark, varying in shape and size, mostly curved, hard; externally greyish brown to dark brown, rough, irregularly cracked; internally yellowish brown to reddish brown, with fine longitudinal striations.

Microscopical (Figs. 2a, 2b) Transverse section of the stem bark shows periderm and phloem tissue. Periderm: lenticels, rectangular cork cells with brown substance and groups of sclereids some containing reddish brown to brown substance. Phloem tissue: polygonal parenchyma some containing starch grains or prismatic crystals, groups of sclereids some containing reddish brown to brown substance, bast fibres some containing prismatic crystals, and phloem rays.

Siamese Neem Bark in powder possesses the diagnostic microscopical characters of the unground drug. Rectangular cork cells with reddish brown to brown substance, sclereids containing reddish brown to brown substance, phloem rays containing starch grains, and fibres with prismatic sheath are characteristic.

Packaging and storage Siamese Neem Bark shall be kept in well-closed containers, protected from light, and stored in a dry place.

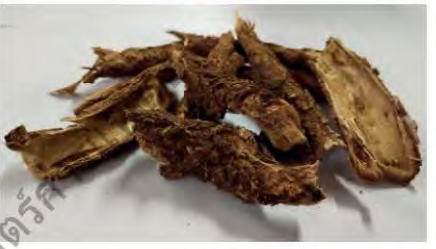
1

2

3

4

5



6

1 cm

Fig. 1 *Azadirachta indica* A. Juss. var. *siamensis* Valeton
1. habit (a) and bark (b) 2. flowering branches 3. flowers
4. blooming flower (side view) and flower buds 5. ripe fruits 6. crude drug

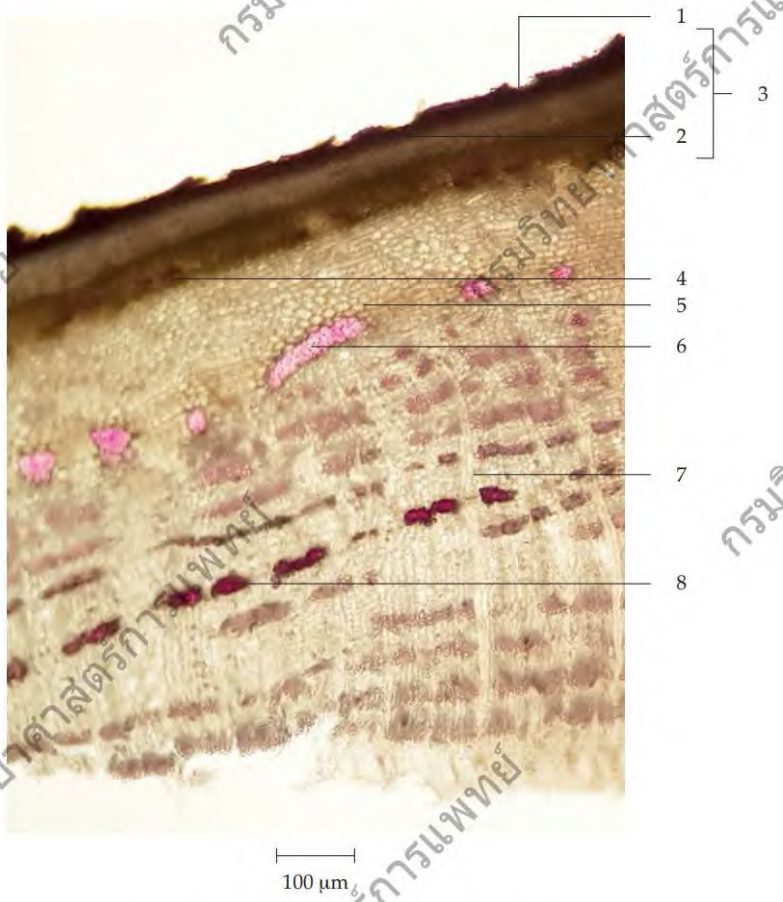


Fig. 2a Photomicrograph of Transverse Section of the Stem Bark of *Azadirachta indica* A. Juss. var. *siamensis* Valeton

1. lenticel
2. cork
3. periderm
4. sclereid
5. parenchyma
6. bast fibre
7. phloem ray
8. group of sclereids with reddish brown to brown substance

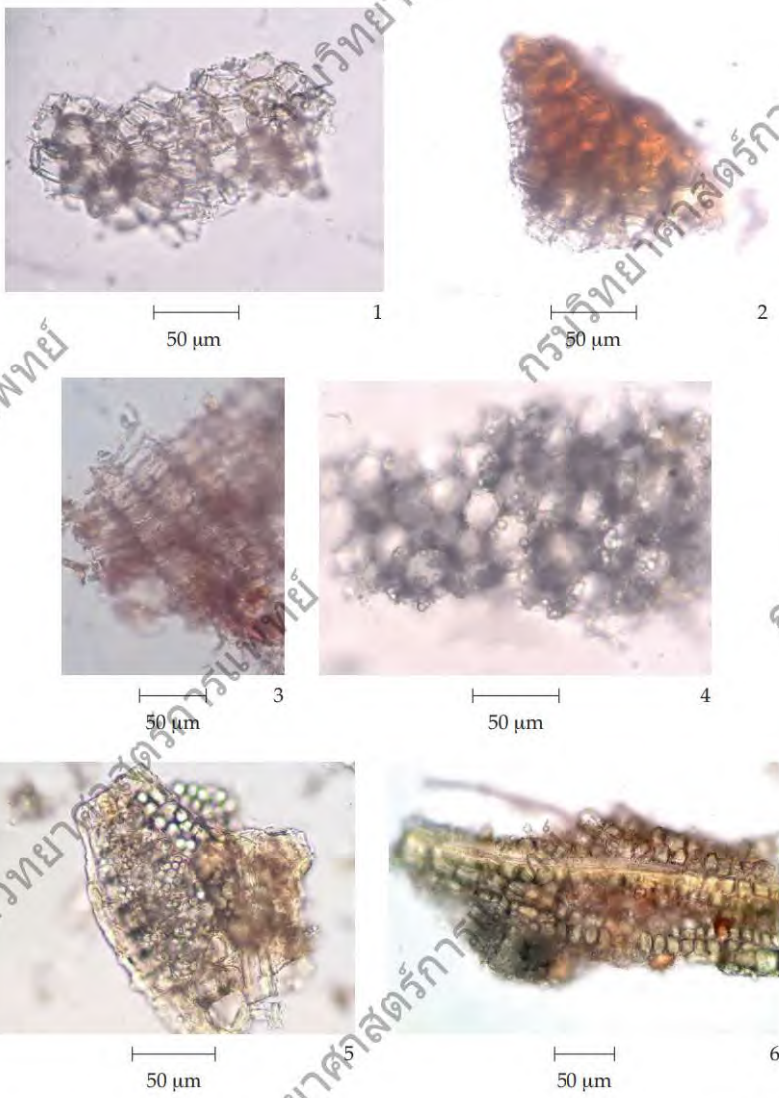


Fig. 2b Photomicrographs of Powdered Drug of the Stem Barks of *Azadirachta indica* A. Juss. var. *siamensis* Valeton

1. cork in surface view
2. cork in surface view, some containing brown substance
3. cork in sectional view
4. parenchyma, some containing starch grains
5. phloem ray in tangential longitudinal view, some containing starch grains or prismatic crystals
6. medullary ray in tangential longitudinal view, with fibres and prismatic sheath

Fig. 2b (continued)

7. medullary ray in radial longitudinal view, with fibres and prismatic sheath
8. sclereids containing reddish brown to brown substance
9. various-sized and -shaped sclereids
10. simple and compound starch grains, prismatic crystals and sclereid
11. reddish brown substance

Identification

A. Reflux 2 g of the sample, in *fine powder*, with 20 mL of *ethyl acetate* for 1 hour and filter (solution 1). Evaporate 5 mL of solution 1 to dryness and dissolve the residue in a few drops of *acetic anhydride*. Add slowly a few drops of *sulfuric acid*: a reddish brown colour is produced.

B. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel 60 F254* as the coating substance and a mixture of 49 volumes of *hexane*, 49 volumes of *ethyl acetate*, and 2 volumes of *methanol* as the mobile phase and allowing the solvent front to ascend 10 cm above the line of application. Apply separately to the plate as bands of 8 mm, 10 µL each of solutions (A) and (B). Prepare solution (A) by evaporating 5 mL of solution 1 to dryness and dissolve the residue in 1 mL of *dichloromethane*. For solution (B) dissolve 1 mg of 6-*deacetylnimbin* in 1 mL of *dichloromethane*. After removal of the plate, allow it to dry in air and spray with a 10 per cent v/v solution of *sulfuric acid* in *ethanol* and heat at 110° for 5 minutes; the band due to 6-deacetylnimbin is brownish black (hR_f value about 40). One pink and five brown bands are observed (Fig. 3).

Loss on drying Not more than 10.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Total ash Not more than 12.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 3.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 5.0 per cent w/w (Appendix 7.12).

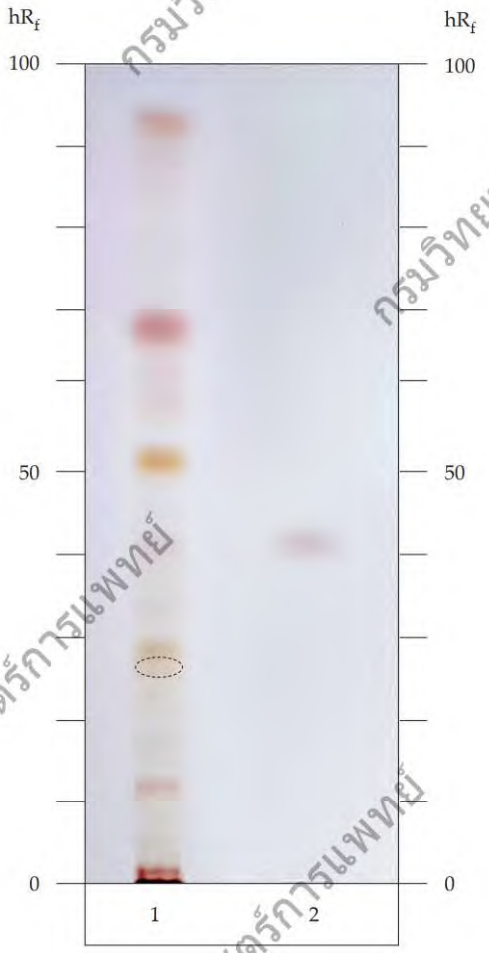


Fig. 3 Thin-Layer Chromatogram of Ethyl Acetate Extract of the Stem Barks of *Azadirachta indica* A. Juss. var. *siamensis* Valeton, Detected With a 10 Per Cent V/V Solution of *Sulfuric Acid* in *Ethanol*

1 = solution (A)
2 = solution (B)
⬭ = band developed in some samples

ทับทิม, เปลือกผล (THAPTHIM, PLUEAK PHON)

มะเก๊าะ, เปลือกผล (MAKO, PLUEAK PHON); พิลา, เปลือกผล (PHILA, PLUEAK PHON)
Punicae Granati Pericarpium
Pomegranate Peel

Category Antidiarrheal, antidysentery.

