Thai Herbal Pharmacopoeia 2021

SUPPLEMENT 2024

กระทรวงสาธารณสุข
MINISTRY OF PUBLIC HEALTH

กรมวิทยาศาสตร์การแพทย์
DEPARTMENT OF MEDICAL SCIENCES

กรมวิทยาศาสตร์การแพทย์
DEPARTMENT OF MEDICAL SCIENCES

Thai Herbal Pharmacopoeia 2021
SUPPLEMENT 2024

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PREFACE

Similar to modern drugs, herbal drugs and herbal drug preparations require quality control to ensure their safety and efficacy. To safeguard users of plant-based drugs, in 1989, Department of Medical Sciences, Ministry of Public Health initiated the Thai Herbal Pharmacopoeia (THP). The main goal of the THP is to set standards for quality control of herbal drugs and herbal preparations commercialized in Thailand, ensuring their identity, quality, safety- and efficacy-related aspects. Since then, a series of the THP publications has been released.

The Thai Herbal Pharmacopoeia 2021 Supplement 2024 is the most current publication in the THP series, containing 17 newly developed monographs of herbal drugs and herbal drug preparations. For convenient access and to encourage environmental responsibility, it is published as an electronic book downloadable from the Bureau of Drug and Narcotic, Department of Medical Sciences website. Another access channel is the Thai Herbal Pharmacopoeia application available from online and mobile stores.

The establishment of the current THP 2021 Supplement 2024 is carried out by six subcommittees under the supervision of the Thai Pharmacopoeia Committee: 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 wish to express their sincere gratitude to contributors, government agencies, academic institutions, organizations, and individuals who provide advice and share their time and expertise. Without their contributions, this achievement would never have been possible.

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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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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:
Chirayupin **Chandraprasong** (deceased), B.Sc., M.Sc., Hon. Ph.D., FRI (2010–2015)
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 **Dechwisisissakul**, B.Sc., M.Sc. in Pharm. (2010–)
Jiranuch **Jamtaweekul**, B.Sc. in Pharm., M.Sc. in Pharm. (2010–2015, 2017–)
Thaweesak **Juengwatanatrakul**, B. Pharm., M.Sc. in Pharm., Ph.D. (2024–)
Ornusa **Khamsuk**, B.S., M.S., Ph.D. (2014–2019)
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–)
Sukontip **Sirimongkol**, B.S. (Forestry), M.S. (Forestry), Ph.D. (2024–)
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–)[1]

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

Members: Director, Research Development and Innovation Department, The Government Pharmaceutical Organization (2024–)
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. (2017–2024)
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)

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

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–)

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)
Kornvika **Charupant**, B.S. in Pharm., M.Sc. in Pharm., Ph.D. (2008–)
Boonchua **Dhorranintra**, M.D., Dr. med.(magna cum laude) (Freiburg U.) FRCP(T) (2000–2010)
Supatra **Im-erb**, B.Sc. in Pharm., M.Sc. (1989–1997)

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)
Rachanee **Pinthaworn**, B.Sc. in Pharm. (2005–2009)
Manat **Pohmakotr**, B.Sc., M.Sc., Dr. rer. nat. (1989–2005)
Arunee **Poompanich**, B.Sc. in Pharm. (1993–2015)
Sompol **Prakongpan**, B.Sc. in Pharm., M.Sc., Ph.D. (1989–1997)
Sunibhond **Pummangura**, B.Sc. in Pharm., M.Sc., M.S.P., Ph.D. (1989–1997)
Kamphol **Raksrivong**, B.Sc. in Pharm. (1993–1997)
Churairat **Rakwatin**, B.Sc. in Pharm. (2006–)
Nidapan **Ruangrittinon**, B.Sc. in Pharm., M.Sc. in Pharm. (2005–)
Chanai **Sambhandharaksa** (deceased), B.S. Phar., Hon. D.Sc. in Pharm. (MU) (1989–2008)
M.L. Othong **Sawasdimongkol** (deceased), B.Sc. in Pharm. (1993–2015)
Nantana **Sittichai**, B.Sc. in Pharm., M.S. (2005–)
Nongluck **Sookvanichsilp**, B.Sc. in Pharm. (Hons.), M.Sc. in Pharm., Dr.Phm.Sc., LL.B., B.B.A. (2005–)
Suntana **Sutadarat**, B.Ed. (Hons.), M.A., Ph.D. (1989–1996, 1998–)
Parkpoom **Tengamnuay**, B. Pharm., Ph.D. (1993–)
Charurat **Tantraporn**, B.A., M.A. (1997–2000)
Opa **Vajragupta**, B.S. (Pharm.), M.Sc., Ph.D. (2000–2003)
Rewadee **Vongsaroj** (deceased), B.Sc. in Pharm., M.Sc. (1989–1997)
Chongdee **Wongpinairat**, B.Sc. in Pharm., M.Sc., Ph.D. (1989–1997)
Sumana **Vardhanabhuti** (deceased), B.Sc. in Pharm., M.Sc. in Pharm., M.P.H., Cert. in Immunol. (WHO) (1989–1997)
M.L. Pranod **Xumsaeng** (deceased), Ph.G., B.Sc. in Pharm. (1989–1991)

Secretaries:

Manas **Attawish**, B.S. (Pharm.) (1997–2013)
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)
Kamphol **Raksrivong**, B.Sc. in Pharm. (1980–2000)
Nongluck **Ruangwises**, B.S. (Pharm.), M.S., Ph.D. (1989–1991)
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*

Jidapha **Kanogsunthornrat**, B.Sc. in Pharm., M.P.H. (2019–)

Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L. (2019–)

Puangkaew **Lukkannatinaporn**, B.Sc. in Pharm., M.Sc. (Pharmacy)

Santi **Nimnoi**, B.S. in Pharm. (2019–)

Brompoj **Prutthiwanasan**, B.S. in Pharm., M.Sc. in Pharm., Ph.D. (2024–)

Churairat **Rakwatin**, B.Sc. in Pharm. (2019–)

Nidapan **Ruangrittinon**, B.Sc. in Pharm., M.Sc. in Pharm. (2019–)

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.)
Jaree **Bansiddhi**, B.Sc., M.Sc.
Thaweephol **Dechatiwongse Na Ayudhya**, B.Sc. in Pharm.
Pranom **Dechwisissakul**, B.Sc., M.Sc. in Pharm.
Walapa **Juladusitpornchai**, B.Sc. in Pharm.
Sarunyaporn **Kongchira**, B.Sc. in Pharm., M.S.
Kamphol **Raksrivong**, B.Sc. in Pharm.
Nongluck **Ruangwises**, B.S. (Pharm.), M.S., Ph.D.
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*:**

The following individuals were engaged in the production of THP Volume I (1989–1995):

Jaree **Bansiddhi**, B.Sc., M.Sc.
Nuchattra **Chansuvanich**, B.Sc., M.S.
Pranee **Chavalittumrong**, B.Sc. in Pharm., M.Sc. in Pharm.
Pranom **Dechwisissakul**, B.Sc., M.Sc. in Pharm.
Warunee **Jirawattanapong**, B.Sc. in Pharm.
Walapa **Juladusitpornchai**, B.Sc. in Pharm.
Sirichai **Krabesri**, B.Sc. in Pharm., M. Pharm., LL.B., B.L.
Amporn **Kun-anake**, B.Sc. in Pharm.
Vitit **Nammoonnoy**, B.A.
Daroon **Pecharaply**, B.Sc., M.S.
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.
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***Photos*:**

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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, and THP 2021 Supplement 2023, or visit the BDN website at: http://bdn.go.th/thp/home. The "Thai Herbal Pharmacopoeia" application is also downloadable from Google Play Store and App Store.

AMENDMENTS

AMENDMENTS TO THP 2021 VOLUME I

MONOGRAPHS

BUABOK pp. 29–37

Replace with the following:

บัวบก (BUABOK)

ผักหนอก (PHAK NOK)
Centellae Asiaticae Herba
Centella

Synonyms Asiatic Pennywort, Gotu Kola, Indian Pennywort, Indian Water Navelwort

Category Mild diuretic, anti-inflammatory, wound healing (topical).

Centella is the dried aerial part of *Centella asiatica* (L.) Urb. (*C. coriacea* Nannf., *Hydrocotyle asiatica* L., *H. lunata* Lam., *Trisanthus cochinchinensis* Lour.) (Family Umbelliferae), Herbarium Specimen Number: DMSC 1461, Crude Drug Number: DMSc 1261.

Constituents Centella contains triterpenoid saponins, including asiaticoside and madecassoside and their aglycones which are asiatic acid and madecassic acid, respectively. It also contains volatile oil, pectin, trace of alkaloids, etc.

Description of the plant (Figs. 1a, 1b) Slender trailing herb, rooting at nodes. Leaves simple, 1 to 6 in rosette at each node, orbicular to reniform, more or less cupped, glabrous and shiny above, paler beneath, 1 to 7 cm in diameter, apex rounded, base cordate, margin entire, crenate, or usually repand-dentate; petiole (1–)4 to 10(–50) cm long. Inflorescence in single umbel, bearing solitary or 2 to 5 together in the axils; peduncle shorter than petiole. Flowers usually 3, middle one sessile, lateral ones pedicellate; involucres 2, ovate; petals 5, minute, white or rose-tinged; ovary laterally flattened, style filiform. Fruit small, compressed, about 8 mm long, orbicular to ellipsoid, manifestly ribbed, slightly hairy when young.

Description Odour, characteristic; taste, slightly bitter-sweet.

Macroscopical (Fig. 1a) Aerial part, greenish brown, rough and brittle; stem thin, long, twisted; leaves rennate or cordate, brittle; petiole long.

Microscopical (Figs. 2a–2d) Transverse section of the fresh leaf shows upper epidermis, a layer of rectangular cells, polygonal and straight-walled in surface view; stomata, anisocytic, some paracytic and rarely anomocytic. Palisade cells, a layer of large columnar cells. Spongy cells, parenchymatous, some containing calcium oxalate crystals in the forms of rosette aggregate or prism. Collenchyma, occurring beneath upper and lower epidermises in the midrib. Vascular bundles, xylem in the upper part and phloem in the lower part; vessels, annular, spiral, scalariform, or reticulate. Lower epidermis, a layer of rectangular cells, slightly wavy-walled in surface view; stomata, anisocytic, paracytic or anomocytic. Oil ducts, occurring beneath collenchyma in the middle of midrib.

Transverse sections of the fresh petiole and stolon show epidermal layer with cuticle. Collenchyma, present. Parenchyma containing chloroplastids, oil droplets, spreading circularly beneath collenchyma. Vascular bundles, collateral. The centre of petiole, hollow. Unicellular trichomes may also be found, but rare, in the section near the base of petiole.

Centella in powder possesses the diagnostic microscopical characters of the unground drug.

1

2

3

1 cm

4

5

Fig. 1a *Centella asiatica* (L.) Urb.
1. habit 2. leaves 3. flowers and fruits 4. inflorescence 5. leaves, flowers and fruits

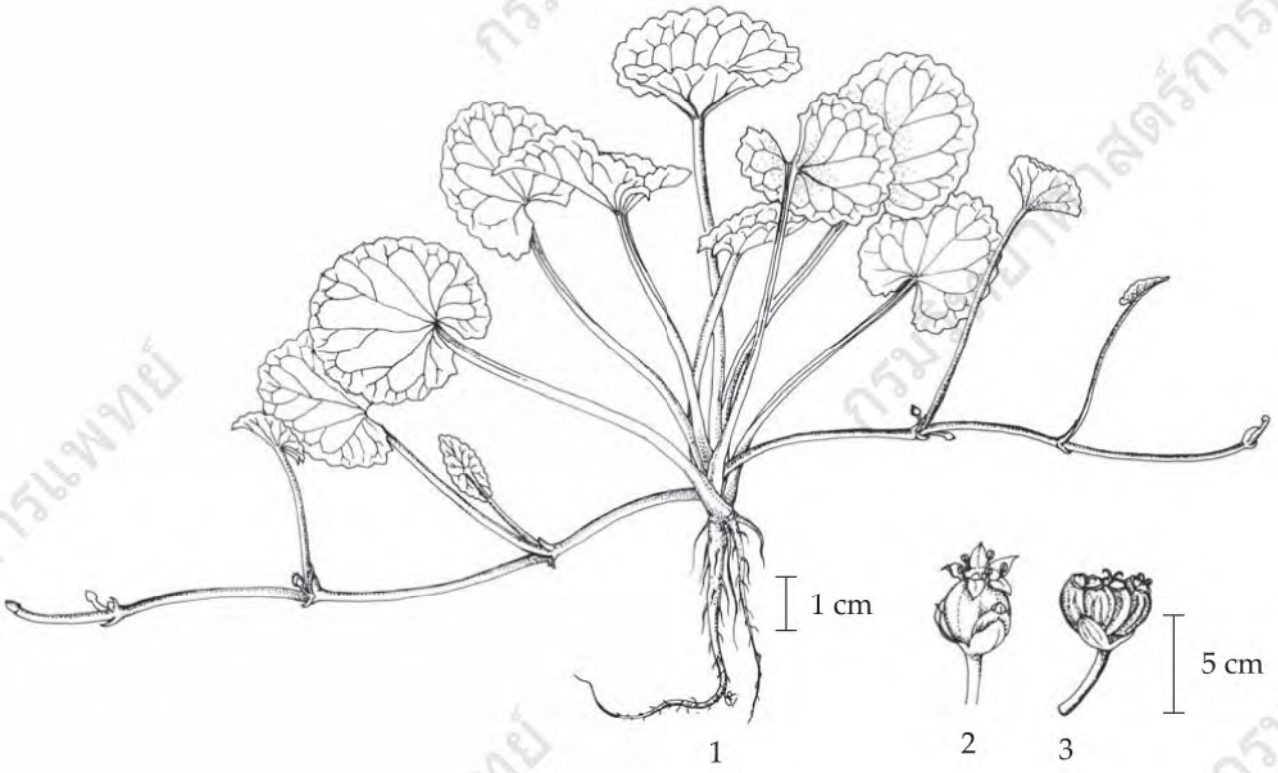
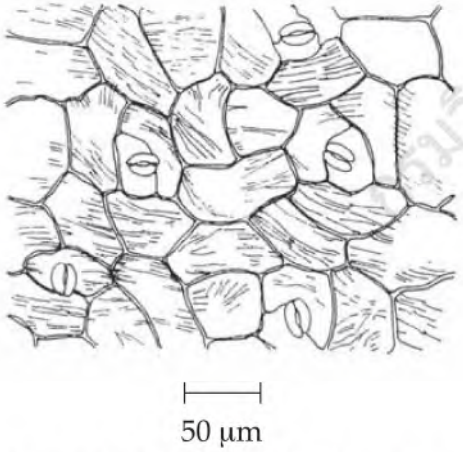
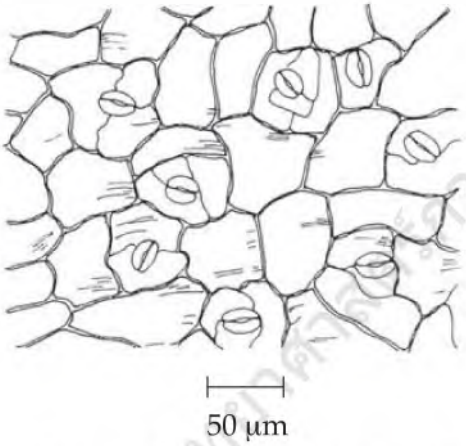


Fig. 1b *Centella asiatica* (L.) Urb.
1. habit 2. inflorescence 3. fruits

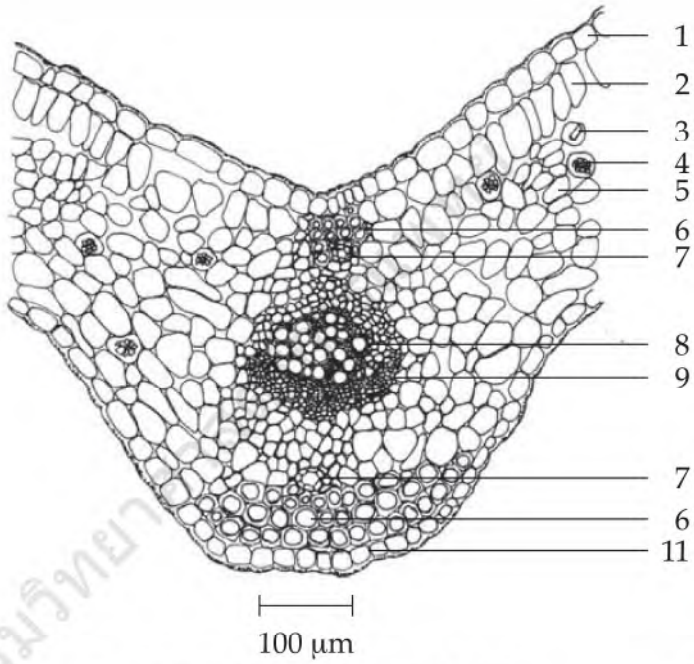


Upper Epidermis of the Lamina

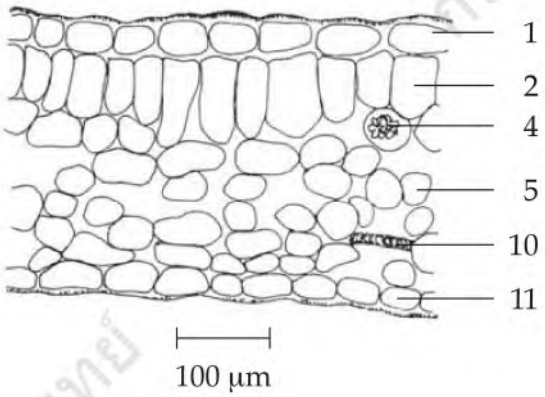


Lower Epidermis of the Lamina

Fig. 2a Line Drawings of Epidermises of the Fresh Leaf of *Centella asiatica* (L.) Urb.



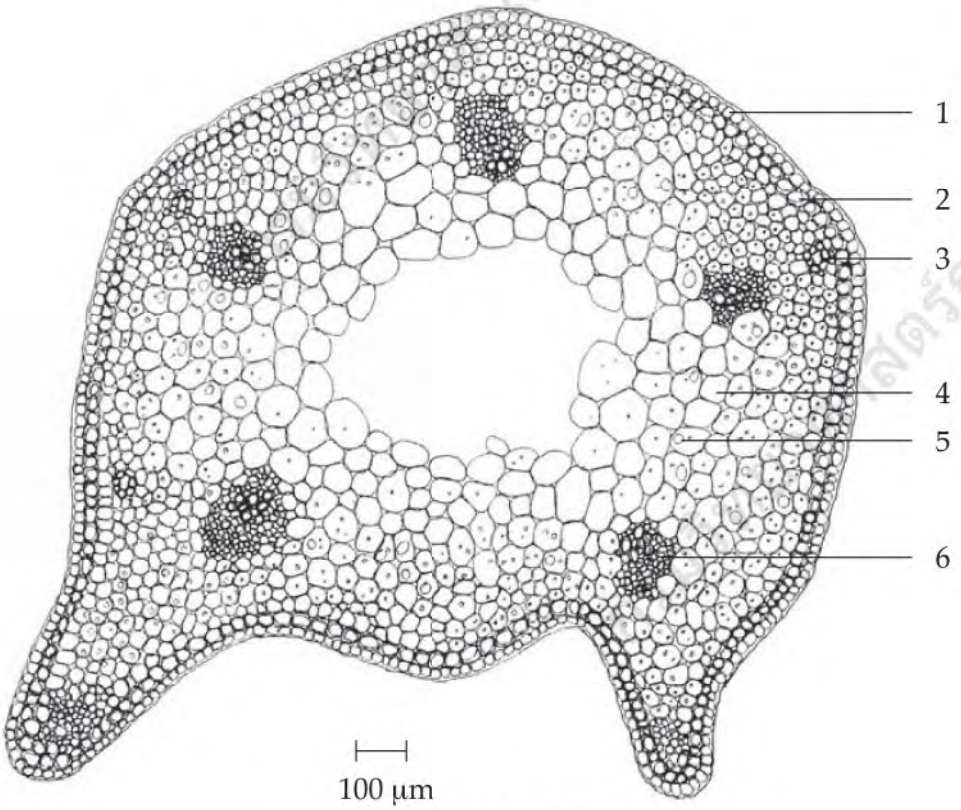
Transverse Section of the Midrib



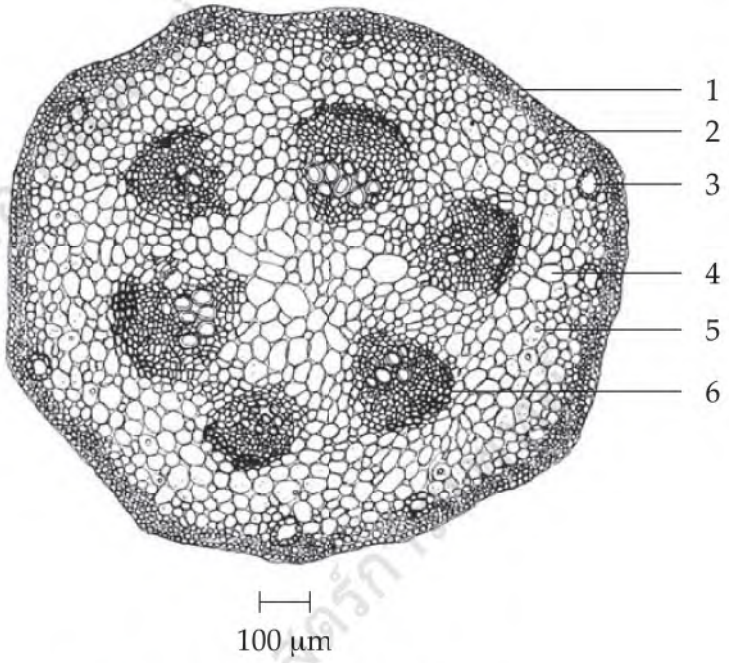
Transverse Section of the Lamina

Fig. 2b Line Drawings of Transverse Sections of the Fresh Leaf of *Centella asiatica* (L.) Urb.

1. upper epidermis
2. palisade cell
3. prismatic crystal
4. rosette aggregate crystal
5. spongy cell
6. collenchyma
7. oil duct
8. xylem
9. phloem
10. vessel
11. lower epidermis



Transverse Section of the Petiole



Transverse Section of the Stolon

Fig. 2c Line Drawings of Transverse Sections of the Fresh Petiole and Stolon of *Centella asiatica* (L.) Urb.

1. epidermis
2. collenchyma
3. oil duct
4. parenchyma
5. oil droplet
6. vascular bundle

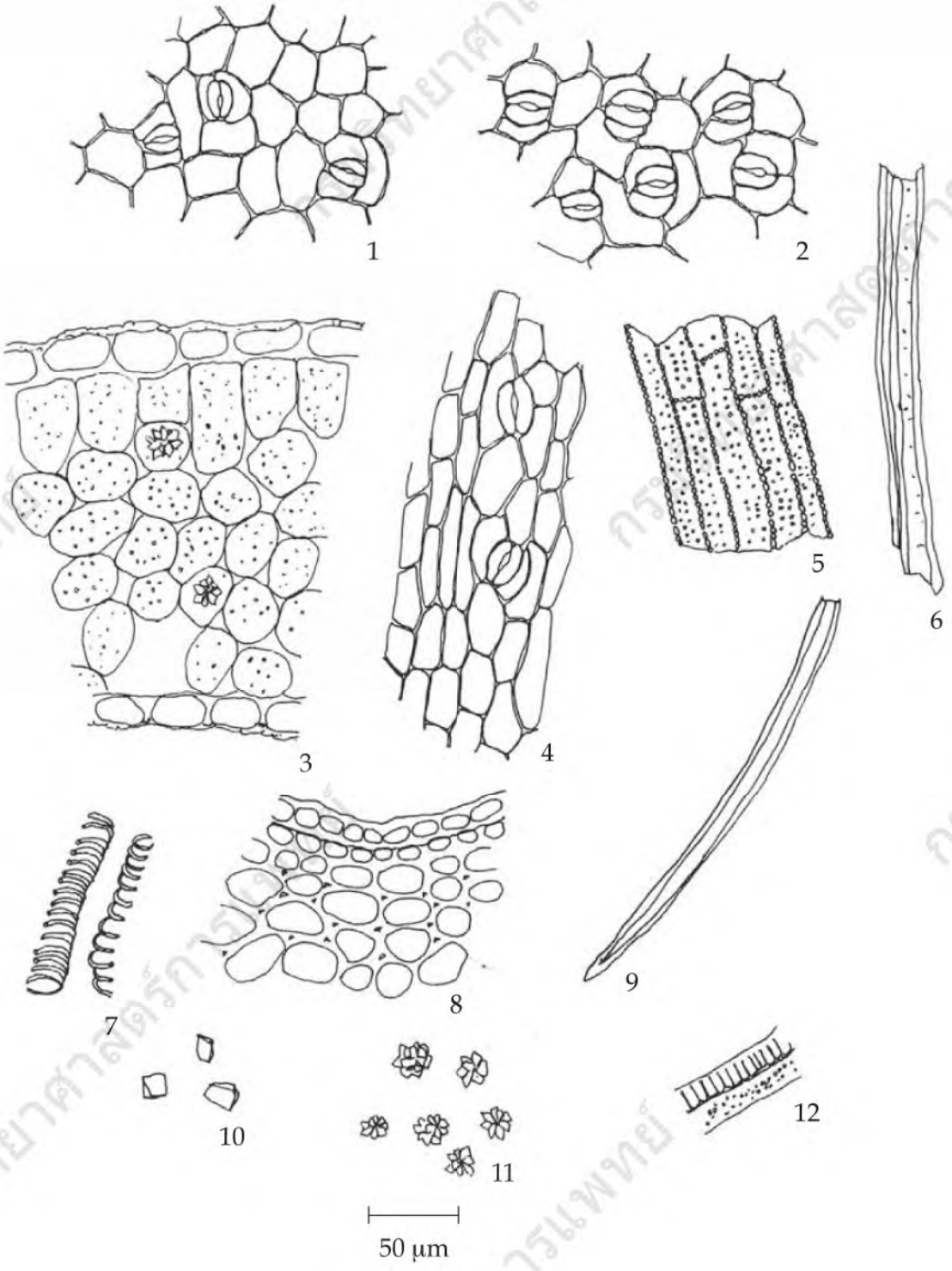


Fig. 2d Line Drawings of Powdered Drug of the Aerial Parts of *Centella asiatica* (L.) Urb.

1. upper epidermis
2. lower epidermis
3. lamina in sectional view
4. epidermis with stomata from petiole
5. pitted vessels
6. fibres
7. spiral vessels
8. epidermis and collenchyma, in sectional view
9. unicellular trichome
10. prismatic crystals
11. rosette aggregate crystals
12. scalariform and pitted vessels

Warning Excessive oral administration should be avoided during pregnancy and lactation.

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

Identification

A. Warm 500 mg of the sample, in powder, with 5 mL of *ethanol* for 5 minutes and filter (solution 1). To 2 mL of solution 1, add a few drops of *sulfuric acid*: a green colour develops.

B. Evaporate 2 mL of solution 1 to dryness and dissolve the residue in 2 mL of *acetic anhydride*. Add slowly 1 mL of *sulfuric acid* to form two layers: a green colour develops in the upper layer and a brownish red ring forms at the zone of contact.

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

D. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel G* as the coating substance and a mixture of 60 volumes of *chloroform*, 28 volumes of *methanol* and 4 volumes of *water* as the mobile phase. Apply separately to the plate, 5 µL each of the following solutions. Prepare solution (A) by refluxing 1 g of the sample, in powder, with 20 mL of *ethanol* for 10 minutes and filtering. Evaporate the filtrate under reduced pressure at 40° until dryness, and dissolve the residue in 4 mL of *ethanol*. For solution (B), dissolve 1 mg of *asiaticoside* in 2 mL of *ethanol*. For solution (C), dissolve 1 mg of *asiatic acid* in 2 mL of *ethanol*. 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 purple spot (hR_f value 27 to 28) and a violet spot (hR_f value 72 to 74) corresponding to the asiaticoside and the asiatic acid spots from solutions (B) and (C), respectively. Several other spots of different colours are observed (Table 1); see also Fig. 3.

E. The chromatogram of the Sample preparation shows several peaks, two of which correspond to the asiaticoside and madecassoside peaks of the Standard preparations, as obtained in the *Contents of asiaticoside and madecassoside*.

Table 1 hR_f Values of Components in Ethanolic Extract of the Aerial Parts of *Centella asiatica* (L.) Urb.

Spot	hR_f Value	Detection
		Anisaldehyde TS
1	2	green
2	5	green
3	8	green
4	16	green
5*	27–28	purple
6	33–34	violet
7	43	violet
8	63–64	violet
9	67	green
10**	72–74	violet
11	79–80	brown-violet
12	84	brown-green
13	87–88	violet-green
14	91–92	green

*asiaticoside
**asiatic acid

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 7.0 per cent w/w (Appendix 7.6).

Total ash Not more than 17.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 15.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 24.0 per cent w/w (Appendix 7.12).

Contents of asiaticoside and madecassoside Not less than 3.0 per cent w/w for the sum of asiaticoside and madecassoside, calculated on the dried basis. Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Mobile phase A Use *acetonitrile*.

Mobile phase B Use *water*.

Standard preparation A Dissolve a suitable quantity of *asiaticoside*, accurately weighed, in sufficient *methanol* to obtain a stock solution having a known concentration of about 250 μg of asiaticoside per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions having known concentrations ranging from 10 to 60 μg per mL.

Standard preparation B Dissolve a suitable quantity of *madecassoside*, accurately weighed, in sufficient *methanol* to obtain a stock solution having a known concentration of about 300 µg of madecassoside per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions having known concentrations ranging from 30 to 180 µg per mL.

Sample preparation Transfer about 200 mg of Centella, in *coarse powder*, accurately weighed, into a 50-mL round-bottomed flask and add 25 mL of *methanol*. Heat under a reflux condenser for 1 hour, filter into a 50-mL volumetric flask, and add the same solvent to volume. Filter through a membrane having a 0.22-µm porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (5 cm × 2.1 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (1.7 µm), (b) *Mobile phase* at a flow rate of about 0.6 mL per minute, and (c) an ultraviolet photometer set at 205 nm.

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	15	85
1.5	60	40
2	0	100
3	0	100
4	15	85

To determine the suitability of the chromatographic system, chromatograph *Standard preparation A* and *Standard preparation B* having known concentrations of 30 µg per mL of asiaticoside and 90 µg per mL of madecassoside, respectively, and record the peak responses as directed under *Procedure* and *Calculation*: the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure Separately inject equal volumes (about 4 µL) of *Standard preparation A* and *Standard preparation B* into the chromatograph, record the chromatograms, and measure the responses for asiaticoside and madecassoside peaks. Plot the readings and draw the standard curves of best fit: the curves show the correlation coefficient of not less than 0.999. Inject about 4 µL of *Sample preparation* into the chromatograph, record the chromatogram, and measure the responses for asiaticoside and madecassoside peaks.

Calculation By reference to the standard curves, calculate the sum of asiaticoside ($C_{48}H_{78}O_{19}$) and madecassoside ($C_{48}H_{78}O_{20}$) contents, in the portion of the Centella taken.

Dose 0.6 g three times a day.

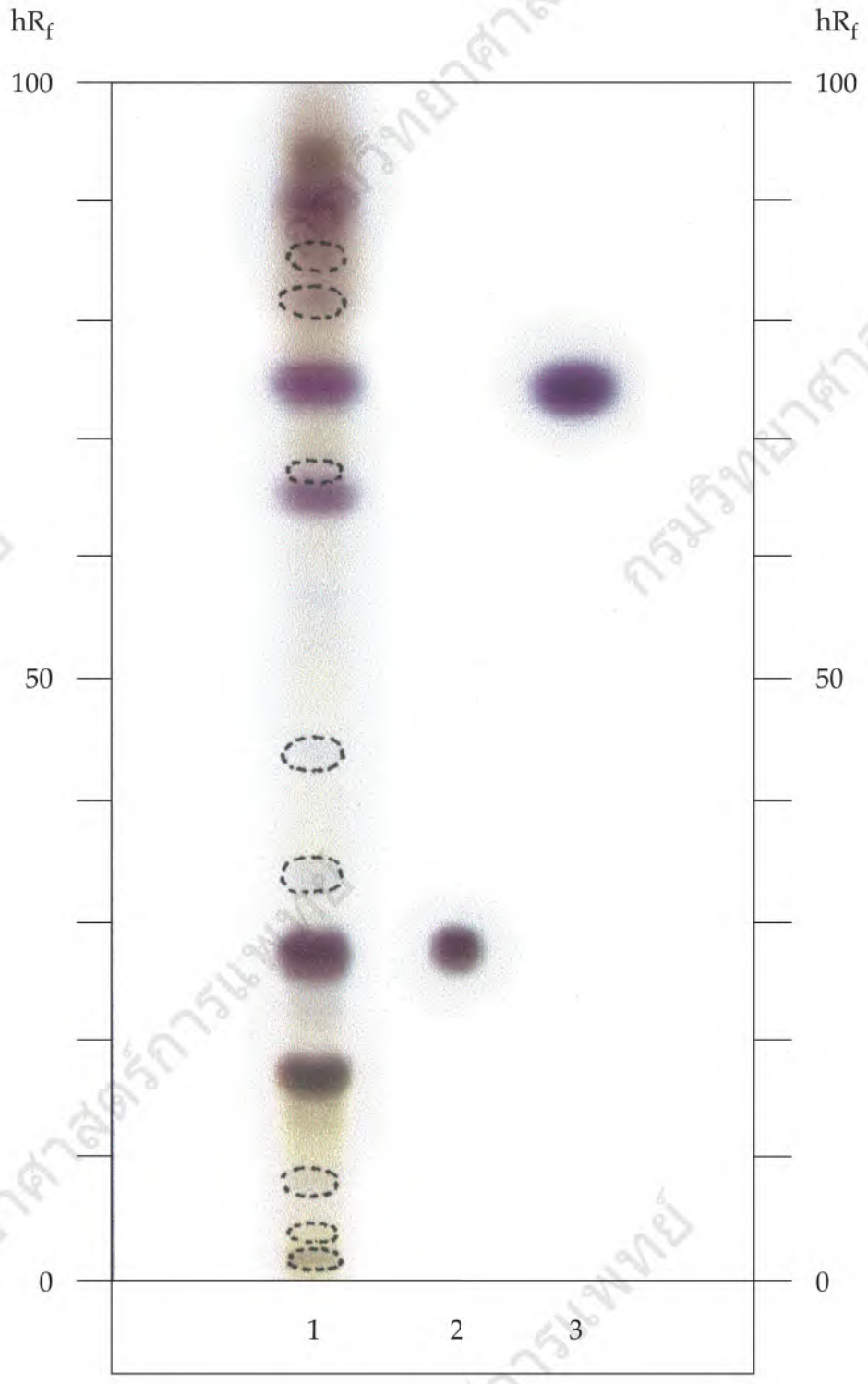


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Aerial Parts of *Centella asiatica* (L.) Urb., Detected with *Anisaldehyde TS*

1 = solution (A)
2 = solution (B)
3 = solution (C)
◌ = spots developed in some samples

KHAMIN CHAN pp. 177–185

Replace with the following:

ขมิ้นชัน (KHAMIN CHAN)

Curcumae Longae Rhizoma, Curcumae Domesticae Rhizoma
Turmeric

Synonyms Curcuma, Indian Saffron, Yellow Root

Category Stomachic, carminative, pharmaceutic aid (colouring agent), astringent.

Turmeric is the dried rhizome of *Curcuma longa* L. (*C. domestica* Valeton) (Family Zingiberaceae), Herbarium Specimen Number: DMSC 31, 1410, 1458, Crude Drug Number: DMSc 0012.

Constituents Turmeric contains yellow volatile oil, of which turmerone and zingiberene are its major components, and curcuminoids, of which curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin are its major components.

Description of the plant (Figs. 1a, 1b) Perennial herb with a thick, ellipsoid-ovate rhizome, orange inside, giving rise to short blunt daughter rhizomes called fingers; leafy shoots up to 1 m tall, bearing 6 to 10 leaves. Leaves simple, glabrous, lamina, elliptic, oblong-elliptic or lanceolate, 30 to 45 cm long, 10 to 15 cm wide, apex acuminate, base narrow; petiole as long as lamina (rather abruptly broadened to leaf sheath, forming a pseudostem). Inflorescence scape from the apex of the rhizome; peduncle 15 cm or more long; spike 10 to 15 cm long, 5 to 7 cm in diameter; bract, white or white with green, 5 to 6 cm long, each subtending flowers; bracteole thin, pale green and tinged with pink, elliptic to ovate, up to 3.5 cm long. Flowers as long as the bracts; calyx whitish tubular, unilateral split, unequally toothed; corolla white, tubular at base, upper half cup-shaped with 3 unequal lobes inserted on edge of cup lip; lateral staminode petaloid, oblong, folder under the dorsal petal, staminode and lip creamy-white with yellow median band, filament united to another about the middle of the pollen sac, spurred at base; ovary trilocular. Fruit capsule, globose to ellipsoid. Seed arillate.

Description

Macroscopical (Fig. 1a) Dried rhizome occurs as an ovate, oblong or pear-shaped of round turmeric; cylindrical and often short-branched of long turmeric; the round about half as broad as long, the long 2 to 5 cm long and 1 to 2 cm thick; externally yellowish to yellowish brown, with root scars and annulations, the latter from the scars of leaf bases; fracture horny; internally orange-yellow to orange, waxy, showing a cortex separated from a central cylinder (about twice as broad as cortex) by a distinct endodermis; in both cortex and central cylinder, scattered bundles are seen.

Microscopical (Figs. 2a, 2b) Transverse section of the rhizome shows epidermis consisting of a layer of rectangular cells; covering trichomes, unicellular, up to 280 μm long. Hypodermis composed of 3 to 6 layers in the mature rhizome, but absent in the younger. Cork, 4 to 6 layers of rectangular cells. Cortex composed of thin-walled parenchyma cells containing numerous starch grains, yellowish oil droplets and yellow colouring matter occasionally seen; starch grains, simple, flattened, rounded to oval or irregular in outline, very faint transverse striations could be seen in some granules. Endodermis, a layer of thin-walled cells. Stele, thin-walled parenchyma cells containing numerous starch grains, yellowish oil droplets and yellow colouring matter. Fibrovascular bundles, non-lignified walled cells, scattered in cortex and stele; vessels, spiral, scalariform and reticulate.

Turmeric in powder possesses the diagnostic microscopical characters of the unground drug.

