1. Pharmacopoeia for Herbal Medicines

I History of Japanese Pharmacopoeia

Pre-Pharmacopoeia

- Pre-Pharmacopoeia in Japan was the WAZAIKYOKUHOU, which was published on 1100 AD in china and used on 17 century.
- In 1835, Rouan Udagawa translated the Nederland Pharmacopoeia for Japanese Langue.
- After the Meiji revolution on 1868, the quality control of the medicine was carried out to use the European Pharmacopoeia method in Tokyo (1873), Kyoto (1875) and Yokohama (1876).
- For example, Digitalis, Cinchona bark, Ipec, morphine, atropine and quinine were controlled by the European Pharmacopoeia method.

Cultivation and Conservation of Medicinal Plant in ASEAN Countries and Japan

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1. **Pharmacopoeia for Herbal Medicines**
2. **GACP**
3. **Conservation**

Plant Variety

Rehmannia glutinosa Libosch.

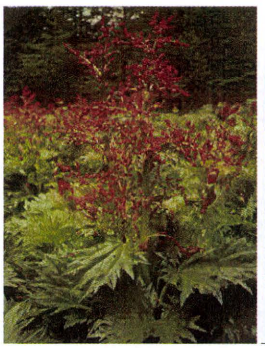
Rehmannia glutinosa Libosch.
var. *purpurea* Makino
x
Rehmannia glutinosa Libosch.

'Fukuchiyama 1gou' (1988/12/13)

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/10000/2198/2198_3_1.jpg

Rheum L.

'Shinshudaiou'
(1988/08/18)



http://www.hinsyu.maff.go.jp/vips/cmm/file_library/10000/1536/1536_3_2.jpg

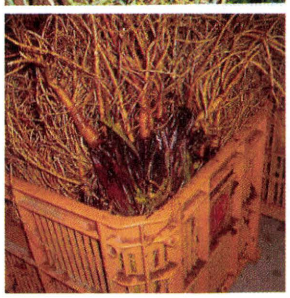
'Shinshudaiou S'
(2006/12/14)

http://www.hinsyu.maff.go.jp/ps/cmm/file_library/20000/17251/17251_3_1.jpg

Bupleurum falcatum L.

'Shinayakamishima'
(2006/12/14)

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/20000/15830/15830_3_1.jpg



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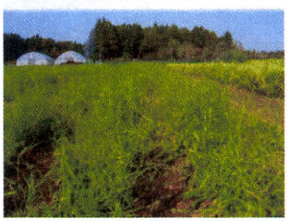
"Kitashizuka"
(2009/03/16)



http://www.hinsyu.maff.go.jp/vips/cmm/file_library/30000/20827/20827_3_1.jpg

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/30000/20827/20827_3_3.jpg

Part 2

★ *Curcuma zedoaria* Roscoe:(莪述)

★ *Platycodon grandiflorum* A. De Candolle:(桔梗)

★ *Cnidium officinale* Makino:(川芎)

★ *Coix lacryma-jobi* L. var. *ma-yuen* Stapf:(薏苡仁)

★ *Carthamus tinctorius* L.:(紅花)

Coix lacryma-jobi L. var. *ma-yuen* Stapf

'Hatochikara'	(1990/12/05)
'Hatomusume'	(1993/08/03)
'Ohotsuku1gou'	(1995/03/23)
'Hatohikari'	(1996/06/13)
'Hatojirou'	(1998/01/22)
'Hatoyutaka'	(2007/03/15)
'Kitanohato'	(2007/03/15)
'Akishizuku'	(2010/03/18)

New Varieties bred at NIBIO

'Kitanohato'

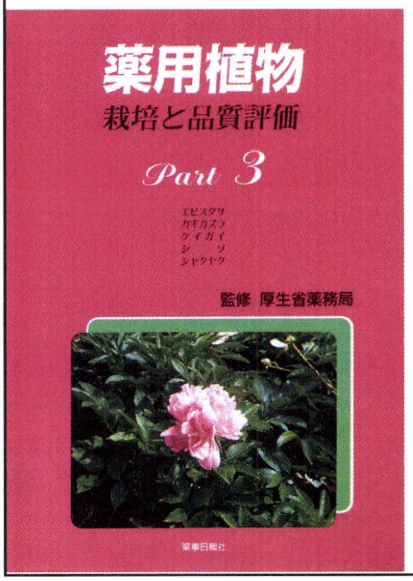
2007/03/15 品種登録(No.15003)
2007/04/27 韓国へ品種登録(No.1860)

'Hatoroman'

出願中 2010/02
(No.24630)

Left: Okayama
Right: Hatoroman

Part 3



★ *Cassia obtusifolia* L.:（決明子）

★ *Uncaria rhynchophylla* Miquel:（釣藤鉤）

★ *Schizonepeta tenuifolia* Briquet:（荊芥穂）

★ *Perilla frutescens* Britton var. *acuta* Kudo:（蘇葉）

★ *Paeonia lactiflora* Pallas:（芍薬）

Perilla frutescens Britton var. *acuta* Kudo:（蘇葉）

Paeonia lactiflora Pall.