Pomegranate Peel is the dried pericarp of *Punica granatum* L. (*P. nana* L.) (Family Lythraceae), Herbarium Specimen Number: DMSC 5334, Crude Drug Number: DMSc 1232.

Constituents Pomegranate Peel contains hydrolysable tannins (e.g., punicalin and punicalagin) and phenolic acids (e.g., ellagic acid and gallic acid). It also contains alkaloids, flavonoids, etc.

Description of the plant (Fig. 1) Deciduous tree or shrub, 1.5 to 7(–10) m tall, much-branched, especially near base; bark dark grey, glabrous; branches opposite, slender, 4-angled when young, becoming terete with age; branchlet usually ending in spine or sometimes leaf-bearing. Leaves simple, opposite or subopposite, lanceolate, elliptic-oblanceolate or oblong, 1 to 9 cm long, 0.5 to 2.5 cm wide, apex acute, obtuse or emarginate, base cuneate or attenuate, margin entire, upper surface glabrous, shiny, lower surface with prominent midrib; petiole 0.2 to 1 cm long. Flowers solitary or in terminal and axillary cluster of 1 to 6, sessile or subsessile; calyx tube orange-red or pale yellow, campanulate to urceolate, 2 to 3 cm long, 1 to 1.5 cm wide, lobes 5 to 9, triangular; petals 5 to 9, obovate, apex obtuse, thin and crinkled, red, white or variegated; stamens numerous, included or exserted, filament different in length, anther yellow; ovary inferior, glabrous, 8- to 13-loculed, each locule with numerous ovules. Fruit a berry, globose with persistent calyx at apex, 5 to 13 cm in diameter, varied in colour, from yellow green, red, to black-violet. Seeds numerous, obpyramidal, juicy, red, pink or yellowish sarcotesta.

Description Odour, mild; taste, astringent.

Macroscopical (Fig. 1) Irregular pieces of pericarp, varied in shape and size, 1 to 3 mm thick, brittle; externally reddish brown, brownish yellow to dark brown, somewhat lustrous, rough, with numerous warty protuberances, occasionally with raised tubular persistent calyx and a short, stout peduncle or its scar; internally yellow to reddish brown with raised reticulate remnants of the peduncle, brittle, fracture yellow and somewhat granular.

Microscopical (Figs. 2a, 2b) Transverse section of the pericarp shows epidermis, lenticel, cork, parenchyma, sclereid, and vascular tissue. Epidermis: a layer of yellow or yellowish brown thick-walled epidermal cells covered with thick cuticle layer and several layers of hypodermal sclereids. Lenticel and cork layer: several layers of thin-walled rectangular cells. Parenchyma: several layers of slightly thick-walled polygonal cells, some containing starch grains, rosette aggregates, and/or prismatic crystals. Sclereid: solitary or in small groups. Vascular tissue: secondary phloem and xylem.

Pomegranate Peel in powder possesses the diagnostic microscopical characters of the unground drug. Yellow or yellowish brown epidermal cells, various sizes and shapes of thick-walled sclereids, and rosette aggregate and prismatic crystals are present. Starch grains are found in abundance.

Fig. 1 *Punica granatum* L.
1. habit 2. flowers 3. close-up flower 4. longitudinal section of flower
5. fruits 6. crude drug

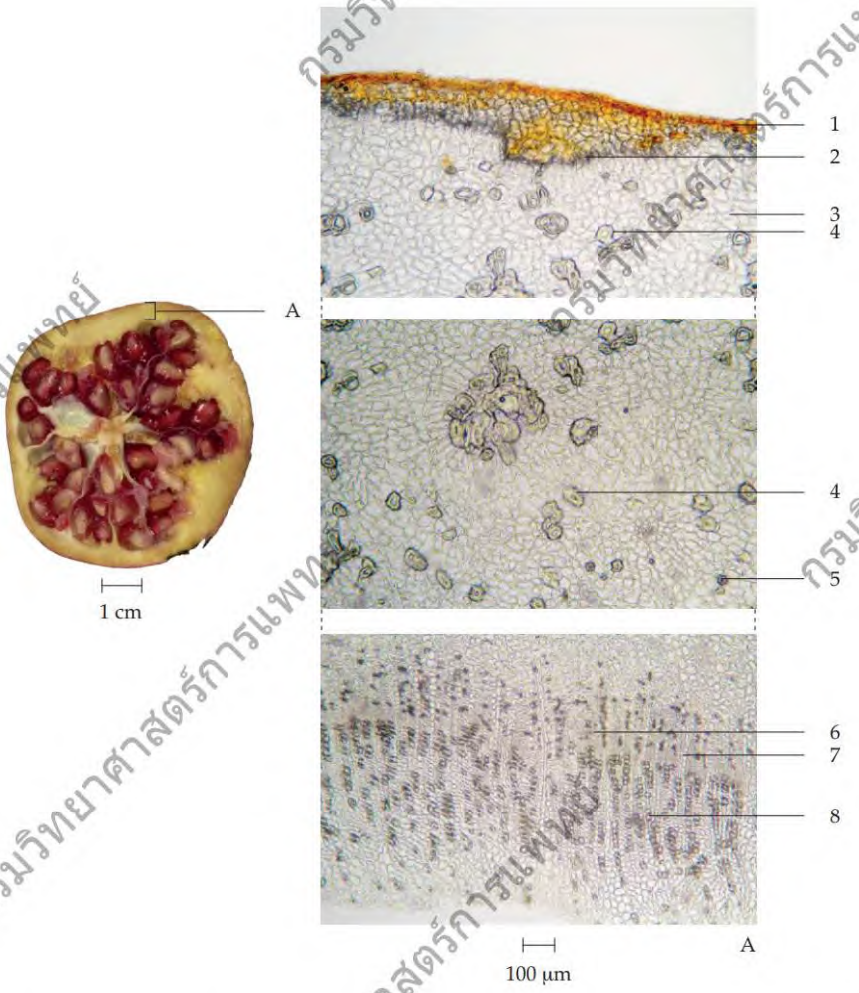


Fig. 2a Photomicrograph of Transverse Section of the Pericarp of *Punica granatum* L.
A. Transverse Section of Pericarp
1. epidermis
2. cork
3. parenchyma
4. sclereid
5. rosette aggregate crystal
6. phloem
7. phloem ray
8. vessel

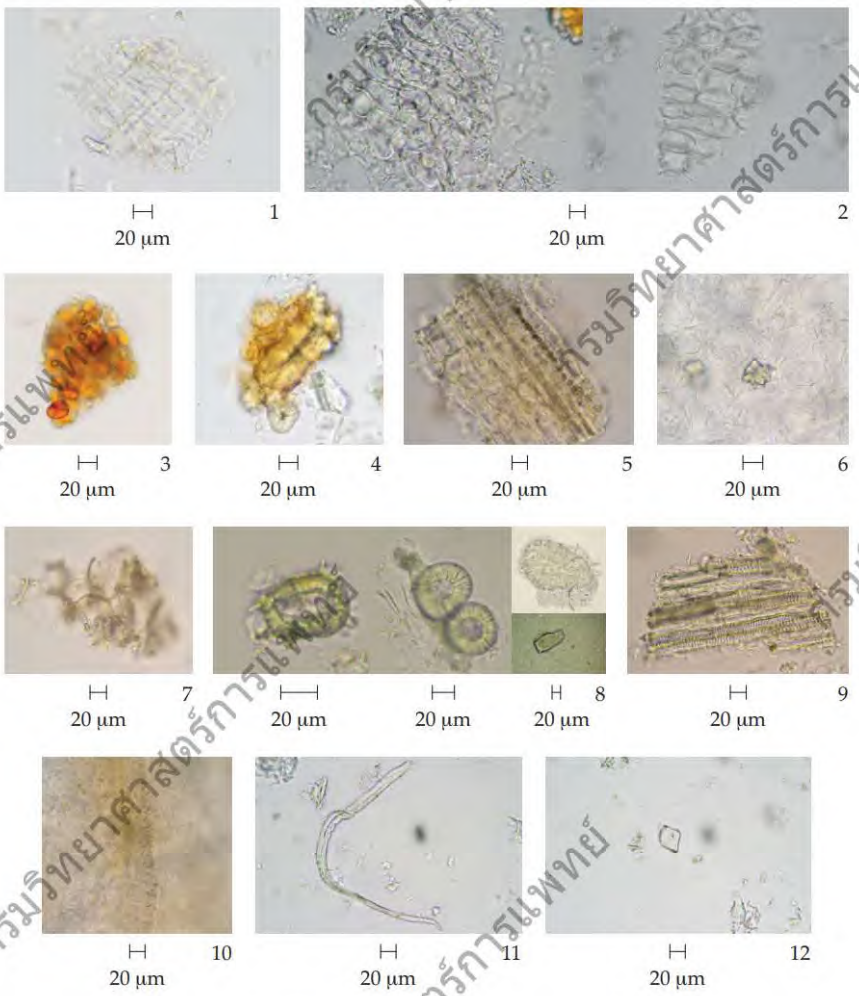


Fig. 2b Photomicrographs of Powdered Drug of the Pericarps of *Punica granatum* L.

1. cork in sectional view
2. parenchyma
3. yellowish brown epidermis
4. yellowish epidermis associated with sclereid
5. parenchyma containing rosette aggregate crystals in longitudinal view
6. rosette aggregate crystal
7. parenchyma containing starch grains
8. various shapes and sizes of sclereids
9. reticulate and pitted vessels
10. spiral vessel and parenchyma
11. fibre
12. prismatic crystal

Packaging and storage Pomegranate Peel shall be kept in well-closed containers, protected from light, and stored in a cool and dry place.

Identification

A. Sonicate 5 g of the sample, in powder, with 100 mL of *ethanol* for 30 minutes and filter. Evaporate the filtrate to dryness, dissolve the residue in 10 mL of *ethanol* upon warming and filter. To 1 mL of the filtrate, add a few drops of a 1 per cent w/v solution of *iron(III) chloride* and shake well: a blue-green colour develops.

B. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel F254* as the coating substance and a mixture of 50 volumes of *toluene*, 40 volumes of *ethyl acetate*, and 10 volumes of *formic acid* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply separately to the plate as bands of 6 mm, 2 µL each of solutions (A) and (B). Prepare solution (A) by sonicating 500 mg of the sample, in *No. 250 powder*, with 10 mL of *ethanol* and filter. For solution (B) dissolve 1 mg of *gallic acid* in 1 mL of *methanol*. After removal of the plate, allow it to dry in air. Examine the plate under ultraviolet light (254 nm), marking the quenching bands. The chromatogram obtained from solution (A) shows a quenching band (hR_f value 39 to 41), corresponding to the gallic acid band obtained from solution (B). Subsequently spray the plate with *anisaldehyde TS* and heat at 105° for 10 minutes; the band corresponding to gallic acid is violet. Two brown and four violet bands are also observed (Fig. 3).