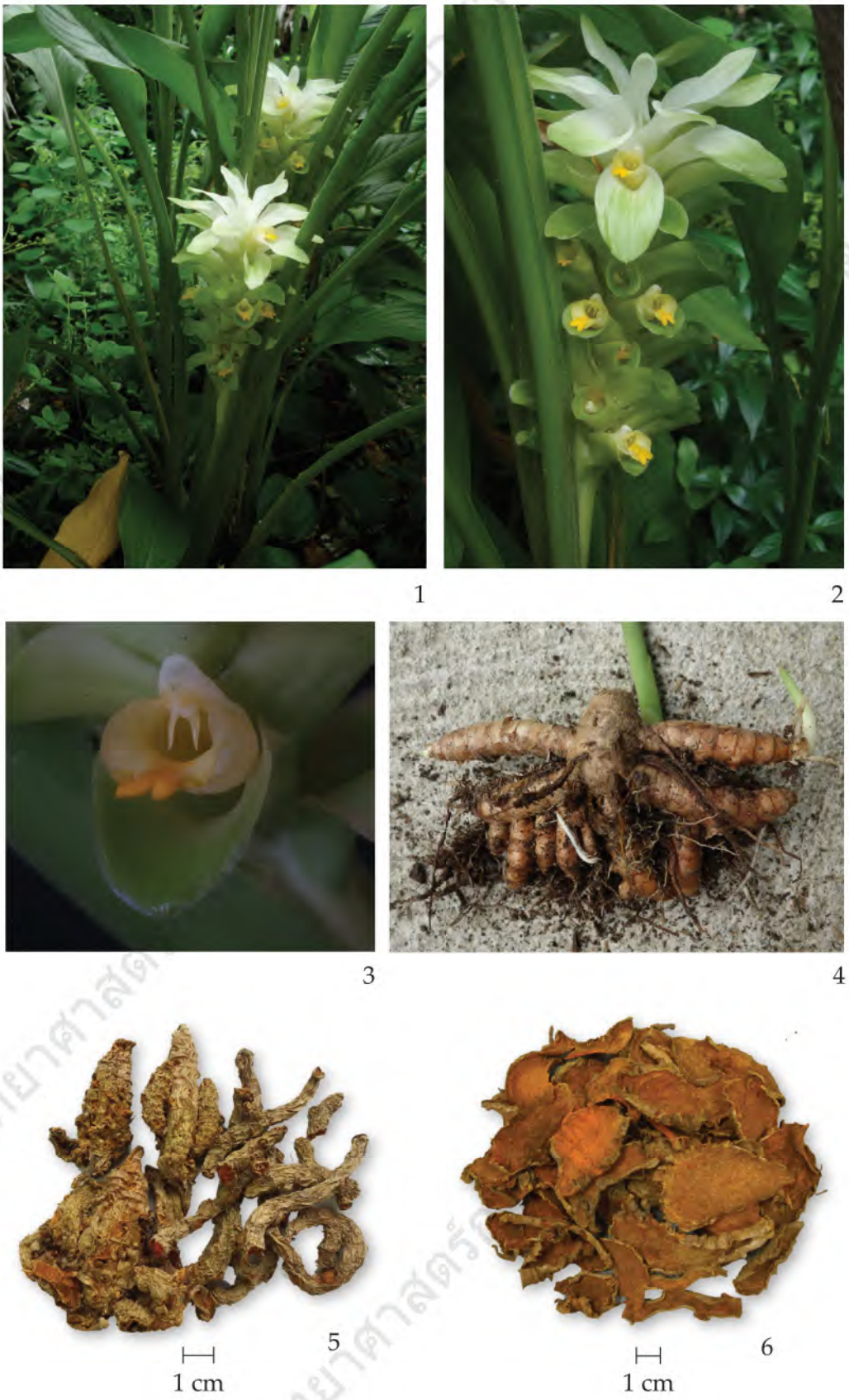


Fig. 1a *Curcuma longa* L.
1. habit 2. inflorescence 3. flower 4. rhizome 5. and 6. crude drug

Fig. 1b *Curcuma longa* L.
1. habit 2. inflorescence 3. rhizome

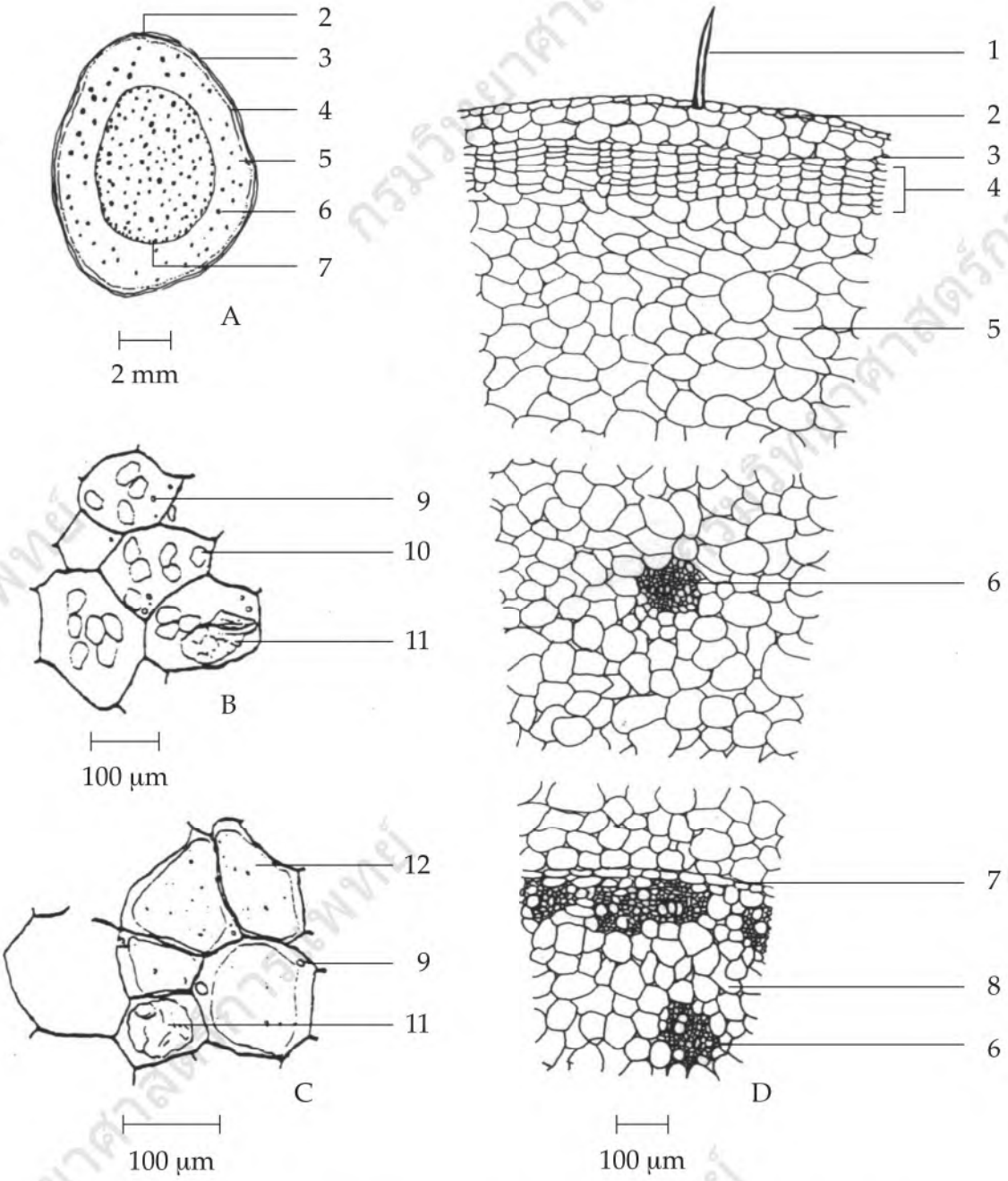
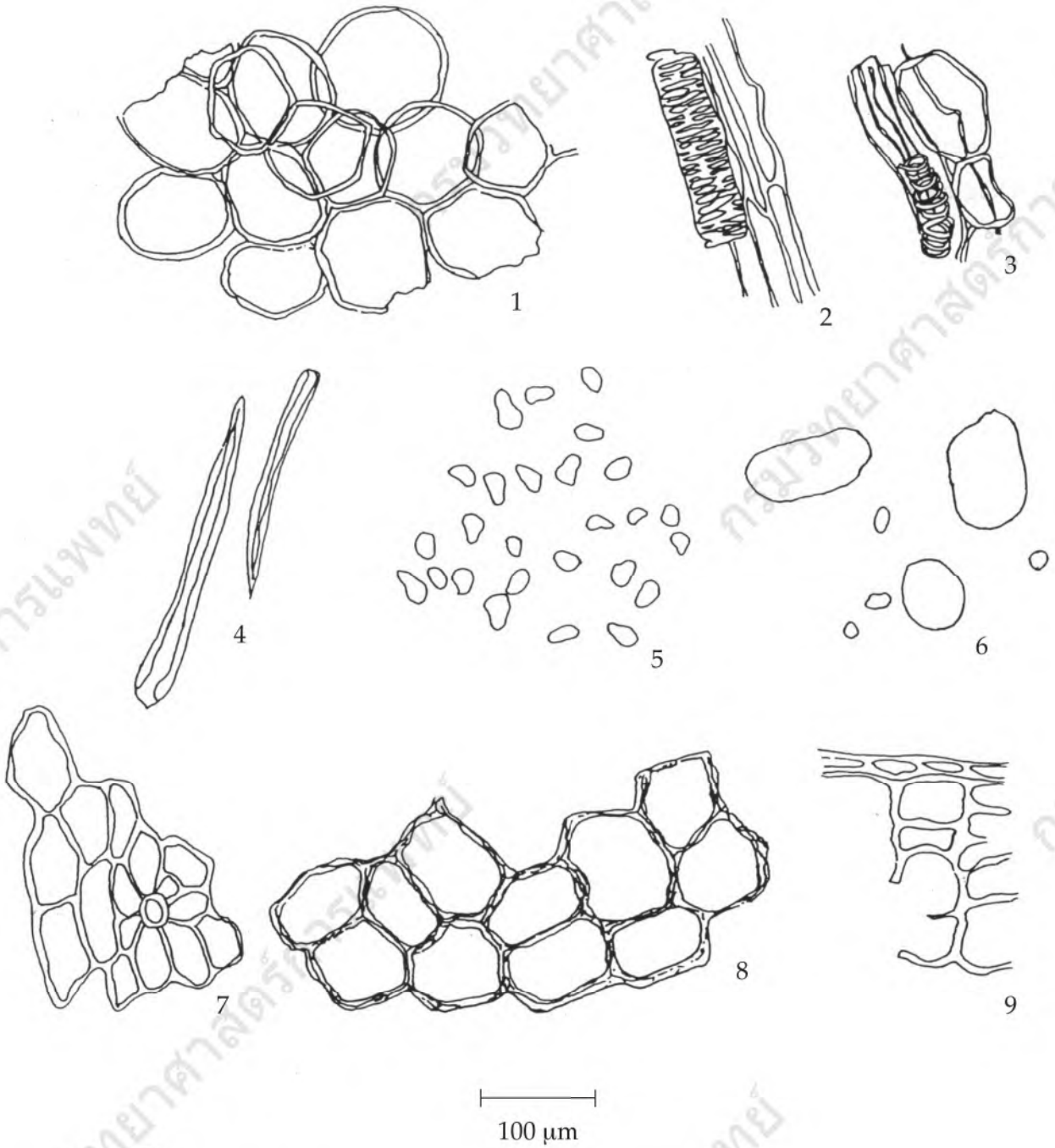


Fig. 2a Line Drawings of Transverse Section of the Rhizome of *Curcuma longa* L.

A. Diagram
B. Parenchyma of Untreated Rhizome
C. Parenchyma of Steam-Treated Rhizome
D. Part of Transverse Section

1. unicellular covering trichome
2. epidermis
3. hypodermis
4. cork layers
5. cortical parenchyma containing starch granules
6. vascular bundles
7. endodermis
8. stele parenchyma containing starch granules
9. oil droplet
10. starch granule
11. orange-yellow colouring matter
12. yellow gelatinized starch mass



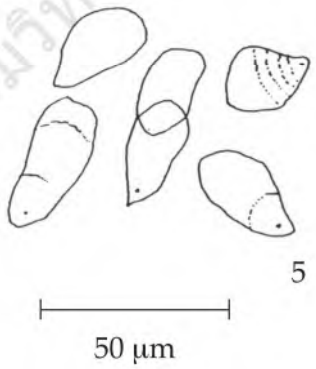


Fig. 2b Line Drawings of Powdered Drug of the Rhizomes of *Curcuma longa* L.

1. parenchyma
2. reticulate vessel
3. spiral vessel
4. unicellular trichomes
5. starch granules
6. altered starch grains
7. epidermis in surface view
8. cork in surface view
9. epidermis and hypodermis, in sectional view

Packaging and storage Turmeric 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. Extract 10 mg of the sample, in powder, with 2 mL of *acetic anhydride*, add a few drops of *sulfuric acid* and observe under ultraviolet light (366 nm): the solution shows blood-red colour.

B. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using *silica gel G* as the coating substance and a mixture of 49 volumes of *benzene*, 49 volumes of *chloroform*, and 2 volumes of *ethanol* as the mobile phase and allowing the solvent front to ascend 17 cm above the line of application. Apply separately to the plate, 5 μL each of the following two solutions. Prepare solution (A) by placing 1 g of the sample, in powder, in a stoppered test-tube, adding 3 mL of *methanol*, and shaking for a few minutes. Set aside for 1 hour and filter. For solution (B) dissolve 1 mg of *curcumin* in 1 mL of *methanol*. After removal of the plate, allow it to dry in air and examine under ultraviolet light (366 nm), locating the spots. The chromatogram obtained with solution (A) shows a yellow-brown spot (hR_f value 28 to 34) corresponding to the *curcumin* spot from solution (B). Other two yellow-brown spots correspond in hR_f values to the spot numbers 2 and 3. Several spots of higher and lower hR_f values are observed (Table 1); see also Fig. 3. Spray the plate with a 10 per cent w/v solution of *phosphomolybdic acid* in *ethanol* and heat at 105° for 5 minutes; the spot due to curcumin is orange-brown. The spots due to those of numbers 2, 3, 10, 14, and 15 in Table 1 are orange, orange-brown, blue, blue, and blue, respectively. Other spots of different colours are observed (Table 1); see also Fig. 3.

Alternatively, use *silica gel GF254* as the coating substance and a mixture of 80 volumes of *dichloromethane*, 18 volumes of *hexane*, and 2 volumes of *methanol* as the mobile phase. Apply separately to the plate as bands of 8 mm, 5 μL each of the following four solutions. Prepare solution (A) by shaking 2 g of the sample, in powder, with 20 mL of *ethanol* for an hour and filtering through a membrane having a 0.22-μm porosity, if necessary. For solution (B) dissolve 1 mg of *curcumin* in 1 mL of *ethanol*. For solution (C) dissolve 1 mg of *demethoxycurcumin* in 1 mL of *ethanol*. For solution (D) dissolve 1 mg of *bisdemethoxycurcumin* in 1 mL of *ethanol*. 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), through the cut-off filter; locating the bands.
The chromatogram obtained with solution (A) shows three yellow-brown fluorescent bands (hR_f values 45 to 50, 25 to 30, and 10 to 15) corresponding to the *curcumin* band from solution (B), demethoxycurcumin band from solution (C), and bisdemethoxycurcumin band from solution (D). Other two yellow-brown fluorescent bands are also observed. Spray the plate with *anisaldehyde TS* and heat at 105° for 5 minutes; the bands due to curcumin, demethoxycurcumin, and bisdemethoxycurcumin are red. One blue and three pink bands are observed; see also Fig. 4.

Table 1 hR_f Values of Components in Methanolic Extract of the Rhizomes of *Curcuma longa* L.

Spot	hR_f Value	Detection	
		UV 366	10 Per Cent W/V Solution of *Phosphomolybdic Acid* in *Ethanol*
1	5–8	light brown	brown
2	11–15	yellow-brown	orange
3	17–20	yellow-brown	orange-brown
4	21–24	blue-green	blue
5	28–34	yellow-brown	orange-brown
6	35–38	blue-green	blue
7	39–42	yellow	pale yellow
8	44–46	–	blue
9	48–51	–	blue
10	52–53	–	blue
11	57–60	–	blue
12	62–66	–	blue
13	71–74	–	blue
14	80–85	–	blue
15	87–90	–	blue

2 = bisdemethoxycurcumin
3 = demethoxycurcumin
5 = *curcumin*
10 = curcumol
14 = *dl*-turmerone
15 = ar-curcumene (ar = aromatic)

Water Not more than 10.0 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 10.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 9.0 per cent w/w (Appendix 7.12).

Volatile oil Not less than 6.0 per cent v/w (Appendix 7.3H). Use 10 g, in *fine powder*, accurately weighed. Use 100 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. Calculate the content of volatile oil with reference to the anhydrous substance.

Curcuminoids content Not less than 5.0 per cent w/w of curcuminoids, calculated as curcumin, when determined by the following method.

Standard curcumin solution Dissolve about 25 mg of Curcumin RS, accurately weighed, in sufficient *methanol* to produce 250.0 mL.

Standard curcumin curve Transfer into six 100-mL volumetric flasks, 1, 2, 3, 4, 5, and 6 mL, respectively, of *Standard curcumin solution*, dilute to volume with *methanol*, and mix. Measure the absorbances of the standard solutions relative to the blank at 420 nm (Appendix 2.2). Plot the readings and draw the curve of best fit: the curve shows the correlation coefficient of not less than 0.999.

Sample preparation Transfer about 300 mg of Turmeric, in *fine powder* and accurately weighed, into a 25-mL Erlenmeyer flask and macerate with 10 mL of *methanol*. Set aside at room temperature for 6 hours with frequent shaking. Dilute 1.0 mL of the clear supernatant liquid with *methanol* to produce 25.0 mL. Transfer 1.0 mL of this solution into a 25-mL volumetric flask, dilute to volume with *methanol* and mix well.

Procedure Measure the absorbance of *Assay preparation* at the maximum at about 420 nm, using *methanol* as the blank (Appendix 2.2).

Calculation By reference to the standard curve, calculate the content of curcuminoids as curcumin in the sample.

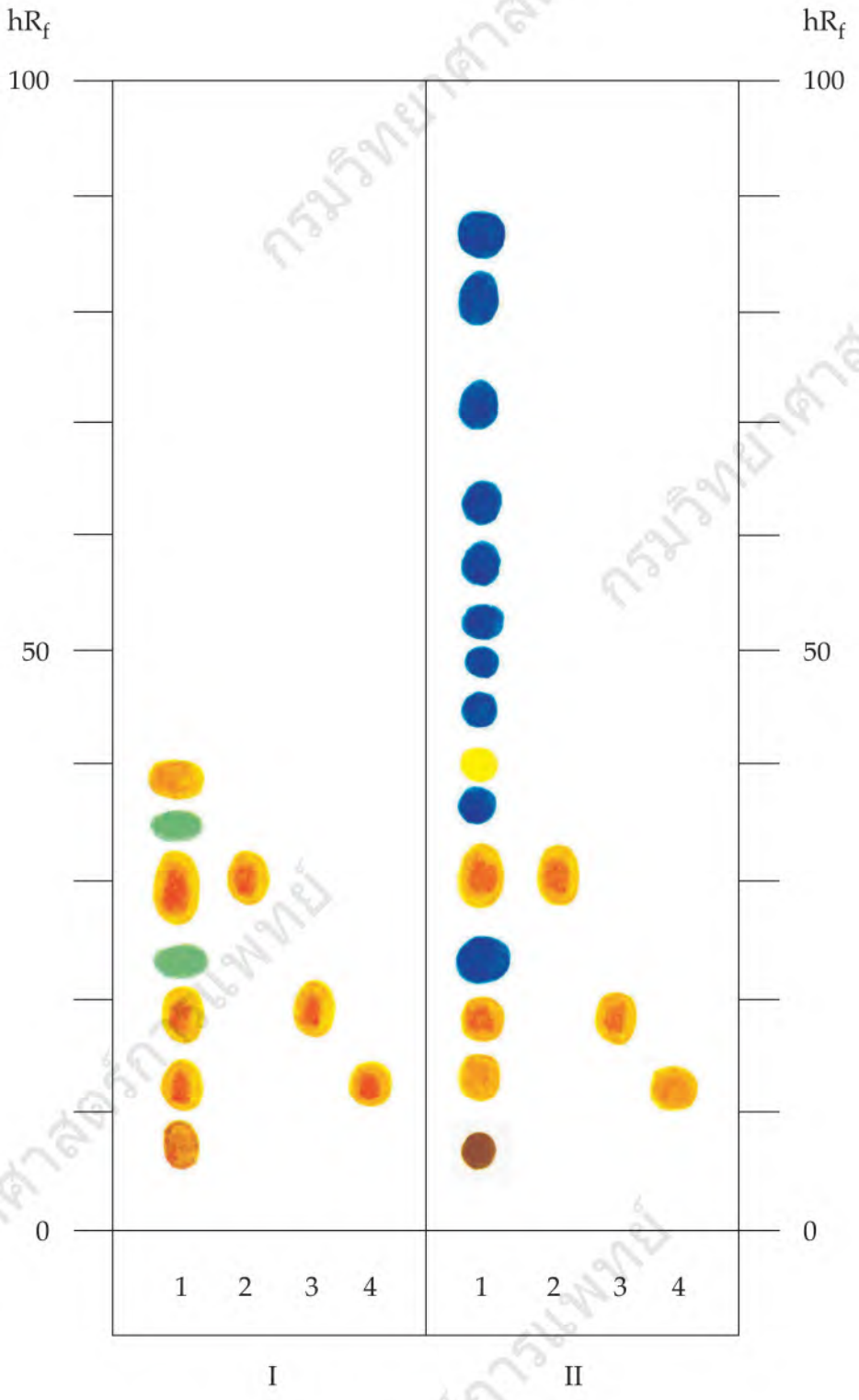


Fig. 3 Thin-Layer Chromatogram of Methanolic Extract of the Rhizomes of *Curcuma longa* L.
1 = solution (A)
2 = solution (B)
3 = a 0.1 per cent w/v solution of demethoxycurcumin in *methanol*
4 = a 0.1 per cent w/v solution of bisdemethoxycurcumin in *methanol*
I = detection under UV light (366 nm)
II = detection with a 10 per cent w/v solution of *phosphomolybdic acid* in *ethanol*

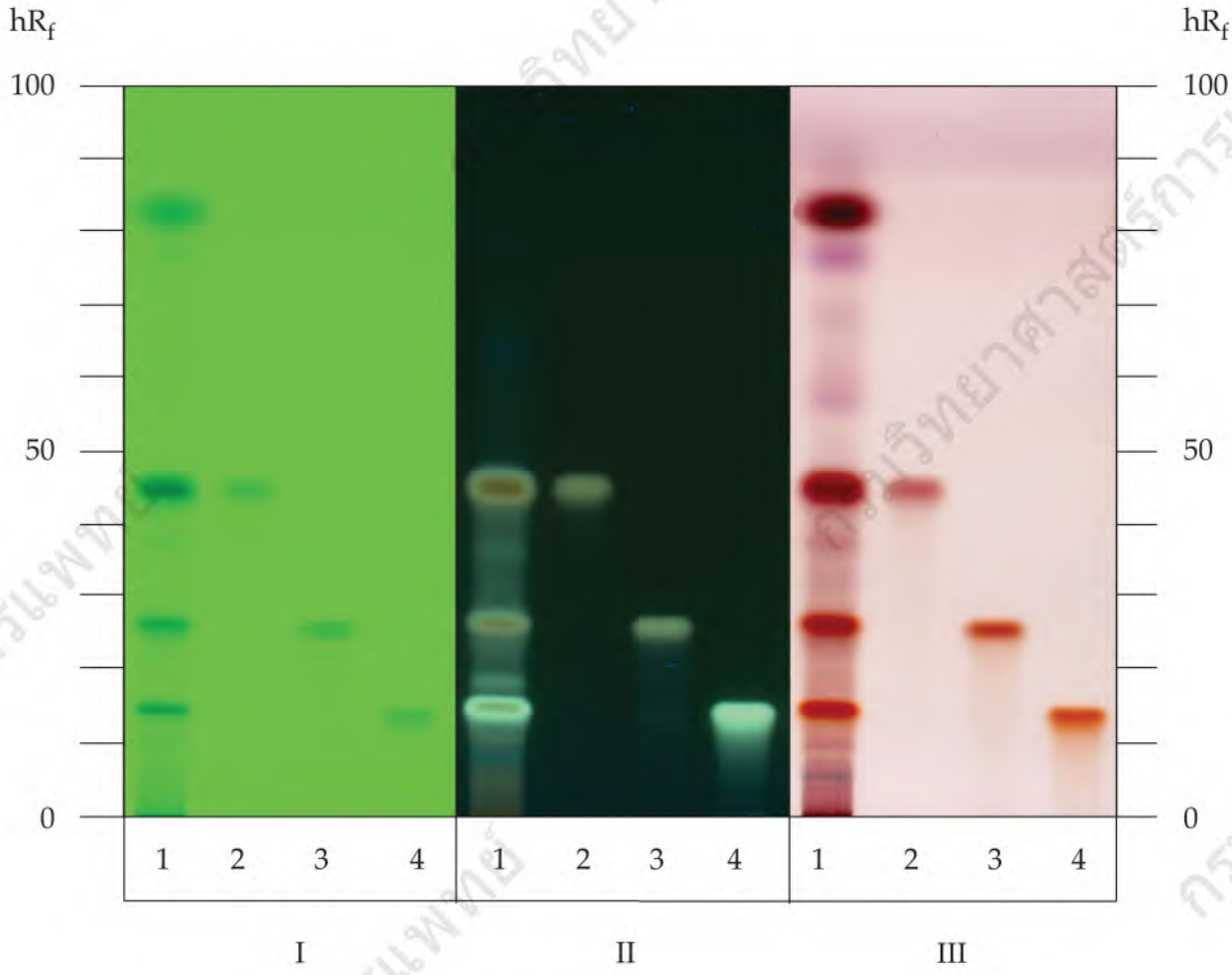


Fig. 4 Thin-Layer Chromatogram of Ethanolic Extract of the Rhizomes of *Curcuma longa* L.

1 = solution (A)
2 = solution (B)
3 = solution (C)
4 = solution (D)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with *anisaldehyde TS*

AMENDMENTS TO THP 2021 VOLUME II

APPENDIX

1.11H POWDER FINENESS AND SIEVES pp. 854–856

Replace with the following:

1.11H POWDER FINENESS AND SIEVES

Powders

The degree of coarseness or fineness of a powder is differentiated and expressed by reference to the nominal mesh aperture size of the sieves used.

The following terms are used in the description of powders:

COARSE POWDER A powder all the particles of which pass through a sieve with a nominal mesh aperture of 1.70 mm and not more than 40.0 per cent through a sieve with a nominal mesh aperture of 355 μm.

MODERATELY COARSE POWDER A powder all the particles of which pass through a sieve with a nominal mesh aperture of 710 μm and not more than 40.0 per cent through a sieve with a nominal mesh aperture of 250 μm.

MODERATELY FINE POWDER A powder all the particles of which pass through a sieve with a nominal mesh aperture of 355 μm and not more than 40.0 per cent through a sieve with a nominal mesh aperture of 180 μm.

FINE POWDER A powder all the particles of which pass through a sieve with a nominal mesh aperture of 180 μm.

VERY FINE POWDER A powder all the particles of which pass through a sieve with a nominal mesh aperture of 125 μm.

When the fineness of a powder is described by means of a number, it is intended that all the particles of the powder shall pass through a sieve of which the nominal mesh aperture, in μm, is equal to that number.

When a batch of a vegetable drug is being ground and sifted, no portion of the drug shall be rejected, but it is permissible, except in the case of assays, to withhold the final tailings, if an approximately equal amount of tailings from a preceding batch of the same drug has been added before grinding.

When the use of sieves is inappropriate, the definition is expressed in terms of the particle size as determined by suitable microscopical examination.

Sieves

Wire mesh sieves used in sifting powdered drugs are identified by numbers indicating the nominal mesh aperture.

The sieves should be made of wires of uniform circular cross-section. The wires may be of stainless steel or of other suitable material except that plated wire is not permitted. Sieves should conform to the specifications which are concordant with the recommended International standard ISO 3310-1:2000 (E), shown in the following table.

Calibration and recalibration of test sieves is in accordance with the most current edition of ISO 3310-1. Sieves should be carefully examined for gross distortions and fractures, especially at their screen frame joints, before use. Sieves may be calibrated optically to estimate the average opening size, and opening variability, of the sieve mesh. Alternatively, for the evaluation of the effective opening of test sieves in the size range of 212 to 850 μm, Standard Glass Spheres are available from the national or international organization, e.g. NIST[1]. Unless otherwise specified in the individual monograph, perform the sieve analysis at controlled room temperature and a relative humidity between 20 and 70 per cent.

CLEANING TEST SIEVES Ideally, test sieves should be cleaned using only an air jet or a liquid stream. If some apertures remain blocked by test particles, careful gentle brushing may be used as a last resort. Washing sieves in hot water is not recommended since the sieves can distort and rupture during heating and cooling. If it is necessary to use water, it should be used at ambient temperature and the sieve dried by first using a volatile water-miscible solvent to remove the water and then a low-pressure air jet to remove the solvent. This procedure should be carried out in a fume hood or cabinet that conforms to local regulations.

Method for Determining Powder Fineness

Place the specified quantity of the test powder upon the appropriate sieve having a close-fitting receiving pan and cover. Shake the sieve in a rotary horizontal direction and vertically by tapping on a hard surface for not less than the specified time or until sifting is practically complete. Avoid prolonged shaking that would result in increasing the fineness of the powder during the testing. In the case of oily or other powders that tend to clog the openings, carefully brush the screen at intervals during the test. Breaking up lumps that form during the sifting. Weigh accurately the amount remaining on the sieve and in the receiving pan.

The fineness of a powdered drug or chemical may be determined also by screening through the sieves in mechanical sieve shaker, which reproduces the circular and tapping motion given to testing sieves in hand sifting but with a uniform mechanical action, following the directions provided by the manufacturer of the shaker.

[1]US National Institute of Standards and Technology.

Number of Sieve*	Nominal Mesh Aperture Size	Preferred Average Wire Diameter	Percentage Sieving Area	US Sieve No.**
μm	mm	mm		
4000	**4.00**	**1.40**	**55**	**5**
3350	3.35			6
2800	**2.80**	**1.12**	**51**	**7**
2360	2.36	1.00	49	8
2000	**2.00**	**0.90**	**48**	**10**
1700	1.70	0.80	46	12
1400	**1.40**	**0.71**	**44**	**14**
1180	1.18	0.63	43	16
1000	**1.00**	**0.56**	**41**	**18**
μm	μm	μm		
850	850			20
710	**710**	**450**	**37**	**25**
600	600	400	36	30
500	**500**	**315**	**38**	**35**
425	425	280	36	40
355	**355**	**224**	**38**	**45**
300	300	200	36	50
250	**250**	**160**	**37**	**60**
212	212	140	36	70
180	**180**	**125**	**35**	**80**
150	150	100	36	100
125	**125**	**90**	**34**	**120**
106	106	71	36	140
90	**90**	**63**	**35**	**170**
75	75	50	36	200
63	**63**	**45**	**34**	**230**
53	53	36	35	270
45	**45**	**32**	**34**	**325**

*Entries in bold are ISO "principal sizes".

**The list of United States standard sieves is included for information purposes.

Method for Determining the Particle Size

The following method-sieving is used for the determination of particle size in herbal drug powders and topical powders. Sieving generally falls into three main types, manual sieving, mechanical sieving and air-jet sieving. Manual sieving and mechanical sieving are most suitable where the majority of the particles are larger than about 75 μm. For particles smaller than 75 μm, air-jet sieving or other means of agitation may be more appropriate.

Mechanical sieving methods using mechanical agitation or electromagnetic agitation, and that can induce either a vertical oscillation or a horizontal circular motion, or tapping, or a combination of both tapping and horizontal circular motion is available. Entrainment of the particles in an air stream may be used in air jet sieving.

The relative humidity of the environment in which the sieving is carried out must be controlled to prevent moisture uptake or loss by the sample. If the substance being examined is known to develop an electrostatic charge, an antistatic agent, such as colloidal silicon dioxide and/or aluminium oxide, may be added at a 0. 5 per cent w/w level to minimize this effect.

1. Manual sieving

SINGLE SIEVE Place a quantity of the substance being examined, as specified in the individual monograph, upon the sieve with a specified number or a nominal mesh aperture, in μm, with a close-fitting receiving pan and cover. Shake the sieve in a rotary horizontal direction for not less than 3 minutes, and gently tap on the sieve frequently in vertical direction. Weigh accurately the amount in the receiving pan, and calculate the percentage.

TWO SIEVES Place the accurately weighed content of 5 single-dose units or of 1 multiple-dose unit upon the upper sieve. Shake the sieve in a left-to-right horizontal direction by gently tapping on the sieve for 3 minutes. Weigh accurately the amount remaining on the coarser sieve and passing through the finer sieve. Calculate the percentage of the fraction.

2. Mechanical sieving

Unless otherwise specified, weigh accurately the test sieves having a 200-mm in diameter and the receiving pan. Place 25 to 100 g of the substance being examined, accurately weighed, depending on the bulk density of the material, upon the top or coarsest sieve whereas the bottom sieve and cover is assembled with a close-fitting receiving pan. Set the mode and the frequency of agitation, and agitate the nest of sieves for 5 minutes, then weigh accurately each sieve and the receiving pan and determine the weight of substance on each sieve.

Calculate the percentage. Repeat these steps until the weight on any of the test sieve does not change by more than 5 per cent or 100 mg of the previous weight on that sieve. If less than 5 per cent of the total sample weight is present on a given sieve, the end-point for that sieve is increased to a weight change of not more than 20 per cent of the previous weight on that sieve.

3. Air-jet sieving

A single sieve is used at a time. It requires sequential analyses on individual sieves starting with the finest sieve to obtain a particle size distribution. Unless otherwise specified, weigh accurately the test sieve having a 200-mm in diameter. Place 25 to 100 g of the substance being examined, accurately weighed, depending on the bulk density of the material, upon the sieve with a cover. Set the pressure and air-jet for 5 minutes, then weigh accurately the sieve and determine the weight of substance on it. Calculate the percentage. Repeat these steps until the weight on the test sieve does not change by more than 5 per cent or 100 mg of the previous weight on that sieve. If less than 5 per cent of the total sample weight is present on a given sieve, the end-point for that sieve is increased to change of not more than 20 per cent of the previous weight sieve.

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),

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[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

ยาแคปซูลบัวบก (BUABOK CAPSULES)

Centella Capsules

Category Anti-inflammatory, wound healing.

Centella Capsules contain an amount of powdered Centella equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amounts for the sum of asiaticoside ($C_{48}H_{78}O_{19}$) and madecassoside ($C_{48}H_{78}O_{20}$), calculated on the dried basis.

Strength available 400 mg (powder).

Dose One capsule three times a day after meals.

Packaging and storage Centella Capsules shall be kept in well-closed containers, protected from light, and stored in a dry place at a temperature not exceeding 30°.

Labelling The label on the container states (1) the amounts for the sum of asiaticoside and madecassoside; (2) the expiration date.

Identification

A. The capsule contents exhibit diagnostic structures of the powdered drug described under *Centella*.

B. The capsule contents comply with the tests for Identification A, B, C, and D described under *Centella*.

C. The chromatogram of the Assay preparation shows several peaks, two of which correspond to the asiaticoside and madecassoside peaks of the Standard preparations as obtained in the *Assay*.

Loss on drying Of the capsule contents, not more than 14.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Microbial limit Comply with the requirements for Category 4 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 Use *water*.

Standard preparation A Dissolve a suitable quantity of *asiaticoside*, accurately weighed, in sufficient *methanol* to obtain a stock solution having a known concentration of about 250 μg of asiaticoside per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions having known concentrations ranging from 10 to 60 μg per mL.

Standard preparation B Dissolve a suitable quantity of *madecassoside*, accurately weighed, in sufficient *methanol* to obtain a stock solution having known concentrations of about 300 μg of madecassoside per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions having known concentrations ranging from 30 to 180 μg per mL.

Assay preparation Weigh and mix the contents of not less than 20 Centella Capsules and grind to *fine powder*. Transfer about 200 mg, accurately weighed, into a 50-mL round-bottomed flask and add 25 mL of *methanol*. Heat under a reflux condenser for 1 hour, filter into a 50-mL volumetric flask, and add the same solvent to volume. Filter through a membrane having a 0.22-μm porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (5 cm × 2.1 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (1.7 μm), (b) *Mobile phase* at a flow rate of about 0.6 mL per minute, and (c) an ultraviolet photometer set at 205 nm.

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	15	85
1.5	60	40
2	0	100
3	0	100
4	15	85

To determine the suitability of the chromatographic system, chromatograph *Standard preparation A* and *Standard preparation B* having known concentrations of 30 μg per mL of asiaticoside and 90 μg per mL of madecassoside, respectively, and record the peak responses as directed under *Procedure* and *Calculation*: the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure Separately inject equal volumes (about 4 μL) of *Standard preparation A* and *Standard preparation B* into the chromatograph, record the chromatograms, and measure the responses for asiaticoside and madecassoside peaks. Plot the readings and draw the standard curves of best fit: the curves show the correlation coefficient of not less than 0.999. Inject about 4 μL of *Assay preparation* into the chromatograph, record the chromatogram, and measure the responses for asiaticoside and madecassoside peaks.

Calculation By reference to the standard curves, calculate the sum of asiaticoside ($C_{48}H_{78}O_{19}$) and madecassoside ($C_{48}H_{78}O_{20}$) contents in the portion of the Capsules taken.

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

ยาชงบัวบก (YA CHONG BUABOK)

Centella Tea

Category Antipyretic, anti-inflammatory.

Centella Tea contains an amount of powdered Centella equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amounts for the sum of asiaticoside ($C_{48}H_{78}O_{19}$) and madecassoside ($C_{48}H_{78}O_{20}$), calculated on the dried basis.

Strength available 2 g (powder), supplied in a sachet.

Dose One or two sachets, prepared as an infusion by soaking with 120 to 200 mL of boiling water for 10 minutes, three times after meals.

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

Labelling The label on the container states (1) the amounts for the sum of asiaticoside and madecassoside; (2) the expiration date.

Identification

A. The tea contents exhibit diagnostic structures of the powdered drug described under *Centella*.

B. The tea contents comply with the tests for Identification A, B, C, and D described under *Centella*.

C. The chromatogram of the Assay preparation shows several peaks, two of which correspond to the asiaticoside and madecassoside peaks of the Standard preparations as obtained in the *Assay*.

Loss on drying Of the tea contents, not more than 14.0 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 Use *water*.

Standard preparation A Dissolve a suitable quantity of *asiaticoside*, accurately weighed, in sufficient *methanol* to obtain a stock solution having a known concentration of about 250 µg of asiaticoside per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions having known concentrations ranging from 10 to 60 µg per mL.

Standard preparation B Dissolve a suitable quantity of *madecassoside*, accurately weighed, in sufficient *methanol* to obtain a stock solution having known concentrations of about 300 µg of madecassoside per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions having known concentrations ranging from 30 to 180 µg per mL.

Assay preparation Grind the contents of not less than 20 sachets of Centella Tea to *fine powder*. Transfer about 200 mg, accurately weighed, into a 50-mL round-bottomed flask and add 25 mL of *methanol*. Heat under a reflux condenser for 1 hour, filter into a 50-mL volumetric flask, and add the same solvent to volume. Filter through a membrane having a 0.22-µm porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (5 cm × 2.1 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (1.7 μm), (b) *Mobile phase* at a flow rate of about 0.6 mL per minute, and (c) an ultraviolet photometer set at 205 nm.

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	15	85
1.5	60	40
2	0	100
3	0	100
4	15	85

To determine the suitability of the chromatographic system, chromatograph *Standard preparation A* and *Standard preparation B* having known concentrations of 30 μg per mL of asiaticoside and 90 μg per mL of madecassoside, respectively, and record the peak responses as directed under *Procedure* and *Calculation*: the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure Separately inject equal volumes (about 4 μL) of *Standard preparation A* and *Standard preparation B* into the chromatograph, record the chromatograms, and measure the responses for asiaticoside and madecassoside peaks. Plot the readings and draw the standard curves of best fit: the curves show the correlation coefficient of not less than 0.999. Inject about 4 μL of *Assay preparation* into the chromatograph, record the chromatogram, and measure the responses for asiaticoside and madecassoside peaks.

Calculation By reference to the standard curves, calculate the sum of asiaticoside ($C_{48}H_{78}O_{19}$) and madecassoside ($C_{48}H_{78}O_{20}$) contents in the portion of the Tea taken.

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

ช่อดอกเพศเมียกัญชง (CHO DOK PHET MIA KANCHONG)

Hemp Flos Feminar
Hemp Female Flower

Category Source of cannabidiol.

Hemp Female Flower is the dried female flowering top 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 5340, Crude Drug Number: DMSc 1219.

Constituents Hemp Female Flower contains cannabinoids (e.g., cannabidiol or CBD, Δ^9-tetrahydrocannabinol or Δ^9-THC or THC). It also contains monoterpenes (e.g., *d*-limonene, β-myrcene, α-pinene, and γ-terpinolene), sesquiterpenes (e.g., β-caryophyllene, and α-humulene), etc.

Description of the plant (Fig. 1) Herbaceous plant, dioecious, occasionally monoecious, at least 2 m tall and up; stem and branches angular, erect, covered with rather short stiff hairs. Leaves palmately compound or reduced to simple, 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 axillary and terminal, 1 to 5 cm long. Flower small, unisexual; 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, yellowish brown to white or greenish, mottled with purple pericarp crustaceous, finely reticulate. Seed 1, shiny.

Description Odour, slightly tea-like; taste, bland or slightly bitter.

Macroscopical (Fig. 1) Hemp Female Flower occurs as flowering stem with sugar leaves, and female inflorescences, olive green to brownish. Flowering stem, angular, covered with rather short hairs. Sugar leaves, usually reduced to simple. Female inflorescence, axillary and terminal, 1 to 5 cm long; female flower, enveloped by perigonal bract, membranous spathe-like, dark green. Fruit an achene, ovoid or ellipsoid, with 1 shiny seed.

Microscopical (Figs. 2a–2f) Transverse section of the reduced leaf of the female flowering top through the midrib shows upper epidermis, mesophyll, vascular tissue, and lower epidermis. Upper epidermis: a layer of rectangular cells, covered with cuticle layer; unicellular trichomes, some containing cystolith; multicellular glandular trichomes with short stalk; multicellular multiseriate glandular trichomes. Mesophyll: 1 or 2 layers of cylindrical palisade cells, some containing rosette aggregate crystals; spongy cells, irregularly shaped, loosely arranged; and parenchyma, some containing rosette aggregate crystals. Vascular tissue: phloem and xylem, scattering in the mesophyll. Lower epidermis: a layer of rectangular cells, covered with cuticle layer; raised stomata; unicellular trichomes, some containing cystolith; and multicellular multiseriate glandular trichomes.