New Varieties bred at NIBIO

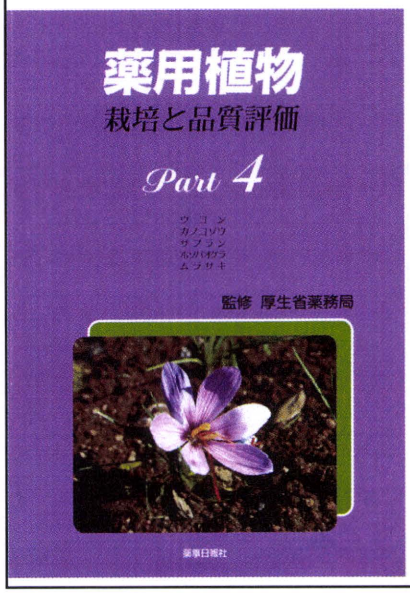
'Sekihou'
(1999/11/25)

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/10000/8610/8610_3_1.jpg

"Kitasaishou"
1996/03/18 品種登録

'Benishizuka'
2009/10 出願中

Part 4



★ *Curcuma longa* L.:(鬱金)

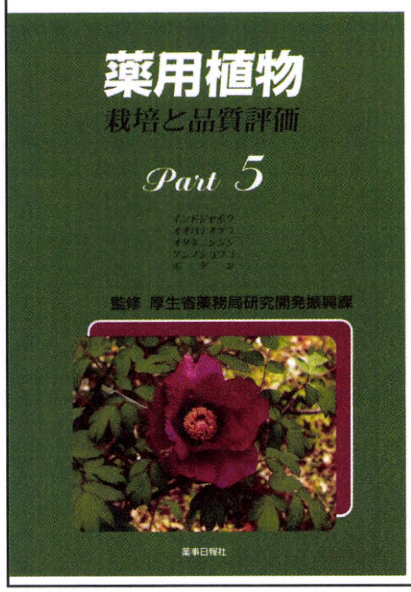
★ *Valeriana fauriei* Briquet:(吉草根)

★ *Crocus sativus* L.:(サフラン)

★ *Atractylodes lancea* De Candolle:(蒼朮)

★ *Lithospermum erythrorhizon* Siebold et Zuccarini:(紫根)

Part 5



★ *Rauwolfia serpentina* Bentham:(印度蛇木根)

★ *Atractylodes ovata* De Candolle:(白朮)

★ *Panax ginseng* C. A. Meyer:(人参)

★ *Geranium thunbergii* Siebold et Zuccarini
:(ゲンノショウコ)

★ *Paeonia suffruticosa* Andrews:(牡丹皮)

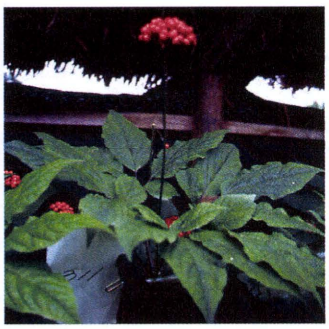
Panax ginseng C. A. Meyer

'Kaishusan'
(2002/01/16)

No picture

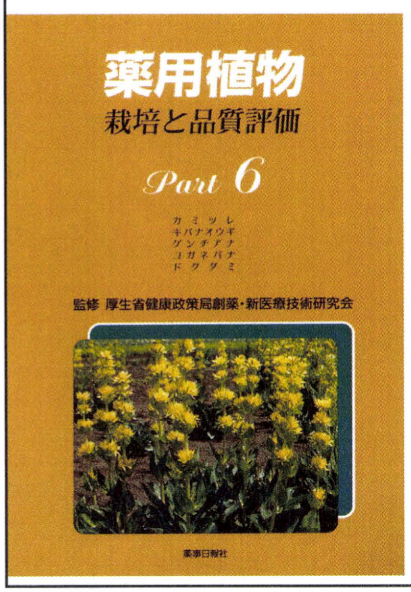
'Shinanoreikon'
(2004/03/09)