Loss on drying Not more than 11.0 per cent w/w after drying 5 g at 105° for 5 hours (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 0.5 per cent w/w (Appendix 7.6).

Total ash Not more than 5.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 17.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 36.0 per cent w/w (Appendix 7.12).

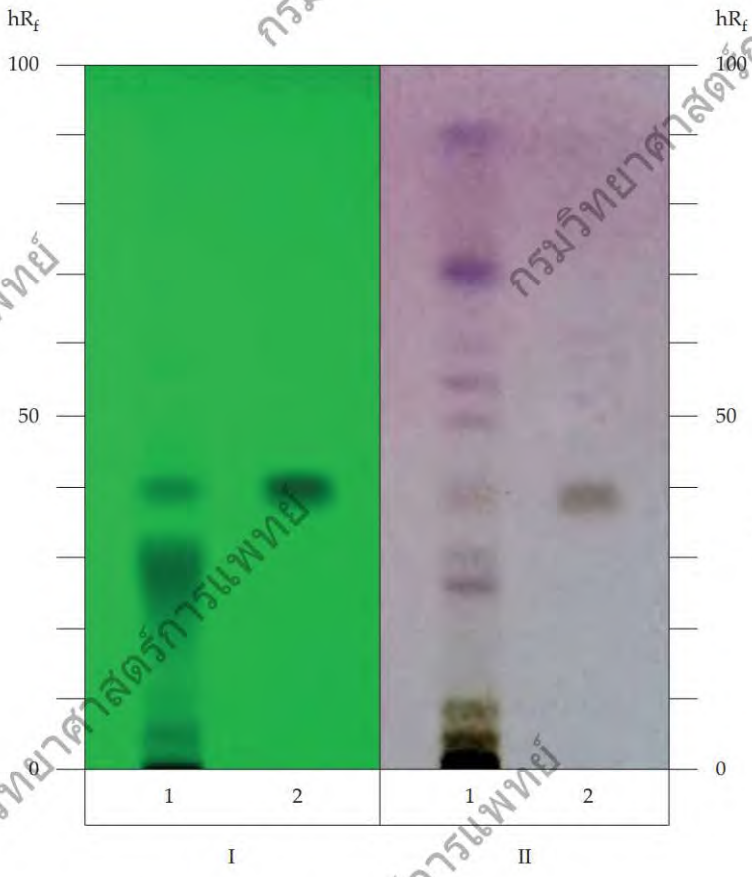


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Pericarps of *Punica granatum* L.
1 = solution (A)
2 = solution (B)
I = detection under UV light (254 nm)
II = detection with *anisaldehyde TS*

ทองพันชั่ง, ราก (THONG PHAN CHANG, RAK)

ทองคันชั่ง, ราก (THONG KHAN CHANG, RAK); หญ้ามันไก่, ราก (YA MAN KAI, RAK)
Rhinacanthi Nasuti Radix
Snake Jasmine Root

Synonyms Dainty Spur Root, White Crane Flower Root

Category Antifungal (topical).

Snake Jasmine Root is the dried root of *Rhinacanthus nasutus* (L.) Kurz (*Justicia nasuta* L., *Rhinacanthus communis* Nees) (Family Acanthaceae), Herbarium Specimen Number: DMSC 5263, Crude Drug Number: DMSc 1173.

Constituents Snake Jasmine Root contains naphthoquinones (e.g., rhinacanthin A, rhinacanthin B, and rhinacanthin C). It also contains triterpenoids, flavonoids, etc.

Description of the plant (Fig. 1) Subshrub, up to 2 m tall; stem erect, stout, quadrangular, much branched, finely striated, densely pubescent when young, becoming glabrescent with age; young branch hairy. Leaves simple, opposite decussate, ovate-elliptic, elliptic to lanceolate, 6 to 12 cm long, 2 to 5 cm wide, apex acute to shortly acuminate, base cuneate or attenuate, margin entire or slightly undulate, abaxially densely pubescent, adaxially sparsely pubescent to subglabrous, secondary veins 5 or 6 pairs; petiole 1 to 1.5 cm long. Inflorescence paniculate, terminal or axillary, up to 50 cm long; rachis densely pubescent; bract lanceolate, about 2 mm long, about 0.5 mm wide; bracteole minute. Flower white to greenish white, bilabiate, sessile to subsessile; calyx 5 to 6 mm long, deeply 5-lobed, lobe lanceolate, up to 4 mm long, about 0.7 mm wide, both surfaces pubescent, outer surface with glandular trichome; corolla tube 1.5 to 2.5 cm long, upper lip upright, oblong, 8 to 9 mm long, 2 to 3 mm wide, revolute, lower lip obovate, 3-lobed, with red marking at base, 1 to 1.5 mm long, 1 to 1.3 mm wide; stamens 2, attached to apex of corolla tube, filament short, glabrous; ovary superior, elliptic, 2-loculed, each locule 2-ovuled, style slender, sparsely pubescent, stigma 2-lobed. Fruit a capsule, oblong-elliptic, 1.5 to 2 cm long, about 2 mm wide. Seeds 4, subglobose, about 2.5 mm in diameter, papillose.

Description Odour, characteristic; taste, bland to slightly bitter.

Macroscopical (Fig. 1) Cylindrical, up to 4 mm in diameter, with small lateral roots, greyish brown; surface with longitudinal wrinkles.

Microscopical (Figs. 2a, 2b, 2c) Transverse section of primary growth of the root shows epidermis, cortex, vascular tissue, and pith. Epidermis: 1 to 2 layers of polygonal cells with greenish brown cell wall. Cortex: numerous round parenchyma, some containing cystoliths or microcrystals; red liquid substance in intercellular space of parenchyma; and 1 to 2 layers of endodermis. Vascular tissue: 1 to 2 pericycle layers; vascular bundle, alternate; and 5 arches of xylem tissues and phloem tissues. Pith: thin-walled round parenchyma.

Transverse section of secondary growth of the root illustrates periderm, cortex, and vascular tissue. Periderm: numerous layers of rectangular cork cells. Cortex: numerous round parenchyma; lithocyst, oblong parenchyma, some containing microcrystals; red liquid substance in intercellular space; and crushed brown layers of endodermis cells. Vascular tissue: secondary phloem comprising parenchyma and groups of sclereids; secondary xylem consisting of vessels, xylem ray and xylem fibres; and primary vascular tissue in the centre.

Snake Jasmine Root in powder possesses the diagnostic microscopical characters of the unground drug. Lithocysts, cystoliths, and reddish substance are characteristic.

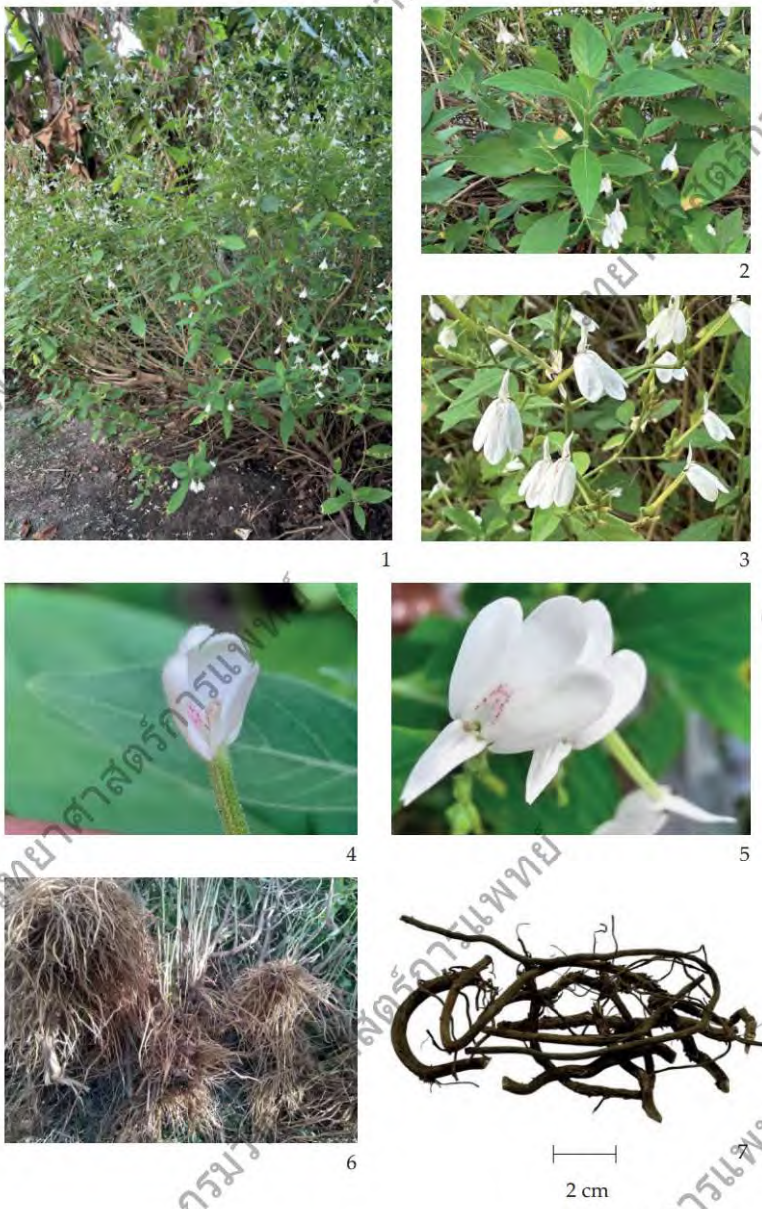


Fig. 1 *Rhinacanthus nasutus* (L.) Kurz
1. habit 2. leaves and flowers 3. part of inflorescences 4. partially bloomed flower 5. flowers (top view) 6. fresh roots 7. crude drug

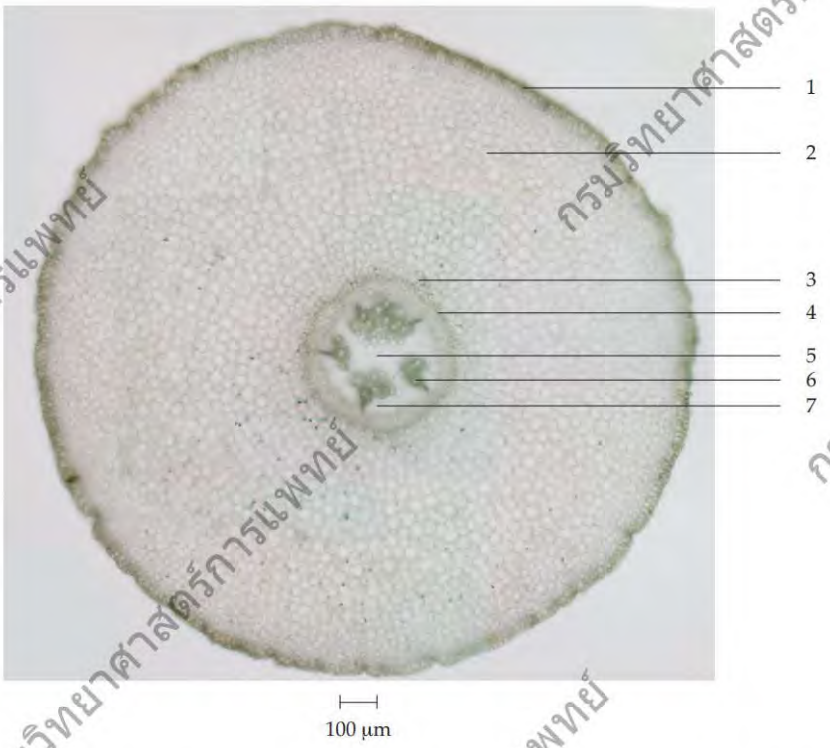


Fig. 2a Photomicrograph of Transverse Section of Primary Growth of the Root of *Rhinacanthus nasutus* (L.) Kurz