1

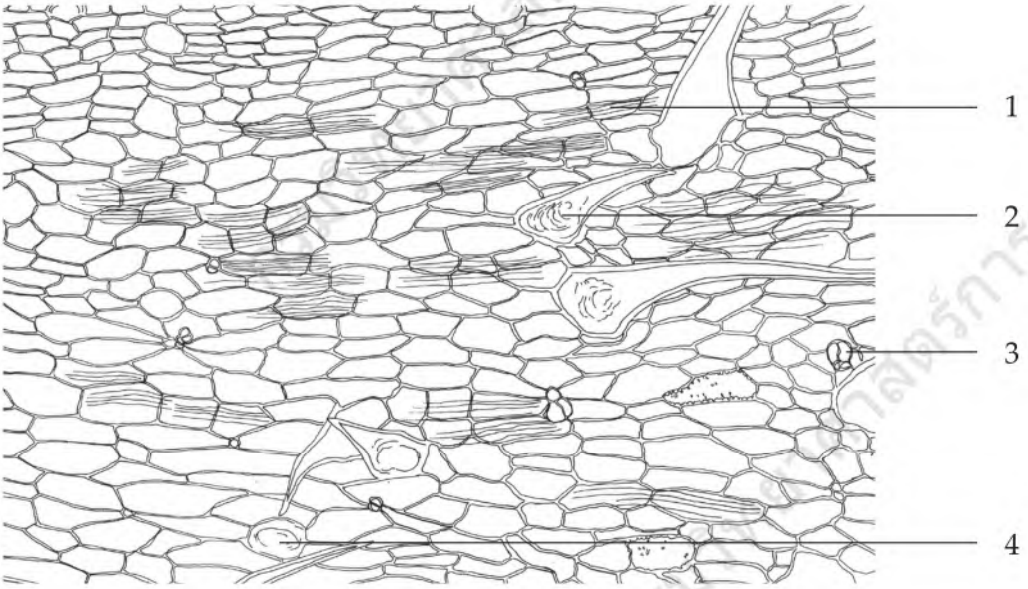
2

3

4

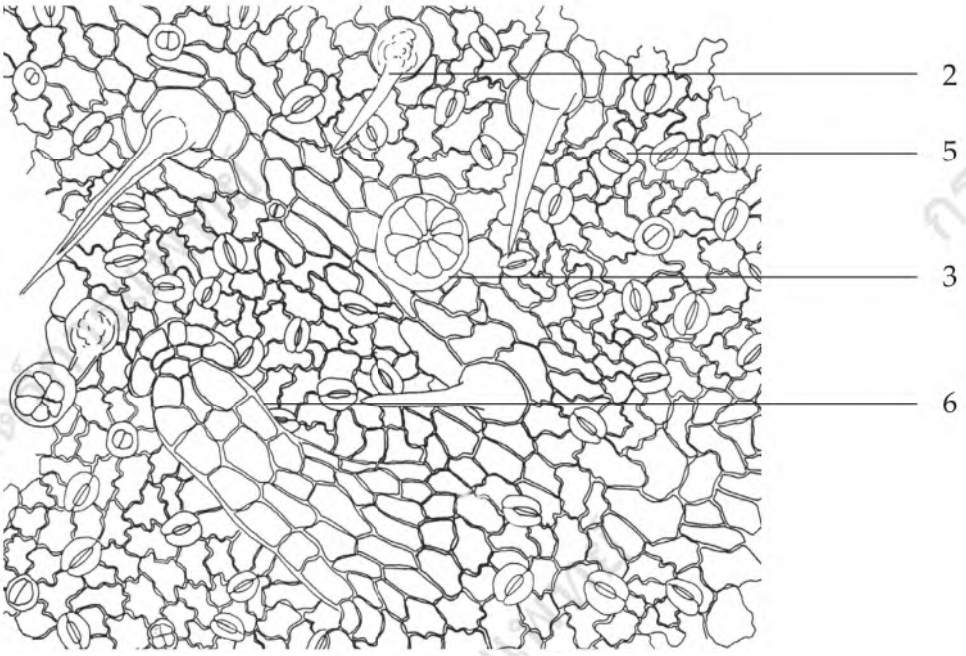
2 cm

Fig. 1 *Cannabis sativa* L.
1. habit 2. female flowering top 3. female flowering twig 4. crude drug



50 μm

Upper Epidermis of the Lamina

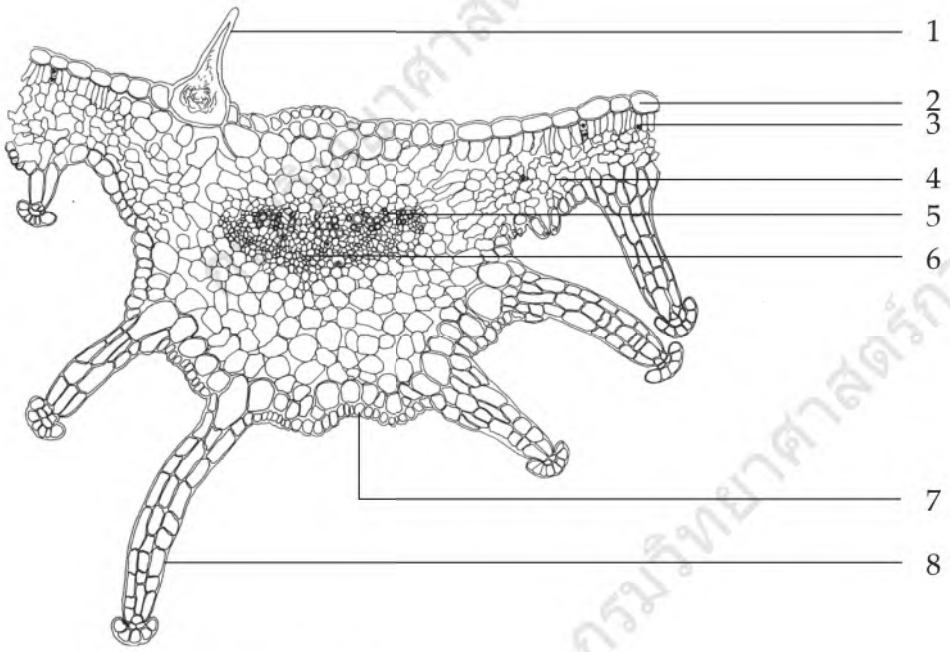


50 μm

Lower Epidermis of the Lamina

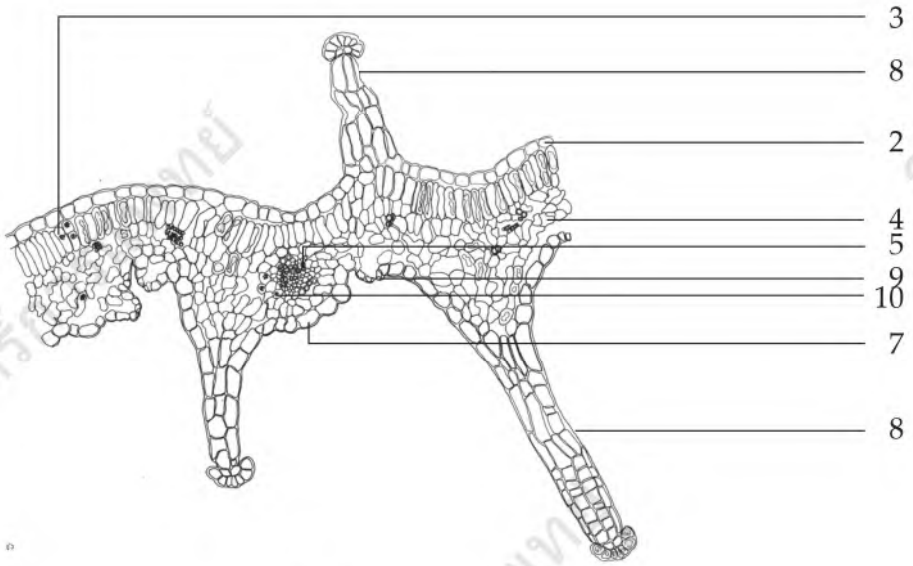
Fig. 2a Line Drawings of Epidermises of the Reduced Leaf of the Female Flowering Top of *Cannabis sativa* L.

1. epidermis with striation
2. unicellular trichome with cystolith
3. multicellular glandular trichome
4. cicatrix with cystolith
5. anomocytic stoma
6. multicellular multiseriate glandular trichome



50 μm

Transverse Section of the Lamina Through the Midrib



50 μm

Transverse Section of the Lamina

Fig. 2b Line Drawings of Transverse Sections of the Reduced Leaf of the Female Flowering Top of *Cannabis sativa* L.

1. unicellular trichome with cystolith
2. upper epidermis
3. palisade cell containing rosette aggregate crystal
4. spongy cell
5. vessel
6. phloem
7. lower epidermis
8. multicellular multiseriate glandular trichome
9. stoma
10. parenchyma containing rosette aggregate crystal

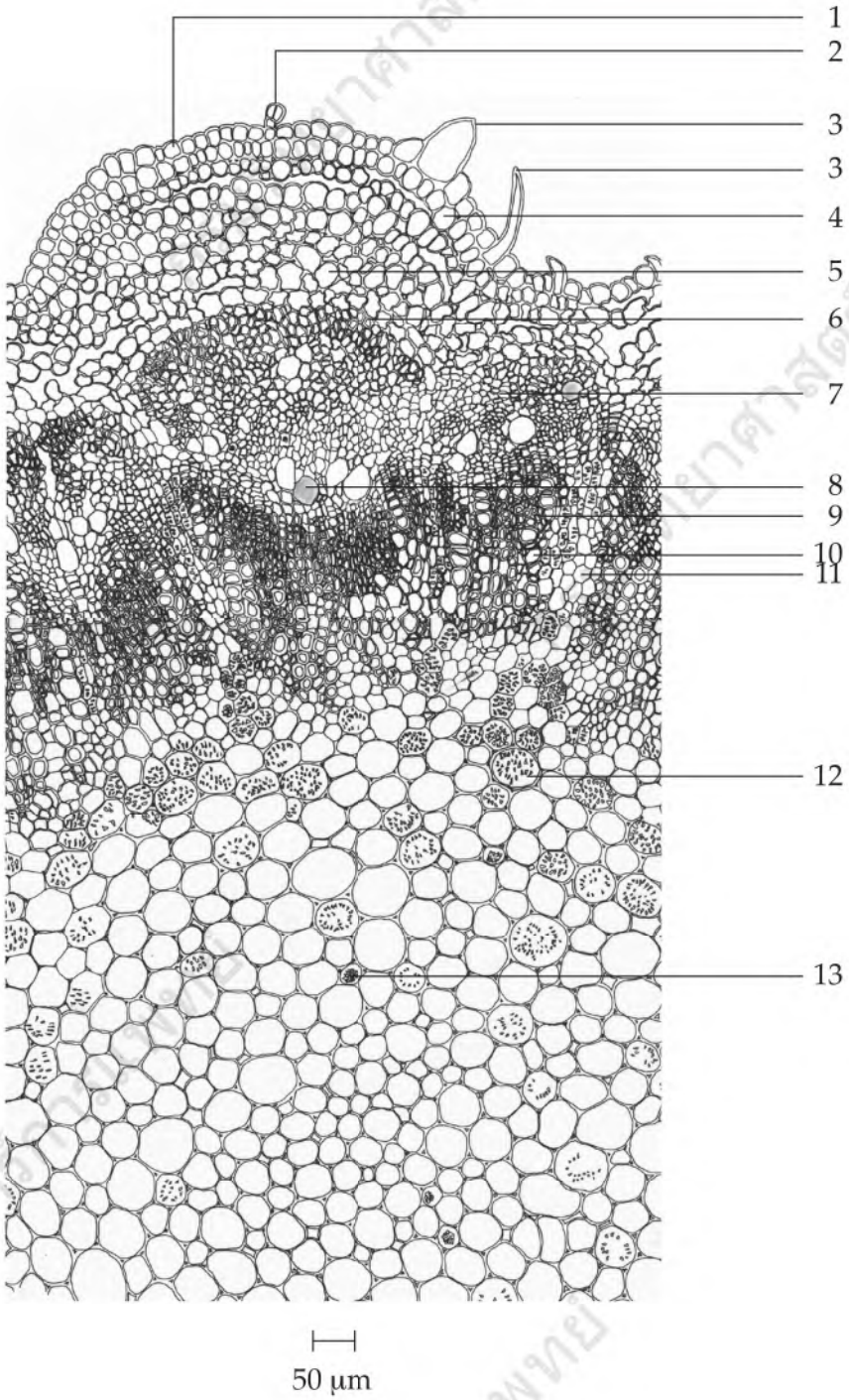
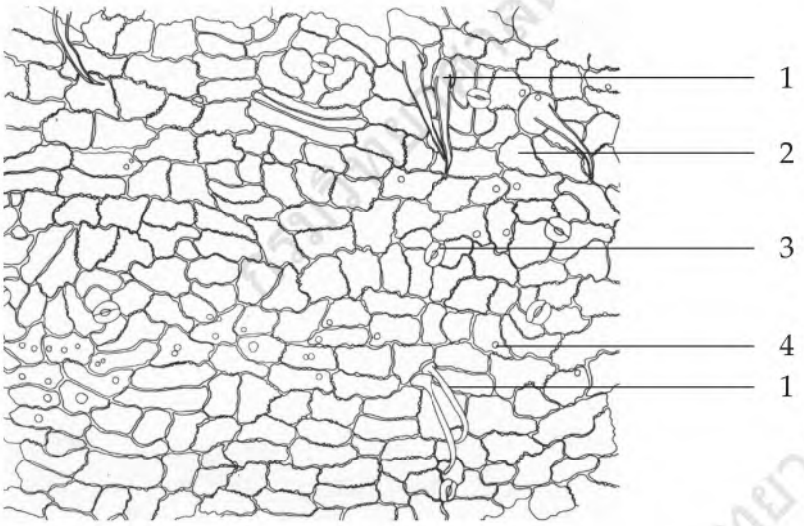
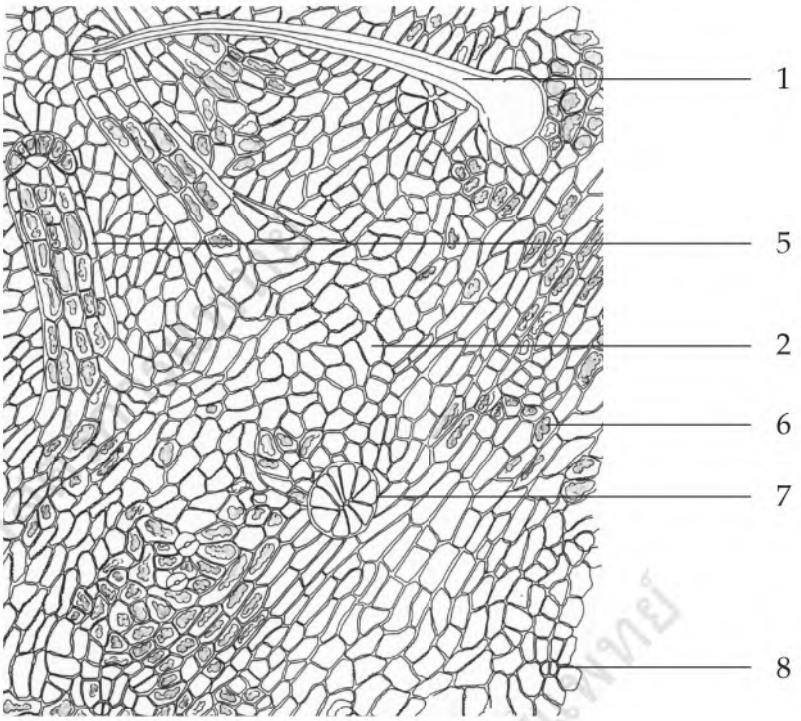


Fig. 2c Line Drawing of Transverse Section of the Peduncle of the Female Inflorescence of *Cannabis sativa* L.

1. epidermis
2. multicellular glandular trichome with short stalk
3. unicellular trichome
4. collenchyma
5. parenchyma
6. phloem fibre
7. phloem
8. brown substance
9. xylem fibre
10. vessel
11. xylem ray
12. parenchyma with pitted wall
13. parenchyma containing rosette aggregate crystal



Upper Epidermis of the Perigonal Bract



Lower Epidermis of the Perigonal Bract

Fig. 2d Line Drawings of Epidermises of the Perigonal Bract of the Female Inflorescence of *Cannabis sativa* L.

1. unicellular trichome
2. epidermis
3. anomocytic stoma
4. oil droplet
5. multicellular multiseriate glandular trichome
6. brown substance
7. multicellular glandular trichome
8. cicatrix

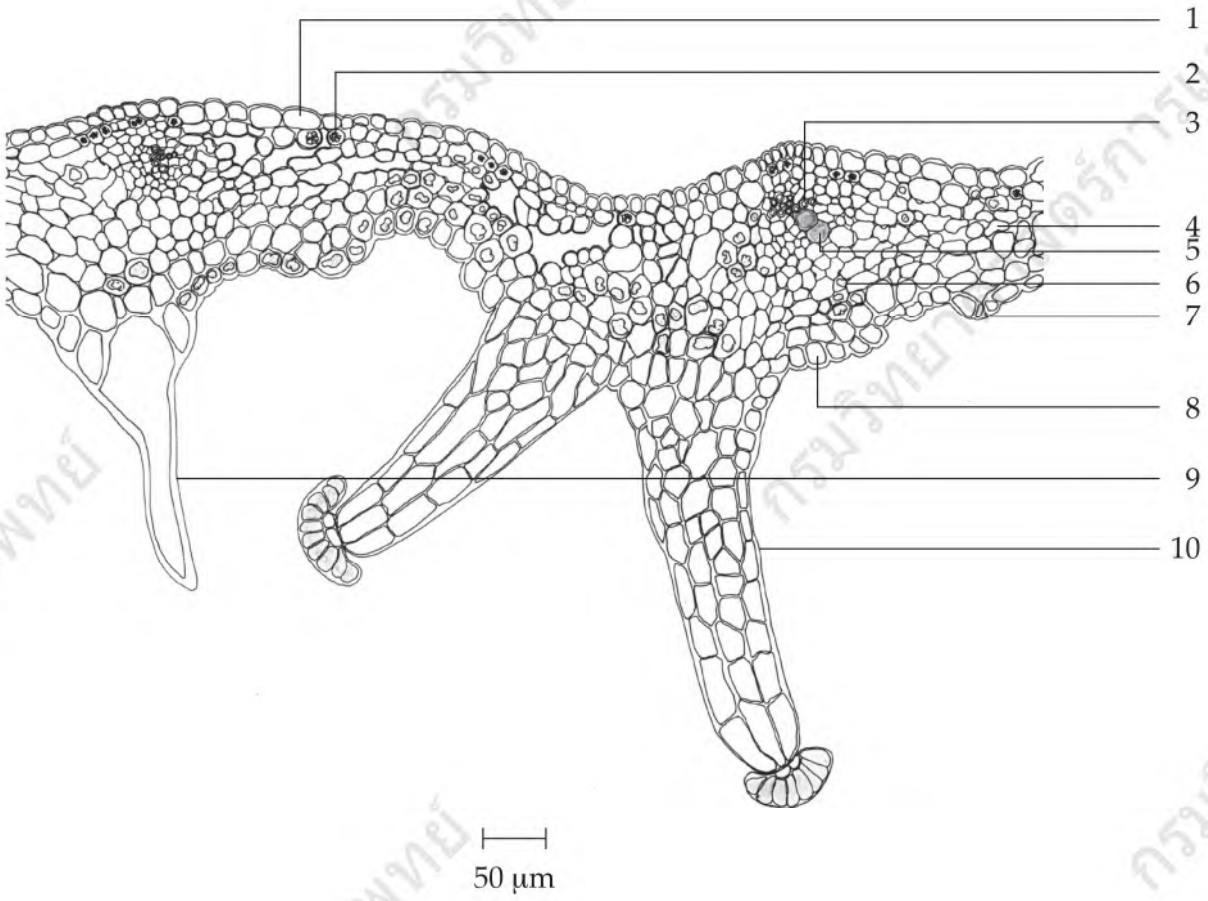


Fig. 2e Line Drawing of Transverse Section of the Perigonal Bract of the Female Inflorescence of *Cannabis sativa* L.

1. upper epidermis
2. parenchyma containing rosette aggregate crystal
3. vascular tissue
4. parenchyma
5. parenchyma containing brown substance
6. brown substance
7. stoma
8. lower epidermis
9. unicellular trichome
10. multicellular multiseriate glandular trichome

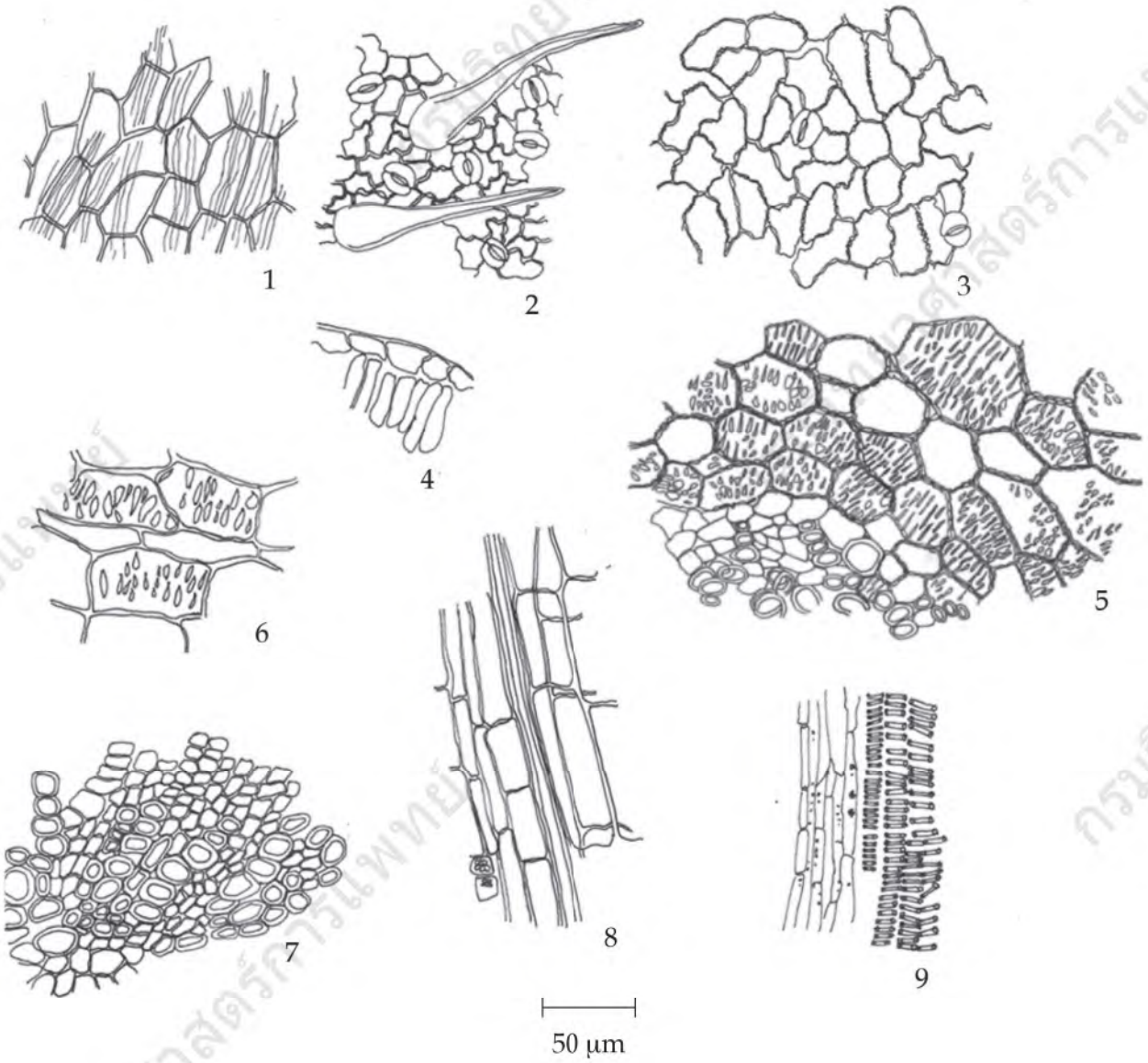


Fig. 2f Line Drawings of Powdered Drug of the Female Flowering Tops of *Cannabis sativa* L.

1. upper epidermis of the reduce leaf in surface view, showing cuticular striation
2. lower epidermis of the leaf in surface view, showing anomocytic stomata and unicellular trichomes
3. upper epidermis of perigonal bract in surface view, showing anomocytic stomata
4. upper epidermis and palisade cells of lamina, in sectional view
5. vascular tissue and parenchyma of peduncle, in sectional view
6. parenchyma and pitted parenchyma
7. xylem tissue in sectional view
8. parenchyma and fibres, in longitudinal view
9. pitted parenchyma, some containing rosette aggregate crystals, associated with spiral vessels, in longitudinal view

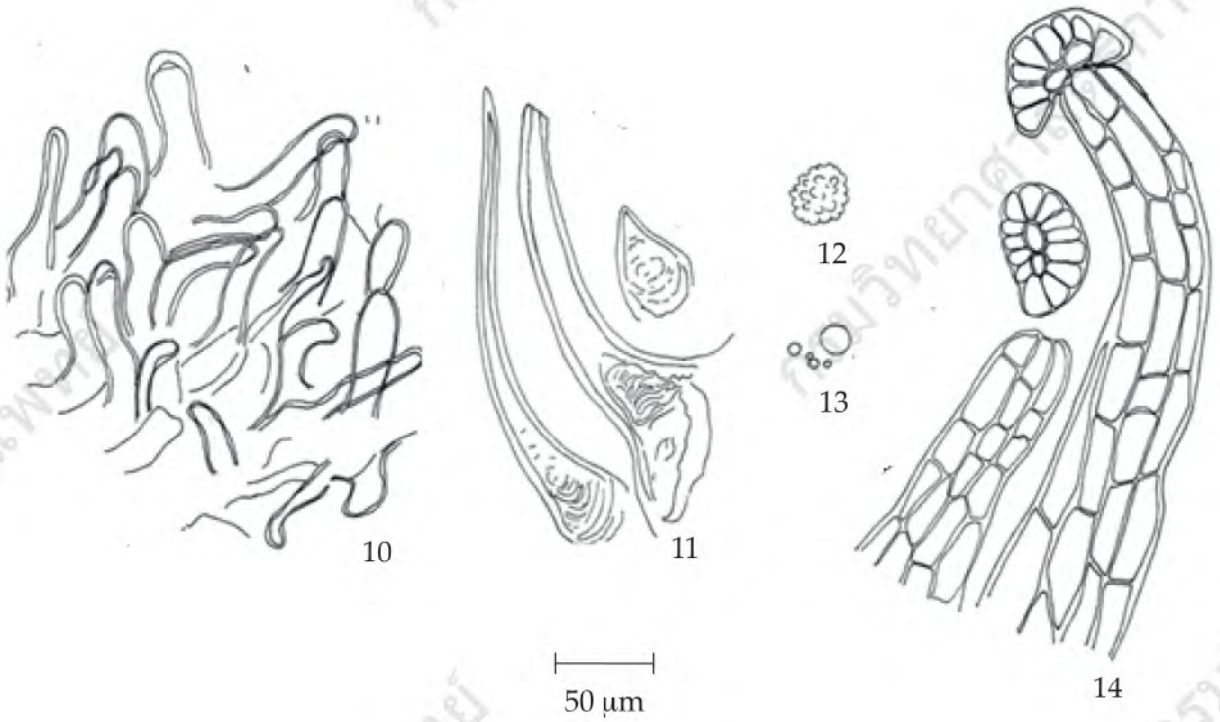


Fig. 2f (continued)

10. long papillae from stigma
11. short and long unicellular trichomes with cystolith
12. cystolith
13. oil droplets
14. multicellular multiseriate glandular trichomes

In surface view, the lamina shows upper epidermis, slightly rectangular cells with striation, unicellular trichomes with cystolith and cicatrices; lower epidermis, slightly wavy rectangular cells, anomocytic stomata, unicellular trichomes some containing cystolith, multicellular glandular trichomes with short stalk, and multicellular multiseriate glandular trichomes.

Transverse section of the peduncle of the female inflorescence shows epidermis, cortex, vascular tissue, and pith. Epidermis: a layer of rectangular cells, covered with cuticle layer; unicellular trichomes, some containing cystolith; multicellular glandular trichomes. Cortex: collenchyma, annular; parenchyma, some containing brown substance or rosette aggregate crystals. Vascular tissue: collateral vascular bundles, phloem and xylem; group of fibres. Pith: parenchyma with pitted-walled and thin-walled parenchyma, some containing rosette aggregate crystals.

Transverse section of the perigonal bract of the female inflorescence shows upper epidermis, mesophyll, vascular tissue, and lower epidermis. Upper epidermis: a layer of rectangular cells, unicellular trichomes, and stomata. Mesophyll: parenchyma, some containing rosette aggregate crystals. Vascular tissue: phloem and xylem. Lower epidermis: a layer of rectangular cells, unicellular trichomes, and multicellular multiseriate glandular trichomes.

In surface view, the perigonal bract shows slightly wavy upper epidermal cells, anomocytic stomata, and unicellular trichomes; lower epidermis, varying in size and shape, some with brown substance, anomocytic stomata, cicatrices, multicellular glandular trichomes, multicellular multiseriate glandular trichomes.

Hemp Female Flower in powder possesses the diagnostic microscopical characters of the unground drug. Unicellular trichomes and multicellular multiseriate glandular trichomes can be seen in abundance. However, unicellular trichomes with cystolith, together with glandular trichomes, are unique. Long papillae of stigma, and various-sized lower epidermis of perigonal bracts are found.

Additional information The two major cannabinoids found in Hemp Female Flower, Δ^9-tetrahydrocannabinol (Δ^9-THC or THC) and cannabidiol (CBD), are initially produced by Hemp Female Flower in their carboxylic acid forms which are Δ^9-tetrahydrocannabinolic acid (THCA) and cannabidiolic acid (CBDA), respectively, before converted into Δ^9-THC and CBD by heating, light, or natural degradation, through decarboxylation process.

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

Identification

A. Macerate 100 mg of the sample, in powder, with 10 mL of *petroleum ether* (*boiling range, 60° to 80°*) for 10 minutes and filter. Evaporate 1 mL of the filtrate to dryness. Dissolve the residue in 1 mL of *methanol*. Add 1 drop of *Fast Blue B salt TS* and 1 drop of a 10 per cent w/v solution of *sodium hydrogen carbonate*: an orange-red colour is produced.

B. The chromatogram of the Sample preparation shows several peaks, two of which correspond to the cannabidiol and tetrahydrocannabinol peaks of the Standard preparations, as obtained in the *cannabidiol and Tetrahydrocannabinol contents* (Fig. 3).

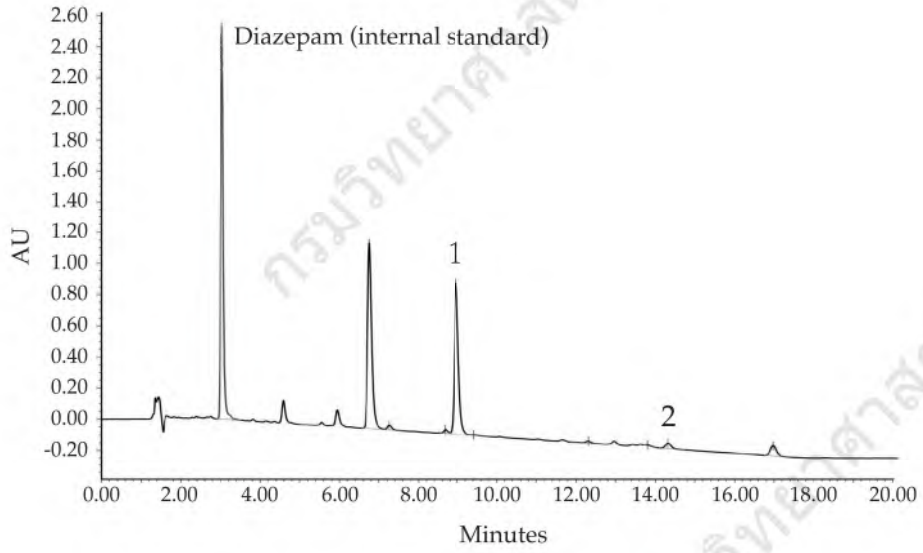


Fig. 3 HPLC Chromatogram of Hemp Female Flower Showing Cannabidiol (1) and Tetrahydrocannabinol (2)

C. 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 75 volumes of *xylene*, 25 volumes of n-*hexane*, and 5 volumes of *diethylamine* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply separately to the plate, 2 mL each of the solutions (A), (B), and (C). Prepare solution (A) by shaking 100 mg of the sample, in *No. 250 powder*, with 5 mL of *methanol*, for 10 minutes and filtering. For solution (B), dissolve 200 µg of Cannabidiol RS in 1 mL of *methanol*. Solution (C) contains 200 µg per mL of Tetrahydrocannabinol RS in *methanol* (Lipomed® or equivalent is suitable.). After removal of the plate, allow it to dry in air and examine under ultraviolet light (254 nm), marking the quenching spots. The chromatogram obtained from solution (A) shows two quenching spots (hR_f values 37 to 41 and 33 to 35), corresponding to the cannabidiol and the tetrahydrocannabinol spots from solutions (B) and (C), respectively. Subsequently, spray the plate with *Fast Blue B salt TS* and examine under visible light. The chromatogram obtained from solution (A) shows an orange spot due to cannabidiol and a red spot due to tetrahydrocannabinol. Three pale red spots are also observed (Fig. 4).

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).

Acid-insoluble ash Not more than 6.0 per cent w/w (Appendix 7.6).

Total ash Not more than 19.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 13.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 21.0 per cent w/w (Appendix 7.12).

Cannabidiol and Tetrahydrocannabinol contents Not less than 3.0 per cent w/w of cannabidiol ($C_{21}H_{30}O_2$) and not more than 0.4 per cent w/w of tetrahydrocannabinol ($C_{21}H_{30}O_2$). Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Mobile phase A Dissolve 3.153 g of *ammonium formate* in a 10 per cent v/v solution of *acetonitrile* and dilute with the same solvent to 1000.0 mL. Adjust with *formic acid* to a pH of 3.75±0.05.

Mobile phase B Prepare a 90 per cent v/v solution of *acetonitrile*.

Diluent Prepare a mixture of the equal volumes of *acetonitrile* and *water*.

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

Standard stock preparation B Dissolve an accurately weighed quantity of Cannabidiol RS in *Diluent* to obtain a stock solution having a known concentration of about 1 mg per mL.

Internal standard preparation Dissolve an accurately weighed quantity of Diazepam RS in *Diluent* to obtain a stock solution having a known concentration of about 500 μg per mL. Dilute this solution with *Diluent* to obtain a solution having a final concentration of about 50 μg per mL.

Standard preparations Dilute *Standard stock preparation A* and *Standard stock preparation B*, quantitatively, and stepwise with *Diluent* to obtain five solutions having known concentrations of about 2, 25, 50, 75, and 100 μg each of tetrahydrocannabinol and cannabidiol per mL. Upon dilution, add sufficient amount of *Internal standard preparation* so that each final solution contains diazepam at a concentration of about 50 μg per mL.

System suitability preparation Dilute *Standard stock preparation A* and *Standard stock preparation B*, quantitatively, and stepwise with *Diluent* to obtain a solution having known concentrations of about 50 μg each of tetrahydrocannabinol and cannabidiol per mL. Upon dilution, add sufficient amount of *Internal standard preparation* so that each final solution contains diazepam at a concentration of about 50 μg per mL.

Sample preparation Transfer about 200 mg of Hemp Female Flower, in *No. 250 powder*, accurately weighed, to a screw-capped centrifuge tube, add 10 mL of a mixture of 9 volumes of *methanol* and 1 volume of *chloroform*, sonicate for 30 minutes, centrifuge at 4,000 rpm for 5 minutes and allow to cool to room temperature. Evaporate 200.0 μL of the supernatant to dryness under a fume hood. Dissolve the residue in 2.0 mL of *Internal standard preparation*, sonicate for 2 minutes, and filter through a polyvinylidene fluoride membrane having a 0.45-μm porosity.

(**Note** In case the concentrations of tetrahydrocannabinol and cannabidiol in the Sample preparation are not in the concentration ranges of standard curve, allow to adjust the volume of the filtrate taken for evaporation.)

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 (3.5 μm), equipped with a similarly packed guard column (5 mm × 3.9 mm) and maintained at a temperature of 30°±1°, (b) *Mobile phase* at a flow rate of about 1.0 mL per minute (**Note** Make adjustments, if necessary to obtain the relative retention times of 0.2 for diazepam, 0.6 for cannabidiol and 1.0 for tetrahydrocannabinol), and (c) an ultraviolet photometer set at 228 nm.

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	30	70
15	10	90
30	10	90
31	30	70
40	30	70

To determine the suitability of the chromatographic system, chromatograph *System suitability preparation*, 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 Separately inject about 30 µL each of *Standard preparations* into the chromatograph, record the chromatograms and measure the responses for cannabidiol and 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 30 µL of *Sample preparation* into the chromatograph, record the chromatogram and measure the responses for cannabidiol and tetrahydrocannabinol peaks.

Calculation By reference to the standard curve, calculate the content of cannabidiol ($C_{21}H_{30}O_2$) and tetrahydrocannabinol ($C_{21}H_{30}O_2$) in the portion of the Hemp Female Flower taken.

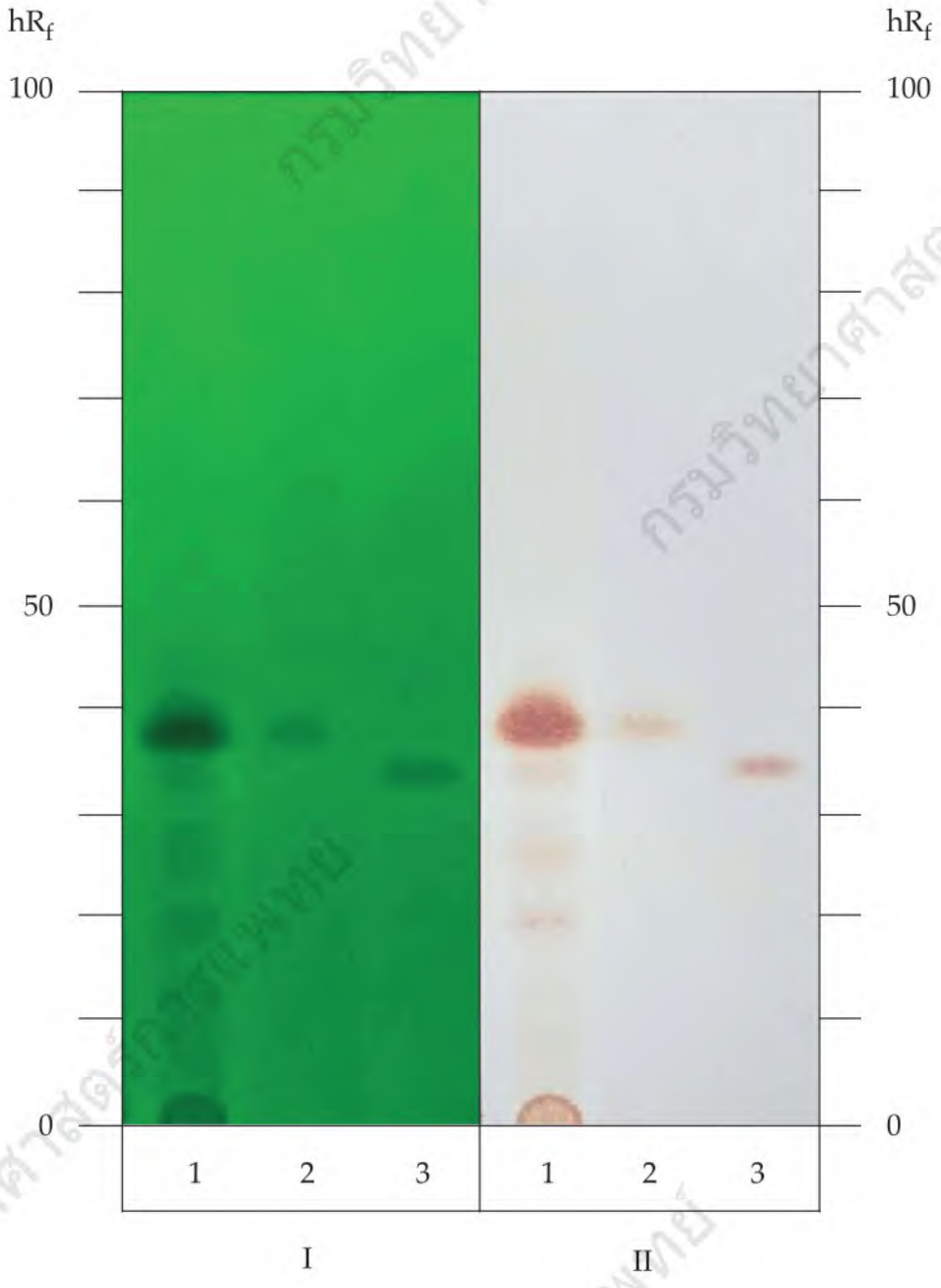


Fig. 4 Thin-Layer Chromatogram of Methanol Extract of the Female Flowering Tops of *Cannabis sativa* L.

1 = solution (A)
2 = solution (B)
3 = solution (C)
I = detection under UV light (254 nm)
II = detection with *Fast Blue B salt TS*

ขันทองพยาบาท (KHAN THONG PHAYABAT)

ดูกไส (DUK SAI), ยางปลวก (YANG PLUAK)
Suregadae Multiflorae Radix
False Lime Root

Category Anti-pruritic (topical), anti-allergic (topical).

False Lime Root is the dried root of *Suregada multiflora* (A. Juss.) Baill. (*Gelonium multiflorum* A. Juss.) (Family Euphorbiaceae), Herbarium Specimen Number: DMSC 5339, Crude Drug Number: DMSc 1238.

Constituents False lime Root contains diterpene lactones.

Description of the plant (Fig. 1) Shrub or tree, 2 to 15 m tall, dioecious, branched, glabrous. Leaves simple, alternate, elliptic, elliptic-oblong or ovate-lanceolate, 9 to 15 cm long, 3 to 7 cm wide, apex acute, base cuneate, margin entire, slightly wavy, blade with scattered oil glands, secondary veins 5 to 7 pairs; petiole short; stipule minute, caducous. Inflorescence axillary, fasciculated; peduncle 0.3 to 1 cm long. Flower greenish, pedicel about 5 mm long. Male flowers 5 to 10; sepals 5, round to obovate, 3 to 4 mm long, 2.5 to 3.5 mm wide; stamen numerous; receptacle with numerous small disc glands among the filaments unequal; pistillode minute. Female flower: sepals 5, longer than male flower; disc with papery margin, concave, sometimes with minute staminodes; ovary superior, 3-loculed; stigmas 3, shortly bifid, spreading. Fruit a capsule, globose, about 3 cm in diameter, 3-lobed, fleshy, subglabrous, base shallowly concave. Seeds 3; aril creamy white.

Description Odour, characteristic; taste bland.

Macroscopical (Fig. 1) Irregularly cut or sliced, various sizes, shapes, and thickness; cut surface smooth, light yellow, annual rings maybe seen in some pieces. Cork may be attached in some pieces.

Microscopical (Figs. 2a, 2b) Transverse section of the root shows periderm and vascular tissue. Periderm: lenticels, several layers of rectangular cork cells. Vascular tissue: phloem, comprising sclereids, fibres, parenchyma, some containing rosette aggregate or prismatic crystals and/or starch grains, and phloem ray; xylem, comprising parenchyma, some containing starch grains, fibres, vessels, xylem ray, and prismatic crystals.

False Lime Root in powder possesses the diagnostic microscopical characters of the unground drug. Xylem ray with prismatic crystals and starch grains can be found in abundance. Large bordered-pitted vessels can also be seen.

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

Identification

A. Sonicate 500 mg of the sample, in powder, with 10 mL of *ethanol* for 30 minutes and filter. To 2 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 60 volumes of *toluene*, 35 volumes of *ethyl acetate*, and 5 volumes of *formic acid* 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 6 mm, 1 µL of the test solution prepared by sonicating 3 g of the sample, in *No. 250 powder*, with 60 mL of *ethanol* for 30 minutes and filtering. Evaporate the filtrate to dryness under reduced pressure at 50°. Dissolve the residue in 2 mL of *ethanol*. After removal of the plate, allow it to dry in air and examine under ultraviolet light (254 nm), marking the quenching bands. Spray the plate with *anisaldehyde TS* and heat at 105° for 10 minutes; seven violet bands are observed (Fig. 3).