1. epidermis
2. parenchyma
3. endodermis
4. pericycle
5. pith
6. primary xylem
7. primary phloem

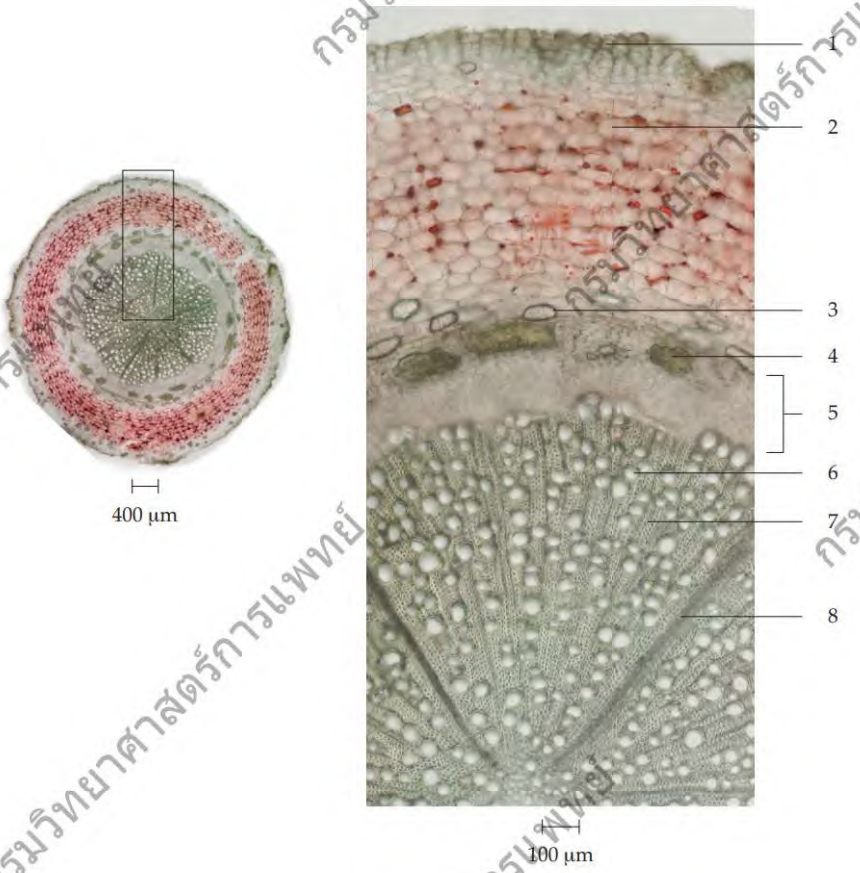


Fig. 2b Photomicrographs of Transverse Section of Secondary Growth of the Root of *Rhinacanthus nasutus* (L.) Kurz

1. cork
2. parenchyma
3. cystolith
4. sclereid
5. secondary phloem
6. vessel
7. xylem fibre
8. xylem ray

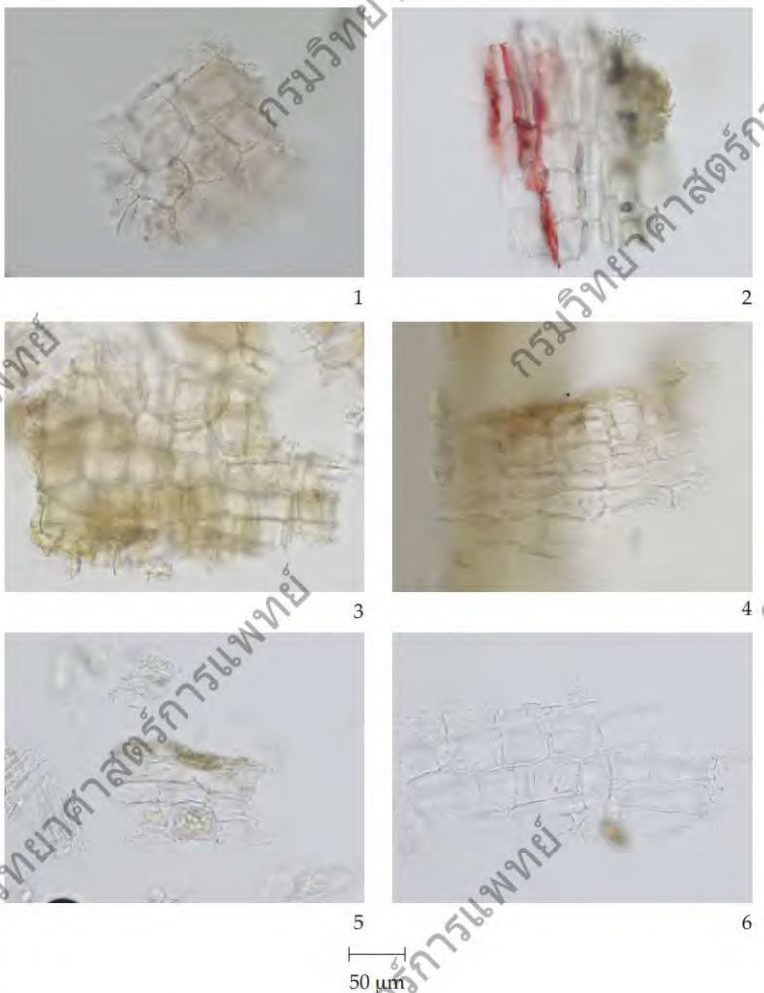


Fig. 2c Photomicrographs of Powdered Drug of the Roots of *Rhinacanthus nasutus* (L.) Kurz

1. parenchyma
2. reddish substance in intercellular space of parenchyma
3. cork in surface view
4. cork in sectional view
5. parenchyma and cystolith
6. parenchyma, some containing microcrystals

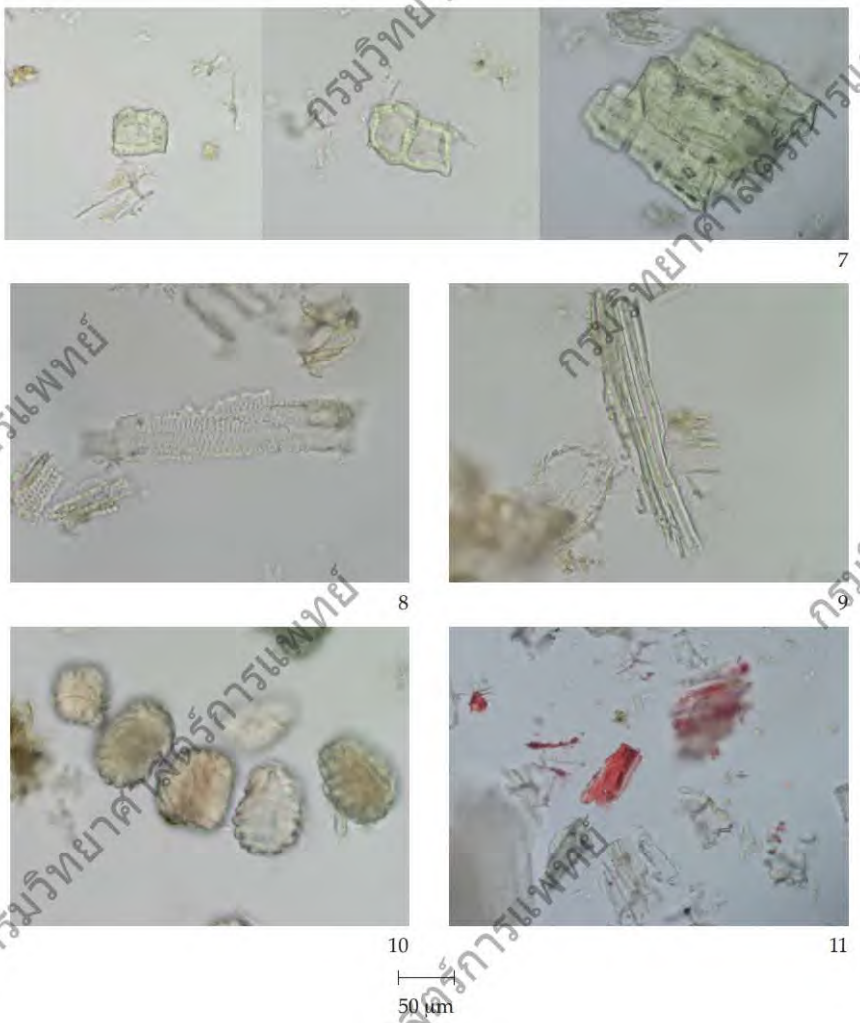


Fig. 2c (continued)

7. sclereids
8. bordered-pitted vessel
9. fibres
10. cystoliths
11. reddish substances

Packaging and storage Snake Jasmine Root shall be kept in well-closed containers, protected from light, and stored in a dry place.

Identification

A. To 1 g of the sample, in powder, add 20 mL of *chloroform*, heat in a water-bath for 5 minutes, and filter immediately, and allow to cool (solution 1): a reddish solution is obtained.

B. To 10 mL of solution 1, add 10 mL of *ammonia TS* and shake: the aqueous layer becomes pale orange-brown.

C. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel G F254* as the coating substance and a mixture of 70 volumes of *hexane* and 30 volumes of *ethyl acetate* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply to the plate as a band of 8 mm, 20 µL of the test solution, prepared by sonicating 100 mg of the sample, in *fine powder*, with 2 mL of *methanol* for 10 minutes and filtering. After removal of the plate, allow it to dry in air and examine the plate under ultraviolet light (254 nm), marking the quenching bands. Examine the plate under ultraviolet light (366 nm) through the cut-off filter; one brown and three blue fluorescent bands are observed. Subsequently spray the plate with the solution prepared by dissolving 500 mg of *vanillin* in 40 mL of *sulfuric acid*, adding 10 mL of *ethanol*, and mixing. Then heat at 105° for 10 minutes. Two brown and three purple bands are observed (Fig. 3).

Loss on drying Not more than 9.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 2.0 per cent w/w (Appendix 7.6).

Total ash Not more than 16.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 7.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 35.0 per cent w/w (Appendix 7.12).