Fig. 1 *Suregada multiflora* (A. Juss.) Baill.
1. habit 2. branch with male inflorescences 3. male inflorescence 4. male flower 5. female flower and fruits 6. ripe fruits 7. crude drug

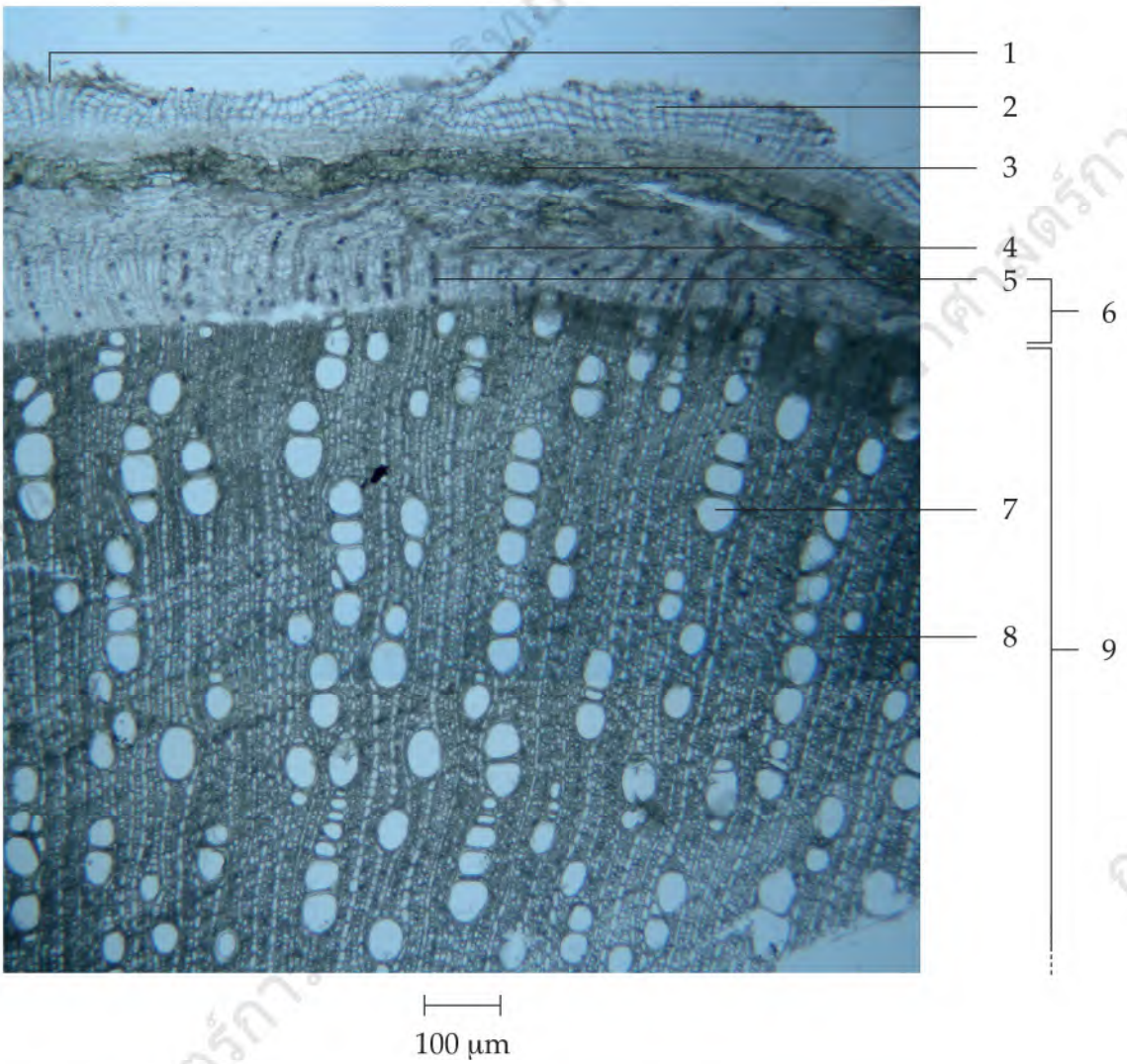


Fig. 2a Photomicrograph of Transverse Section of the Root of *Suregada multiflora* (A. Juss.) Baill.

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

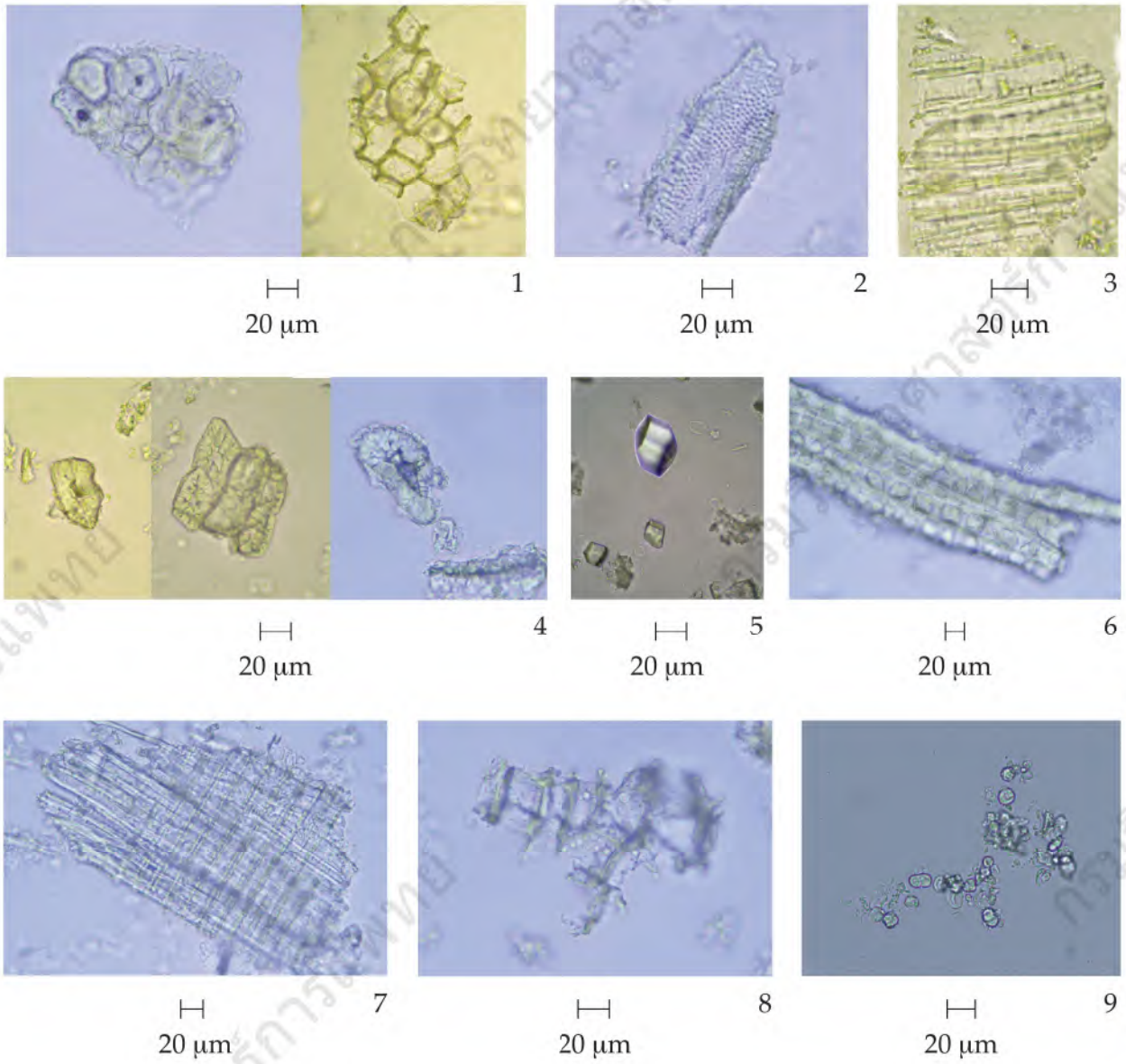


Fig. 2b Photomicrographs of Powdered Drug of the Roots of *Suregada multiflora* (A. Juss.) Baill.

1. cork in surface view beneath sclereids
2. bordered-pitted vessel
3. xylem parenchyma some containing starch grains and xylem fibres, in longitudinal view
4. sclereids
5. prismatic crystals
6. xylem ray, fibres, and prismatic sheath, in tangential longitudinal view
7. xylem ray, with underlying fibres, containing prismatic crystals, in radial longitudinal view
8. xylem parenchyma containing starch grains
9. simple and compound starch grains

Loss on drying Not more than 2.0 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 5.0 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 6.0 per cent w/w (Appendix 7.12).

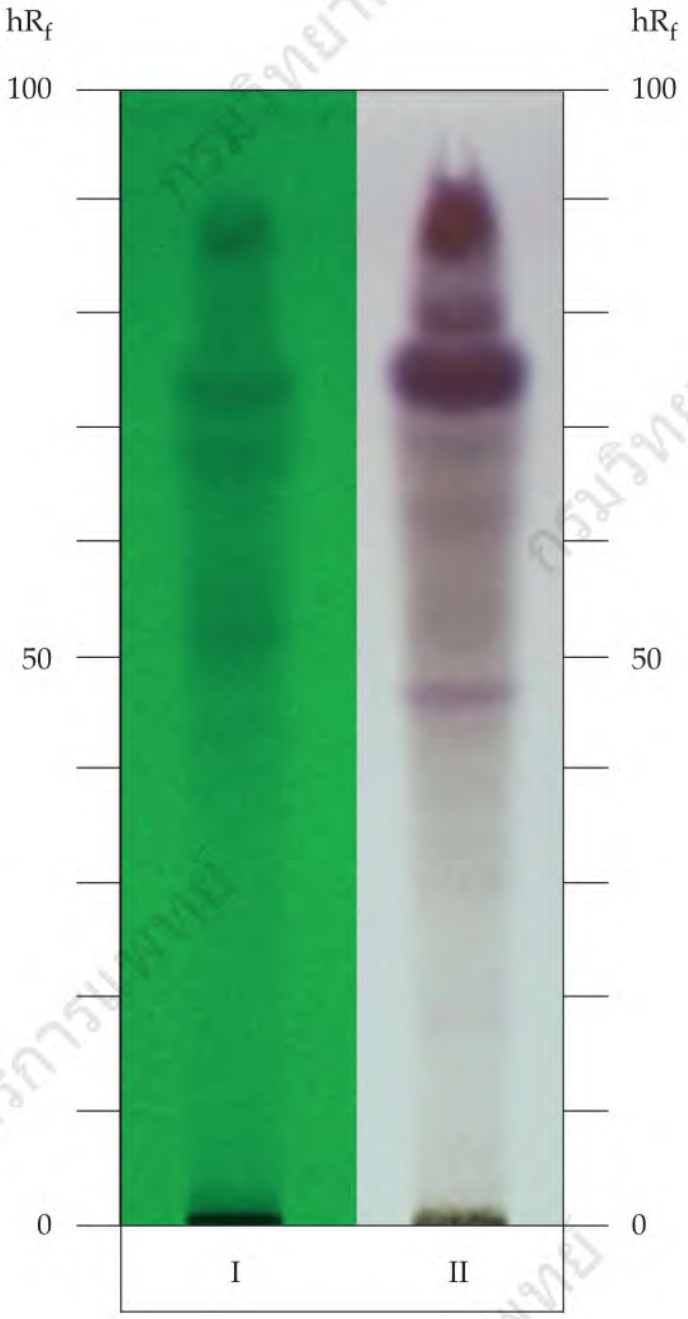


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Roots of *Suregada multiflora* (A. Juss.) Baill.
I = detection under UV light (254 nm)
II = detection with *anisaldehyde TS*

ข่อย, เปลือกต้น (KHOI, PLUEAK TON)

Strebli Asperidis Cortex
Siamese Rough Bush Bark

Synonyms Demon Tree Bark, Sandpaper Tree Bark, Tooth Brush Tree Bark

Category Antifilarial, antidiarrheal.

Siamese Rough Bush Bark is the dried stem bark of *Streblus asper* Lour. (*Diplothorax tonkinensis* Gagnep., *Streblus monoicus* Gagnep., *Trophis cochinchinensis* Poir.) (Family Moraceae), Herbarium Specimen Number: DMSC 5338, Crude Drug Number: DMSc 1235.

Constituents Siamese Rough Bush Bark contains triterpenoids, including lupeol and α-amyrin. It also contains cardiac glycosides (e.g., asperoside, strebloside).

Description of the plant (Fig. 1) Tree or shrub, up to 15 m tall, monoecious or dioecious; stem much-branched, lenticel conspicuous when young; outer bark greyish, scabrous; inner bark whitish, thick, exuding white latex; branches usually drooping or straggling; branchlet with short stiff hairs. Leaves simple, spirally arranged to distichous, elliptic, oblong, obovate, or subobovate, 1 to 8(–13) cm long, 0.5 to 3.5(–6.5) cm wide, apex acute to acuminate, base rounded, subcordate or obtuse, margin crenate to dentate, coriaceous, hispidulous to puberulous, and/or scabrous on both surfaces, lower part of midrib somewhat prominent in lower surface, lateral veins 4 to 8 pairs; petiole 1 to 5 mm long, puberulous; stipule small, puberulous, caducous. Male inflorescence axillary, capitate, in pairs or solitary; peduncle 0.2 to 1.5 cm long, sparsely puberulous; bracts few, small, narrowly elliptic, at base of inflorescence; bracteoles 2, at base of calyx, larger than bract. Female inflorescence axillary, uniflorous or biflorous; peduncle 0.4 to 2 cm long, puberulent; bracts few, 0.5 to 2 mm long, sparsely puberulous. Male flowers in a head of 4 to 15 flowers, 0.4 to 1 cm in diameter, subsessile; perianth 1.5 to 2 mm long, puberulent; stamens 4, 2 to 2.5 mm long, anther about 1 mm long. Female flowers 1 to 2; perianth 2 to 2.5 mm long, elongated to 5 to 8 mm long in fruit, reflexed, puberulent; ovary superior, about 1 mm long, style 1 to 3 mm long, stigma 2 to 4 mm long, elongating to 1.2 cm long, bifid. Fruit a drupe, subglobose to ovoid, about 6 mm in diameter, indehiscent, enclosed by enlarged calyx lobes when young, yellow to orange when mature. Seed 1, globose, 4 to 5 mm in diameter, greyish white.

Description Odour, indistinct; taste, bitter and astringent.

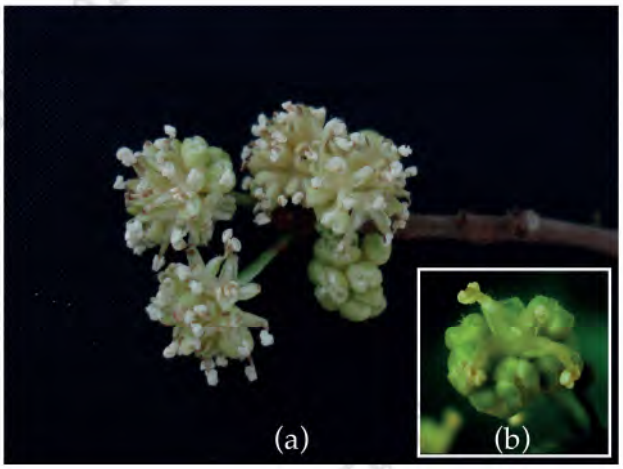
Macroscopical (Fig. 1) Stem bark, irregular-shaped and -sized, curved, simple or double quill. Outer bark, smooth or longitudinally wrinkled, yellow to brownish. Inner surface of inner bark, smooth to rough with fibre, yellow to brownish.

Microscopical (Figs. 2a, 2b) Transverse section of the bark shows periderm, cortex, and phloem tissue. Periderm: lenticels, several layers of rectangular cork cells with brown substance and layers of cork cambium. Cortex: several layers of sclereids underneath periderm, and parenchyma cells. Phloem tissue: parenchyma (cells some containing prismatic crystals or rosette aggregate crystals), laticifers, and phloem rays.

Siamese Rough Bush Bark in powder possesses the diagnostic microscopical characters of the unground drug. Broad phloem ray and articulated laticifer are characteristic.

1

2



3

4

5

2 cm

Fig. 1 *Streblus asper* Lour.
1. habit (a), bark (b) 2. female flowers 3. male inflorescences (a), male flower (b)
4. fruit (side view) 5. crude drug

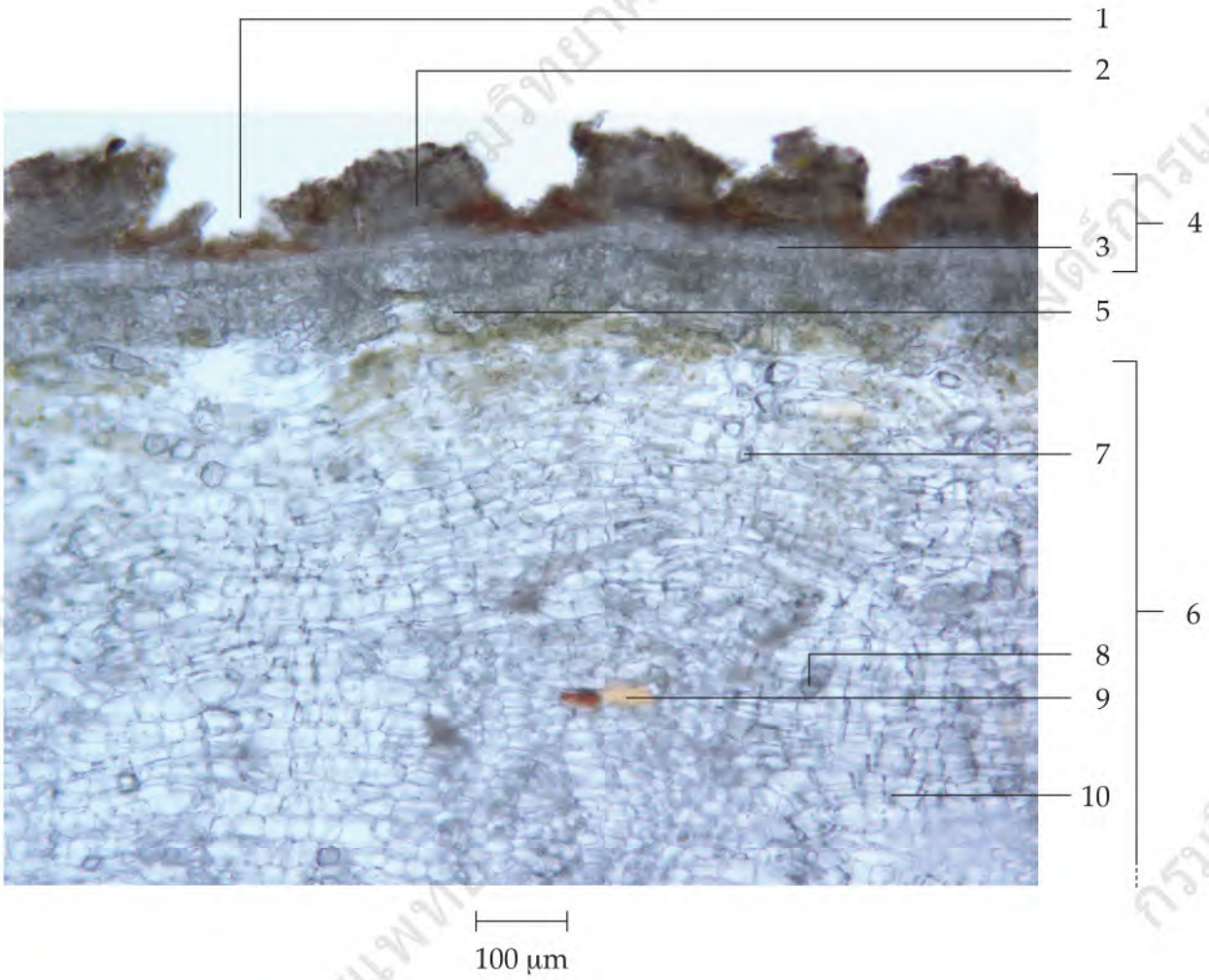


Fig. 2a Photomicrograph of Transverse Section of the Stem Bark of *Streblus asper* Lour.

1. lenticel
2. cork
3. cork cambium
4. periderm
5. sclereid
6. phloem
7. prismatic crystal
8. rosette aggregate crystal
9. laticifer
10. phloem ray

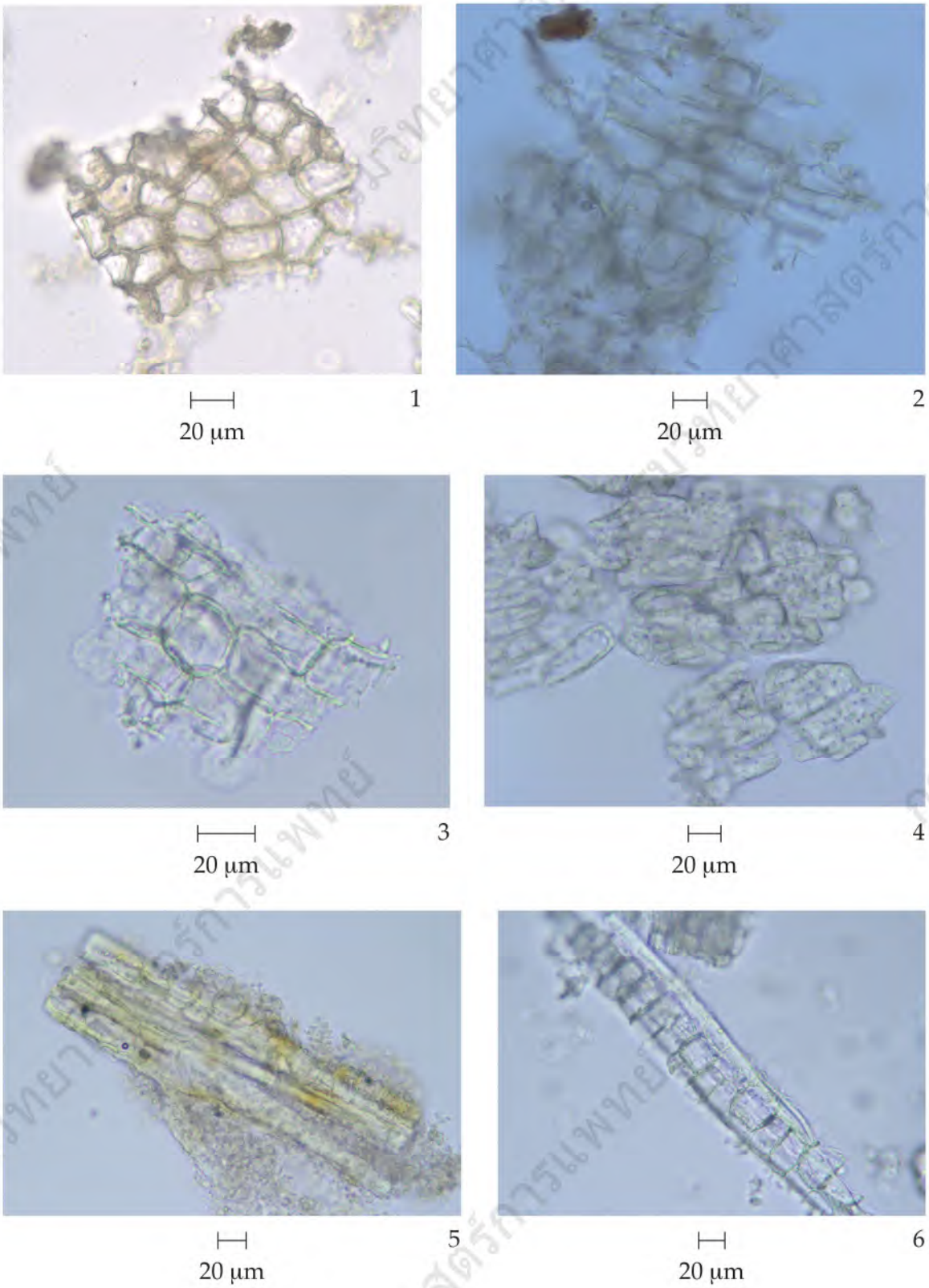


Fig. 2b Photomicrographs of Powdered Drug of the Stem Barks of *Streblus asper* Lour.
1. cork in surface view
2. cork and parenchyma, in sectional view
3. parenchyma
4. groups of sclereids
5. phloem in tangential longitudinal view
6. phloem in radial longitudinal view

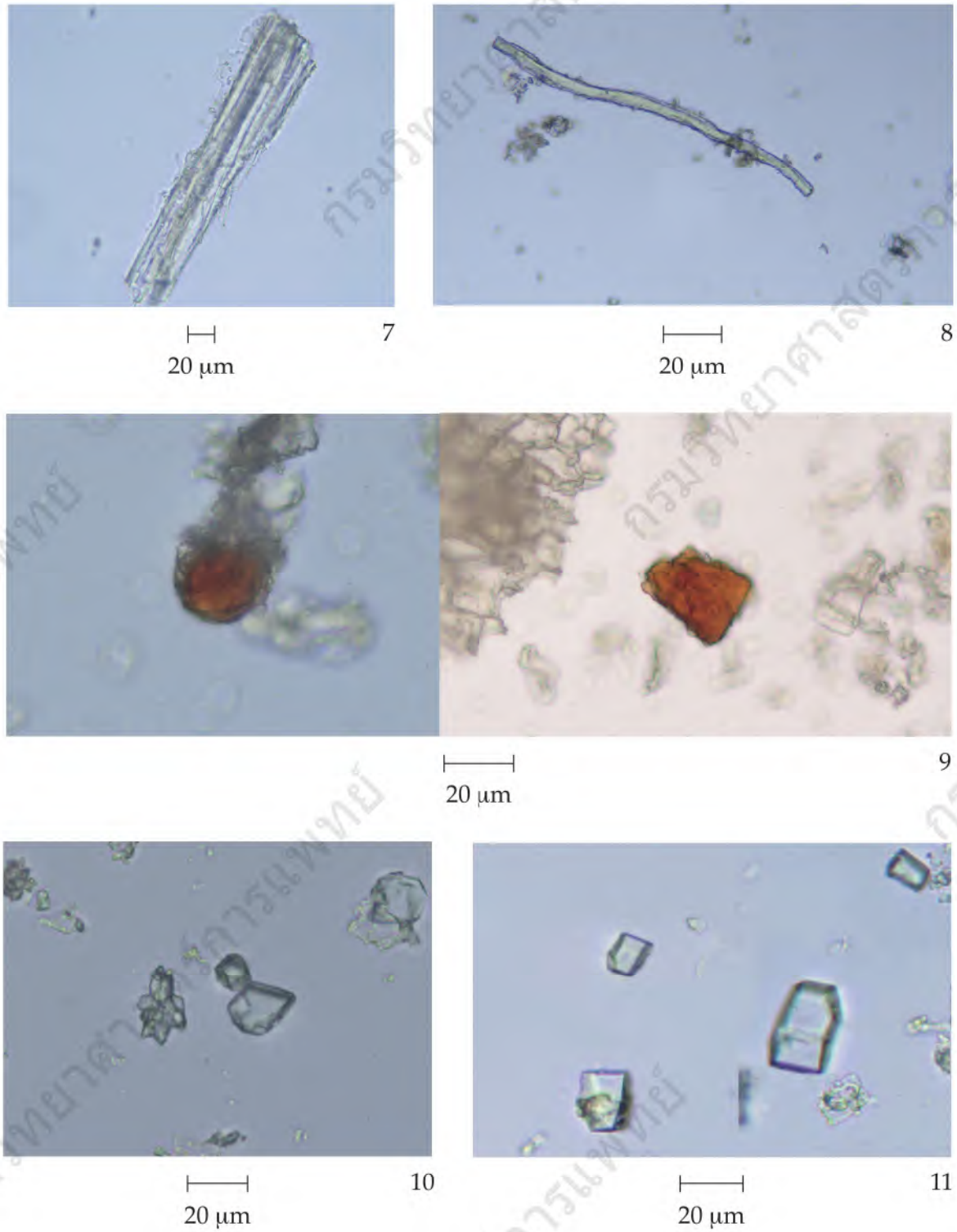


Fig. 2b (continued)

7. fibres
8. laticifer
9. brown substance
10. rosette aggregate and prismatic crystals
11. prismatic crystals

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

Identification

A. Sonicate 500 mg of the sample, in powder, with 10 mL of *ethanol* for 30 minutes and filter (solution 1). Evaporate 2 mL of solution 1 to dryness and dissolve the residue in 1 mL of *acetic anhydride*. Slowly add 1 mL of *sulfuric acid* to form two layers: a reddish brown to brown ring forms at the zone of contact.

B. To 2 mL of solution 1, add a few drops of a 1 per cent w/v solution of *iron(III) chloride* and shake well: a blue-green colour develops.

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 60 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 of solution (A) and 1 µL of solution (B). Prepare solution (A) by sonicating 3 g of the sample, in *No. 250 powder*, with 60 mL of *ethanol* for 30 minutes and filtering. Evaporate the filtrate to dryness under reduced pressure. Dissolve the residue in 2 mL of *ethanol*. For solution (B), dissolve 1 mg of *lupeol* in 0.5 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 10 minutes; the chromatogram obtained from solution (A) shows a violet band (hR_f value 72 to 75), corresponding to the lupeol band obtained from solution (B). Eight violet bands are also observed (Fig. 3).

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).

Acid-insoluble ash Not more than 8.0 per cent w/w (Appendix 7.6).

Total ash Not more than 17.0 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 9.0 per cent w/w (Appendix 7.12).

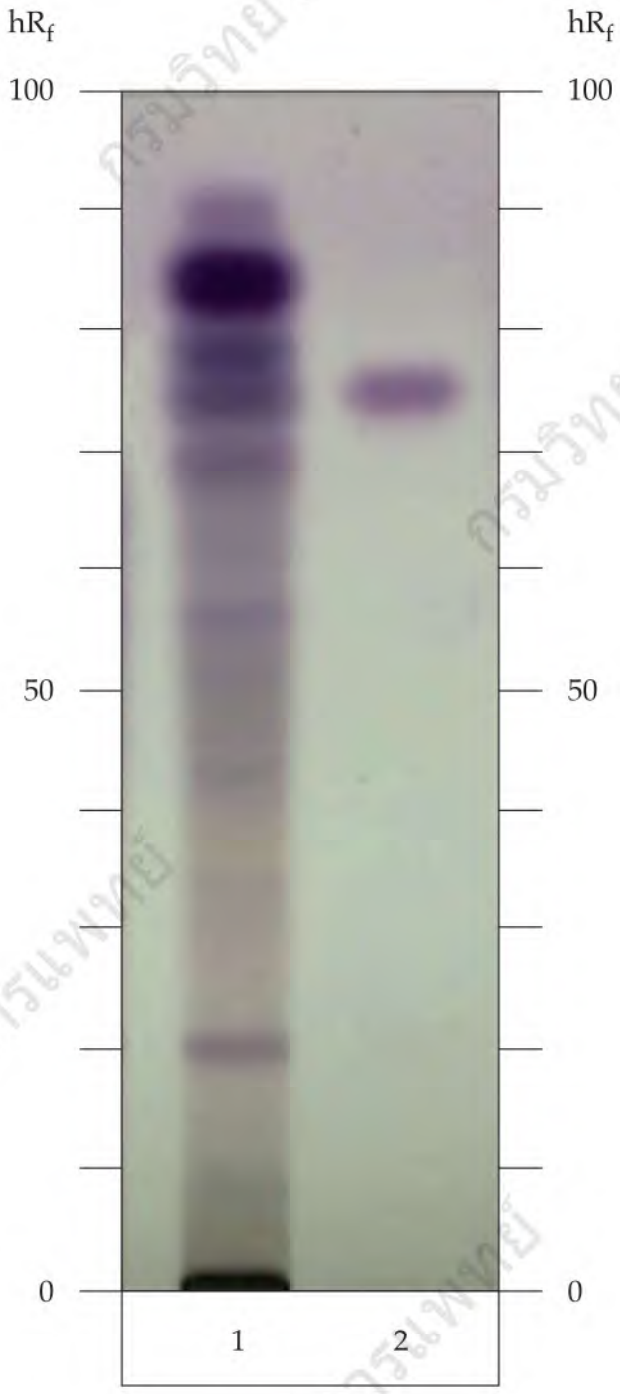


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Stem Barks of *Streblus asper* Lour., Detected With *Anisaldehyde TS*
1 = solution (A)
2 = solution (B)

ยาแคปซูลกระชาย (KRACHAI CAPSULES)

Fingerroot Capsules

Category Carminative, antiflatulent, tonic.

Fingerroot Capsules contains an amount of powdered Fingerroot equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of pinostrobin ($C_{16}H_{14}O_4$), and not less than 80.0 per cent of the labelled amount of volatile oil, calculated on the anhydrous basis.

Strength available 500 mg (powder).

Dose Three to four capsules three times a day after meals.

Packaging and storage Fingerroot Capsules 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 pinostrobin in mg per sachet; (2) the amount of volatile oil; (3) the expiration date.

Identification

A. The capsules contents exhibit diagnostic structures of the powdered drug described under *Fingerroot*.

B. The capsules contents comply with the tests for Identification A, B, and C described under *Fingerroot*.

Water Of the capsule contents, not more than 9.0 per cent v/w (Azeotropic Distillation Method, Appendix 4.12).

Microbial limit Comply with the requirements for Category 4 in the "Limits for Microbial Contamination" (Appendix 10.5).

Assay

FOR VOLATILE OIL Remove, as completely as possible, the contents of not less than 20 Fingerroot Capsules, mix, and transfer about 10 g, accurately weighed, to a 500-mL round-bottomed flask. Use 100 mL of *water* as the distillation liquid and distil at a rate of 2 to 3 mL per minute for 5 hours. Use 2.0 mL of *xylene* in the graduated tube (Appendix 7.3H). Calculate the content of volatile oil, in mL, in the portion of the Capsules taken with reference to the anhydrous substance.

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

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

Mobile phase B Use *water*.

Standard preparations Dissolve a suitable quantity of *pinostrobin*, accurately weighed, in sufficient *methanol* to obtain a stock solution having a known concentration of about 1 mg of pinostrobin per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain five solutions having known concentrations ranging from 40 to 240 µg per mL.

Assay preparation Remove, as completely as possible, the contents of not less than 20 Fingerroot Capsules and grind to *fine powder*. Macerate about 100 mg, accurately weighed, in 20.0 mL of *methanol* for 24 hours. Pass a portion of the supernatant through a 0.22-µm polyvinylidene fluoride filter.

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	60	40
1.2	60	40
1.5	85	15
2.0	85	15
2.2	60	40

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (5 cm × 2.1 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (1.7 μm), (b) *Mobile phase* at a flow rate of about 0.6 mL per minute, and (c) an ultraviolet photometer set at 290 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 120 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 Separately inject about 2 μL each of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for pinostrobin 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 2 μL of *Assay preparation* into the chromatograph, record the chromatogram, and measure the response for pinostrobin peak.

Calculation By reference to the standard curve, calculate the content of pinostrobin ($C_{16}H_{14}O_4$) in the portion of the Capsules taken.

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

ยาชงกระชาย (YA CHONG KRACHAI)

Fingerroot Tea

Category Carminative, antiflatulent, tonic.

Fingerroot Tea contains an amount of powdered Fingerroot equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of pinostrobin ($C_{16}H_{14}O_4$), and not less than 80.0 per cent of the labelled amount of volatile oil, calculated on the anhydrous basis.

Strengths available 1 and 1.5 g (powder), supplied in a sachet.

Dose One sachet, prepared as an infusion by soaking each with 120 mL of boiling water for 5 minutes, three times a day.

Packaging and storage Fingerroot 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 pinostrobin in mg per sachet; (2) the amount of volatile oil; (3) the expiration date.

Identification

A. The tea contents exhibit diagnostic structures of the powdered drug described under *Fingerroot*.

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

Water Of the tea contents, not more than 9.0 per cent v/w (Azeotropic Distillation Method, Appendix 4.12).

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

Assay

FOR VOLATILE OIL Mix the contents of not less than 20 sachets of Fingerroot Tea and transfer about 10 g, accurately weighed, to a 500-mL round-bottomed flask. Use 100 mL of *water* as the distillation liquid and distil at a rate of 2 to 3 mL per minute for 5 hours. Use 2.0 mL of *xylene* in the graduated tube (Appendix 7.3H). Calculate the content of volatile oil, in mL, in the portion of the Tea taken with reference to the anhydrous substance.

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

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

Mobile phase B Use *water*.

Standard preparations Dissolve a suitable quantity of *pinostrobin*, accurately weighed, in sufficient *methanol* to obtain a stock solution having a known concentration of about 1 mg of pinostrobin per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain five solutions having known concentrations ranging from 40 to 240 µg per mL.

Assay preparation Grind the contents of not less than 20 sachets of Fingerroot to *fine powder*. Macerate about 100 mg, accurately weighed, in 20.0 mL of *methanol* for 24 hours. Pass a portion of the supernatant through a 0.22-µm polyvinylidene fluoride filter.

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	60	40
1.2	60	40
1.5	85	15
2.0	85	15
2.2	60	40

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (5 cm × 2.1 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (1.7 μm), (b) *Mobile phase* at a flow rate of about 0.6 mL per minute, and (c) an ultraviolet photometer set at 290 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 120 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 Separately inject about 2 μL each of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for pinostrobin 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 2 μL of *Assay preparation* into the chromatograph, record the chromatogram, and measure the response for pinostrobin peak.

Calculation By reference to the standard curve, calculate the content of pinostrobin ($C_{16}H_{14}O_4$) in the portion of the Tea taken.

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

กวาวเครือ (KWAO KHRUEA)

กวาวเครือขาว (KWAO KHRUEA KHAO), หัวกวาวเครือ (HUA KWAO KHRUEA)
Puerariae Mirificae Radix
Pueraria Mirifica Root

Category Estrogen-like effect.

Pueraria Mirifica Root is the dried, peeled tuberous root of *Pueraria candollei* Graham ex Benth. var. *mirifica* (Airy Shaw & Suvat.) Niyomdham (*P. mirifica* Airy Shaw & Suvat.) (Family Leguminosae), Herbarium Specimen Number: DMSC 5364, Crude Drug Number: DMSc 1255.

Constituents Pueraria Mirifica Root contains isoflavones and their glycosides (e.g., daidzein, genistein, puerarin). It also contains chromenes (e.g., deoxymiroestrol, isomiroestrol, miroestrol).

Description of the plant (Fig. 1) Woody climber, up to 12 m long; stem twining, glabrous, branched, ribbed and flaking with age; tuberous root globose to ovoid, 5 to 40 cm in diameter; bark pale yellow, glabrous, flesh whitish, woody with age. Leaves pinnately trifoliate, alternate, 12 to 20 cm long; petiole up to 40 cm long, pulvinus at base; stipule attenuate, 2 to 4 mm long; petiolule 1 to 7 cm long, pulvinus at base; terminal leaflet broadly ovate, 15 to 24 cm long, 10 to 20 cm wide, 3-lobed when juvenile; lateral leaflets opposite, obliquely ovate, 10 to 22 cm long, 8 to 18 cm wide, 2(–3)-lobed when juvenile; apex acuminate, base broadly ovate or obtuse, margin entire, pubescent, lateral veins 7 to 10 pairs. Inflorescence racemose, terminal, 20 to 50 cm long. Flower 1 to 1.3 cm long, bluish purple to pale purple; bracteole triangular to ovate, 1 to 2 mm long, about 1 mm wide, brown pubescent; calyx campanulate, 2 to 6 mm long, 4-lobed, brown pubescent; corolla standard rounded, 0.8 to 1.2 cm wide, margin inflexed, with yellowish to purplish white blotch; wings lanceolate, 0.8 to 1.2 cm long, base clawed; keel elliptic, 0.8 to 1.2 cm long, ventrally adnate, apex rounded; stamens 10, monadelphous, 0.9 to 1.5 cm long, white; ovary superior, oblong, 0.5 to 1 cm long, pubescent, 1-loculed, ovules 7 to 10. Fruit a pod, flattened, oblong, 2 to 6 cm long, 0.6 to 1 cm wide, acuminate at both ends, tomentose. Seeds 1 to 5, reniform, 2 to 5 mm long, 2 to 4 mm wide, 1 to 2 mm thick, purplish brown to brown.

Description Odourless; taste, slightly sweetish.

Macroscopical (Fig. 1) Dried sliced tuberous root, without root bark, varied in shape and size; cut surface, white to pale yellow, and fibrous.

Microscopical (Figs. 2a, 2b) Transverse section of the peeled tuberous root shows cortex and vascular tissue. Cortex: parenchyma, varied in size and shape, some containing starch grains and/or some prismatic crystals; layers of thick-walled sclereids. Vascular tissue: phloem and xylem; anomalous type; outer region, radially arranged; inner region, radially arranged with some scattered small bundles.

Pueraria Mirifica Root in powder possesses the diagnostic microscopical of the unground drug. Parenchyma with both simple and compound starch grains can be seen in abundance. Large bordered-pitted vessels, thick-walled sclereids, and fibres with prismatic sheath may also be seen.