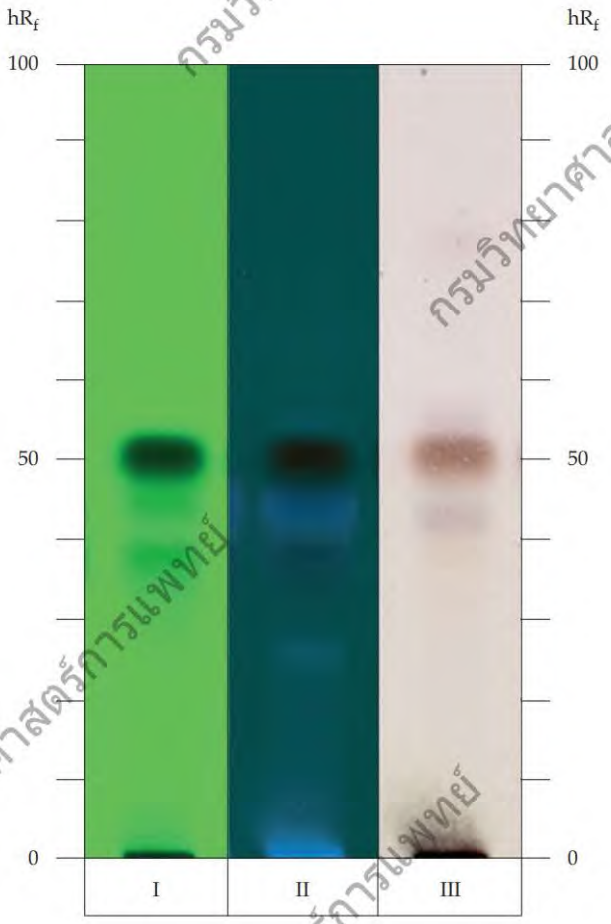


Fig. 3 Thin-Layer Chromatogram of Methanolic Extract of the Roots of *Rhinacanthus nasutus* (L.) Kurz
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with the vanillin-sulfuric acid solution as described in Identification C

ตองแตก (TONG TAEK)

Baliospermi Solanifolii Radix
Baliospermum Solanifolium Root

Category Mild laxative, anthelmintic.

Baliospermum Solanifolium Root is the dried root of *Baliospermum solanifolium* (Burm.) Suresh [*B. axillare* Blume, *B. montanum* (Willd.) Müll. Arg., *Croton solanifolius* Burm.] (Family Euphorbiaceae), Herbarium Specimen Number: DMSC 5310, Crude Drug Number: DMSc 1233.

Constituents Baliospermum Solanifolium Root contains phorbol esters (e.g., baliospermin, 12-deoxyphorbol-13-palmitate, and montanin) and propiophenones. It also contains triterpenoids, flavonoids, sterols, etc.

Description of the plant (Fig. 1) Monoecious (rarely dioecious) shrub 1 to 3 m tall; branched at base, young branch green, appressed pubescent, glabrous at maturity. Leaves simple, alternate, ovate to oblong, 8 to 21 cm long, 3 to 10 cm wide, apex obtuse or acute, base usually rounded, rarely cuneate, margin serrate or crenate, 2- to 5-lobed, chartaceous, glabrous or strigose on both surfaces, venation basally 3- to 5-nerved, nerves 6 to 8 pairs along midrib, basally with 2 glands; petiole 1 to 13 cm long. Inflorescence paniculate, axillary and terminal; male inflorescence 1 to 8(–16) cm long; female inflorescence up to 1 cm long. Flower whitish green to yellowish; sepals 5 to 6, connate at base; petal absent. Male flowers many, 2 to 3 mm in diameter; pedicel 0.2 to 1.2 cm long; sepal orbicular to ovate, about 1.5 mm long, about 1 mm wide; disc annular, cup-shaped, 1 to 1.5 mm in diameter; stamens 10 to 12, filament 0.5 to 1 mm long, anther oblong. Female flowers 1 to 3, axillary or inserted at the base of male inflorescence, 2 to 4 mm in diameter; pedicel 0.2 to 1.1 cm long; sepal ovate or triangular, 1 to 2 mm long, 0.8 to 1 mm wide, externally pubescent; ovary superior, subglobose, 1 to 3 mm in diameter, pubescent, style stout, stigmas 3, widening into shortly split wings. Fruit a 3-lobed capsule, septicidally and loculicidally dehiscent, pendulous, subglobose, 0.8 to 1.3 cm in diameter, pubescent; calyx persistent, accrescent up to (3–)5 mm long, up to 2(–3) mm wide. Seed ovoid, 3 to 6 mm long and about 3 mm wide, marbled, carunculate.

Description Odour, mild; taste bland.

Macroscopical (Fig. 1) Pieces of cylindrical roots, some with lateral roots. Externally dark brown to greyish brown, longitudinally wrinkled or furrowed. Texture hard and tough; bark brown to dark brown or, wood pale yellow.

Microscopical (Figs. 2a, 2b) Transverse section of the root shows periderm and vascular tissue. Periderm: several layers of thin-walled rectangular cork cells. Vascular tissue: phloem tissue, polygonal parenchyma cells containing rosette aggregate crystals or starch grains, phloem ray, and laticifers; vascular cambium, several layers of thin-walled rectangular cells; xylem tissue, vessels, xylem rays, mostly uniseriate, occasionally 2- to 3-seriate, fibres, and parenchyma containing starch grains or rosette aggregate crystals.

Fig. 1 *Baliospermum solanifolium* (Burm.) Suresh
1. Leaves 2. flowering branches showing male flowers, female flowers and young fruit
3. female flower (a) and young male flower (b) 4. male flowers
5. dehiscing fruit 6. seeds 7. crude drug

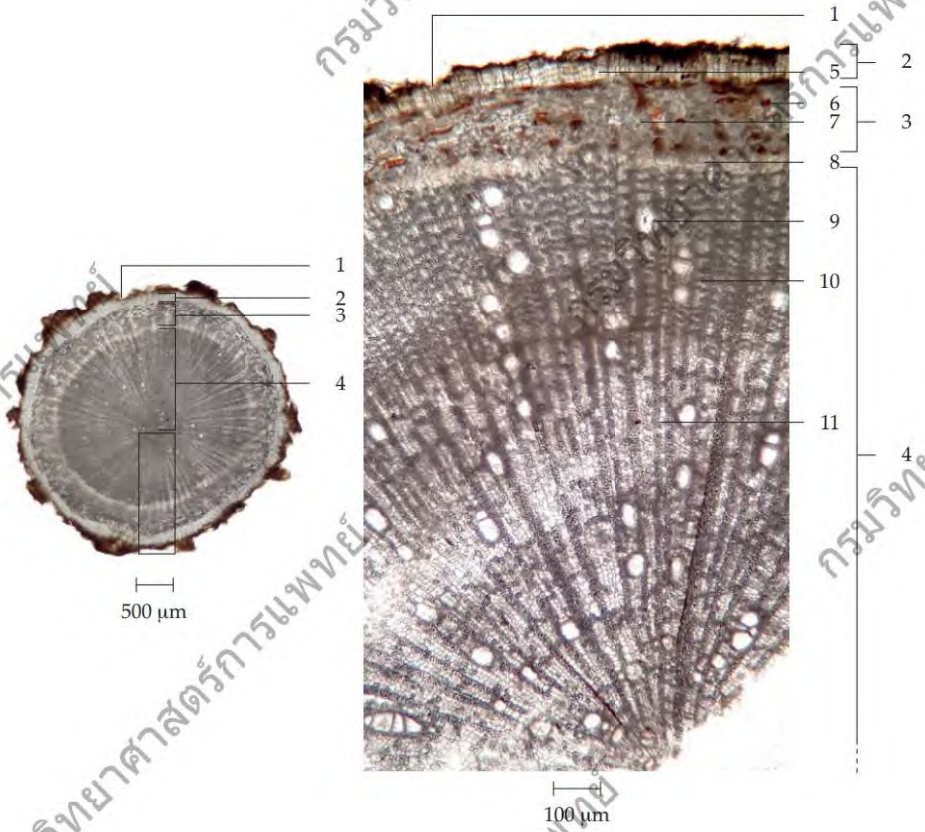


Fig. 2a Photomicrographs of Transverse Section of the Root of *Baliospermum solanifolium* (Burm.) Suresh

1. lenticel
2. periderm
3. phloem
4. xylem
5. cork
6. laticifer
7. phloem parenchyma
8. vascular cambium
9. vessel
10. xylem fibre
11. xylem ray containing starch grains

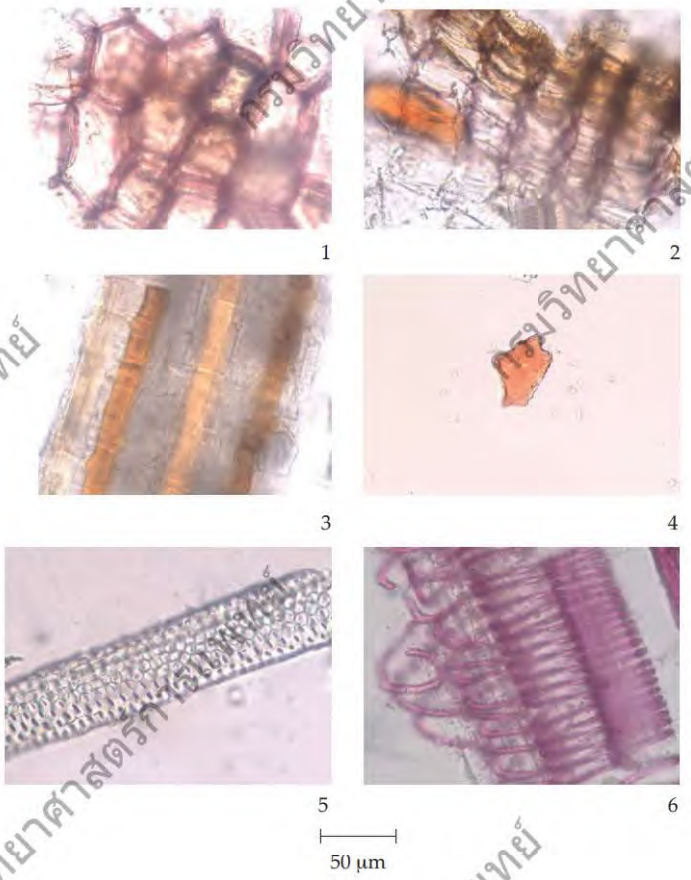


Fig. 2b Photomicrographs of Powdered Drug of the Roots of *Baliospermum solanifolium* (Burm.) Suresh

1. cork in surface view
2. cork in sectional view
3. phloem parenchyma and laticifers in longitudinal view
4. resinous substance
5. bordered-pitted vessel
6. spiral and reticulate vessels, stained with phloroglucinol and hydrochloric acid