Fig. 1 *Pueraria candollei* Graham ex Benth. var. *mirifica* (Airy Shaw & Suvat.) Niyomdham 1. habit 2. inflorescences 3. flowers 4. pods 5. tuberous roots 6. crude drug

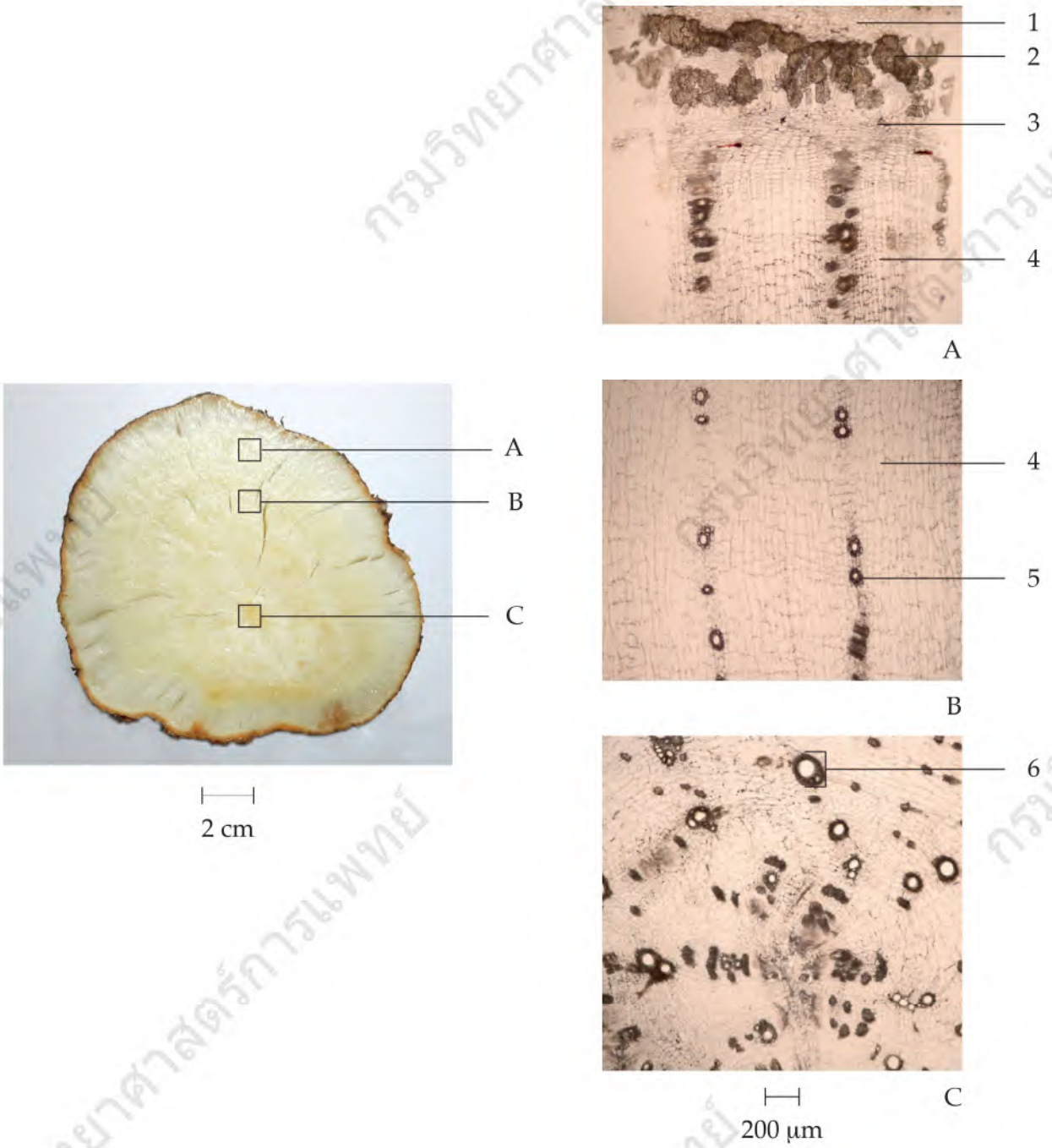


Fig. 2a Photomicrographs of Transverse Section of the Peeled Tuberous Root of *Pueraria candollei* Graham ex Benth. var. *mirifica* (Airy Shaw & Suvat.) Niyomdham

A. Cortex and Outer Region of Vascular Tissue
B. Outer Region of Xylem
C. Inner Region of Vascular Tissue

1. parenchyma
2. sclereid
3. phloem ray
4. xylem ray
5. vessel
6. vascular bundle

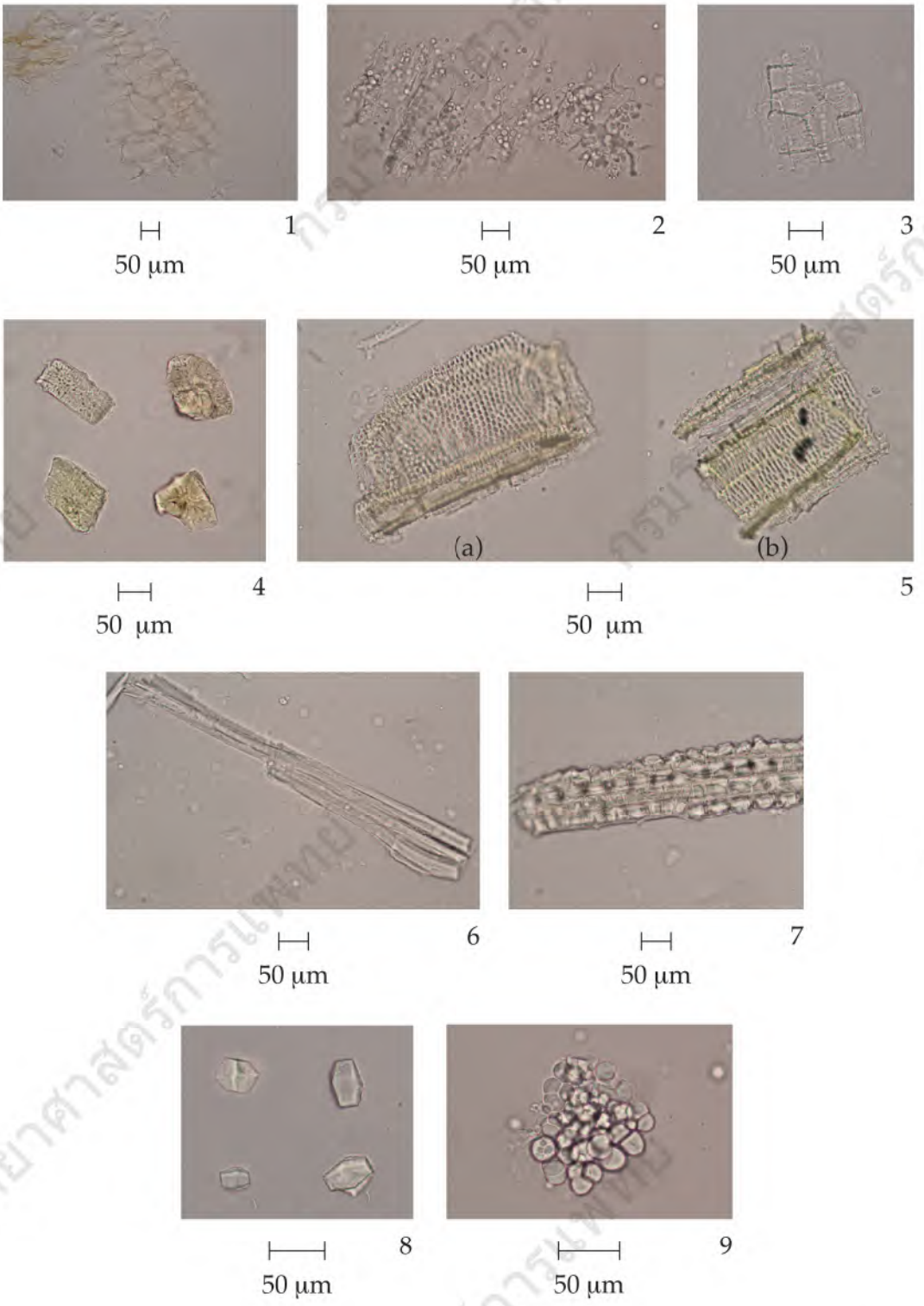


Fig. 2b Photomicrographs of the Powdered Drug of the Peeled Tuberous Roots of *Pueraria candollei* Graham ex Benth. var. *mirifica* (Airy Shaw & Suvat.) Niyomdham

1. parenchyma
2. parenchyma containing starch grains
3. xylem parenchyma
4. sclereids
5. large bordered-pitted (a) and reticulate-pitted (b) vessels, with adjacent xylem parenchyma
6. fragment of fibres
7. fibres with prismatic sheath
8. prismatic crystals
9. starch grains

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

Identification

A. Sonicate 1 g of the sample, in powder, with 10 mL of *methanol* for 30 minutes and filter. To 2 mL of the filtrate, add a few drops of *ninhydrin TS* and warm on a water-bath: a violet 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 87 volumes of *dichloromethane* and 13 volumes of *methanol* as the mobile phase and allowing the solvent front to ascend 12 cm above the line of application. Apply to the plate as bands of 8 mm, 20 µL of solution (A), 2 µL each of solutions (B) and (C). Prepare solution (A) by sonicating 1 g of the sample, in powder, with 10 mL of *methanol* for 30 minutes and filtering. Evaporate the filtrate to dryness under reduced pressure at 50°. Dissolve the residue in 1 mL of *methanol*. For solution (B), dissolve 1 mg of *puerarin* in 1 mL of *methanol*. For solution (C), dissolve 1 mg of *daidzein* 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 quenching bands (hR_f values 6 to 10 and 60 to 65) corresponding to the puerarin and daidzein bands obtained from solutions (B) and (C), respectively. Several bands of higher and lower hR_f values are also observed. Subsequently examine the plate under ultraviolet light (366 nm) through the cut-off filter; the bands corresponding to puerarin and daidzein show blue fluorescence. Other four blue fluorescent 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 1.0 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 7.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 44.0 per cent w/w (Appendix 7.12).

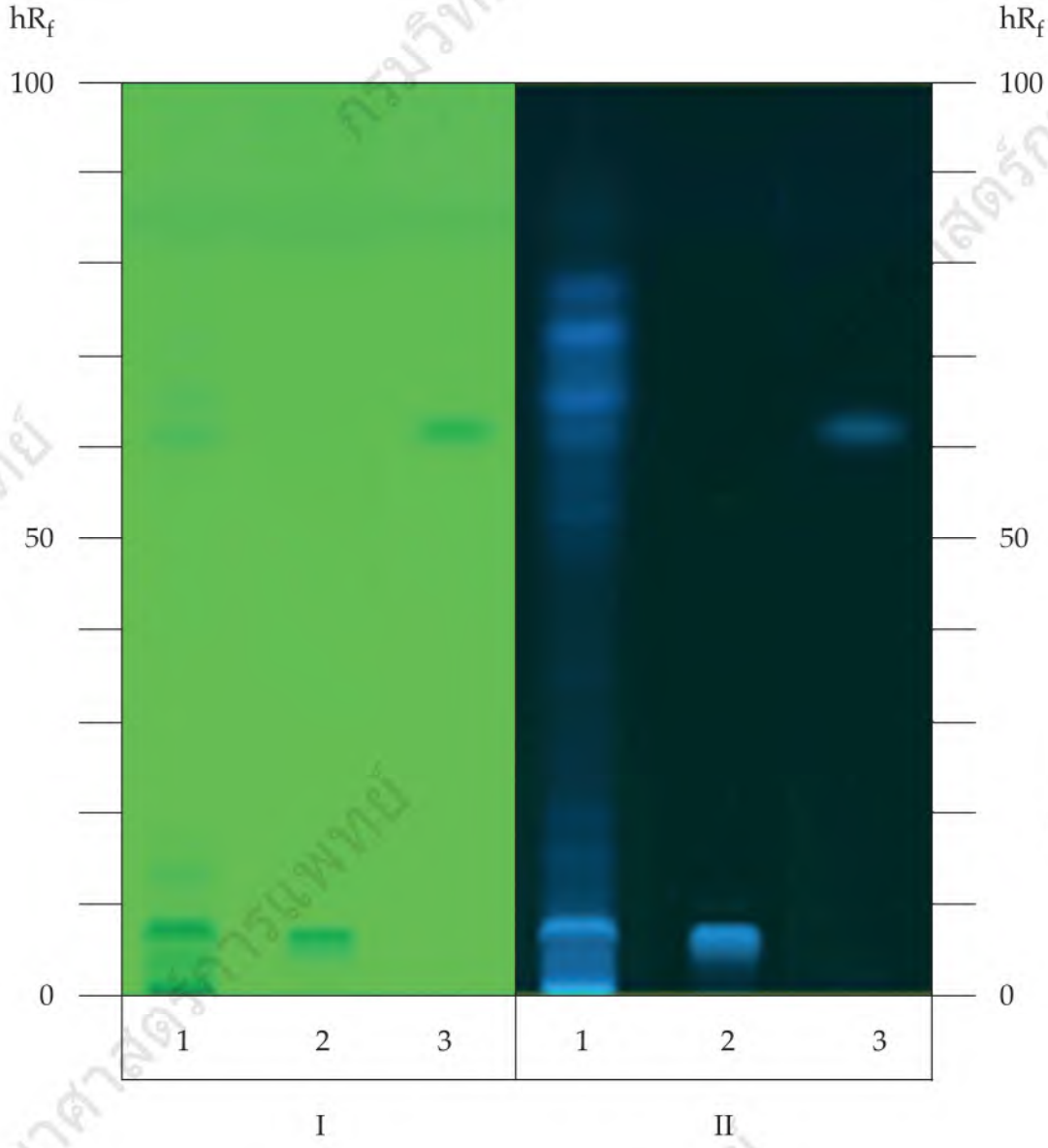


Fig. 3 Thin-Layer Chromatogram of Methanolic Extract of the Peeled Tuberous Roots of *Pueraria candollei* Graham ex Benth. var. *mirifica* (Airy Shaw & Suvat.) Niyomdham

1 = solution (A)
2 = solution (B)
3 = solution (C)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)

กวาวเครือแดง (KWAO KHRUEA DAENG)

Buteae Superbae Radix
Butea Superba Root

Category Androgen-like effect.

Butea Superba Root is the dried tuberous root of *Butea superba* Roxb. ex Willd. [*Plaso superba* (Roxb. ex Willd.) Kuntze, *Rudolphia superba* (Roxb. ex Willd.) Poir.] (Family Leguminosae), Herbarium Specimen Number: DMSC 5363, Crude Drug Number: DMSc 1254.

Constituents Butea Superba Root contains isoflavones and their glycosides (e.g., biochanin A, formononetin, prunetin).

Description of the plant (Fig. 1) Woody climber with tubers; bark pale greyish brown, flaking; root tuberous, spindle, 1 to 1.8 m long, 8 to 15 cm in diameter, with red exudate when cut. Leaves pinnately trifoliate, alternate; petiole 15 to 27 cm long, pubescent; terminal leaflet broadly ovate or orbiculate, 13 to 27 cm long, 13.5 to 27 cm wide, apex cuspidate, base broadly obtuse, cuneate or obtuse, margin entire, both surfaces brown tomentose when young, lateral veins 7 to 9 pairs; lateral leaflet ovate, 15 to 25.5 cm long, 12 to 20 cm wide, apex cuspidate, base oblique, margin entire, tomentose, lateral veins 6 to 8 pairs; petiolule about 1 cm long; stipule triangular, 5 to 7 mm long, 2 to 3 mm wide; stipel acicular, 3 to 5 mm long. Inflorescence racemose, terminal, 24 to 30.5 cm long; peduncle 1 to 4.5 cm long; bract 4 to 5 mm long, 1 to 2 mm wide. Flower orange-red, 8 to 9 cm long; pedicel 1.3 to 4.5 cm long; calyx 1 to 1.2 cm long; corolla: standard ovate, 4 to 6.5 cm long, 1.8 to 3 cm wide, densely silverly pubescent without and only at base within, apex acute, margin entire; wings oblong, 4.5 to 7 cm long, 1 to 1.2 cm wide, apex acute, base oblique, tomentose on both surfaces; keel elliptic, 6 to 6.5 cm long, 1.5 to 2 cm wide, apex acute, base oblique, margin entire, densely silverly tomentose without and at margin within; stamens 10, diadelphous, filament 6 to 8.5 cm long, anther elliptic, 4 to 5 mm long; ovary superior, oblong, 1.7 to 3 cm long, 0.3 to 1 cm wide, densely tomentose, stalk 2.8 to 3 cm long, tomentose, style 5.7 to 6 cm long, sparely pubescent. Fruit a pod, oblong, 11 to 19 cm long, 2.9 to 4 cm wide, brown, tomentose. Seed flattened, round or reniform, 2.8 to 3.2 cm long, 1.5 to 2 cm wide, brown.

Description Odourless; taste, slightly sweetish.

Macroscopical (Fig. 1) Dried sliced tuberous root, varied in shape and size; texture, hard, tough, and fibrous; cut surface, light brown, with a small dark brown ring in the centre and dark brown resinous ring adjacent to root bark.

Microscopical (Figs. 2a, 2b) Transverse section of the tuberous root shows cork, cortex, and vascular tissue. Cork: several layers of brownish-walled rectangular cells. Cortex: layers of brown, thick-walled, sclereids; parenchyma, containing starch grains and some with brown substances; and groups of fibres. Vascular tissue: phloem and xylem; anomalous type; outer region, radially arranged; inner region, radially arranged with some scattered small bundles.

Butea Superba Root in powder possesses the diagnostic microscopical of the unground drug. Vessels with brown substances are characteristic. Parenchyma with both simple and compound starch grains can be seen in abundance. Large bordered-pitted vessels, thick-walled sclereids, and fibres with prismatic sheath may also be seen.

Fig. 1 *Butea superba* Roxb. ex Willd.
1. habit 2. inflorescences 3. flower 4. pods 5. tuberous roots 6. crude drug

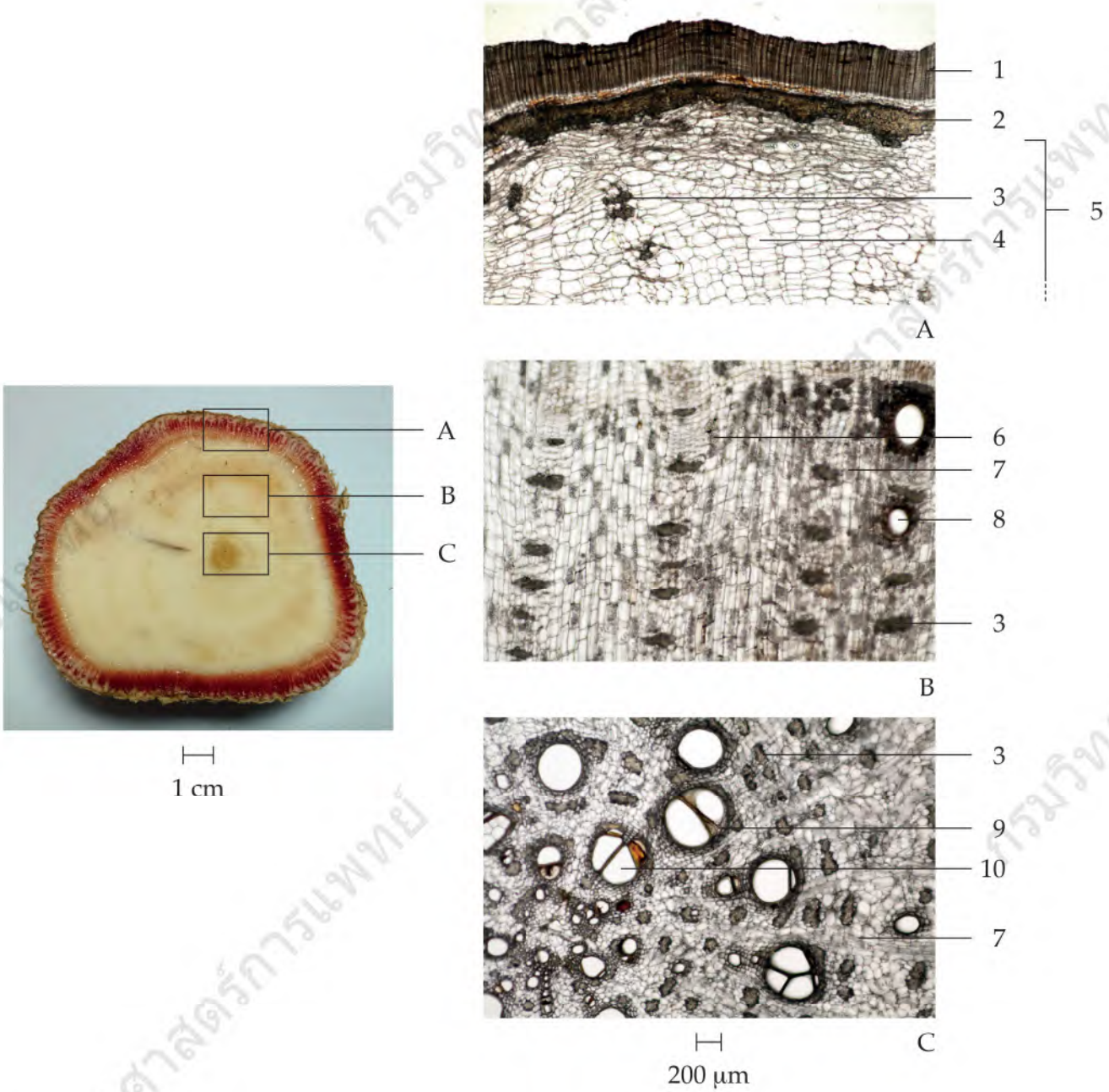


Fig. 2a Photomicrographs of Transverse Section of the Tuberous Root of *Butea superba* Roxb. ex Willd.

A. Periderm, Cortex, and Phloem
B. Xylem
C. Xylem in the Centre

1. cork
2. sclereid
3. group of fibres
4. phloem ray
5. phloem tissue
6. parenchyma containing starch grains
7. xylem ray
8. vessel
9. xylem parenchyma
10. vessel containing brown substance

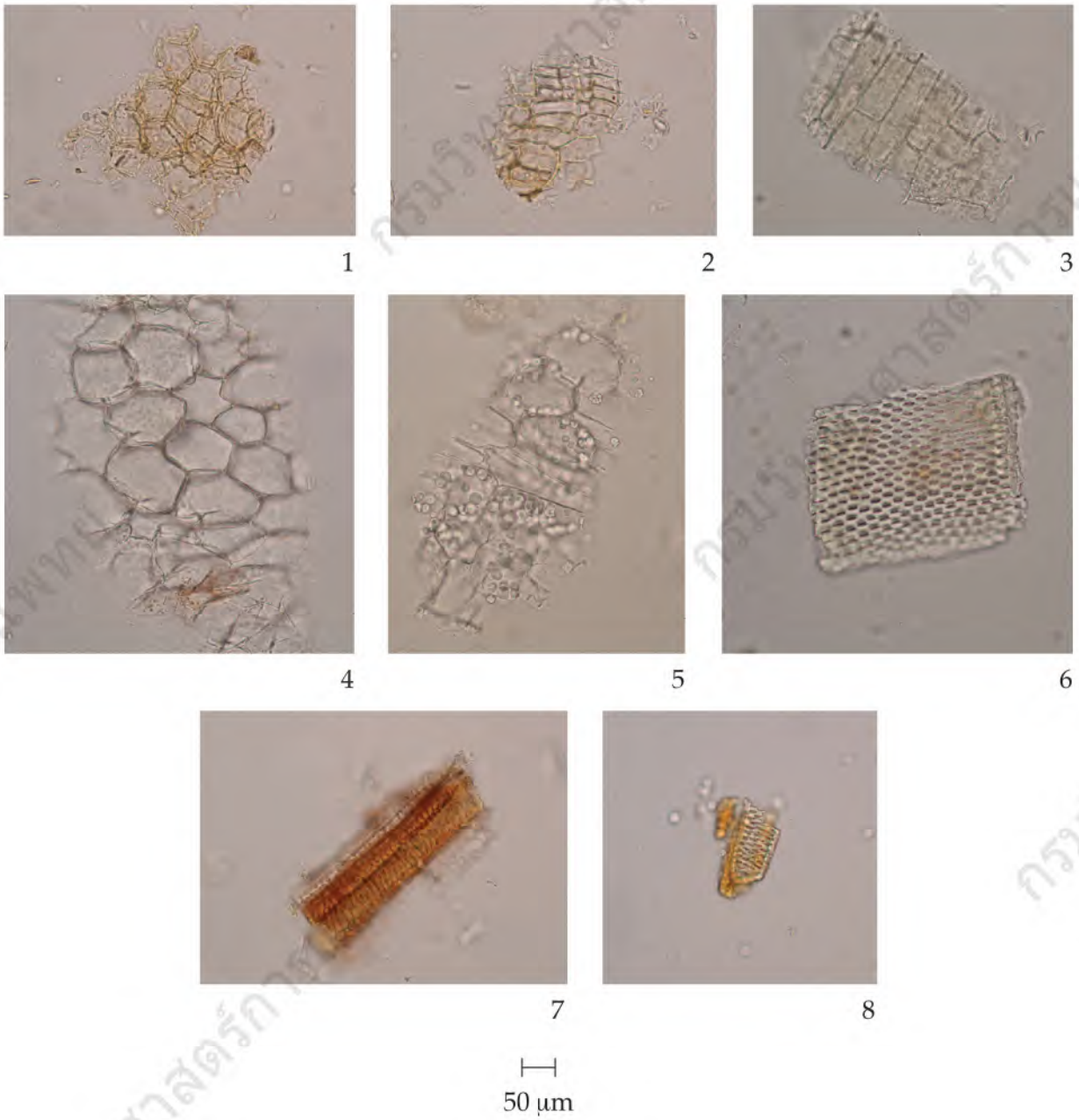


Fig. 2b Photomicrographs of Powdered Drug of the Tuberous Roots of *Butea superba* Roxb. ex Willd.

1. cork in surface view
2. cork in sectional view
3. parenchyma in longitudinal view
4. parenchyma
5. parenchyma containing starch grains
6. large bordered-pitted vessel
7. reticulate-pitted vessels with brown substances
8. reticulate vessel with brown substances

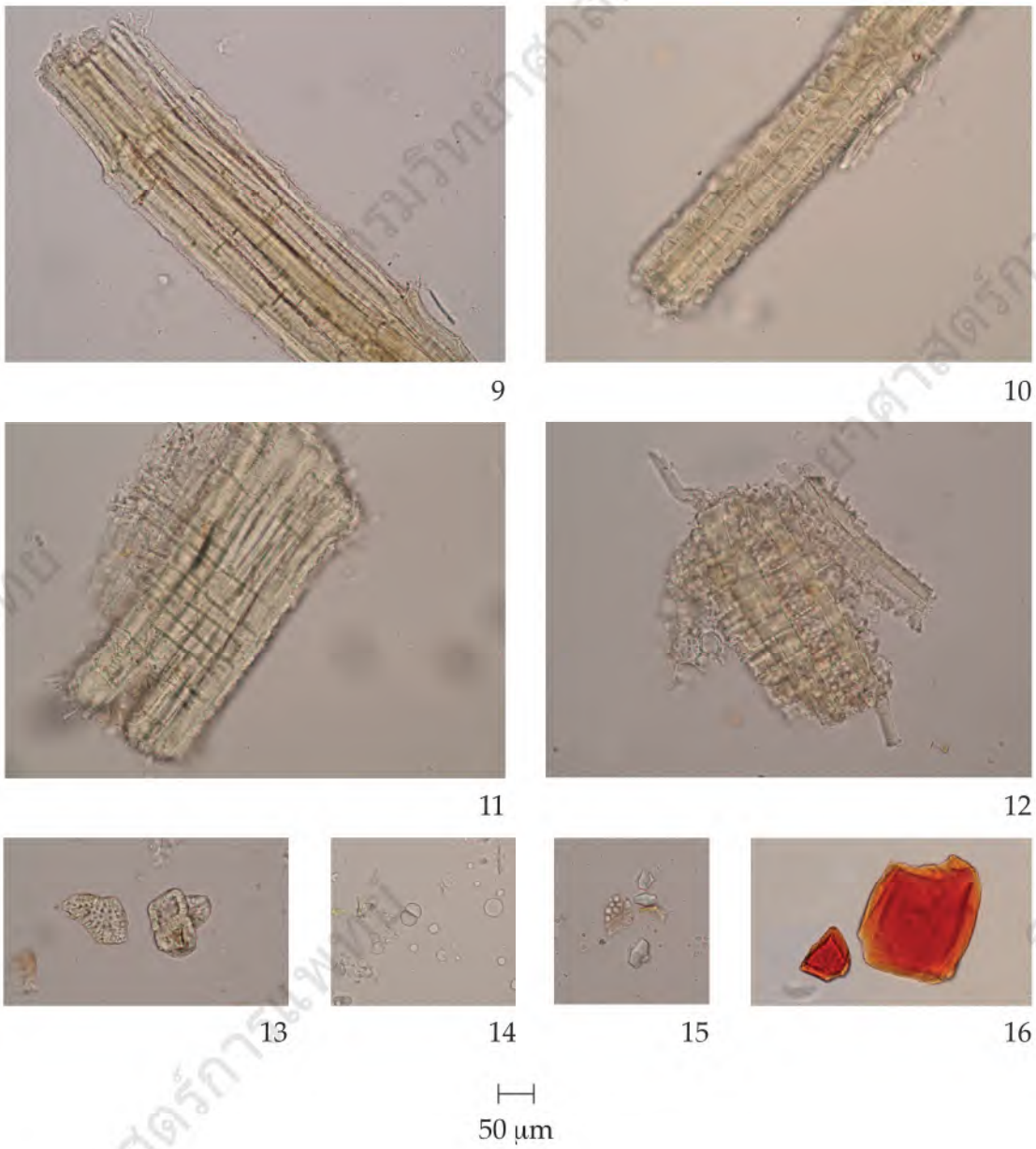


Fig. 2b (continued)

9. fragment of fibres and parenchyma, in longitudinal view
10. fibres and prismatic sheath
11. fragment of medullary ray and fibres, in radial longitudinal view
12. fragment of medullary ray, fibres, and parenchyma, in tangential longitudinal view
13. sclereids
14. starch grains
15. prismatic crystals
16. brown substances

Additional information

1. It is uncertain that Butea Superba Root works as a medicine.
2. There is not enough information to recommend supplementation of Butea Superba Root.

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

Identification

A. Sonicate 1 g of the sample, in powder, with 10 mL of *methanol* for 30 minutes and filter. To 2 mL of the filtrate, add a few drops of *ninhydrin TS* and warm on a water bath: a violet 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 95 volumes of *dichloromethane* and 5 volumes of *methanol* as the mobile phase and allowing the solvent front to ascend 12 cm above the line of application. Apply to the plate as bands of 8 mm, 20 µL of solution (A) and 2 µL of solution (B). Prepare solution (A) by sonicating 1 g of the sample, in powder, with 10 mL of *methanol* for 30 minutes, filtering, and evaporating the filtrate to dryness under reduced pressure at 50°. Dissolve the residue in 1 mL of *methanol*. For solution (B), dissolve 1 mg of *formononetin* 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 44 to 52) corresponding to the formononetin band obtained from solution (B). Other six quenching bands are also observed. Subsequently examine the plate under ultraviolet light (366 nm) through the cut-off filter, the band corresponding to formononetin shows blue fluorescence. Other ten blue fluorescent 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 2.0 per cent w/w (Appendix 7.6).

Total ash Not more than 11.0 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 19.0 per cent w/w (Appendix 7.12).

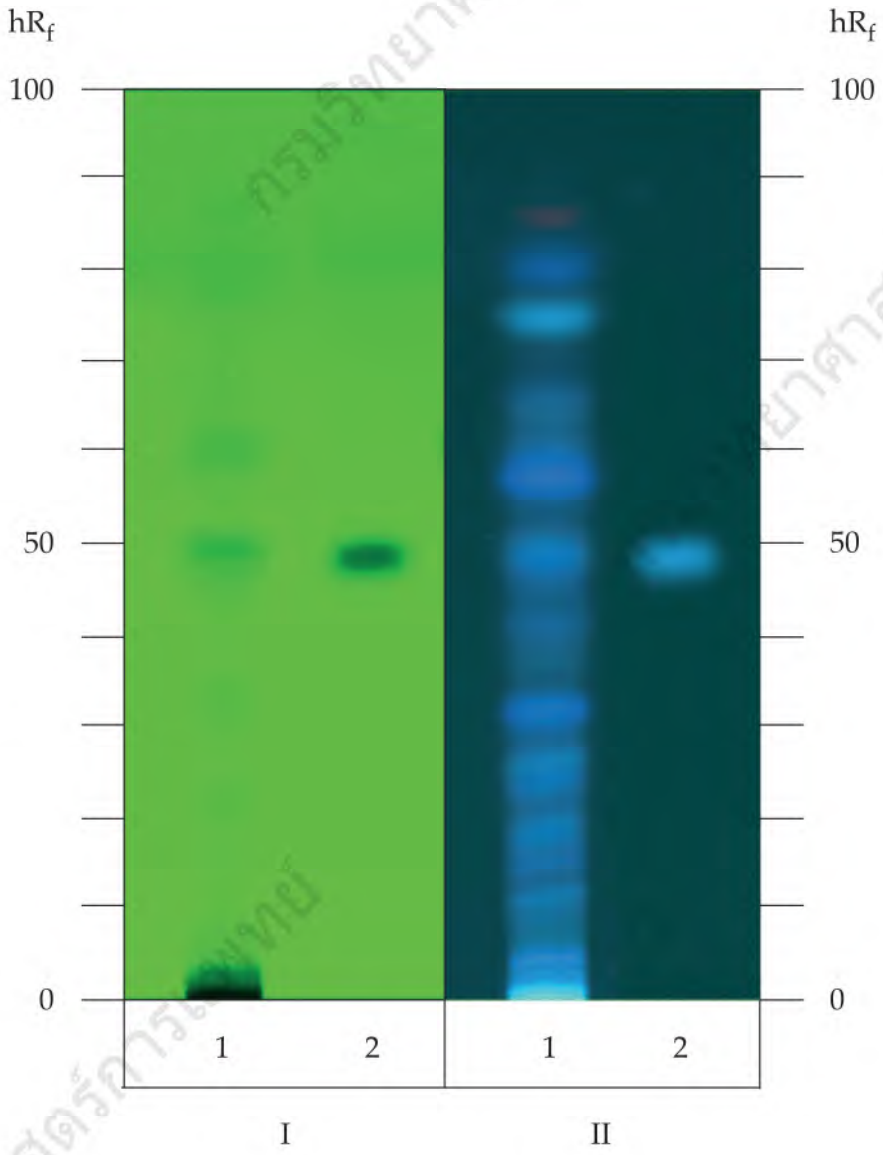


Fig. 3 Thin-Layer Chromatogram of Methanolic Extract of the Tuberous Roots of *Butea superba* Roxb. ex Willd.

1 = solution (A)
2 = solution (B)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)

มะขามแขก, ใบ (MAKHAM KHAEK, BAI)

Sennae Alexandrianae Folium
Alexandrian Senna Leaf

Synonyms Alexandria Senna Leaf, Indian Senna Leaf, Senna Leaf

Category Laxative.

Alexandrian Senna Leaf is the dried leaflets of *Senna alexandriana* Mill. var. *alexandriana* (*Cassia acutifolia* Delile, *Cassia angustifolia* Vahl) (Family Leguminosae), Herbarium Specimen Number: DMSC 5366, Crude Drug Number: DMSc 1241.

Constituents Alexandrian Senna Leaf contains hydroxyanthracenes and its glycosides (e.g., aloe-emodin, sennosides A and B). It also contains flavonoids, sterols, etc.

Description of the plant (Fig. 1) Perennial herb 0.5 to 1.5 m tall; stem erect, glabrous, sparsely pubescent or strigulose. Leaves paripinnately compound, alternate; petiole up to 5 cm long; stipule subulate to lanceolate; leaflets 3- to 8-paired, elliptic to lanceolate, 2.5 to 5 cm long, 1 to 1.5 cm wide, apex acute to obtuse, base oblique, margin entire, pubescent on both surfaces. Inflorescence racemose, terminal or axillary, up to 15 cm long; bract obovate, 7 to 8 mm long. Flower yellow; sepals 5, obovate, 1 to 1.3 cm long, 6 to 8 mm wide; petals 5, bright yellow with distinct veins, obovate, 1 to 1.7 cm long, 0.7 to 1 cm wide, shortly clawed; stamens 10, upper 3 reduced to staminodes, 7 perfect with 2 lower largest; ovary superior, densely hairy, stipitate. Fruit a dehiscent pod, oblong to broadly elliptic or reniform, 4 to 7 cm long, about 2 cm wide, green when young, becoming brownish when mature, flattened. Seeds 4 to 10; stipe 2 to 3 mm long.

Description Odour, faint, characteristic; taste, mucilaginous, slightly bitter.

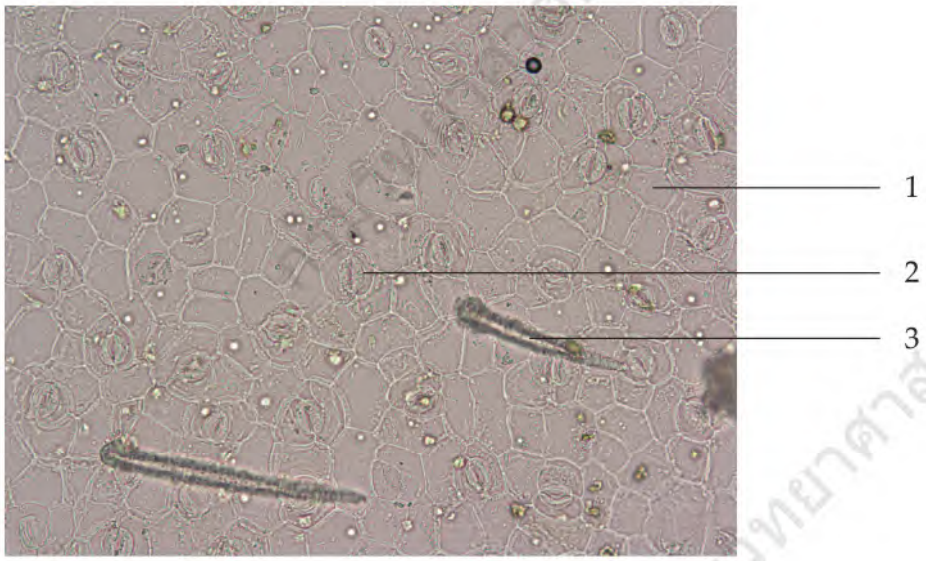
Macroscopical (Fig. 1) Green to brownish green leaflet, entire or broken; entire leaf elongated, lanceolate, 1.5 to 5 cm long, 0.5 to 2 cm wide, apex acute to obtuse, base oblique, blade thin, sometimes marked with transverse or oblique lines, abaxial surface with visible pinnate vernation, margin with anastomosing lateral veins, both surfaces pubescent.

Microscopical (Figs. 2a–2c) Transverse section of the leaflet through the midrib shows upper epidermis, mesophyll, vascular tissue, and lower epidermis. Upper epidermis: cuticle layer, 1 to 2 layers of rectangular cells and thin-walled cells (some containing mucilage), slightly sunken stomata, and warty-walled unicellular trichomes. Mesophyll: unifacial, a layer of cylindrical palisade cells, parenchyma, some of which containing rosette aggregate or prismatic crystals, and angular collenchyma in the midrib. Vascular tissue: collateral bundle, surrounded with fibres and prismatic sheath; and parenchyma, some containing rosette aggregate crystals. Lower epidermis: cuticle layer, 1 to 2 layers of rectangular cells, slightly sunken stomata, and warty-walled unicellular trichomes.

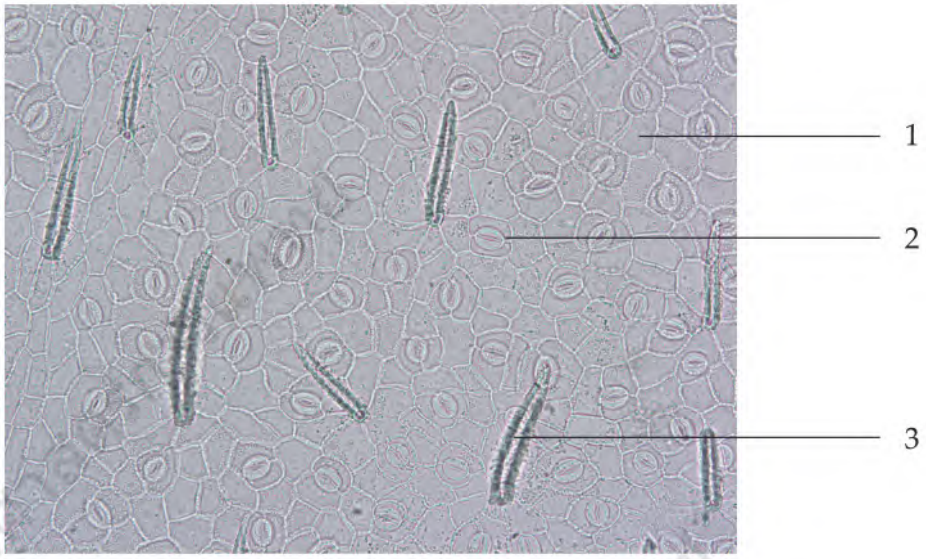
In surface view, the lamina shows upper epidermis and lower epidermis. Both epidermises: polygonal shaped, warty-walled unicellular trichomes; stomata, mostly paracytic, some anomocytic and anisocytic, and cicatrices; some containing mucilage.

Alexandrian Senna Leaf in powder possesses the diagnostic microscopical characters of the unground drug. Warty-walled unicellular trichomes, epidermal cells containing mucilaginous substance, fibres with prismatic sheath, and mesophyll with abundant prismatic and rosette aggregate crystals are characteristic.

Fig. 1 *Senna alexandriana* Mill. var. *alexandriana*
1. habit 2. flowering twig 3. inflorescences 4. flowers 5. mature fruits 6. crude drug



Upper Epidermis of the Lamina



Lower Epidermis of the Lamina

Fig. 2a Photomicrographs of Epidermises of the Leaflet of *Senna alexandriana* Mill. var. *alexandriana*

1. epidermal cell
2. stoma
3. warty-walled unicellular trichome

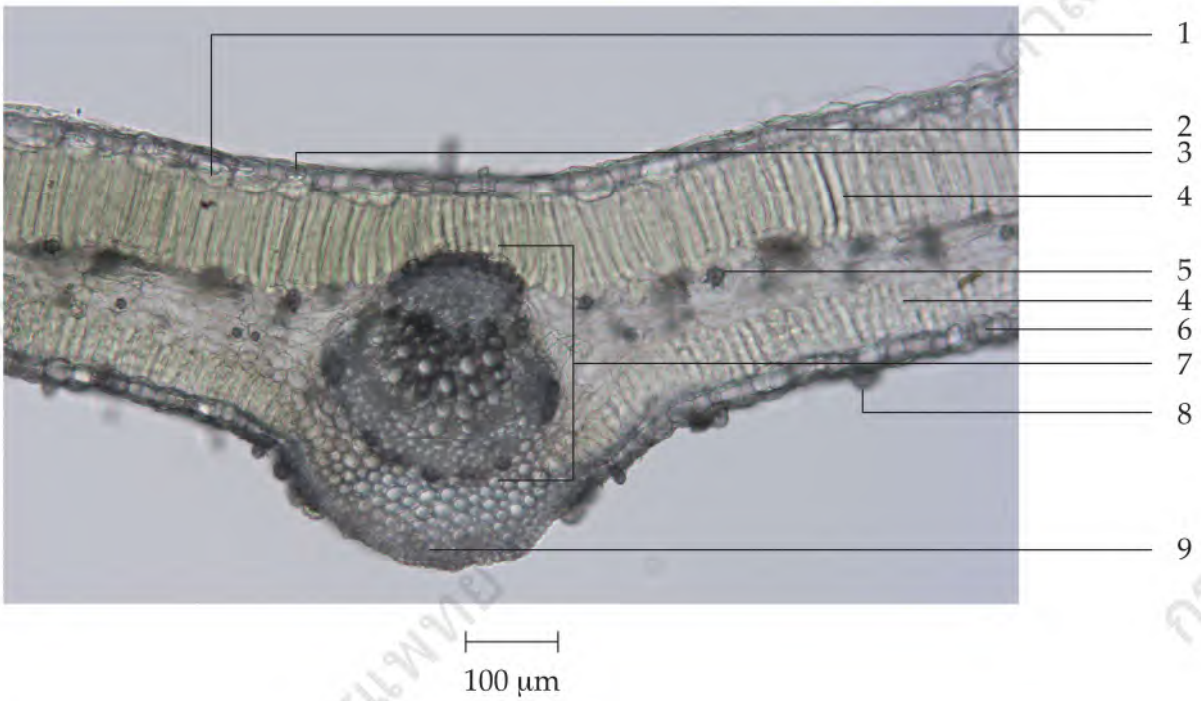


Fig. 2b Photomicrograph of Transverse Section of the Leaflet of *Senna alexandriana* Mill. var. *alexandriana*

1. mucilage cell
2. upper epidermis
3. stoma
4. palisade cell
5. parenchyma containing rosette aggregate crystal
6. lower epidermis
7. vascular tissue
8. part of trichome
9. collenchyma

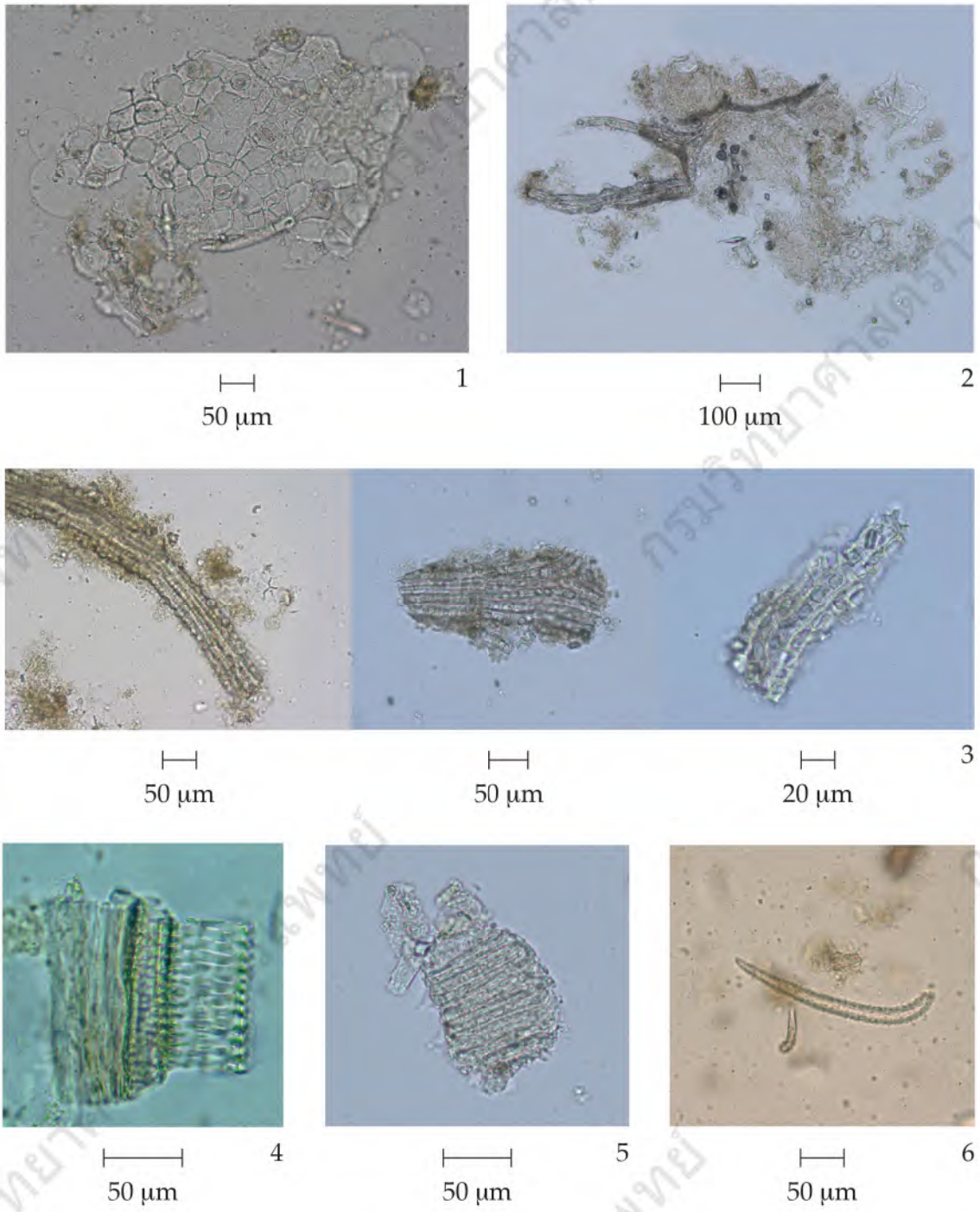


Fig. 2c Photomicrographs of Powdered Drug of the Leaflets of *Senna alexandriana* Mill. var. *alexandriana*

1. epidermis with stomata, unicellular trichome, mucilage cells, cicatrix, and extruded mucilage
2. part of leaflet, in surface view, showing palisade cells, branch of veinlets, prismatic sheath, and rosette aggregate crystals
3. fragments of veinlets showing fibres and prismatic sheath
4. reticulate vessels and fibres
5. palisade cells and parenchyma containing rosette aggregate crystal, in sectional view
6. warty-walled unicellular trichomes

Packaging and storage Alexandrian Senna Leaf 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 30 mL of 0.5 M *potassium hydroxide* and 2 mL of a 3 per cent v/v solution of *hydrogen peroxide*, and heat on a water-bath for 10 minutes. Allow to cool and filter. Acidify the filtrate with sufficient amount of *glacial acetic acid* and then shake with 20 mL of *dichloromethane*. Separate the dichloromethane layer and mix well with 2 mL of *ammonia TS*: the aqueous layer becomes pinkish red.

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 40 volumes of *ethyl acetate*, 40 volumes of *propanol*, 30 volumes of *water*, and 1 volume of *glacial acetic acid* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply to the plate as bands of 6 mm, 2 µL of solution (A), 1 µL each of solutions (B) and (D), and 7 µL of solution (C). Prepare solution (A) by sonicating 500 mg of the sample, in *No. 250 powder*, with 5 mL of a mixture of equal volumes of *ethanol* and *water* for 10 minutes. Centrifuge the resulting solution at 2683 × *g* (4000 rpm) for 5 minutes and use the supernatant. For solution (B), dissolve 5 mg of *sennoside B* in 1 mL of *methanol*. For solution (C), dissolve 5 mg of *sennoside A* in 1 mL of *methanol*. For solution (D), dissolve 5 mg of *rhein* 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 three quenching bands (hR_f values 31 to 35, 50 to 54, and 88 to 92) corresponding to sennoside B, sennoside A, and rhein from solutions (B), (C), and (D), respectively. Spray the plate with a 5 per cent w/v solution of *potassium hydroxide* in *methanol* and heat at 110° for 10 minutes. Immediately examine the plate under ultraviolet light (366 nm); the bands due to sennoside B, sennoside A, and rhein are orange-brown, yellow, and pink-brown fluorescent, respectively. Other two pink fluorescent 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 1.0 per cent w/w (Appendix 7.6).

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

Content of hydroxyanthracene glycosides Not less than 1.8 per cent w/w of hydroxyanthracene glycosides, calculated as sennoside B ($C_{42}H_{38}O_{20}$) when determined by the following method. (**Note** Carry out the determination protected from light.)

Sample preparation Place 150 mg of Alexandrian Senna Leaf, in *fine powder*, accurately weighed, in a 100-mL round-bottomed flask. Add 30.0 mL of *water*, mix, weigh, and place in a water-bath. Heat under a reflux condenser for 15 minutes. Allow to cool, weigh, and adjust to the original weight with *water*. Centrifuge the resulting solution at 2683 × *g* (4000 rpm) for 5 minutes and transfer 20.0 mL of the supernatant liquid to a 150-mL separator. Add 0.1 mL of *dilute hydrochloric acid* and shake with three 15-mL portions of *chloroform*. Allow to separate and discard the chloroform layer. Add 100 mg of *sodium hydrogen carbonate* and shake for 3 minutes. Centrifuge and transfer 10.0 mL of the supernatant liquid to a 100 mL round-bottomed flask with a ground-glass neck. Add 20 mL of *iron(III) chloride TS* and mix. Place the flask in a water-bath so that the water level is above that of the liquid in the flask, and heat under a reflux condenser for 20 minutes. Add 3 mL of *hydrochloric acid* and heat for

a further 20 minutes, with frequent shaking, to dissolve the precipitate. Cool, transfer the mixture to a separator, and shake with three 25-mL portions of *ether* previously used to rinse the flask. Combine the three ether layers and wash with two 15-mL portions of 15 mL of *water*. Transfer the combined ether layers to a volumetric flask and dilute to 100.0 mL with *ether*. Evaporate 10.0 mL carefully to dryness and dissolve the residue in 10.0 mL of a 0.5 per cent w/v solution of *magnesium acetate* in *methanol*.

Procedure Measure the absorbance of *Sample preparation* at 515 nm using *methanol* as the blank.

Calculation Calculate the percentage content of hydroxyanthracene glycosides, calculated as sennoside B, in the portion of Alexandrian Senna Leaf taken, utilizing the specific absorbance of sennoside B to be 240, by the expression:

$$1.25x\ A/W,$$

where A is the absorbance of the sample at 515 nm and W is the weight, in g, of the Alexandrian Senna Leaf taken.

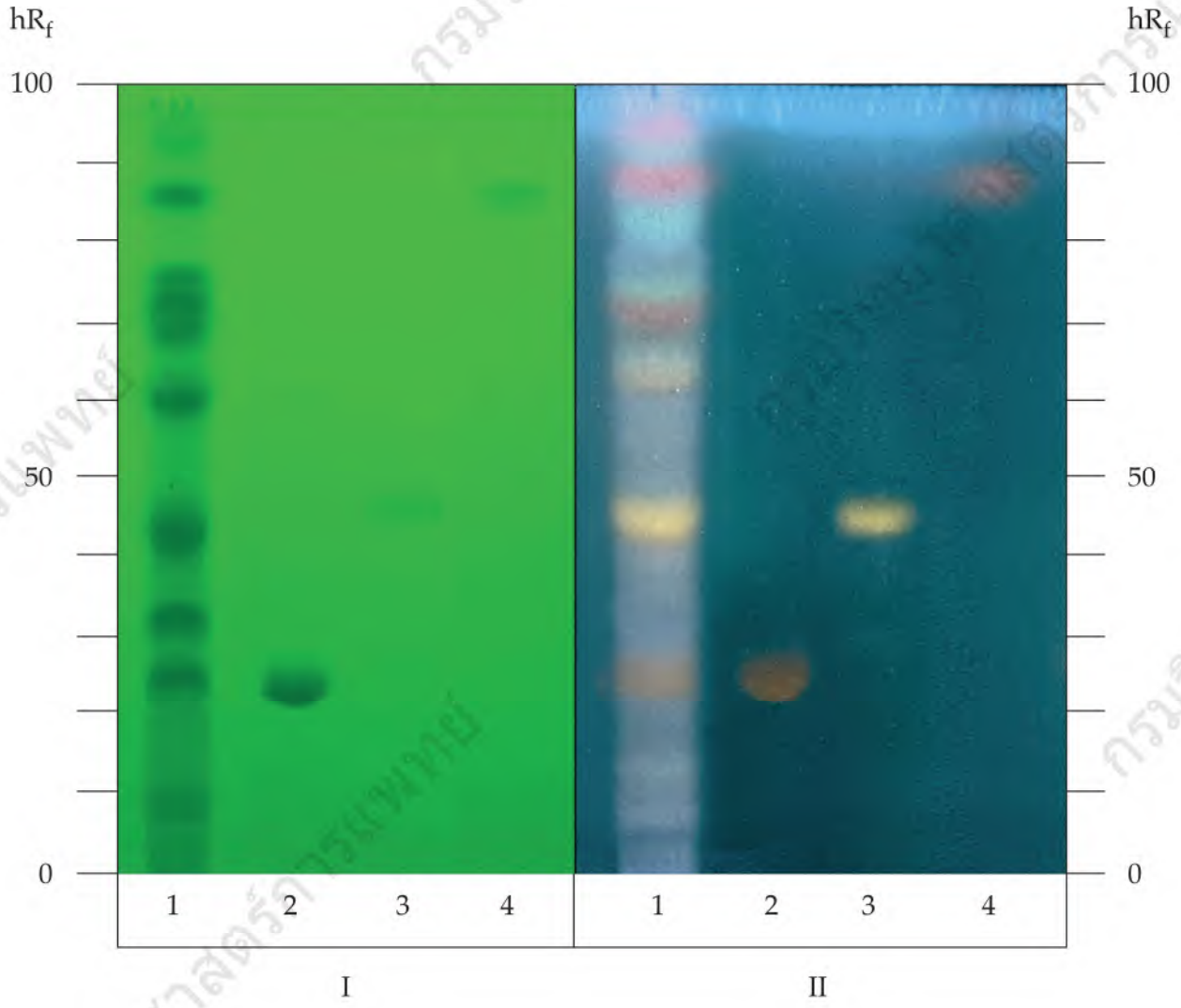


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Leaflets of *Senna alexandriana* Mill. var. *alexandriana*

1 = solution (A)
2 = solution (B)
3 = solution (C)
4 = solution (D)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm) after spraying with a 5 per cent w/v solution of *potassium hydroxide* in *methanol*

ยาแคปซูลใบมะขามแขก (MAKHAM KHAEK CAPSULES, BAI)

Alexandrian Senna Leaf Capsules

Category Laxative.

Alexandrian Senna Leaf Capsules contain an amount of powdered Alexandrian Senna Leaf equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of hydroxyanthracene glycosides, calculated as sennoside B.

Strength available 450 mg (powder).

Dose Three to four capsules, equivalent to about 20 to 30 mg of sennoside B, once at bedtime.

Contra-indication It is contra-indicated in patients with intestinal obstruction, undiagnosed abdominal symptoms, appendicitis and in children under the age of 10 years.

Warning It may cause abdominal pain.

Precaution It should not be used in nursing mothers.

Packaging and storage Alexandrian Senna Leaf Capsules shall be kept in well-closed containers, protected from light, and stored in a dry place at a temperature not exceeding 30°.

Labelling The label on the container states (1) the equivalent amount of hydroxyanthracene glycosides as sennoside B; (2) the expiration date.

Identification

A. The capsule contents exhibit diagnostic structures of the powdered drug described under *Alexandrian Senna Leaf*.

B. The capsule contents comply with the tests for Identification A and B described under *Alexandrian Senna Leaf*.

Loss on drying Of the capsule contents, not more than 8.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Microbial limit Comply with the requirements for Category 4 in the "Limits for Microbial Contamination" (Appendix 10.5).

Assay (**Note** Carry out the determination protected from light.) Remove, as completely as possible, the contents of not less than 20 Alexandrian Senna Leaf Capsules, and grind to *fine powder*. Place about 150 mg, accurately weighed, in a 100-mL round-bottomed flask. Add 30.0 mL of *water*, mix, weigh, and place in a water-bath. Heat under a reflux condenser for 15 minutes. Allow to cool, weigh, and adjust to the original weight with *water*. Centrifuge the resulting solution at 2683 × *g* (4000 rpm) for 5 minutes and transfer 20.0 mL of the supernatant liquid to a 150-mL separator. Add 0.1 mL of *dilute hydrochloric acid* and shake with three 15-mL portions of *chloroform*. Allow to separate and discard the chloroform layer. Add 100 mg of *sodium hydrogen carbonate* and shake for 3 minutes. Centrifuge and transfer 10.0 mL of the supernatant liquid to a 100-mL round-bottomed flask with a ground-glass neck. Add 20 mL of *iron(III) chloride TS* and mix. Place the flask in a water-bath so that the water level is above that of the liquid in the flask, and heat under a reflux condenser for 20 minutes. Add 3 mL of *hydrochloric acid* and heat for a further 20 minutes, with frequent shaking, to dissolve the precipitate. Cool, transfer the mixture to a separator, and shake with three 25-mL portions of *ether* previously used to rinse the flask. Combine the three ether layers and wash with two 15-mL portions of *water*. Transfer the combined ether layers to a 100-mL volumetric flask

and dilute to volume with *ether*. Evaporate 10.0 mL carefully to dryness and dissolve the residue in 10.0 mL of a 0.5 per cent w/v solution of *magnesium acetate* in *methanol*. Measure the absorbance of *Assay preparation* at 515 nm using *methanol* as the blank. Calculate the percentage content of hydroxyanthracene glycosides, calculated as sennoside B, in the portion of the capsules taken, utilizing the specific absorbance of sennoside B to be 240, by the expression:

$$1.25 \times A/W,$$

where A is the absorbance of the Assay preparation at 515 nm and W is the weight, in g, of the portion of the capsules taken.

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

ยาชงใบมะขามแขก (YA CHONG MA KHAM KHAEK, BAI)

Alexandrian Senna Leaf Tea

Category Laxative.

Alexandrian Senna Leaf Tea contains an amount of powdered Alexandrian Senna Leaf equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of hydroxyanthracene glycosides, calculated as sennoside B.

Strength available 2.5 g (powder), supplied in a sachet.

Dose One sachet, prepared as an infusion by soaking each with 200 mL of hot water for 10 minutes, once at bedtime.

Contra-indication It is contra-indicated in patients with intestinal obstruction, undiagnosed abdominal symptoms, appendicitis and in children under the age of 10 years.

Warning It may cause abdominal pain.

Precaution It should not be used in nursing mothers.

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

Labelling The label on the container states (1) the equivalent amount of hydroxyanthracene glycosides, as sennoside B; (2) the expiration date.

Identification

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

B. The tea contents comply with the tests for Identification A and B described under *Alexandrian Senna Leaf*.

Loss on drying Of the tea contents, not more than 8.0 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 (**Note** Carry out the determination protected from light.) Grind the contents of not less than 20 sachets of Alexandrian Senna Leaf Tea to *fine powder*. Place about 150 mg, accurately weighed, in a 100-mL round-bottomed flask. Add 30.0 mL of *water*, mix, weigh, and place in a water-bath. Heat under a reflux condenser for 15 minutes. Allow to cool, weigh, and adjust to the original weight with *water*. Centrifuge the resulting solution at 2683 × *g* (4000 rpm) for 5 minutes and transfer 20.0 mL of the supernatant liquid to a 150-mL separator. Add 0.1 mL of *dilute hydrochloric acid* and shake with three 15-mL portions of *chloroform*. Allow to separate and discard the chloroform layer. Add 100 mg of *sodium hydrogen carbonate* and shake for 3 minutes. Centrifuge and transfer 10.0 mL of the supernatant liquid to a 100-mL round-bottomed flask with a ground-glass neck. Add 20 mL of *iron(III) chloride TS* and mix. Place the flask in a water-bath so that the water level is above that of the liquid in the flask, and heat under a reflux condenser for 20 minutes. Add 3 mL of *hydrochloric acid* and heat for a further 20 minutes, with frequent shaking, to dissolve the precipitate. Cool, transfer the mixture to a separator, and shake with three 25-mL portions of *ether* previously used to rinse the flask. Combine the three ether layers and wash with two 15-mL portions of *water*. Transfer the combined ether layers to a 100-mL volumetric flask

and dilute to volume with *ether*. Evaporate 10.0 mL carefully to dryness and dissolve the residue in 10.0 mL of a 0.5 per cent w/v solution of *magnesium acetate* in *methanol*. Measure the absorbance of *Assay preparation* at 515 nm using *methanol* as the blank. Calculate the percentage content of hydroxyanthracene glycosides, calculated as sennoside B, in the portion of the Tea taken, utilizing the specific absorbance of sennoside B to be 240, by the expression:

$$1.25 \times A/W,$$

where A is the absorbance of the Assay preparation at 515 nm and W is the weight, in g, of the portion of the Tea taken.

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

ยาแคปซูลพริกไทยดำ (PHRIK THAI DAM CAPSULES)

Black Pepper Capsules

Category Stomachic, carminative.

Black Pepper Capsules contain an amount of powdered Black Pepper equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labelled content of alkaloids, calculated as piperine ($C_{17}H_{19}NO_3$), and not less than 80.0 per cent of the labelled amount of volatile oil, calculated on the anhydrous basis.

Strength available 250 mg (powder).

Dose One to two capsules three times a day after meals.

Packaging and storage Black Pepper Capsules shall be kept in well-closed containers, protected from light, and stored in a dry place at a temperature not exceeding 30°.

Labelling The label on the container states (1) the equivalent amount of alkaloid as piperine; (2) the amount of volatile oil; (3) the expiration date.

Identification

A. The capsule contents exhibit diagnostic structures of the powdered drug described under *Black Pepper*.

B. The capsule contents comply with the tests for Identification A, B, and C described under *Black Pepper*.

Water Of the capsule contents, not more than 14.0 per cent v/w (Azeotropic Distillation Method, Appendix 4.12)

Microbial limit Comply with the requirements for Category 4 in the "Limits for Microbial Contamination" (Appendix 10.5).

Assay

FOR VOLATILE OIL Remove, as completely as possible, the contents of not less than 20 Black Pepper Capsules, mix, and transfer about 50 g, accurately weighed, to a 500-mL round-bottomed flask. Use 250 mL of *water* as the distillation liquid and distil at a rate of 2 to 3 mL per minute for 5 hours. Use 2.0 mL of *xylene* in the graduated tube (Appendix 7.3H). Calculate the content of volatile oil, in mL, in the portion of the Capsules taken with reference to the anhydrous substance.

FOR PIPERINE Carry out the determination as described in the "Ultraviolet and Visible Spectrophotometry" (Appendix 2.2).

Standard piperine solution Transfer about 20 mg of *piperine*, accurately weighed, into a 100-mL volumetric flask, add *chloroform* to dissolve, and dilute to volume.

Standard piperine curve Transfer into five 25-mL volumetric flasks 0.2 mL, 0.4 mL, 0.6 mL, 0.8 mL, and 1.0 mL, respectively, of *Standard piperine solution* and add *chloroform* to make 1.0 mL. To each flask add 10.0 mL of *chromotropic acid TS*, shake vigorously and place in a water-bath for 30 minutes. Set aside for a few minutes, stopper, and allow to cool. Then add 10 mL of *dilute sulfuric acid*, mix well, allow to cool, and dilute with sufficient *dilute sulfuric acid* to volume. Measure the absorbances of the piperine-containing solutions relative to the blank at 570 nm (Appendix 2.2). Plot the readings and draw the curve of best fit.

Procedure Weigh and mix the contents of not less than 20 Black Pepper Capsules. Grind to *No. 150 powder* and transfer about 500 mg, accurately weighed, in an extraction thimble and insert the thimble into a soxhlet extractor of appropriate size. Moisten with 0.5 mL of *chloroform*, mix, allow to stand for about 5 minutes, make alkaline with 0.5 mL of *ammonia TS*, and mix. Macerate for 6 to 12 hours or overnight, cover with a pledget of absorbent cotton, add a sufficient quantity of *chloroform*, and extract until complete extraction of the alkaloids is effected (Appendix 7.4). Transfer the total mass to a 250-mL volumetric flask, dilute with *chloroform* to volume and filter. Transfer 1.0 mL of the filtrate to a 25-mL volumetric flask, and proceed as directed under *Standard piperine curve*, beginning with "Add 10.0 mL of *chromotropic acid TS*, ...". Read the absorbance of the resulting solution, and by reference to the Standard piperine curve, calculate the content of alkaloids as piperine ($C_{17}H_{19}NO_3$) in the portion of the Capsules taken.

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

ระย่อม (RAYOM)

กะย่อม (KAYOM), ย่อมตีนหมา (YOM TIN MA)
Rauvolfiae Serpentinae Radix
Indian Snakeroot

Synonym Serpentine Root

Category Antihypertensive, antipyretic.

Indian Snakeroot is the dried root of *Rauvolfia serpentina* (L.) Benth. ex Kurz [*Ophioxylon album* Gaertn., *O. obversum* Miq., *O. salutiferum* Salisb., *O. serpentinum* L., *O. trifoliatum* Gaertn., *Rauvolfia obversa* Baill., *R. serpentina* (L.) Benth. ex Kurz var. *obversa* (Miq.) Bakh. f., and *R. trifoliata* Baill.] (Family Apocynaceae), Herbarium Specimen Number: DMSC 5365, Crude Drug Number: DMSc 1256.

Constituents Indian snakeroot contains indole alkaloids (e.g., ajmalicine, ajmaline, reserpine, serpentine), and tannins, etc.

Description of the plant (Fig. 1) Shrub up to 1 m tall with latex; stem erect, slender, glabrous; branchlet often angled, glabrous; root elongated. Leaves simple, in whorl of 3 to 5, rarely opposite, narrowly elliptic to obovate, 4 to 25 cm long, 1.5 to 10 cm wide, apex acuminate or rarely obtuse, base cuneate, margin entire, papery, glabrous, lateral veins in 7 to 16 pairs, arcuate ascending; petiole 1 to 3.5 cm long. Inflorescence cymose, usually solitary, terminal or axillary, 4.5 to 11.5 cm long; peduncle 3 to 7.8 cm long, glabrous. Flower: pedicel 2.2 to 6.5 mm long; calyx reddish, glabrous, base connate, lobes 5, ovate or lanceolate, 1.8 to 4.2 mm long, 0.5 to 1.5 mm wide, apex acute to acuminate; corolla white, reddish, pinkish or purplish, tube 1.5 to 2 mm long, lobes 5, overlapping to the left in bud, mature corolla salverform, lobe obliquely suborbicular, 2 to 5.6 mm long, glabrous outside, pubescent in mouth and inside to just beneath stamens or in mouth and around stamens with a glabrous band between; stamens 5, inserted at 0.8 to 1.1 cm from base of corolla tube, filament 0.5 to 1 mm long, anther oblong; disc annular, 0.3 to 0.8 mm long; ovary superior, 0.8 to 1.6 mm long, carpels 2, connate at base, style and stigma 6.2 to 9.6 mm long. Fruit a drupe, paired, connate at base, ovoid, 5.4 to 9 mm long, 4.2 to 4.7 mm wide, green when young, becoming blackish purple when ripe. Seed 1, ovoid, flattened, about 4 mm long, about 2.8 mm wide.

Description Odourless; taste, very bitter.

Macroscopical (Fig. 1) Dried roots, various lengths and diameters, stout, thick, tortuous, and frequently curved and twisted. Externally greyish yellow to brown, internally whitish grey. Surface slightly wrinkled and rough with coarse longitudinal markings.

Microscopical (Figs. 2a, 2b) Transverse section of the root shows periderm, cortex, and vascular tissue. Periderm: lenticels, numerous layers of rectangular cork cells, some containing brown substances, and/or starch grains. Cortex: parenchyma, containing starch grains and/or some prismatic crystals. Vascular tissue: phloem and xylem; phloem comprising parenchyma, some containing starch grains and/or some prismatic crystals, and phloem ray; xylem consisting of tracheid-vessels, few vessels, xylem ray (some containing starch grains), pitted parenchyma, and xylem fibres.

Indian Snakeroot in powder possesses the diagnostic microscopical of the unground drug. Tracheid-vessels, rarely found in other crude drug of Dicotyledonae origin, are characteristic. Cork in surface view and starch grains can be seen in abundance.

1

2

3

4

5

Fig. 1 *Rauvolfia serpentina* (L.) Benth. ex Kurz
1. habit 2. inflorescences 3. fruits 4. elongated root 5. crude drug

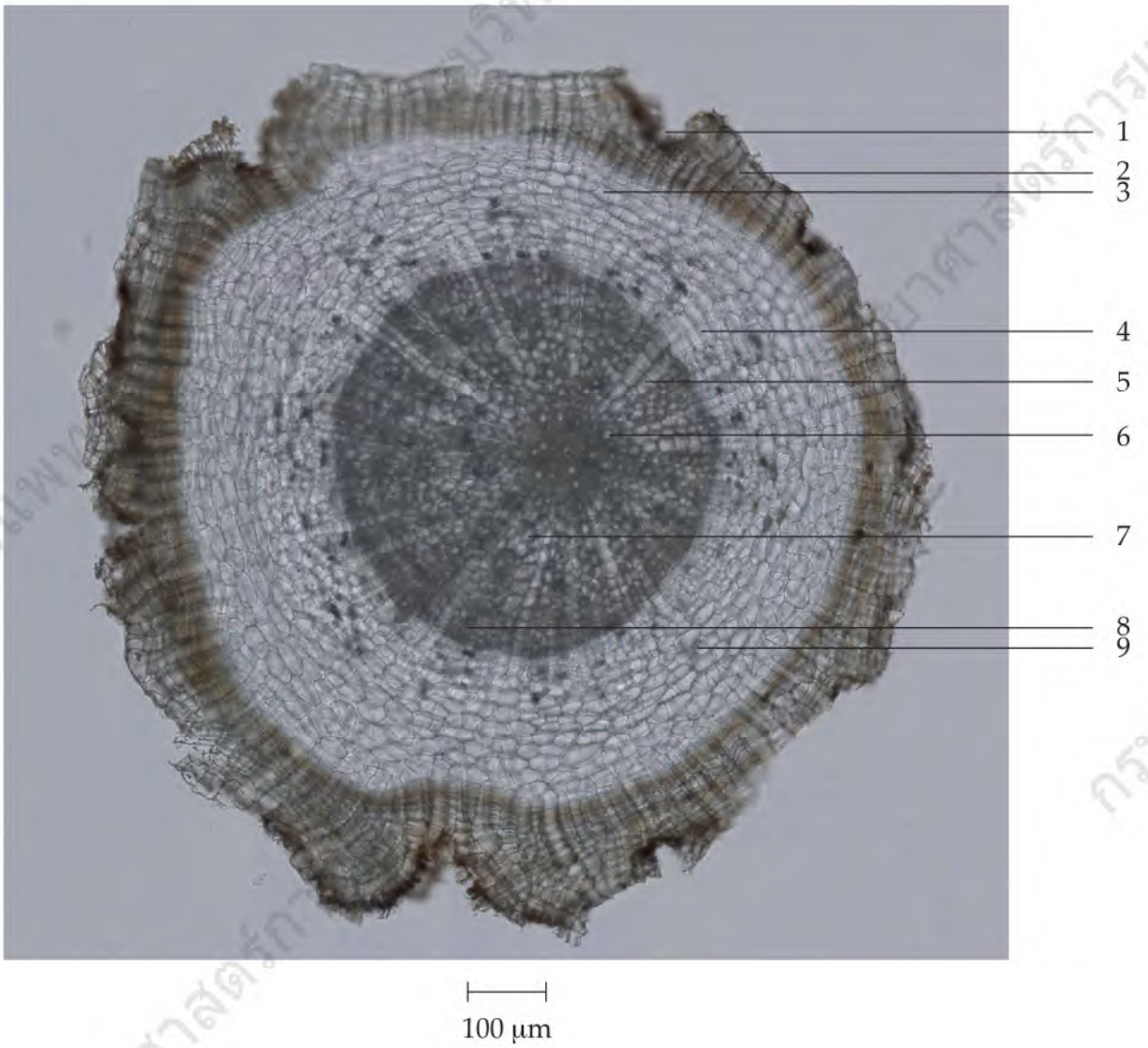


Fig. 2a Photomicrograph of Transverse Section of the Root of *Rauvolfia serpentina* (L.) Benth. ex Kurz

1. lenticel
2. cork
3. parenchyma
4. phloem ray
5. xylem ray
6. vessel
7. pitted parenchyma
8. xylem fibre
9. prismatic crystal

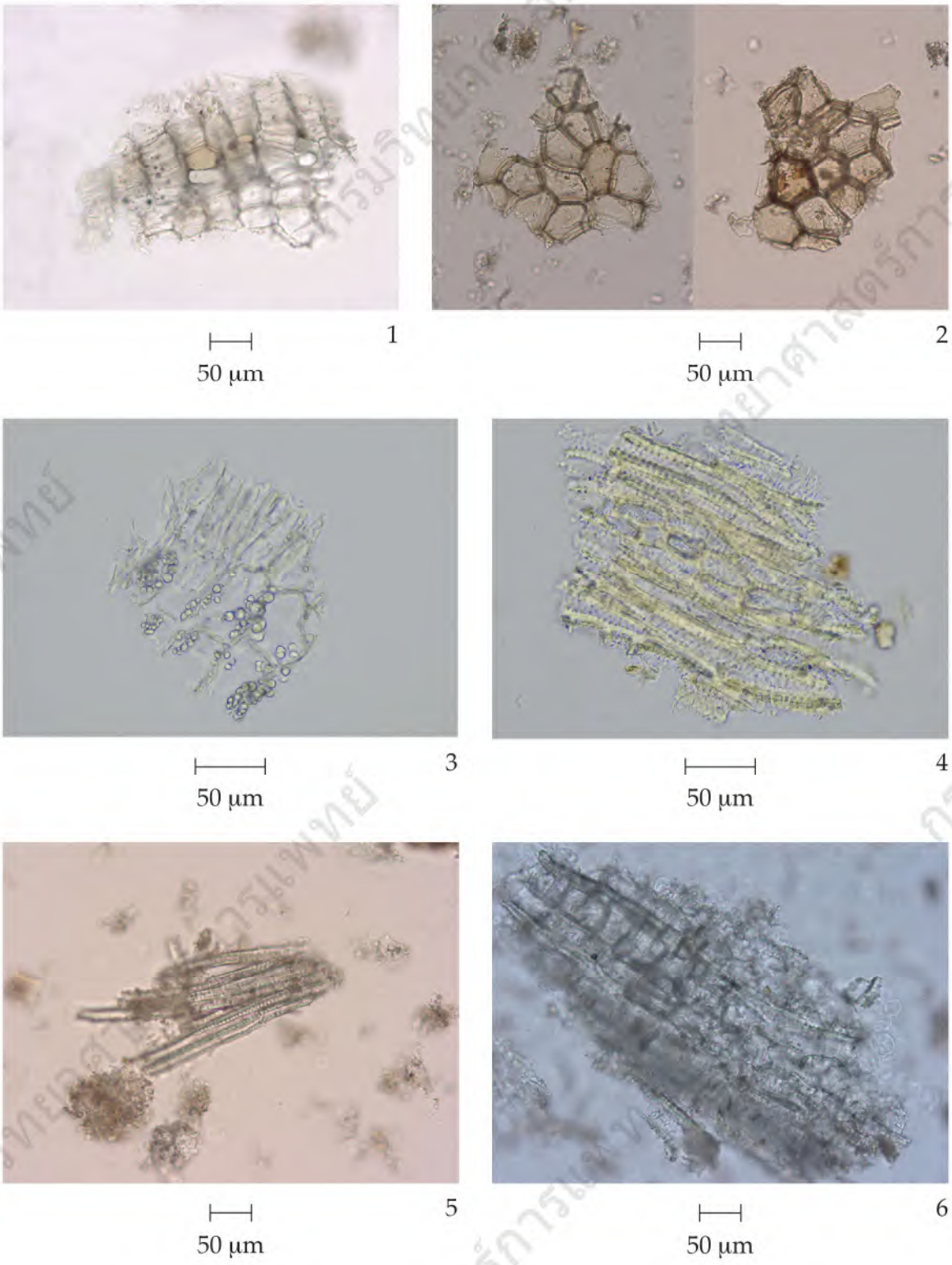


Fig. 2b Photomicrographs of Powdered Drug of the Roots of *Rauvolfia serpentina* (L.) Benth. ex Kurz

1. cork in sectional view
2. cork in surface view, some containing brown substances
3. parenchyma containing starch grains
4. tracheid-vessels and pitted parenchyma, in longitudinal view
5. fibres
6. medullary ray in radial longitudinal view

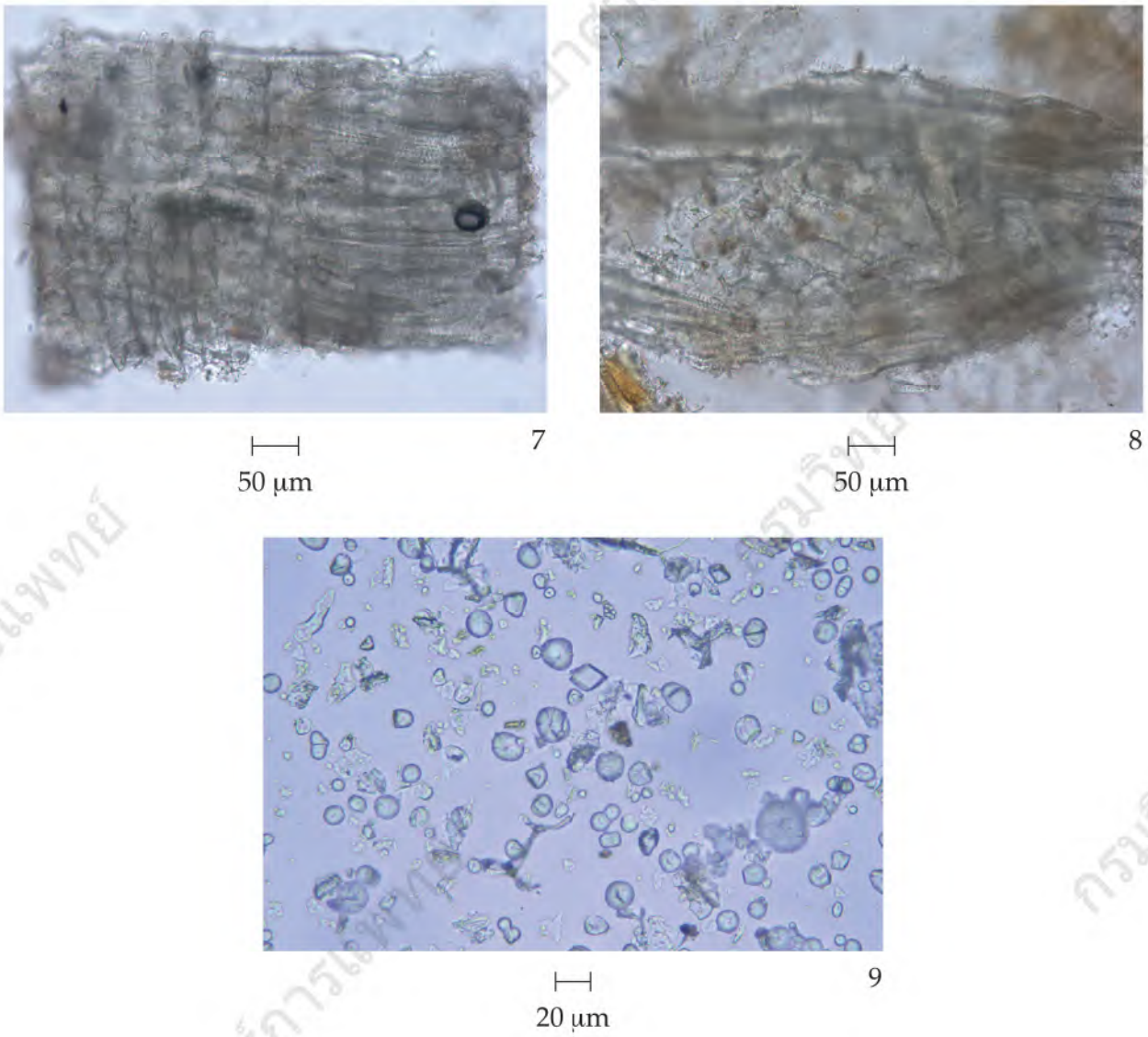


Fig. 2b (continued)

7. medullary ray and tracheid-vessels, in radial longitudinal view
8. medullary ray and pitted parenchyma, in tangential longitudinal view
9. starch grains and prismatic crystals

Contra-indication It is contra-indicated in patients with a history of mental depression.

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

Identification

A. Sonicate 500 mg of the sample, in powder, with 10 mL of *ethanol* for 30 minutes and filter (solution 1). To 2 mL of solution 1, add a few drops of *modified Dragendorff TS*: an orange precipitate is produced.

B. To 2 mL of solution 1, add a few drops of a 1 per cent w/v solution of *iron(III) chloride* and shake well: a blue-green 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 70 volumes of *toluene*, 20 volumes of *diethylamine*, 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 to the plate as bands of 6 mm, 1 µL each of solutions (A), (B), and (C). Prepare solution (A) by sonicating 3 g of the sample, in *No. 250 powder*, with 60 mL of *ethanol* for 30 minutes and filtering. Evaporate the filtrate to dryness under reduced pressure at 50°. Dissolve the residue in 2 mL of *ethanol*. For solution (B), dissolve 2 mg of *reserpine* in 1 mL of *methanol*. For solution (C), dissolve 2 mg of *ajmalicine* 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 quenching bands (hR_f values 60 to 65 and 75 to 80) corresponding to the reserpine band from solution (B) and the ajmalicine band from solution (C), respectively. Other four quenching bands are also observed. Subsequently examine the plate under ultraviolet light (366 nm) through the cut-off filter; the bands corresponding to reserpine and ajmalicine show blue fluorescence. Other four blue fluorescent bands are also observed. Spray the plate with *modified Dragendorff TS*. The bands due to reserpine and ajmalicine are reddish brown. One white and three reddish brown 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 0.5 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 6.0 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).

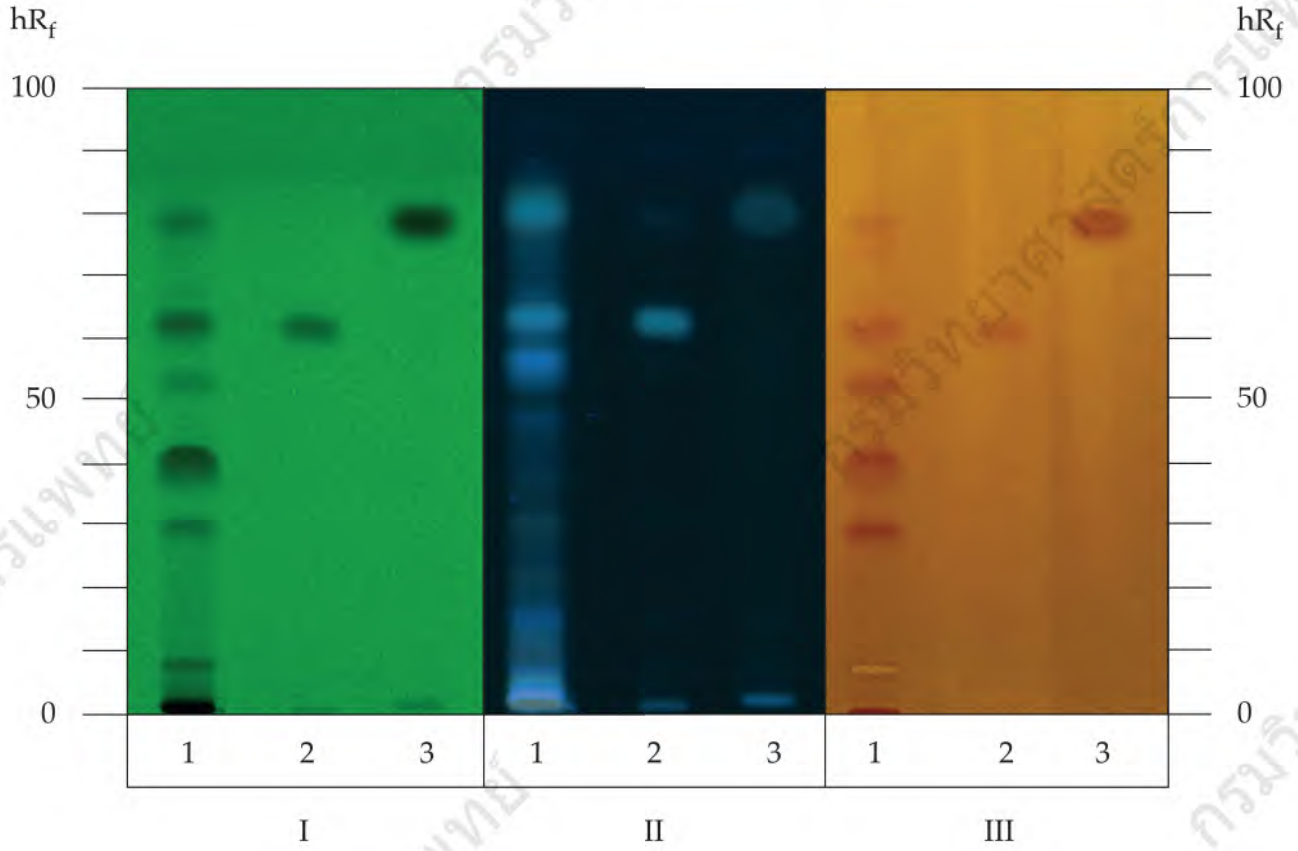


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Roots of *Rauvolfia serpentina* (L.) Benth. ex Kurz

1 = solution (A)
2 = solution (B)
3 = solution (C)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with *modified Dragendorff TS*

ส้มป่อย, ใบ (SOMPOI, BAI)

ส้มขอน, ใบ (SOM KHON, BAI)
Senegaliae Rugatae Folium
Senegalia Rugata Leaf

Category Mild laxative.