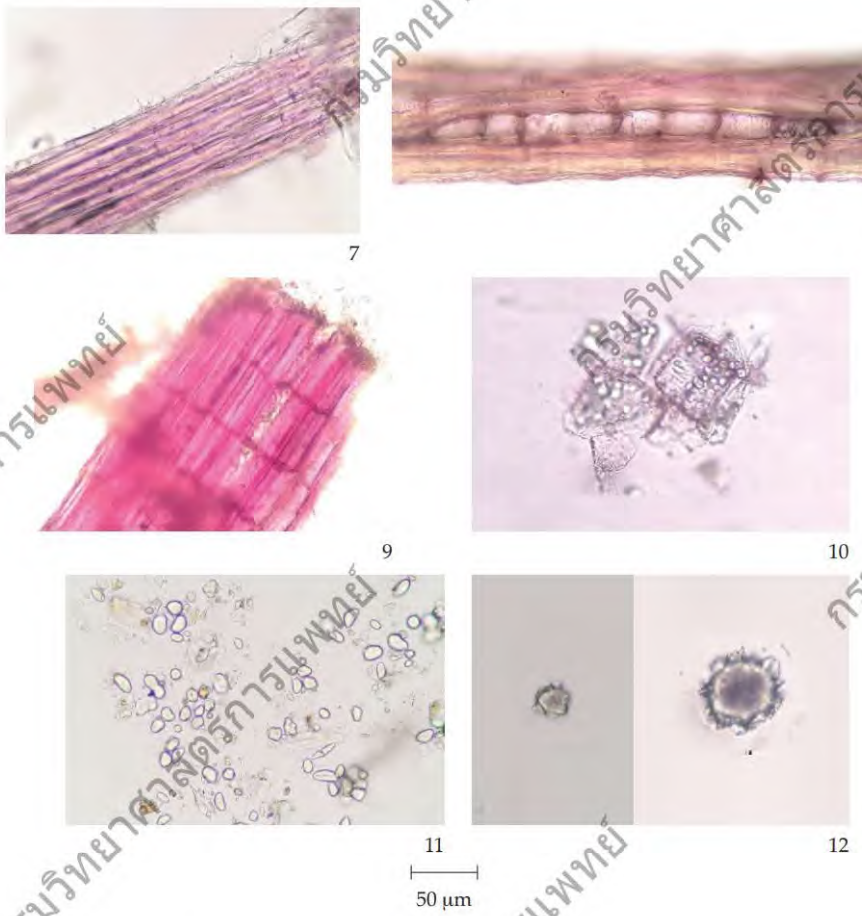


Fig. 2b (continued)

7. group of fibres, stained with phloroglucinol and hydrochloric acid
8. fibres and uniseriate xylem ray in tangential longitudinal view, stained with phloroglucinol and hydrochloric acid
9. xylem rays in radial longitudinal view, stained with phloroglucinol and hydrochloric acid
10. pitted parenchyma containing starch grains, stained with phloroglucinol and hydrochloric acid
11. various-shaped and -sized starch grains
12. rosette aggregate crystals

Baliospermum Solanifolium Root in powder possesses the diagnostic microscopical characters of the unground drug. Various-shaped and -sized starch grains, various-sized rosette aggregate crystals, pitted parenchyma containing starch grains, laticifers, and uniseriate xylem ray are characteristic.

Packaging and storage Baliospermum Solanifolium Root shall be kept in well-closed containers, protected from light, and stored in a dry place.

Identification

A. To 2 g of the sample, in *fine powder*, add 20 mL of *ethanol*, shake for 5 minutes and filter (solution 1). To 10 mL of solution 1, add 4 or 5 pieces of *magnesium ribbon*, shake well, and mix with a few drops of *hydrochloric acid*: a pale pink colour develops.

B. To 1 mL of solution 1, add a few drops of a 2.5 per cent w/v solution of *iron(III) chloride* and shake well: a black-blue colour develops.

C. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel 60 F254* as the coating substance and a mixture of 98 volumes of *dichloromethane* and 2 volumes of *methanol* as the mobile phase and allowing the solvent front to ascend 10 cm above the line of application. Apply to the plate as a band of 8 mm, 10 µL of the test solution prepared by refluxing 10 g of the sample, in *fine powder*, with 100 mL of *ethyl acetate* for 1 hour, allowing to cool for 30 minutes and filtering. Evaporate 5 mL of the filtrate to dryness and dissolve the residue in 1 mL of *dichloromethane*. After removal of the plate, allow it to dry in air and examine the plate under ultraviolet light (366 nm); three yellow and three blue fluorescent bands are observed. Then spray the plate with a 10 per cent v/v solution of *sulfuric acid* in *ethanol* and heat at 110° for 5 minutes; one brown and eight purple bands are observed (Fig. 3).

Loss on drying Not more than 8.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 3.0 per cent w/w (Appendix 7.6).

Total ash Not more than 8.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 1.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 6.0 per cent w/w (Appendix 7.12).

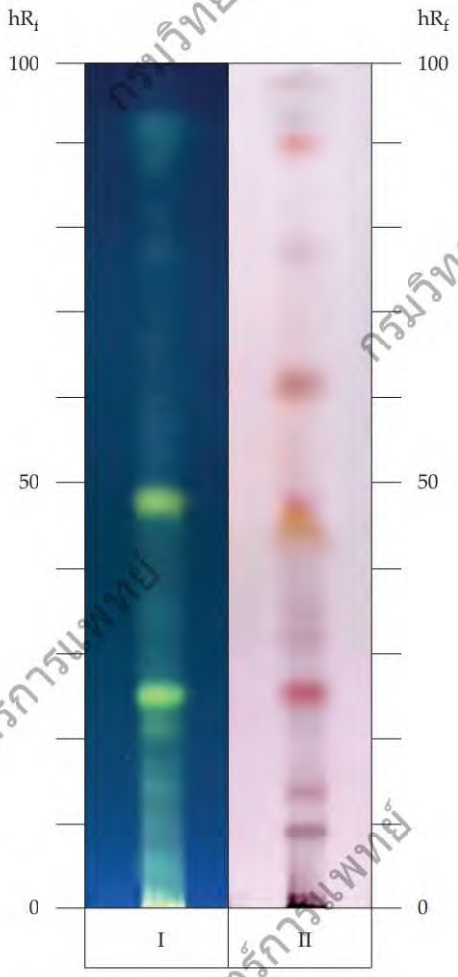


Fig. 3 Thin-Layer Chromatogram of Ethyl Acetate Extract of the Roots of *Baliospermum solanifolium* (Burm.) Suresh

I = detection under UV light (366 nm)

II = detection with a 10 per cent v/v solution of *sulfuric acid* in *ethanol*

ว่านมหาเมฆ (WAN MAHA MEK)

Curcumae Aeruginosae Rhizoma
Curcuma Aeruginosa Rhizome

Category Stomachic.

Curcuma Aeruginosa Rhizome is the dried rhizome of *Curcuma aeruginosa* Roxb. (Family Zingiberaceae), Herbarium Specimen Number: DMSC 5335, Crude Drug Number: DMSc 1234.

Constituents Curcuma Aeruginosa Rhizome contains a volatile oil, of which germacrone, curzerenone, camphor, and 1,8-cineole are its major components. It also contains other terpenoids, flavonoids, etc.

Description of the plant (Fig. 1) Perennial herb, clumped, leafy shoot 0.8 to 1.6 m tall; rhizome subrounded, ovoid or obovoid, 4 to 12 cm long, 2 to 5 cm wide, younger rhizome yellow at tip and covered with pinkish yellow sheath, older one brownish with prominent nodes; internally separated into three parts, outermost whitish, next blue to bluish purple, central greenish blue, branched with rootstocks arranged oppositely, 2 to 3 on each side. Leaves about 11 per pseudostem, simple, alternate, obovate-lanceolate, 30 to 75 cm long, 12 to 17 cm wide, green with red patches on either side of midrib, upper part purplish, glabrous on both surfaces, apex acute, base cuneate, midrib stiff; petiole up to 20 cm long, glabrous; leaf-sheath puberulous outside, green with red streak; ligule membranous, bi-lobed, unequal, 1 to 2 mm long. Inflorescence terminal spike, arising from rhizome, 45 to 65 cm long; scape 30 to 50 cm long; bract ovate to lanceolate, apex acute, 4.5 to 5 cm long, 2.5 to 3 cm wide, greenish with pinkish streak at apex, puberulous on both surfaces; coma bract narrow, obovate to oblanceolate, 4.5 to 5.3 cm long, 1.5 to 2.3 cm wide, with gradient purplish red from apex to base, puberulous on both surfaces. Flowers in cincinnus of 2 to 3 florets, in axile of bracts; bracteole ovate to oblanceolate with side inflexed, 1.8 to 2.2 cm long, 0.8 to 1 cm wide, puberulous with dense hairs at tip ridge, translucent white, apex rounded; calyx tubular, split downward one side, 1.2 to 1.5 cm long, 0.9 to 1.1 cm wide, apex 3-lobed, subequal, lateral lobe apiculate, mid-lobe truncate and slightly shorter, sparsely hairy along ridges and tips; corolla tube 2 to 2.5 cm long, puberulous, with hair-ring in throat, lower half white, upper half red, lobes red, 0.8 to 1.4 cm long, 0.6 to 1.2 cm wide; dorsal lobe concave, hooded, apex acute-mucronate, hairy; lateral lobes shallowly concave, apex rounded, glabrous; staminode pale yellow, rectangular, 1.3 to 1.4 cm long, 6 to 7 mm wide, apex truncate; labellum 1.2 to 1.6 cm long, 1.4 to 1.8 cm wide, 3-lobed, mid-lobe retuse, with glandular hair alongside of yellow mid-band; filament flat; theca about 4.5 mm long; crest less than 1 mm long, apex rounded; spur flat, triangular, point downwards, apex acuminate, about 2.5 mm long; ovary 3-lobed, barrel-shaped, 3.5 to 4 mm long, densely hairy; stylode cylindric, apex acute, about 2.5 mm long; stigma 2-lobed, laterally opened, ciliate, about 1.5 mm wide. Fruits hanging in group, ovate-triangular. Seed rounded, covered with whitish transparent aril.

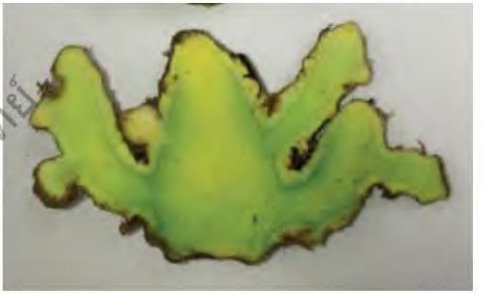
Description Odour, aromatic; taste, slightly bitter.

Macroscopical (Fig. 1) Transverse and/or longitudinal slices varied in shape and size, 2 to 6.5 mm thick, externally light brown; cutting surface smooth or rough, easily broken, yellowish brown to brown.

1

2

3



4

2 cm

5

2 cm

6

1 cm

Fig. 1 *Curcuma aeruginosa* Roxb.
1. habit 2. inflorescence 3. flower 4. longitudinal section of fresh rhizome
5. rhizomes and roots 6. crude drug

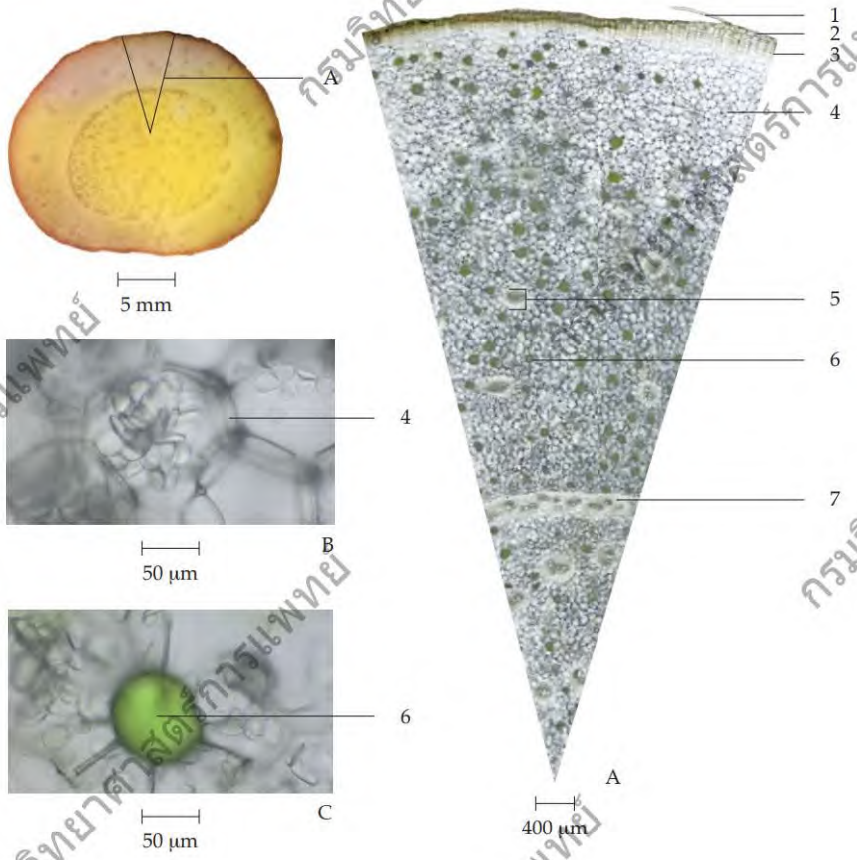


Fig. 2a Photomicrographs of Transverse Section of the Rhizome of *Curcuma aeruginosa* Roxb.
A. Part of Transverse Section
B. and C. Parenchyma With Cell Inclusion
1. unicellular trichome
2. epidermis
3. storied cork
4. parenchyma containing starch grains
5. vascular bundle
6. greenish oleoresin
7. pseudoendodermis

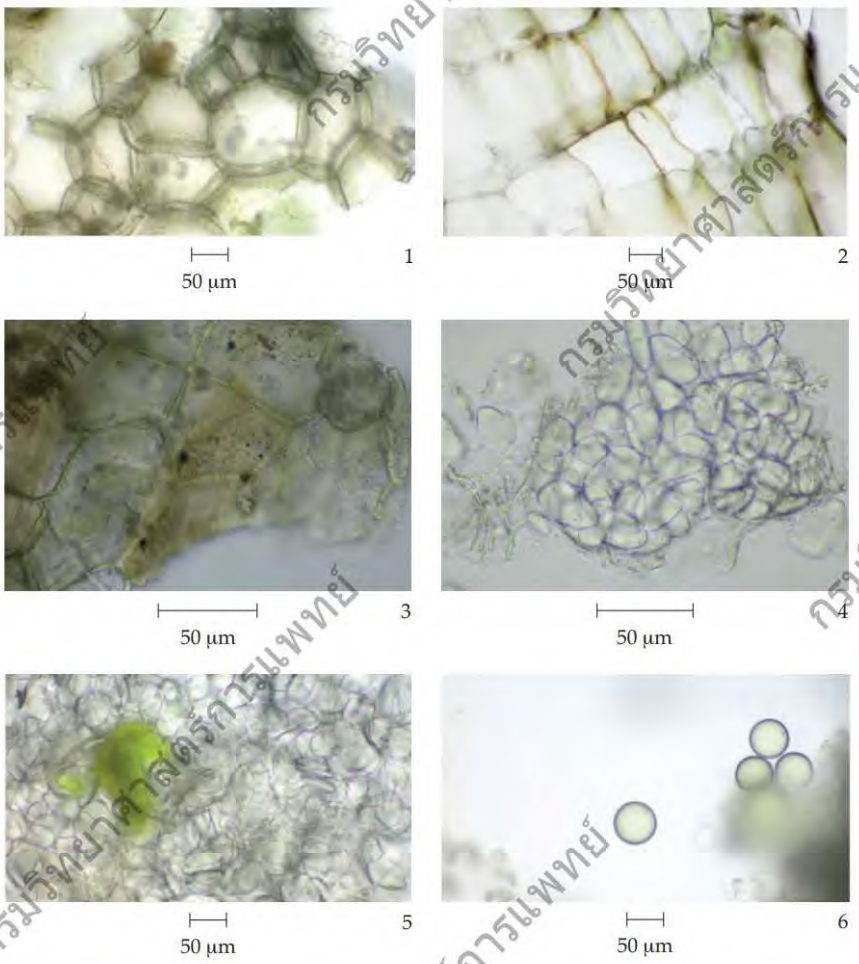


Fig. 2b Photomicrographs of Powdered Drug of the Rhizomes of *Curcuma aeruginosa* Roxb.
1. cork in surface view
2. cork in sectional view
3. parenchyma containing oil droplets and starch grains
4. parenchyma containing starch grains
5. greenish oleoresin, oil droplets, and starch grains
6. oil droplets

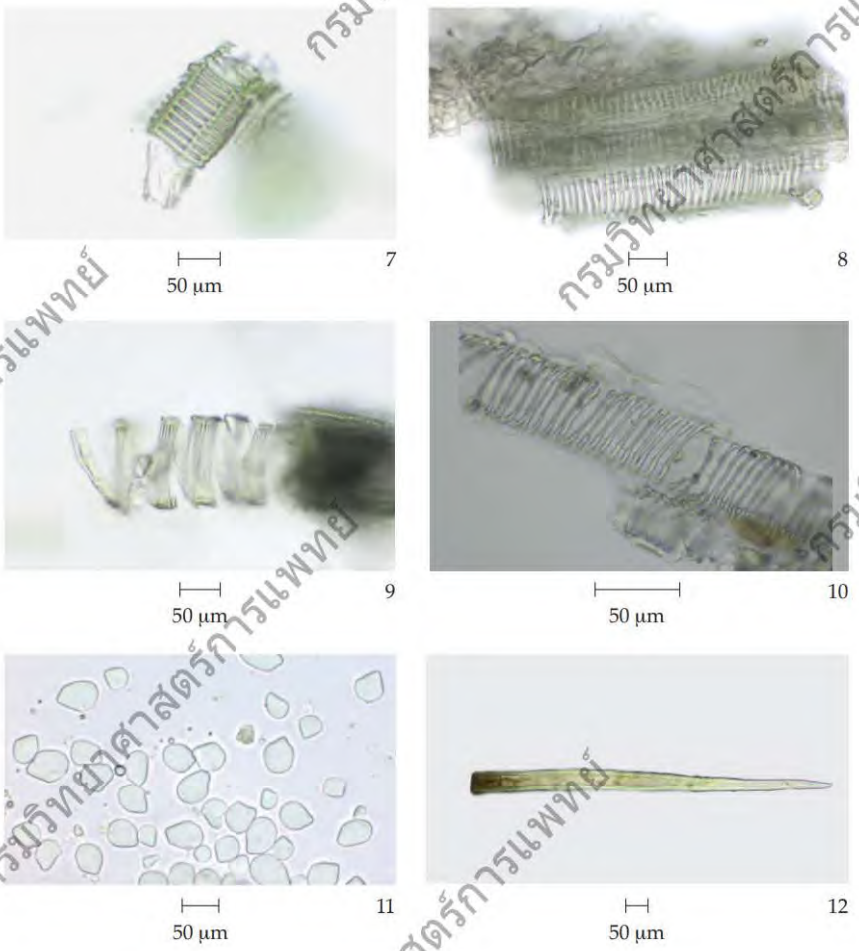


Fig. 2b (continued)

7. scalariform vessel
8. scalariform-reticulate vessels
9. spiral vessel
10. reticulate vessel
11. beaked starch grains
12. multicellular uniseriate trichome

Microscopical (Figs. 2a, 2b) Transverse section of the rhizome shows epidermis, storied cork, parenchyma, pseudoendodermis, and vascular bundle. Epidermis: a layer of rectangular cells with unicellular trichomes. Storied cork: several layers of suberized thin-walled rectangular cells. Parenchyma: thin-walled cells containing numerous starch grains, some with greenish oleoresin and/or yellow oil droplets. Pseudoendodermis: 1 to 2 layers of rectangular parenchyma. Vascular bundle: collateral and scattered; vessels, spiral, scalariform, scalariform-reticulate, and reticulate.

Curcuma Aeruginosa Rhizome in powder possesses the diagnostic microscopical characters of the unground drug. Greenish oleoresin with oil droplets, and typical spiral vessels are characteristic. Parenchyma containing beaked starch grains showing eccentric lamella can be found in abundance. Storied cork, non-lignified scalariform, and reticulate vessels can also be observed.

Packaging and storage Curcuma Aeruginosa Rhizome shall be kept in well-closed containers, preferably of metal or glass, protected from light and stored in a cool and dry place.

Identification

A. To 1 g of the sample, in *No. 250 powder*, add 30 mL of *water* and heat on a water-bath for 20 minutes. Immediately filter through a plug of cotton wool and allow the filtrate to cool. Shake 5 mL of the filtrate with 2 mL of *chloroform* for 2 minutes. Separate the chloroform layer, transfer 1 mL of this layer to a test-tube, and slowly add a few drops of *sulfuric acid* to form a layer: a reddish brown ring forms at the zone of contact.

B. Boil 1 g of the sample, in *No. 250 powder*, with 20 mL of *water*. Allow to cool and filter. Evaporate 10 mL of the filtrate to dryness and add 1 mL of *vanillin-sulfuric acid TS1*: a purple colour develops.

C. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel GF254* as the coating substance and a mixture of 60 volumes of *hexane* and 40 volumes of *ethyl acetate* as the mobile phase. Apply to the plate as a band of 8 mm, 5 μL of the test solution, prepared by refluxing 1 g of the sample, in *No. 250 powder*, with 25 mL of *hexane* for 15 minutes and filtering. Evaporate the filtrate to dryness and dissolve the residue in 1 mL of *methanol*. After removal of the plate, allow it to dry in air and examine the plate under ultraviolet light (254 nm), marking the quenching bands. Subsequently examine the plate under ultraviolet light (366 nm); five blue fluorescent bands are observed. Spray the plate with *anisaldehyde TS* and heat at 105° for 5 minutes. One yellowish orange and nine purple bands are observed (Fig. 3).