Senegalia Rugata Leaf is the dried leaflets of *Senegalia rugata* (Lam.) Britton & Rose [*Acacia concinna* (Willd.) DC.] (Family Leguminosae-Mimosoideae), Herbarium Specimen Number: DMSC 5337, Crude Drug Number: DMSc 1236.

Constituents Senegalia Rugata Leaf contains organic acids of which tartaric acid is its major component; others include ascorbic acid, citric acid, oxalic acid, and succinic acid. It also contains triterpenoids (e.g., lupeol), triterpenoid saponins, etc.

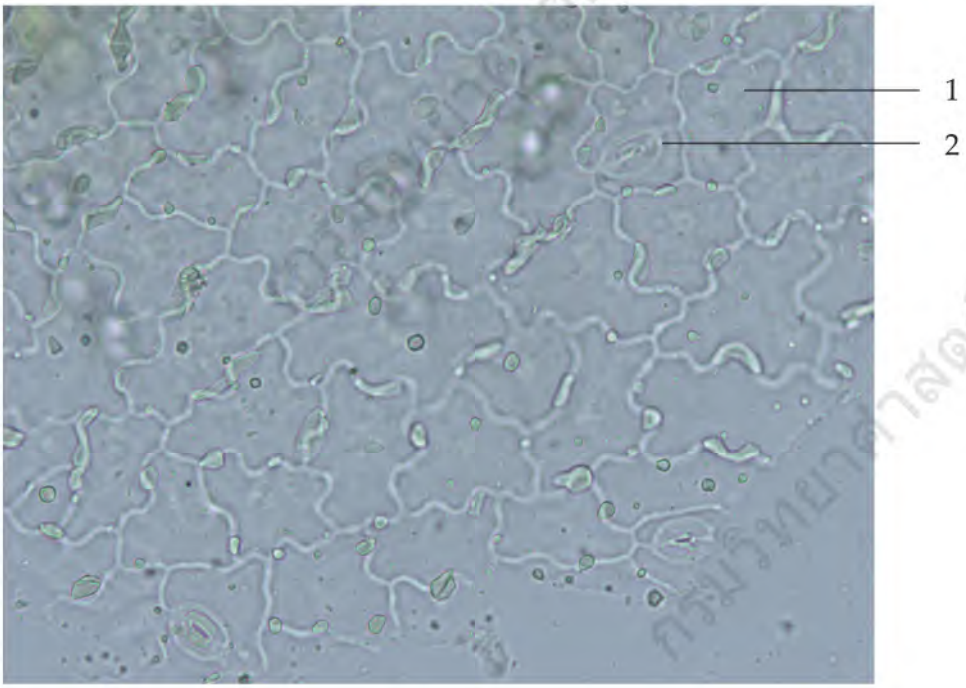
Description of the plant (Fig. 1) Woody climber or scandent shrub, rarely small tree, 3 to 6 m tall; stem and branch spiny, velutinous to tomentose, glabrescent, without glandular hairs. Stipule cordate, 3 to 8 mm long, 1 to 6 mm wide, caducous. Leaves bipinnate, spirally arranged, rachis 6 to 16 cm long; petiole 1.2 to 5.2 cm long, with gland at 0.4 to 2.7 cm above base; pinnae (4–)5 to 10 pairs, (1.5–)2 to 9 cm long, with glands at junctions of 1- to 3-distal pairs; leaflets 10 to 35 pairs per pinna, opposite, sessile, narrowly oblong, 0.3 to 1.2 cm long, 0.8 to 3(–4.8) mm wide, apex asymmetrically rounded to sharply acute, mucronate-apiculate, always bent forwards, base asymmetrically truncate, margin mostly ciliate, both surfaces glabrous to sericeous, main vein marginal at base, not parallel to upper margin, often with 2 or more accessory veins at base, lateral veins conspicuous, reticulate. Inflorescence capitulate, axillary, 1 to 3 heads per node, each consisting of 35 to 45 flowers; peduncle 2.5 to 3.2 mm long, densely pubescent; bract oblong, 0.5 to 1 mm long, reddish. Flower whitish; calyx 2 to 3.2 mm long, tube glabrous to puberulous, lobes 5, triangular to ovate, 0.1 to 0.5(–0.9) mm long, apex acute, glabrous to puberulous; corolla (2.3–)3 to 4 mm long, tube glabrous, lobes 5, ovate to ovate-oblong, 0.5 to 1 mm long, apex acute, glabrous; ovary superior, oblong, 0.8 to 1.5 mm long, glabrous to sericeous, 10- to 12-ovuled, stipitate; stipe 1 to 1.5 mm long. Fruit a pod, oblong, 1 to 1.5 cm long, 1.7 to 2.7 cm wide, margin often sinuate, pod straight, flattened, thick, reddish green, becoming very wrinkled when dried, glabrous, more or less segmented, often falling apart into 1-seeded segments. Seeds 5 to 12, oblong to obovate, 0.6 to 1 cm long, 4.5 to 8 mm wide, flattened, black, and shiny.

Description Odour, indistinct; taste, sour and slightly astringent.

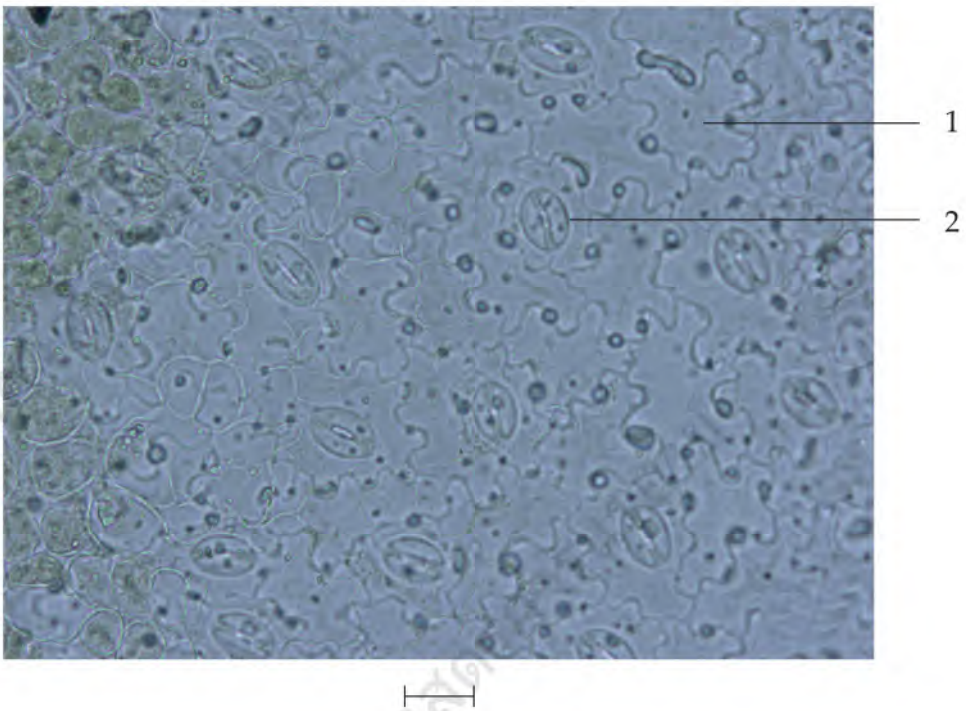
Macroscopical (Fig. 1) A mixture of entire and broken, green to brownish green leaflets, with small amount of rachillae. Complete leaflets narrowly oblong, 0.5 to 1 cm long, 0.6 to 2.8(–4.6) mm wide, apex asymmetrically rounded to sharply acute, mucronate-apiculate, always bent forwards, base asymmetrically truncate, margin mostly ciliate, both surfaces glabrous to sericeous, main vein marginal at base, not parallel to upper margin, often with 2 or more accessory veins at base, lateral veins conspicuous, reticulate.

Microscopical (Figs. 2a–2d) Transverse section of the leaflet through the midrib shows upper epidermis, mesophyll, vascular tissue, and lower epidermis. Upper epidermis: a layer of round or oval cells. Mesophyll: 1 to 3 layers of cylindrical palisade cells, some containing prismatic crystals; spongy cells, oval shaped; lamella collenchyma and parenchyma in the lower part of midrib. Vascular bundle: phloem and xylem. Lower epidermis: a layer of round or oval or rectangular cells.

Fig. 1 *Senegalia rugata* (Lam.) Britton & Rose
1. habit 2. flowering twig 3. head inflorescences 4. flowering head 5. crude drug



Upper Epidermis of the Lamina



Lower Epidermis of the Lamina

Fig. 2a Photomicrographs of Epidermises of the Leaflet of *Senegalia rugata* (Lam.) Britton & Rose
1. epidermis 2. stoma

Fig. 2b Photomicrograph of Transverse Section of the Leaflet of *Senegalia rugata* (Lam.) Britton & Rose

1. upper epidermis
2. palisade cell
3. prismatic crystal
4. vessel
5. spongy cell
6. phloem
7. collenchyma
8. lower epidermis
9. stoma

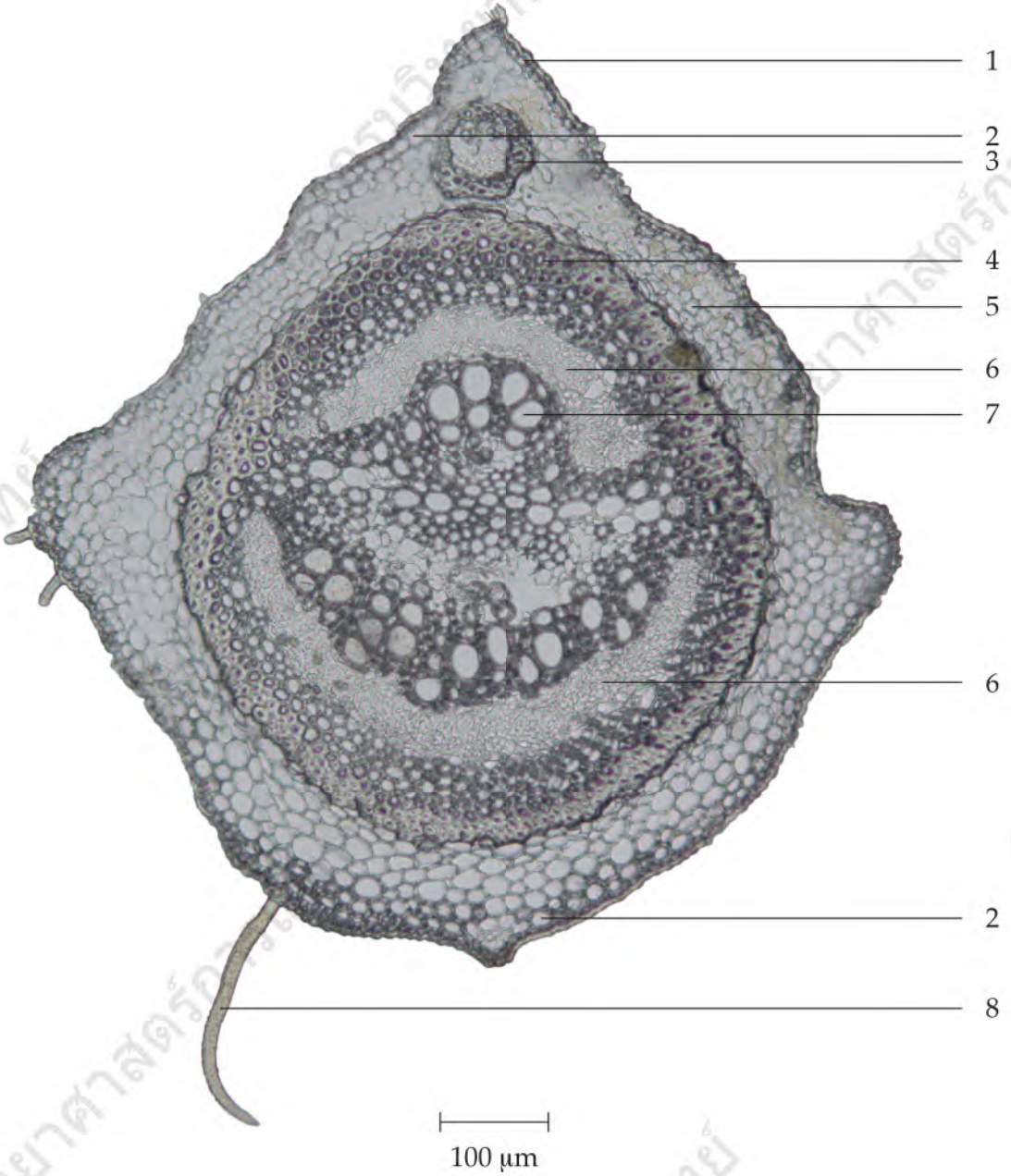


Fig. 2c Photomicrograph of Transverse Section of the Rachilla of *Senegalia rugata* (Lam.) Britton & Rose

1. epidermis
2. collenchyma
3. vascular bundle
4. fibre
5. parenchyma
6. phloem
7. vessel
8. trichome

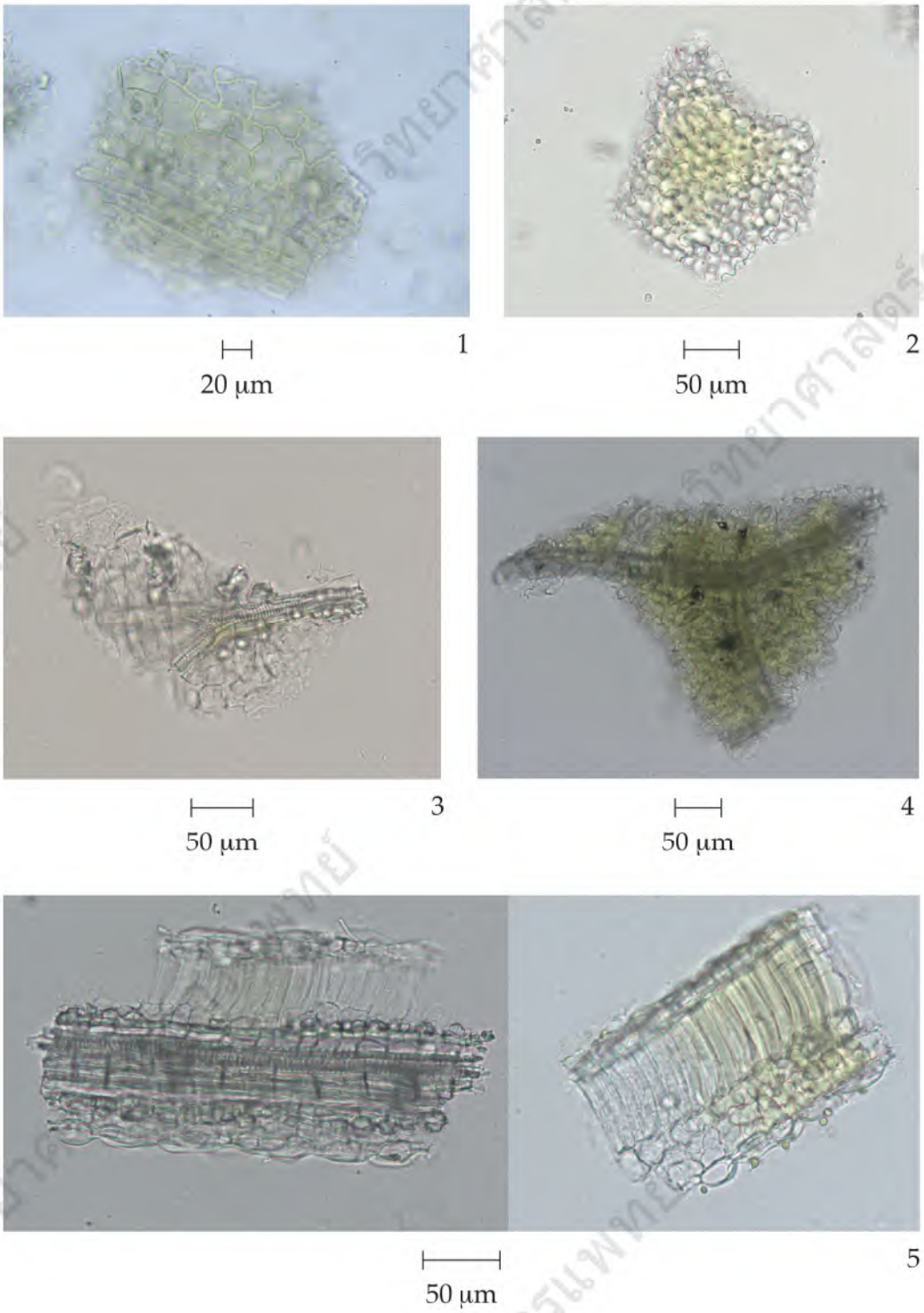


Fig. 2d Photomicrographs of Powdered Drug of the Leaves of *Senegalia rugata* (Lam.) Britton & Rose

1. epidermis of lamina in surface view
2. part of lamina in surface view, showing upper epidermis with underlying palisade cells
3. part of lamina showing veinlets, palisade cells, and prismatic crystals
4. part of lamina in surface view, showing lower epidermis, stomata, veinlets, and spongy cells
5. part of lamina in sectional view, showing upper epidermis, palisade cells, veinlet, spongy cells, prismatic crystals, and lower epidermis

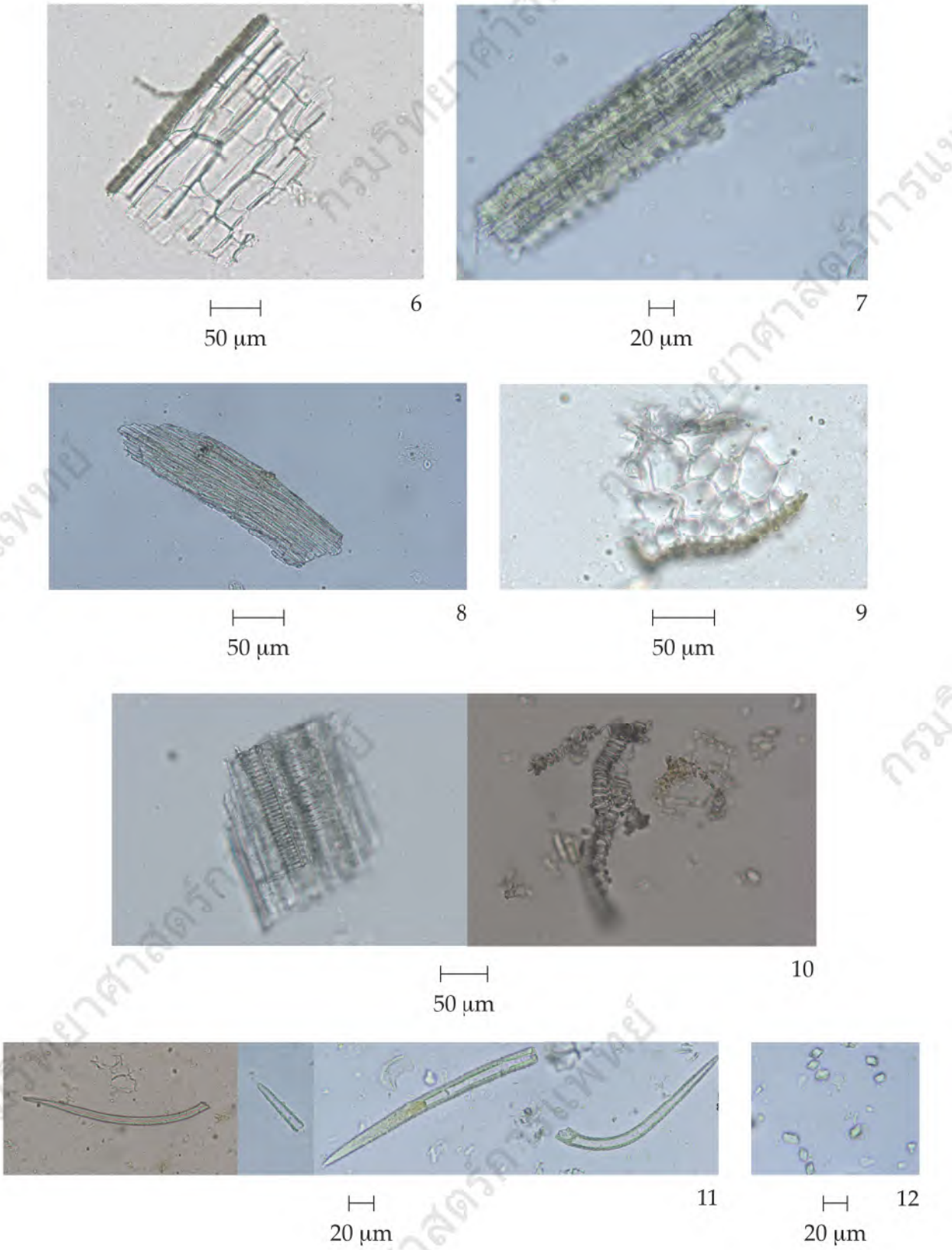


Fig. 2d (continued)

6. epidermis and parenchyma of rachilla, in longitudinal view
7. fragment of fibres with prismatic sheath
8. fragment of fibres
9. epidermis and collenchyma cells
10. spiral, reticulate, and bordered-pitted vessels
11. trichomes
12. prismatic crystals

In surface view, the lamina shows upper and lower epidermises. Upper epidermis: wavy-walled cells, with few paracytic stomata. Lower epidermis: wavy-walled cells, paracytic and anomocytic stomata.

Transverse section of the rachilla illustrates epidermis, cortex, and vascular tissue. Epidermis: a layer of small oval cells, with unicellular and multicellular trichomes. Cortex: lamella collenchyma and parenchyma. Vascular tissue: a large vascular bundle and 1 or 2 small vascular bundles comprising phloem, xylem, and fibres.

Senegalia Rugata Leaf in powder possesses the diagnostic microscopical characters of the unground drug. The combination of unicellular and rarely multicellular trichomes, large prismatic crystals in palisade cells, and large pored bordered-pitted vessels should be characteristic.

Packaging and storage Senegalia Rugata Leaf 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 powder, with 10 mL of *water* on a water-bath for 15 minutes and filter. Shake 5 mL of the filtrate in a screw-capped tube for 15 seconds: a persisting foam is produced for over 30 minutes.

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 70 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 of solution (A) and 1 μL of solution (B). Prepare solution (A) by sonicating 3 g of the sample, in *No. 250 powder*, with 60 mL of *ethanol* for 30 minutes and filtering. Evaporate the filtrate to dryness under reduced pressure. Dissolve the residue in 2 mL of *ethanol*. For solution (B), dissolve 1 mg of *lupeol* in 0.5 mL of *methanol*. After removal of the plate, allow it to dry in air, and spray the plate with *anisaldehyde TS*, and heat at 105° for 5 minutes; the band corresponding to lupeol is violet (hR_f value 72 to 75). One brown and seven violet bands are also 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).

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

Total ash Not more than 10.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 13.0 per cent w/w (Appendix 7.12).

Water-soluble extractive Not less than 26.0 per cent w/w (Appendix 7.12).

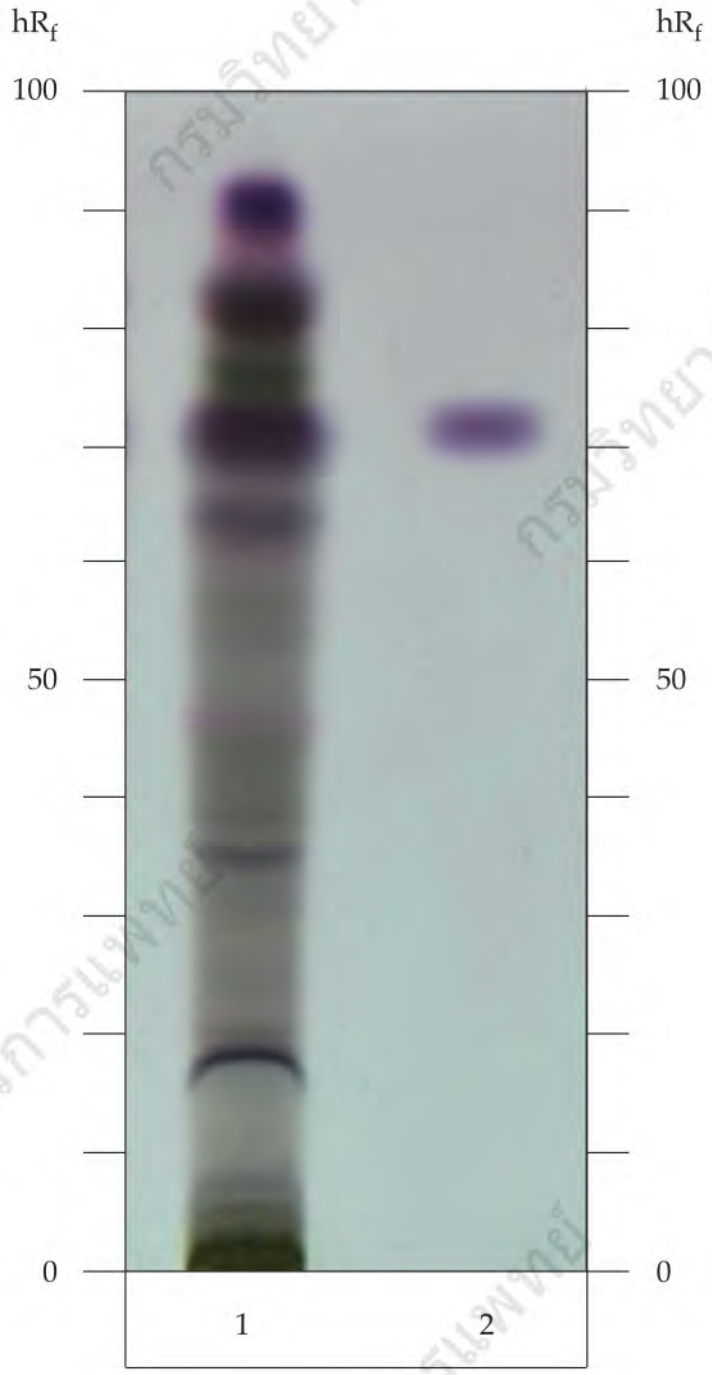


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Leaves of *Senegalia rugata* (Lam.) Britton & Rose, Detected With *Anisaldehyde TS*

1 = solution (A)

2 = solution (B)

ส้มป่อย, ฝัก (SOMPOI, FAK)

ส้มขอน, ฝัก (SOM KHON, FAK)
Senegaliae Rugatae Fructus
Senegalia Rugata Pod

Category Expectorant, laxative.

Senegalia Rugata Pod is the dried ripe pod of *Senegalia rugata* (Lam.) Britton & Rose [*Acacia concinna* (Willd.) DC.] (Family Leguminosae-Mimosoideae), Herbarium Specimen Number: DMSC 5337, Crude Drug Number: DMSc 1237.

Constituents Senegalia Rugata Pod contains triterpenoids (e.g., lupeol) and triterpenoid saponins. It also contains terpenoids, fatty acids, etc.

Description of the plant (Fig. 1) Woody climber or scandent shrub, rarely small tree, 3 to 6 m tall; stem and branch spiny, velutinous to tomentose, glabrescent, without glandular hairs. Stipule cordate, 3 to 8 mm long, 1 to 6 mm wide, caducous. Leaves bipinnate, spirally arranged, rachis 6 to 16 cm long; petiole 1.2 to 5.2 cm long, with gland at 0.4 to 2.7 cm above base; pinnae (4–)5 to 10 pairs, (1.5–)2 to 9 cm long, with glands at junctions of 1- to 3-distal pairs; leaflets 10 to 35 pairs per pinna, opposite, sessile, narrowly oblong, 0.3 to 1.2 cm long, 0.8 to 3(–4.8) mm wide, apex asymmetrically rounded to sharply acute, mucronate-apiculate, always bent forwards, base asymmetrically truncate, margin mostly ciliate, both surfaces glabrous to sericeous, main vein marginal at base, not parallel to upper margin, often with 2 or more accessory veins at base, lateral veins conspicuous, reticulate. Inflorescence capitulate, axillary, 1 to 3 heads per node, each consisting of 35 to 45 flowers; peduncle 2.5 to 3.2 mm long, densely pubescent; bract oblong, 0.5 to 1 mm long, reddish. Flower whitish; calyx 2 to 3.2 mm long, tube glabrous to puberulous, lobes 5, triangular to ovate, 0.1 to 0.5(–0.9) mm long, apex acute, glabrous to puberulous; corolla (2.3–)3 to 4 mm long, tube glabrous, lobes 5, ovate to ovate-oblong, 0.5 to 1 mm long, apex acute, glabrous; ovary superior, oblong, 0.8 to 1.5 mm long, glabrous to sericeous, 10- to 12-ovuled, stipitate; stipe 1 to 1.5 mm long. Fruit a pod, oblong, 1 to 1.5 cm long, 1.7 to 2.7 cm wide, margin often sinuate, pod straight, flattened, thick, reddish green, becoming very wrinkled when dried, glabrous, more or less segmented, often falling apart into 1-seeded segments. Seeds 5 to 12, oblong to obovate, 0.6 to 1 cm long, 4.5 to 8 mm wide, flattened, black, and shiny.

Description Odour, characteristic; taste, slightly sour and astringent.

Macroscopical (Fig. 1) Complete or fragmented pod. Complete pod oblong, 1 to 1.5 cm long, 1.7 to 2.7 cm wide, surface rough, margin often sinuate, straight, flattened, thick, dark brown to blackish, wrinkled, glabrous, more or less segmented, often falling apart into 1-seeded segments. Seed elliptic to orbicular, 0.6 to 1 cm long, 4.5 to 8 mm wide, flattened, blackish, and shiny.

Microscopical (Figs. 2a–2d) Transverse section of the pod shows pericarp and seed. Pericarp: rectangular epidermal layer; sclerenchymatous layers; parenchyma cells, some containing prismatic crystals or starch grains; vascular bundles; thick-walled, filiform, and thin-walled sclereids. Seed: testa, covered with thick cuticle layer, a layer of light-line macrosclereids, sclereids some containing brownish substance, and group of compressed sclereids; cotyledons 2, composed of parenchyma, some containing various sizes of starch grains or rosette aggregate crystals.

Fig. 1 *Senegalia rugata* (Lam.) Britton & Rose
1. habit 2. flowering twig 3. head inflorescences 4. pods
5. fragment of pod showing seeds 6. crude drug

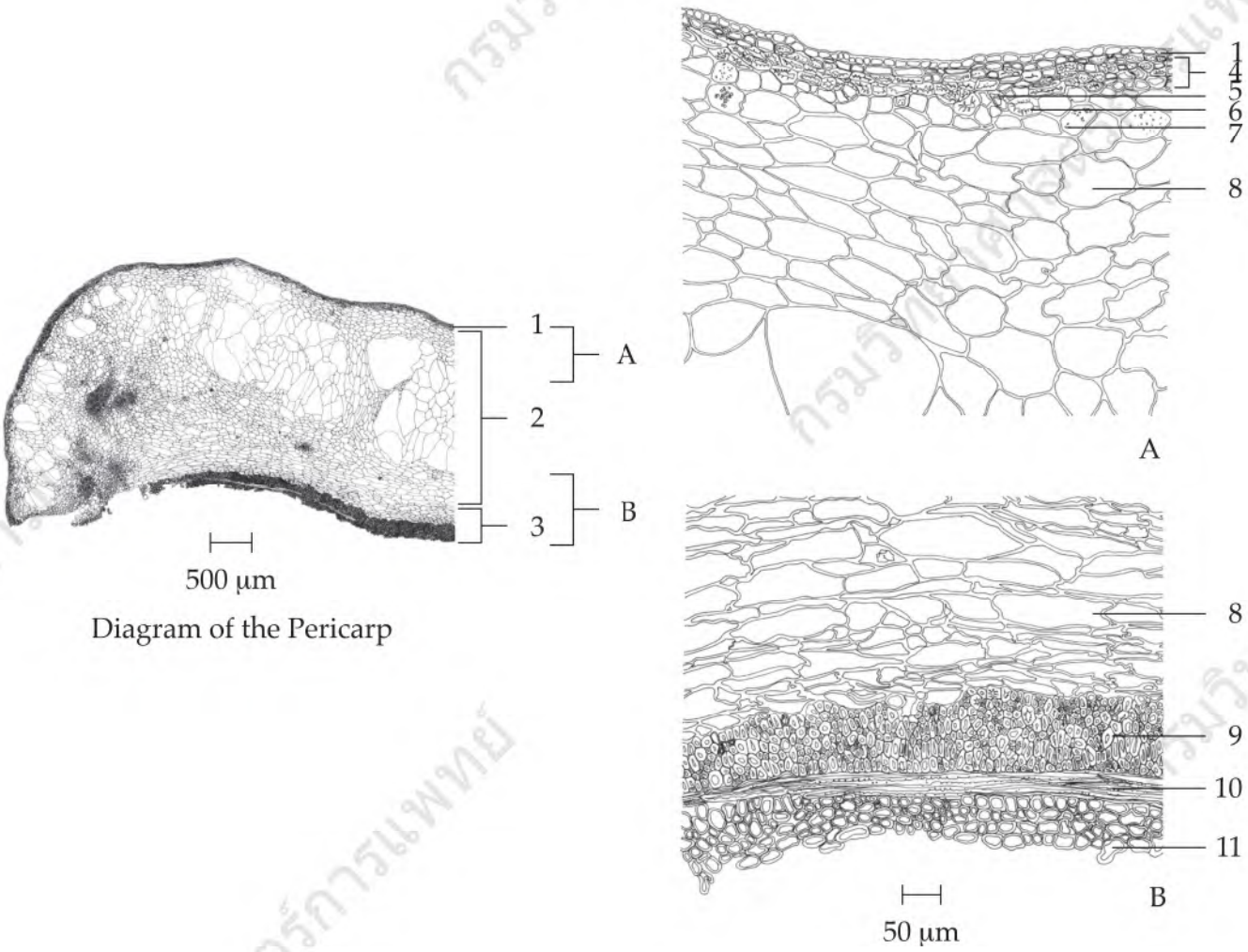


Fig. 2a Line Drawings of Transverse Sections of the Pericarp of *Senegalia rugata* (Lam.) Britton & Rose

A. Epicarp and Part of Mesocarp
B. Part of Mesocarp and Endocarp

1. epicarp
2. mesocarp
3. endocarp
4. sclerenchymatous layers
5. prismatic crystal
6. stone cell
7. starch grains
8. parenchyma
9. thick-walled sclereid
10. filiform sclereid
11. thin-walled sclereid

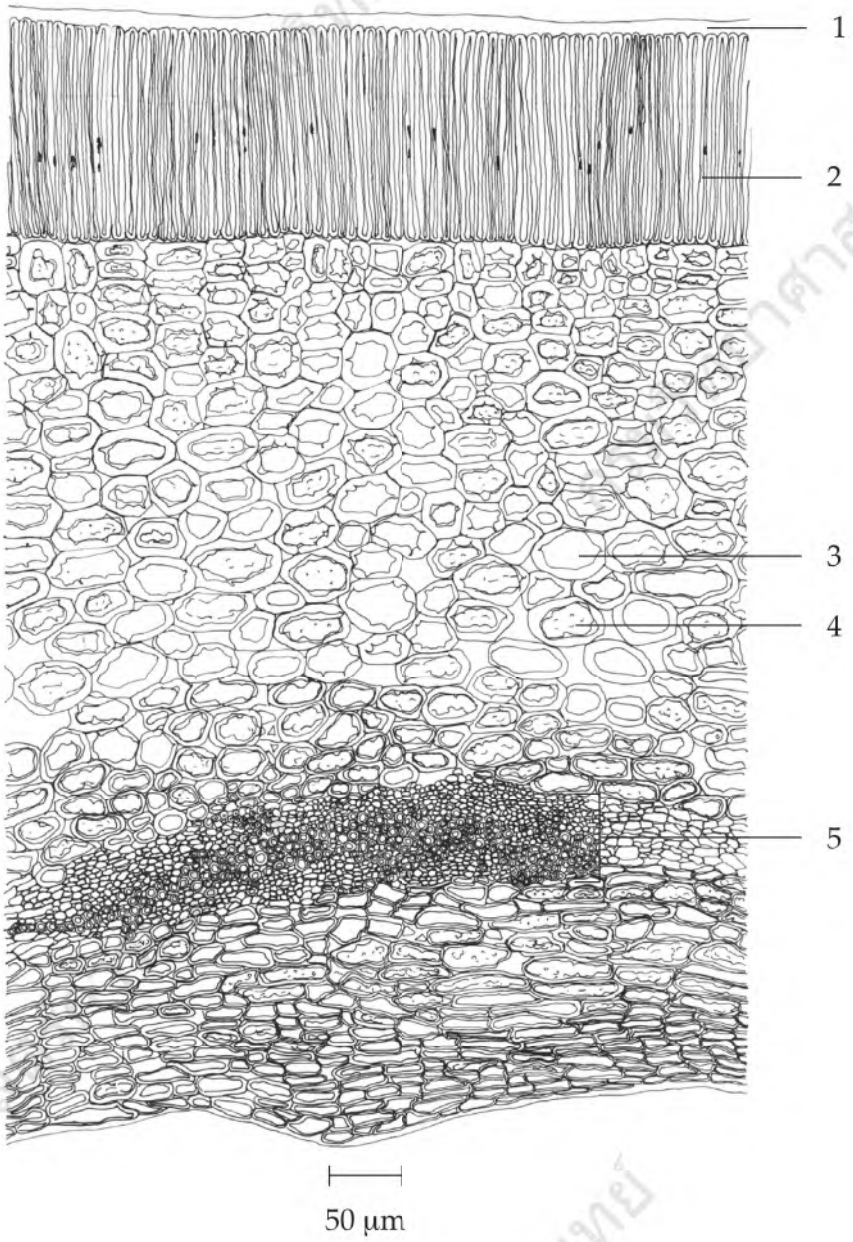


Fig. 2b Line Drawing of Transverse Section of the Testa of *Senegalia rugata* (Lam.) Britton & Rose

1. cuticle
2. macrosclereid
3. sclereid
4. brownish substance
5. group of compressed sclereids

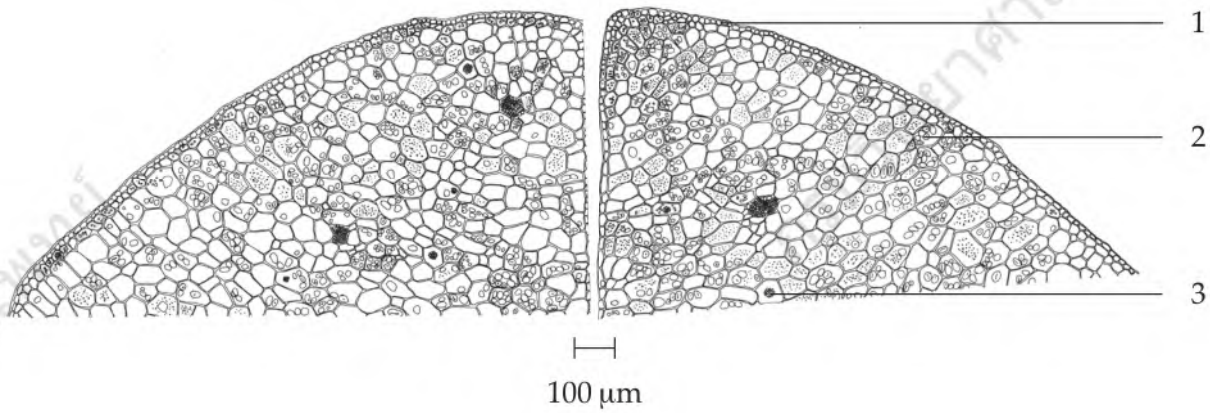


Fig. 2c Line Drawing of Transverse Section of the Cotyledons of *Senegalia rugata* (Lam.) Britton & Rose

1. epidermis
2. parenchyma containing starch grain
3. parenchyma containing rosette aggregate crystal

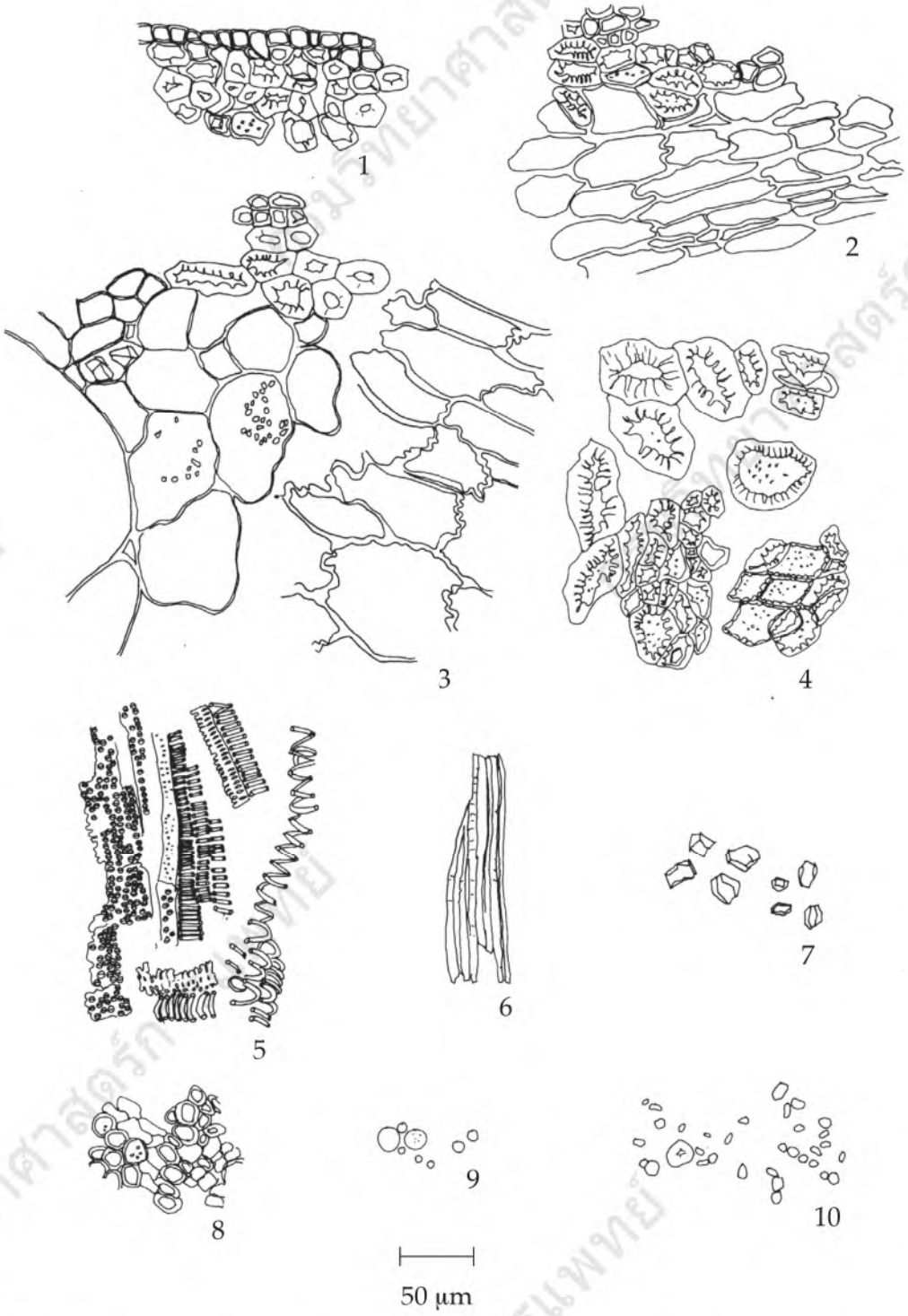


Fig. 2d Line Drawings of Powdered Drug of the Pods of *Senegalia rugata* (Lam.) Britton & Rose

1. epidermis and sclereids of epicarp, in sectional view
2. sclereids and parenchyma
3. sclereids and parenchyma, some containing prismatic crystals or starch grains
4. sclereids
5. bordered-pitted, simple pitted, reticulate and spiral vessels
6. filiform sclereid
7. prismatic crystals
8. thin-walled sclereids
9. oil droplets
10. starch grains

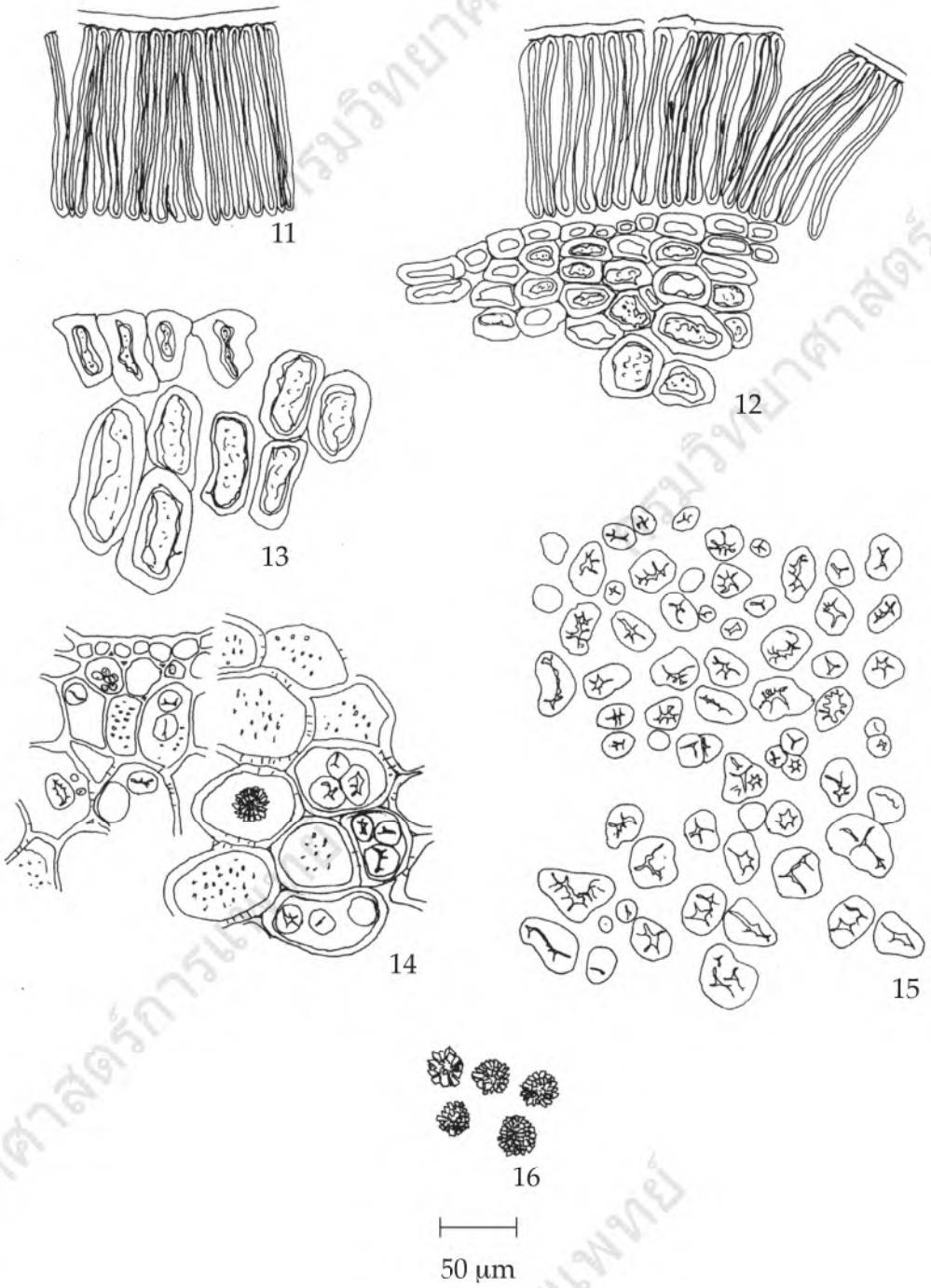


Fig. 2d (continued)

11. macrosclereids of testa in sectional view
12. macrosclereids and sclereids some containing brownish substance
13. sclereids of testa containing brownish substance
14. parenchyma, some containing starch grains or rosette aggregate crystal
15. starch grains
16. rosette aggregate crystals of testa

Senegalia Rugata Pod in powder possesses the diagnostic microscopical characters of the unground drug. Light-line macrosclereids of testa, large starch grains with star hilum in parenchyma, and sclereids with brownish substance are characteristic.

Packaging and storage Senegalia Rugata Pod 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 powder, with 10 mL of *water* on a water-bath for 15 minutes and filter. Shake 5 mL of the filtrate in a screw-capped tube for 15 seconds: a persisting foam is produced for over 30 minutes.

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 60 volumes of *toluene*, 35 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 of solution (A) and 1 µL of solution (B). Prepare solution (A) by sonicating 3 g of the sample, in *No. 250 powder*, with 60 mL of *ethanol* for 30 minutes and filtering. Evaporate the filtrate to dryness under reduced pressure. Dissolve the residue in 2 mL of *ethanol*. For solution (B), dissolve 1 mg of *lupeol* in 0.5 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; the band corresponding to lupeol is violet (hR_f value 72 to 74). Nine violet bands are also observed (Fig. 3).

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 5.0 per cent w/w (Appendix 7.7).

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

Water-soluble extractive Not less than 34.0 per cent w/w (Appendix 7.12).

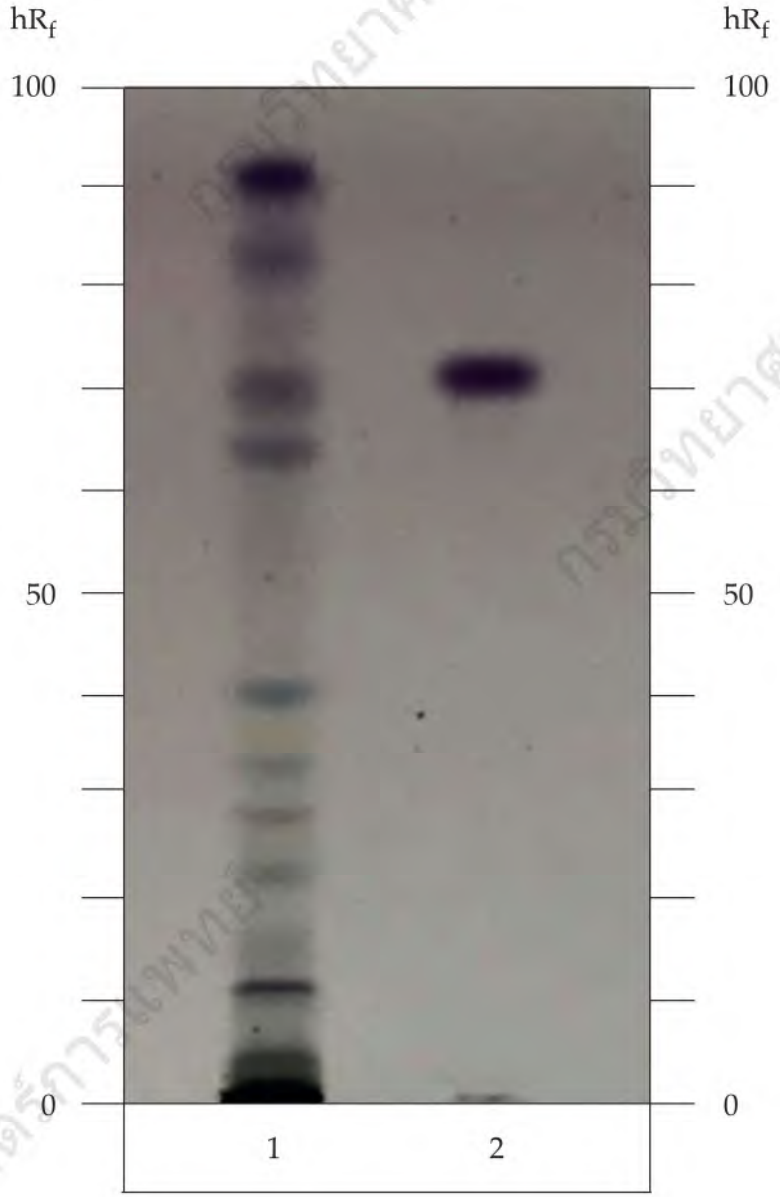


Fig. 3 Thin-Layer Chromatogram of Ethanolic Extract of the Pods of *Senegalia rugata* (Lam.) Britton & Rose, Detected With *Anisaldehyde TS*
1 = solution (A)
2 = solution (B)

ว่านร่อนทอง (WAN RON THONG)

Boesenbergiae Kingii Rhizoma
Boesenbergia Kingii Rhizome

Category Anti-inflammatory.

Boesenbergia Kingii Rhizome is the dried rhizome of *Boesenbergia kingii* Mood & L. M. Prince (Family Zingiberaceae), Herbarium Specimen Number: DMSC 5254, Crude Drug Number: DMSc 1240.

Constituents Boesenbergia Kingii Rhizome contains curcuminoids such as demethoxycurcumin, bisdemethoxycurcumin, and flavonoids (e.g., 5-hydroxy-3,7-dimethoxyflavone, 5-hydroxy-7-methoxyflavone, and pinostrobin). It also contains sesquiterpenes (e.g., longiferone A, longiferone B, and longiferone C) and sterols, etc.

Description of the plant (Fig. 1) Perennial herb; rhizome horizontal runner, 0.5 to 1 cm in diameter, externally orange or brown, internally yellow to orange; leafy shoot up to 1 m tall, bearing 6 to 10 leaves. Leaves simple, distichous; leaf sheath ovate, 10 to 30 cm long, longitudinally ridged, lower portion reddish, upper green, glabrous; petiole 5 to 10 cm long, green, glabrous; ligule slightly bilobed, about 4 mm long, green or white, glabrous; lamina elliptic, 30 to 45 cm long, 10 to 15 cm wide, plicate, glabrous on both sides, apex acute, base rounded to cordate, margin entire, hyaline. Inflorescence radical; peduncle 0.5 to 1 cm long, white, glabrous; basal sheath 1 to 2 cm long, 1 to 1.5 cm wide, white, glabrous; spike 5 to 10 cm long, 1 to 2 cm wide; bract distichous, linear, 1.5 to 2 cm long, red, glabrous; bracteole lanceolate, white, translucent, glabrous, apex 2-dentate. Flowers 4 to 6 per inflorescence; calyx tubular, white, translucent, glabrous, tube 10 to 12 cm long, 3 to 4 mm wide at base, white, yellow-tinged, glabrous; dorsal corolla lobe oblong, white, glabrous, margin involute, lateral corolla lobe oblong, white, glabrous, androecial cup; tube cup-shaped, 0.8 to 1.2 cm long, about 1.2 cm wide, white, glabrous; labellum saccate, 2.2 to 2.5 cm long, 2 to 2.2 cm wide, white to creamy white, throat center bright red, glabrous, margin wavy or wrinkled, apex entire; lateral staminode obovate, about 1 cm long, creamy white, glabrous, apex revolute; stamen 1.2 to 1.4 cm long, filament about 3 mm long, white, glabrous, anther 0.5 to 1 cm long, about 3 mm wide, apex truncate to slightly bilobed, white; ovary inferior, about 3 mm long, 3-loculed, axile placentation, white, glabrous; style filiform, white, glabrous; stigma elongate.

Description Odour, aromatic, turmeric-like; taste, slightly bitter, with acrid aftertaste.

Macroscopical (Fig. 1) Rhizome, runner, cylindrical, 2 to 7 cm long, 2 to 8 mm in diameter; externally yellowish brown, longitudinally wrinkled; internally orange-brown to brown, showing distinct pseudoendodermis.

Microscopical (Figs. 2a, 2b) Transverse section of the rhizome shows epidermis, cortex, and vascular tissue. Epidermis: a layer of thin-walled rectangular cells. Cortex: parenchyma, thin-walled cells, some of which contain numerous starch grains, some with yellow oleoresin and yellow oil droplets; storied cork, layers of thin-walled, suberized rectangular cells; and pseudoendodermis, 1 to 3 layers of thin-walled cells. Vascular tissue: scattered in outer and inner of pseudoendodermis; phloem and xylem.

Boesenbergia Kingii Rhizome in powder possesses the diagnostic microscopical characters of the unground drug. Dentate and septate fibres, numerous beaked simple starch grains, and yellow oleoresins are characteristic.

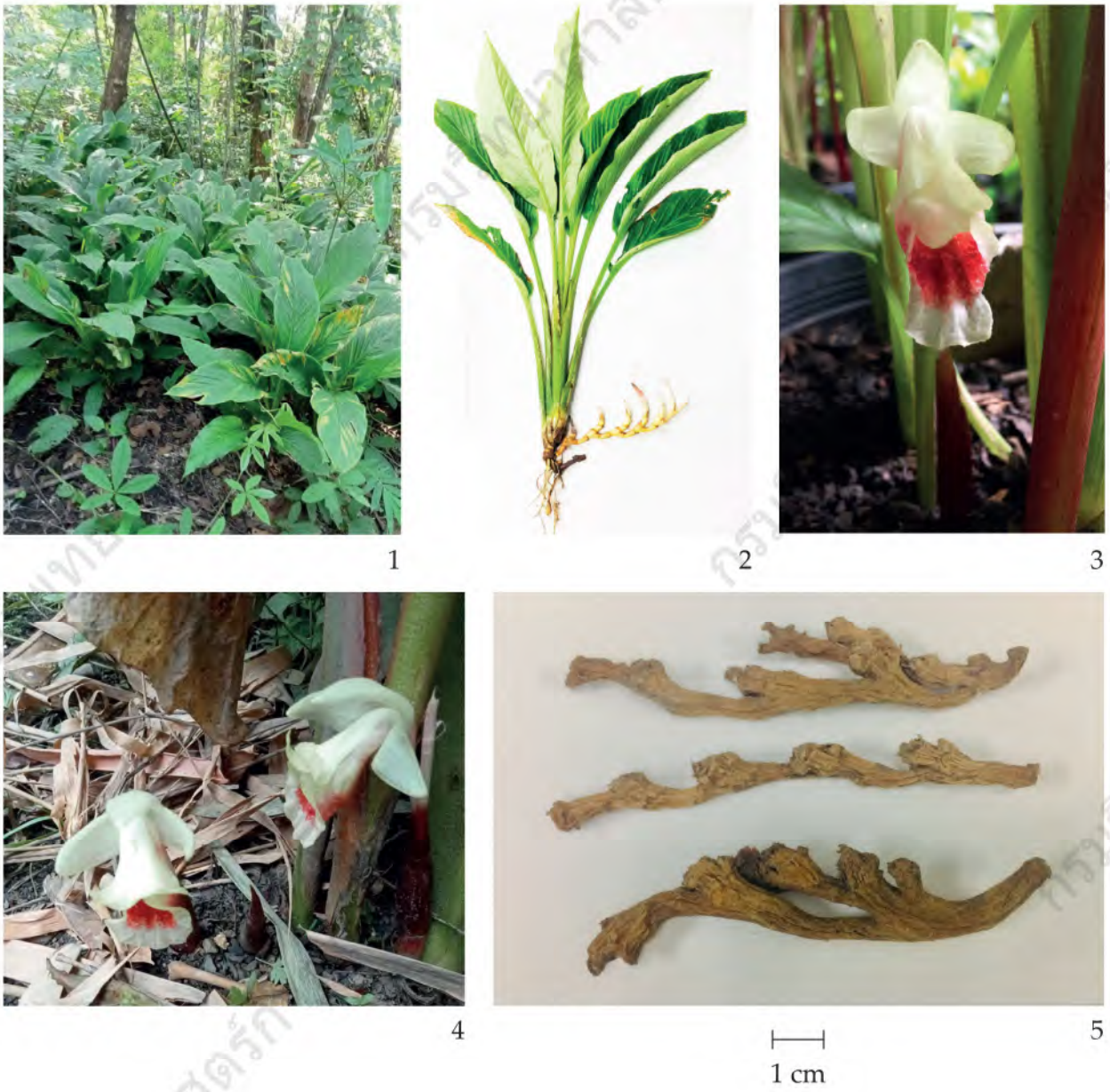


Fig. 1 *Boesenbergia kingii* Mood & L. M. Prince
1. habit 2. plant with flowering shoot 3. flower 4. flowers in different views 5. crude drug

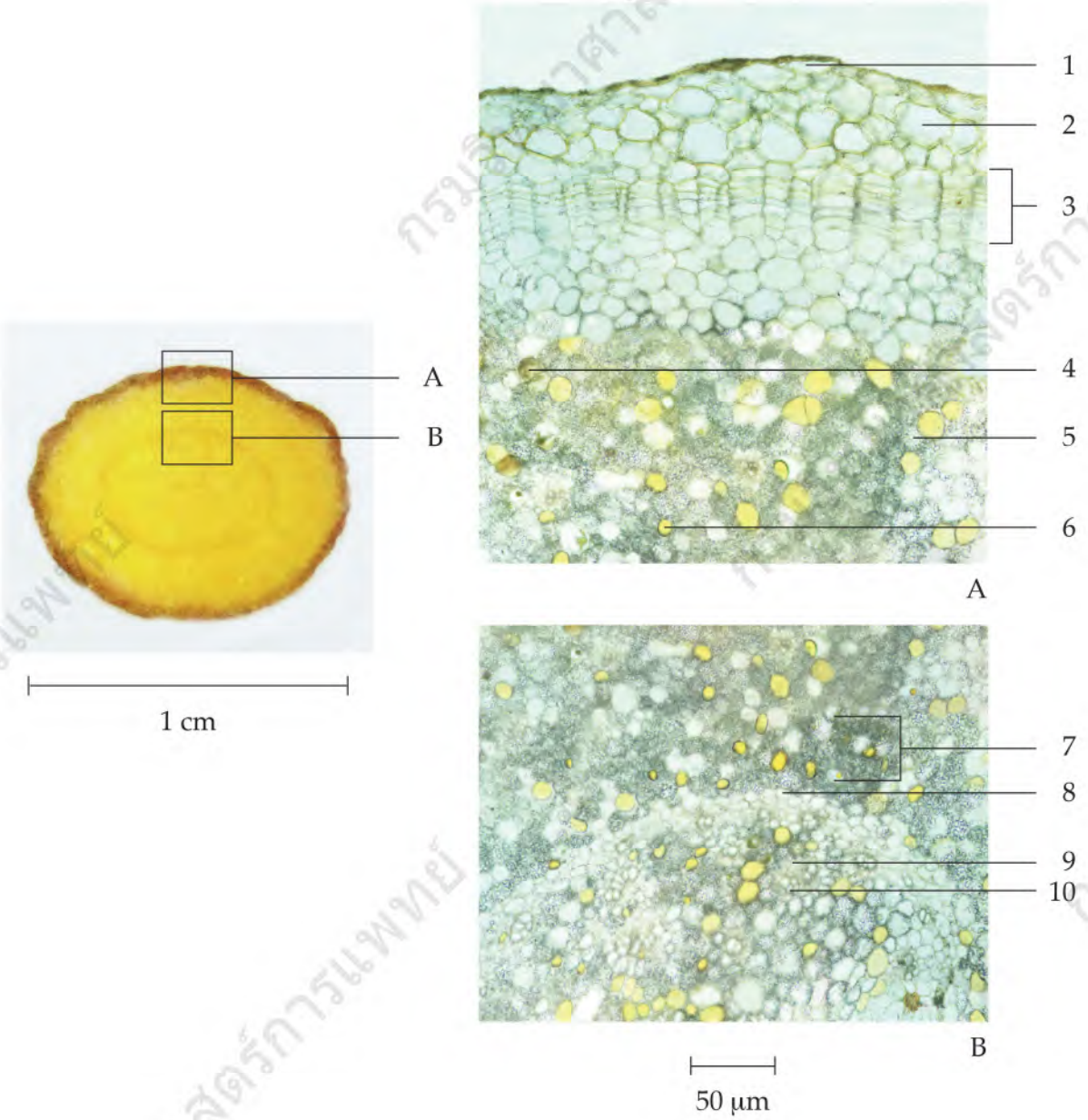


Fig. 2a Photomicrographs of Transverse Sections of the Rhizome of *Boesenbergia kingii* Mood & L. M. Prince

A. and B. Parts of Sectional View

1. epidermal cell
2. parenchyma
3. storied cork layers
4. parenchyma containing yellow oleoresin
5. parenchyma containing starch grains
6. oil droplet
7. vascular bundle
8. pseudoendodermis
9. phloem
10. xylem

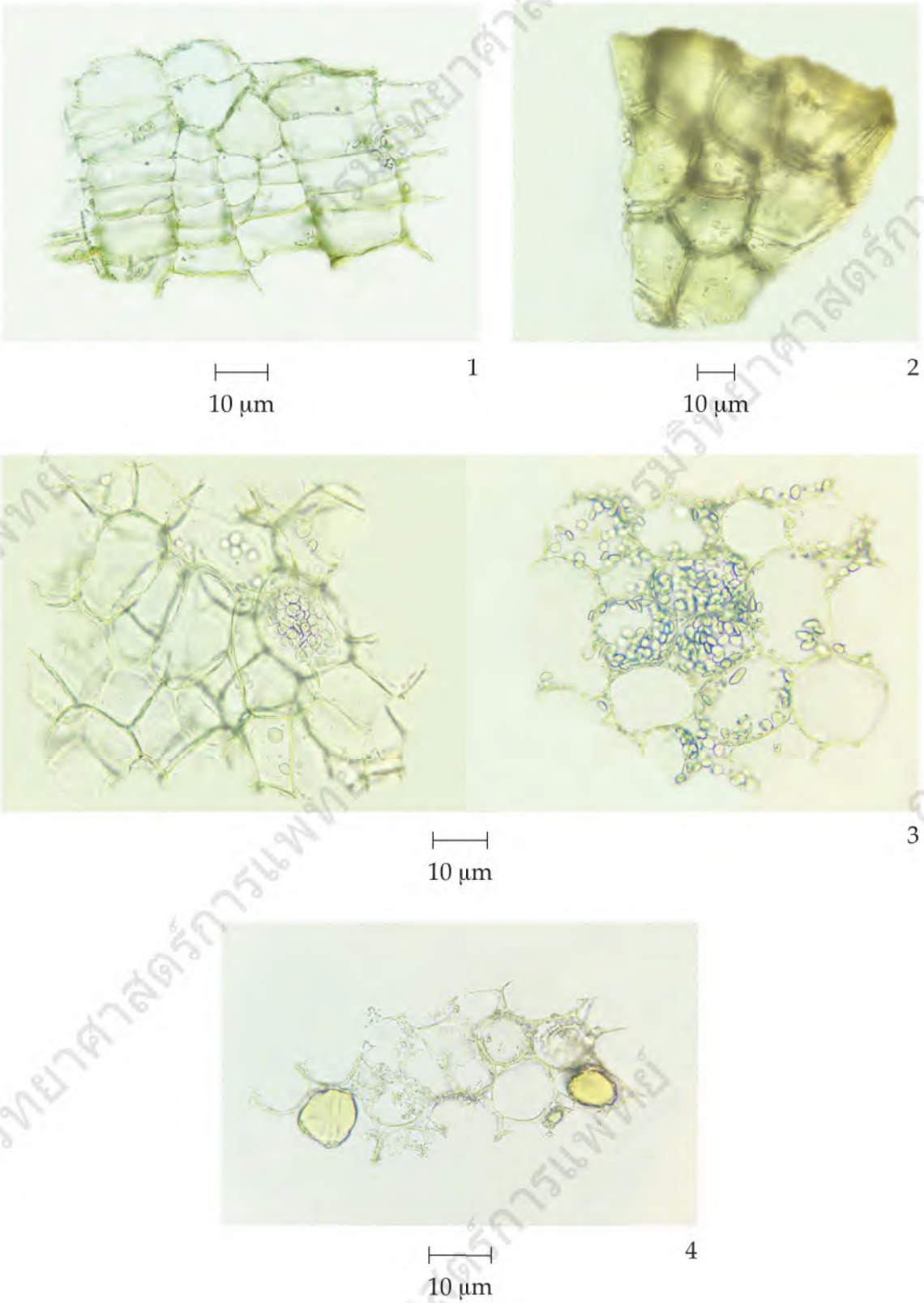


Fig. 2b Photomicrographs of Powdered Drug of the Rhizomes of *Boesenbergia kingii* Mood & L. M. Prince

1. parenchyma and cork, in sectional view
2. cork in surface view
3. parenchyma containing starch grains
4. parenchyma containing yellow oleoresins and starch grains

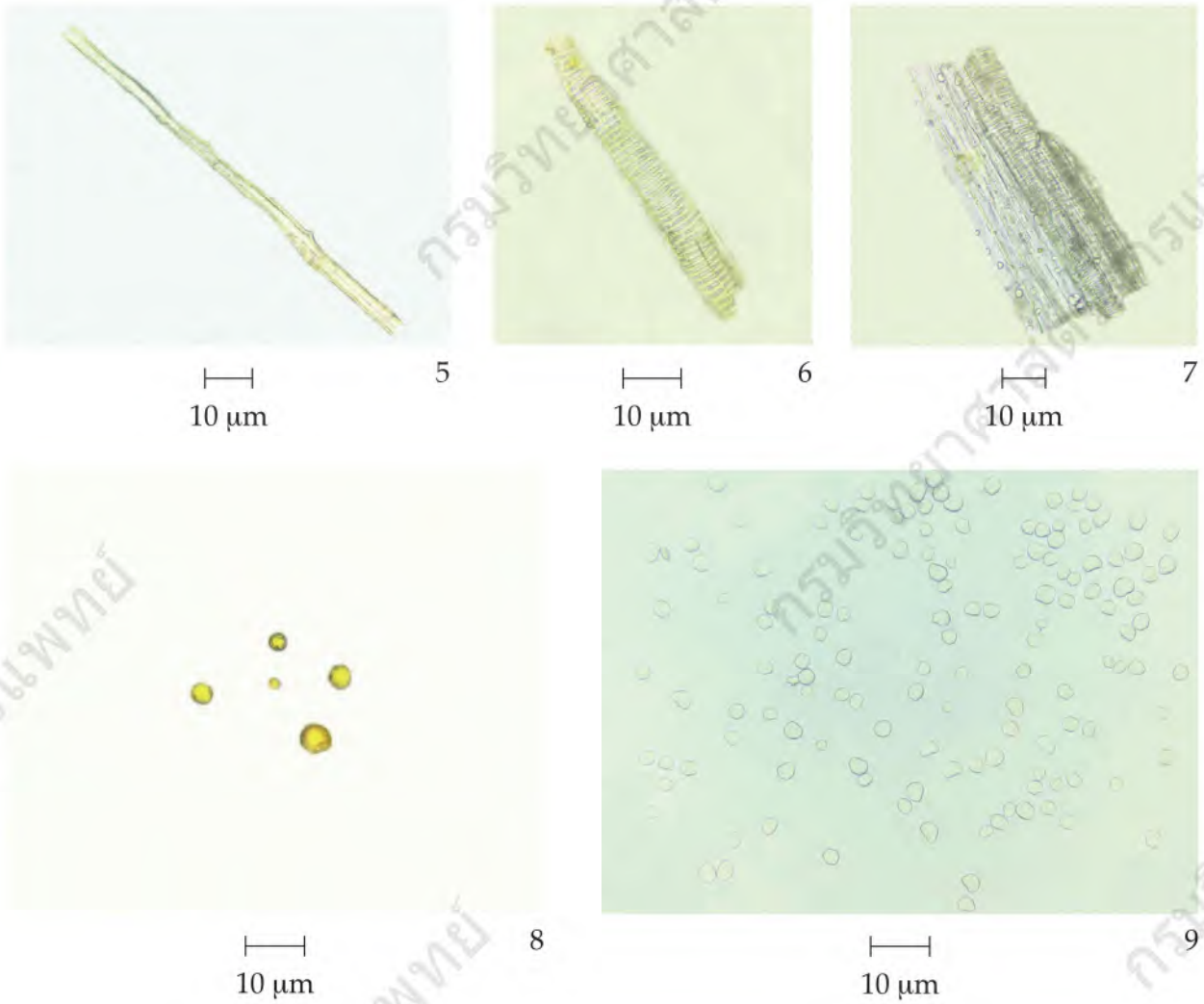


Fig. 2b (continued)

5. dentate and septate fibre
6. scalariform-reticulate vessel
7. parenchyma, fibres, spiral and scalariform-reticulate vessels, and starch grains
8. yellow oleoresins
9. beaked simple starch grains

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

Identification

A. Sonicate 250 mg of the sample, in *fine powder*, with 5 mL of *methanol* for 15 minutes and filter. To 1 mL of the filtrate, add 100 mg of *boric acid*, shake well, and mix with 10 drops of *sulfuric acid*: a red colour develops.

B. Reflux 500 mg of the sample, in *fine powder*, with 5 mL of *ethanol* for 15 minutes and filter. To 1 mL of the filtrate, add 2 pieces of *magnesium ribbon*, shake well, and mix with a few drops of *hydrochloric acid*: a red colour develops.

C. Boil 500 mg of the sample, in *fine powder*, with 5 mL of *water* for 30 minutes 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 greenish brown colour develops with a pale brown precipitate.

D. 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 80 volumes of *toluene* and 20 volumes of *acetic 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 10 mm, 1 µL each of the following two solutions. Prepare solution (A) by sonicating 250 mg of the sample, in *fine powder*, with 2 mL of *methanol* for 15 minutes and filtering. For solution (B) dissolve 1 mg of *bisdemethoxycurcumin* in 2 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 21 to 23) corresponding to the bisdemethoxycurcumin band from solution (B); other quenching bands are also observed. Subsequently examine the plate under ultraviolet light (366 nm) through the cut-off filter; the band corresponding to bisdemethoxycurcumin shows a yellow fluorescence. Three yellow and four blue fluorescent bands are observed. Spray the plate with *vanillin-sulfuric acid TS* and heat at 110° for 10 minutes; the band due to bisdemethoxycurcumin is red. One brown, two orange, three purple, and four red bands are also 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 10.0 per cent w/w (Appendix 7.7).

Ethanol-soluble extractive Not less than 4.5 per cent w/w (Appendix 7.12).

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

Volatile oil Not less than 0.5 per cent v/w, calculated on the anhydrous basis (Appendix 7.3H). Use 50 g, in *fine 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.

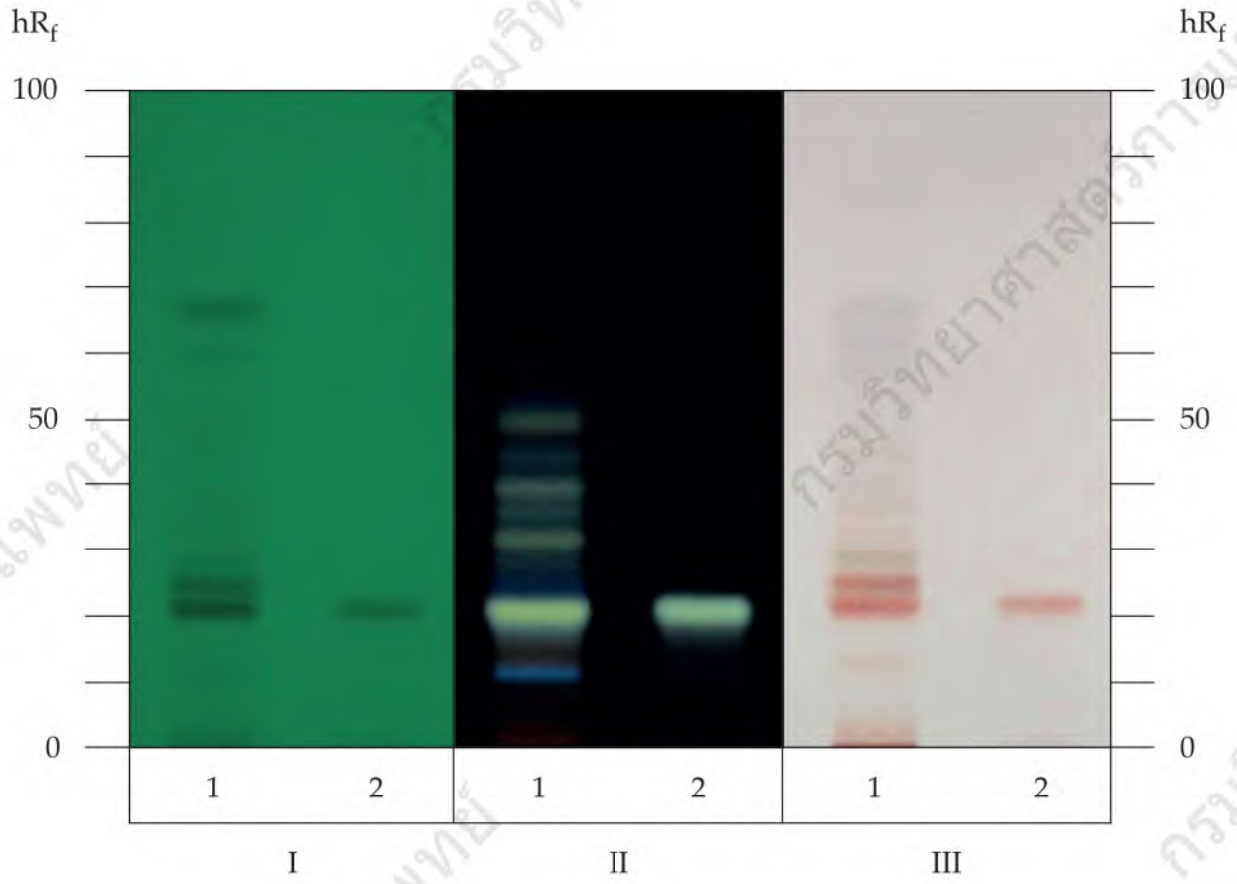


Fig. 3 Thin-Layer Chromatogram of Methanolic Extract of the Rhizomes of *Boesenbergia kingii* Mood & L. M. Prince

1 = solution (A)
2 = solution (B)
I = detection under UV light (254 nm)
II = detection under UV light (366 nm)
III = detection with *vanillin-sulfuric acid TS*

APPENDIX

APPENDIX

The Thai Herbal Pharmacopoeia 2021 Supplement 2024 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. For materials or reagents whose availability is limited, a trademark or supplier's name may be indicated. 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 the 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.

Ammonium Formate $CH_5NO_2 = 63.06$

Use analytical reagent grade of commerce.

DESCRIPTION Colourless, deliquescent crystals.

SOLUBILITY Soluble in *water* and in *ethanol*.

MELTING TEMPERATURE 116° (Appendix 4.3).

WEIGHT PER MILLILITRE 1.27 g (Appendix 4.9).

Store in tightly closed containers in a dry place.

Bisdemethoxycurcumin $C_{19}H_{16}O_4 = 308.33$

Use analytical reagent grade of commerce containing not less than 98.0 per cent.

MELTING TEMPERATURE 224° (Appendix 4.3).

Store in tightly closed containers in a dry place at a temperature between 2° and 8°

Reserpine $C_{33}H_{40}N_2O_9 = 608.68$

Use analytical reagent grade of commerce.

DESCRIPTION Creamy white to slightly yellow crystals or crystalline powder.

SOLUBILITY Very sparingly soluble in *water*; freely soluble in *chloroform*; soluble in *benzene*; slightly soluble in *acetone* and in *methanol*.

MELTING RANGE 264° to 265°, with decomposition (Appendix 4.3).

SPECIFIC ROTATION About -118° at 23°, determined in *chloroform* (Appendix 4.5).

Store in tightly closed containers, protected from light, in a dry place at a temperature between 2° and 8°.

Ajmalicine $C_{21}H_{24}N_2O_3 = 352.42$

Use analytical reagent grade of commerce.

DESCRIPTION Beige powder.

SOLUBILITY Soluble in *ethanol* and in *methanol*.

MELTING TEMPERATURE 258° (Appendix 4.3).

Store in tightly closed containers in a dry place at a temperature between 2° and 8°.

Sennoside A $C_{42}H_{38}O_{20} = 862.72$

Use analytical reagent grade of commerce.

DESCRIPTION Rectangular yellow plates.

SOLUBILITY Insoluble in *water*; sparingly soluble in *methanol*.

MELTING RANGE 200° to 240°, with decomposition (Appendix 4.3).

Store in tightly closed containers in a dry place at a temperature between 2° and 8°.

Sennoside B $C_{42}H_{38}O_{20} = 862.70$

Use analytical reagent grade of commerce.

DESCRIPTION Light yellow prisms or fine needles.

SOLUBILITY Insoluble in *water*; sparingly soluble in *methanol*.

MELTING RANGE 180° to 186°, with decomposition (Appendix 4.3).

Store in tightly closed containers in a dry place at a temperature between 2° and 8°.

Puerarin $C_{21}H_{20}O_9 = 416.40$

Use analytical reagent grade of commerce containing not less the 98.0 per cent.

DESCRIPTION White powder.

Store in tightly closed containers in a dry place at a temperature between 2° and 8°.

Daidzein $C_{15}H_{10}O_4 = 254.24$

Use analytical reagent grade of commerce.

DESCRIPTION Pale yellow prisms.

SOLUBILITY Soluble in *ethanol* and in *ether*.

MELTING RANGE 315° to 323°, with decomposition (Appendix 4.3).

Store in tightly closed containers in a dry place at a temperature between 2° and 8°.

Formononetin $C_{16}H_{12}O_4 = 268.26$

Use analytical reagent grade of commerce.

DESCRIPTION Needles.

MELTING TEMPERATURE About 258° (Appendix 4.3).

Store in tightly closed containers in a dry place at a temperature between 2° and 8°.

1.16H DOSAGE FORMS OF HERBAL DRUGS

GRANULES

Granules are preparations consisting of solid, dry aggregates of powder particles sufficiently resistant to withstand handling. They are intended for oral administration. Some are swallowed as such, some are chewed and some are dissolved or dispersed in water or another suitable liquid before being administered. Granules contain one or more active ingredients with or without added substances including, where necessary, authorized colouring matter and flavouring agents. Granules are presented as single-unit or multiple-unit preparations. For single-unit preparations each dose is enclosed in an individual container, for example, a sachet, a paper packet or a vial. Each dose of a multiple-unit preparation is administered by means of a device suitable for measuring the quantity prescribed.

Several categories of granules may be distinguished: (1) uncoated granules; (2) granules for the preparation for oral liquids (see under Oral Liquids); (3) coated granules; (4) modified-release granules.

Uniformity of dosage units Unless otherwise prescribed in the individual monographs, granules comply with the "Uniformity of Dosage Units" (Appendix 4.28). The test for Content Uniformity is not required for multivitamin and trace element granules and herbal drug granules.

Particle size Topical granules and herbal drug granules comply with the following requirement.

Carry out the determination as described in the "Method for Determining the Particle Size" (Manual Sieving-Two Sieves, Appendix 1.11), use about 10 g of the granules, accurately weighed. Not more than 15 per cent of the granules examined pass through a sieve with a nominal mesh aperture of 180 μm and none passes through a sieve with a nominal mesh aperture of 2000 μm.

Packaging and storage Unless otherwise specified the individual monograph. Granules shall be kept in tightly closed containers and stored in a dry place.

Labelling For single-unit containers the label states the name(s) and amount(s) of active ingredient(s) per container and for multiple-unit containers the label states the name(s) and amount(s) of active ingredient(s) in a suitable quantity by weight.

POWDERS

Powders are preparations consisting of solid, loose, dry particles of varying degrees of fineness that contain one or more active ingredients with or without added substances including, where necessary, flavouring agents and authorized colouring matter. Two categories of powders may be distinguished: (1) oral powders; (2) topical powders.

Minimum fill Powders comply with the test described in the "Minimum Fill" (Appendix 4.26).

Uniformity of dosage units Powders comply with the "Uniformity of Dosage Units" (Appendix 4.28). The test for Content Uniformity is not required for multivitamin and trace element powders and herbal drug powders.

Particle size Topical powders and herbal drug powders comply with the following requirement.

Carry out the determination as described in the "Method for Determining the Particle Size" (Manual Sieving-Single Sieve, Appendix 1.11), use about 10 g of the powder, accurately weighed. Not less than 95 per cent of the powder examined pass through a sieve with a nominal mesh aperture of 125 μm for chemical drugs and the sieve with a nominal mesh aperture of 150 μm for herbal drugs.

Packaging and storage Powders should be kept in tightly closed containers.

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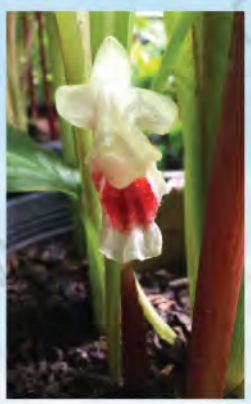

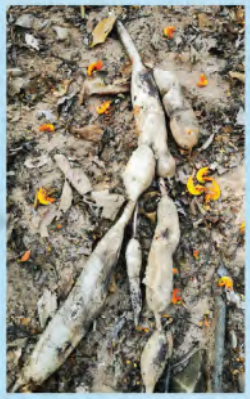

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DEPARTMENT OF MEDICAL SCIENCES