Water Not more than 11.0 per cent v/w (Azeotropic Distillation Method, Appendix 4.12).

Foreign matter Not more than 2.0 per cent w/w (Appendix 7.2).

Acid-insoluble ash Not more than 1.0 per cent w/w (Appendix 7.6).

Total ash Not more than 8.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 5.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 14.0 per cent w/w (Appendix 7.12).

Volatile oil Not less than 1.0 per cent v/w, calculated on the anhydrous basis (Appendix 7.3H). Use 10 g, in *No. 250 powder*, freshly prepared and accurately weighed. Use 200 mL of *water* as the distillation liquid and a 500-mL round-bottomed flask. Distil at a rate of 2 to 3 mL per minute for 5 hours. Use 2.0 mL of *xylene* in the graduated tube.

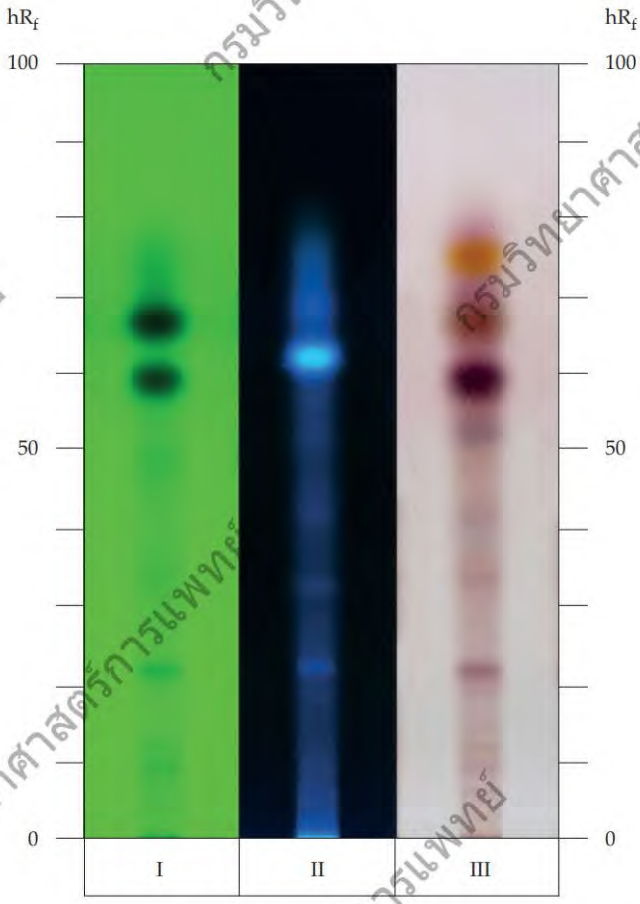


Fig. 3 Thin-Layer Chromatogram of Hexane Extract of the Rhizomes of *Curcuma aeruginosa* Roxb.
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with *anisaldehyde TS*

ยาชงใบกัญชา (YA CHONG KANCHA, BAI)

Cannabis Sativa Leaf Tea

Category Appetite enhancer, sleep aid.

Cannabis Sativa Leaf Tea contains an amount of powdered Cannabis Sativa Leaf equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of tetrahydrocannabinol ($C_{21}H_{30}O_2$), calculated on the dried basis.

Strength available 1 g (powder), supplied in a sachet.

Dose One sachet, prepared as an infusion by soaking each with 180 to 250 mL of boiling water for 5 minutes, once daily.

Warning

1. Ingestion of powdered cannabis sativa leaves is not recommended.
2. It may cause drowsiness, dizziness, headache, nausea and vomiting, and/or low blood pressure.
3. Concomitant use with alcohol, cannabis- and/or caffeine- containing products should be avoided.
4. Risk-benefit should be considered if it is to be used in pregnant or nursing women, adults under 25 years of age, children, and patients with a known history of mental illnesses or compromised cardiovascular symptoms.

Packaging and storage Cannabis Sativa Leaf Tea shall be kept in well-closed containers, protected from light, and stored at a temperature not exceeding 30°.

Labelling The label on the container states (1) the amount of tetrahydrocannabinol in mg per sachet; (2) the expiration date.

Identification

A. The tea contents exhibit diagnostic structures of the powdered drug described under *Cannabis Sativa Leaf*.

B. The tea contents comply with the tests for Identification A, B, and C described under *Cannabis Sativa Leaf*.

Loss on drying Of the Tea contents, not more than 9.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Microbial limit Complies with the requirements for Category 2 in the "Limits for Microbial Contamination" (Appendix 10.5).

Assay Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Mobile phase A Use *acetonitrile*.

Mobile phase B Prepare a 0.1 per cent v/v solution of *trifluoroacetic acid*.

Standard stock preparation Use a solution containing 1 mg per mL of Tetrahydrocannabinol RS in *ethanol* (Lipomed® or equivalent is suitable.).

Standard preparations Transfer 1.0 mL of *Standard stock preparation* to a 50-mL volumetric flask, dilute with *acetonitrile* to volume, and mix. Dilute the solution quantitatively and stepwise with the same solvent to obtain five solutions having known concentrations of 2, 4, 6, 8, and 10 μg per mL.

Assay preparation Grind the contents of not less than 20 sachets of Cannabis Sativa Leaf to *fine powder*. Sonicate about 400 mg, accurately weighed, in 20.0 mL of *acetonitrile* for 20 minutes, and filter. Transfer 1.0 mL of the filtrate to a 20-mLvolumetric flask, dilute to volume with *acetonitrile*, and mix. Filter through a nylon membrane having a 0.45-µm porosity. (**Note** In case the concentration of tetrahydrocannabinol in the Assay preparation is not in the concentration range of standard curve, allow to adjust the volume of the filtrate taken.)

The step gradient of mobile phases is as follows:

Time (Minutes)	*Mobile Phase A* (Per Cent V/V)	*Mobile Phase B* (Per Cent V/V)
0	55	45
1	55	45
9	100	0
11	100	0
13	55	45

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (15 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (2.7 µm), equipped with a similarly packed guard column (5 mm × 3.9 mm), and maintained at a temperature of 35°±1°, (b) *Mobile phase* at a flow rate of about 1.8 mL per minute, and (c) an ultraviolet photometer set at 228 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 6 µg per mL, and record the peak response as directed under *Procedure* and *Calculation*: the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure and **Calculation** Separately inject about 25 µL each of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for tetrahydrocannabinol peaks. Plot the readings and draw the standard curve of best fit: the curve shows the correlation coefficient of not less than 0.999. Inject about 25 µL of *Assay preparation* into the chromatograph, record the chromatogram, and measure the response for tetrahydrocannabinol peak. By reference to the standard curve, calculate the content of tetrahydrocannabinol ($C_{21}H_{30}O_2$) in the portion of the Tea taken.

Other requirements Complies with the requirements described under "Herbal Teas" (Appendix 1.16H).

APPENDIX

APPENDIX

The Thai Herbal Pharmacopoeia 2021 Supplement 2023 is a supplement publication to the Thai Herbal Pharmacopoeia 2021 where complete information on the quality control of herbal drugs and herbal drug preparations are compiled. Thus, it solely lists the reagents used for tests and assays of the herbal drugs contained herein. For information on the relevant appendices, kindly consult the Thai Pharmacopoeia II 2011 Volume I Part 1, the Thai Pharmacopoeia II Volume I Part 1 Supplement 2020 or the Thai Herbal Pharmacopoeia 2021.

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Content of the Appendix

APPENDIX 1 GENERAL INFORMATION

The specifications given below are strictly for the use of the materials as reagents. The inclusion of a material in this Appendix does not imply that it is suitable for use in medicines. Exceptionally, a trademark or supplier may be indicated for certain reagents whose availability is limited. It is however acceptable to use reagents from another source provided that they comply with the standards of the Pharmacopoeia.

1.1 REAGENTS

The name of a substance or solution indicates a reagent included in the following list. The specifications given for reagents do not necessarily guarantee their quality for use in medicine.

Some of the reagents included may be injurious to health. Important cautions have been stated for these reagents. They should be handled in accordance with good laboratory practice and any relevant regulations.

Reagents in aqueous solution are prepared using *water*. Where the name of the solvent is not stated, an aqueous solution is intended.

Unless otherwise specified, the reagents and reagent solutions are to be stored in well-closed containers. The labelling should comply with the relevant national legislation.

Bergenin $C_{14}H_{16}O_9 = 328.27$

Use analytical reagent grade of commerce.

DESCRIPTION White crystalline powder.

MELTING TEMPERATURE 238° (Appendix 4.3).

Store in tightly closed containers in a dry place, at a temperature below –20°.

Friedelin $C_{30}H_{50}O = 426.72$

Use analytical reagent grade of commerce.

DESCRIPTION White powder.

MELTING RANGE 262° to 265° (Appendix 4.3).

Store in tightly closed containers in a cool and dry place.

Mitragynine $C_{23}H_{30}N_2O_4 = 398.50$

Use analytical reagent grade of commerce.

DESCRIPTION Off-white to brown crystalline powder.

SOLUBILITY Slightly soluble in *ethanol* and in *methanol*.

MELTING TEMPERATURE About 100° (Appendix 4.3).

Store in tightly closed containers.

1.16H DOSAGE FORMS OF HERBAL DRUGS

TABLETS

This appendix should be read in conjunction with Appendix 1.16 under Tablets.

Tablets are solid dosage forms containing one or more active ingredients. They are obtained by single or multiple compression (in certain cases they are moulded) and may be uncoated or coated, i.e., sugar-coated and film-coated. They are usually intended for oral administration.

The different categories of tablets that exist include extract tablets, semi-extract tablets, and powdered crude drug tablets. Tablets are normally circular in shape and their surfaces are flat or convex.

Tablets may have lines or break-marks, symbols, or other markings. They should be sufficiently hard to withstand handling, including packaging, storage, and transportation, without crumbling or breaking. Tablets may contain excipients such as diluents, binders, disintegrating agents, glidants, lubricants, colouring matter, and flavouring substances. When such excipients are used, it is necessary to ensure that they do not adversely affect the stability, safety, or efficacy of the active ingredient(s); there must be no incompatibility between and of the components of the dosage form.

Disintegration Tablets comply with the "Disintegration Test for Tablets and Capsules" (Appendix 4.23), provided that the time limit is 30 minutes for uncoated tablets, 60 minutes for film-coated tablets, and 90 minutes for other coated tablets.

Weight variation Weigh accurately twenty tablets and calculate the average weight. Weigh individually each of the twenty tablets and compare the weight of each tablet with the average weight (if assay is not required, the weight of each tablet should be compared with the labelled weight). Unless otherwise directed in the monograph, not more than two of the individual weights deviate from the labelled weight or the average weight by more than the weight variation limit shown in the table and none deviates by more than twice that percentage.

Average Weight or Labelled Weight	Weight Variation Limit
< 300 mg	± 7.5 per cent
≥ 300 mg	± 5.0 per cent

Before being coated with sugar, the tablet cores shall comply with the test for weight variation. Sugar-coated tablets are not required to comply with the test for weight variation while film-coated tablets are.

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