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/20000/13412/13412_3_1.jpg



http://www.hinsyu.maff.go.jp/vips/cmm/file_library/20000/13412/13412_3_2.jpg

Part 6



★ *Matricaria chamomilla* L.: (カモミール)

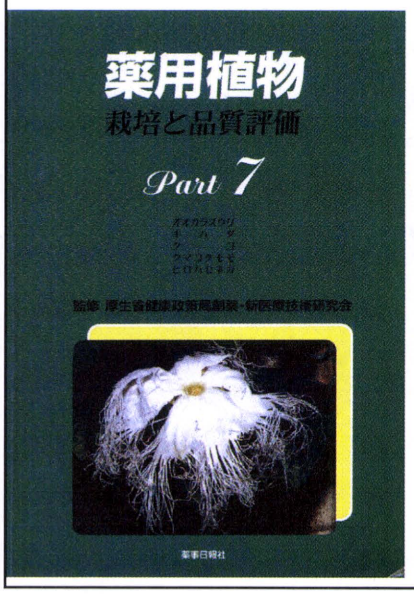
★ *Astragalus membranaceus* Bunge: (黄耆)

★ *Gentiana lutea* L.: (ゲンチアナ)

★ *Scutellaria baicalensis* Georgi : (黄芩)

★ *Houttuynia cordata* Thunberg: (十薬)

Part 7



★ *Trichosanthes bracteata* Voigt:(栝楼根)

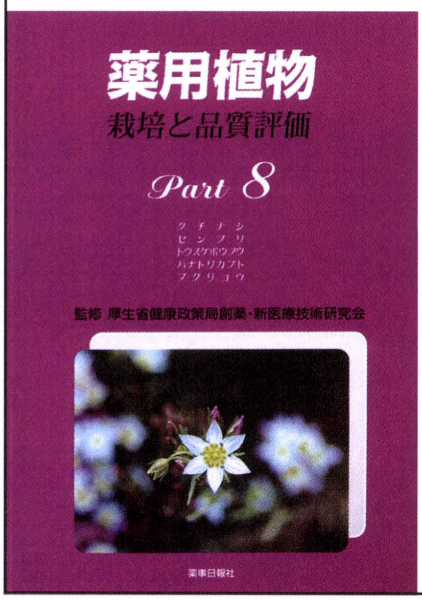
★ *Phellodendron amurense* Ruprecht:(黄柏)

★ *Lycium chinense* Miller
Lycium barbarum L.:(枸杞子, 枸杞葉, 地骨皮)

★ *Arctostaphylos uva-ursi* (L.) Sprengel:(ウワウルシ)

★ *Polygala senega* L. var. *latifolia* Torrey et Gray:(セネガ)

Part 8



★ *Gardenia jasminoides* Ellis :(山梔子)

★ *Swertia japonica* Makino:(当薬)

★ *Saposhnikovia divaricata* Schischkin:(防風)

★ *Aconitum carmichaeli* Debeaux:(附子)

★ *Poria cocos* Wolf:(茯苓)

Swertia japonica Makino

'Mimaki3gou'
(2000/07/31)

No picture

Aconitum

'Sanwa-okukabuto1gou'
(1988/12/13)

No picture

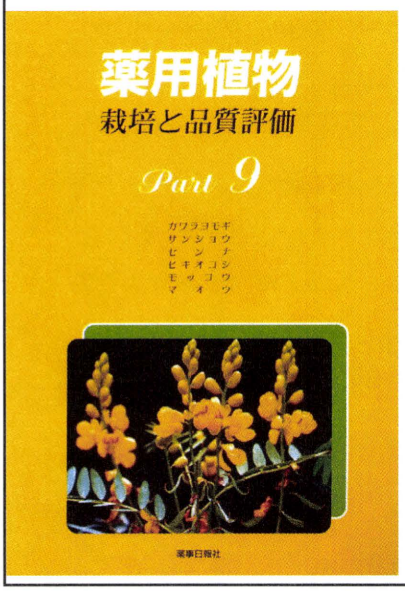
Aconitum 'Okumurasaki1gou'
(2007/08/07)

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/20000/18097/18097_3_3.jpg

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/20000/18097/18097_3_2.jpg

http://www.hinsyu.maff.go.jp/vips/cmm/file_library/20000/18097/18097_3_1.jpg

Part 9



★ *Artemisia capillaris* Thunberg:(茵陳蒿)

★ *Zanthoxylum piperitum* De Candolle:(山椒)

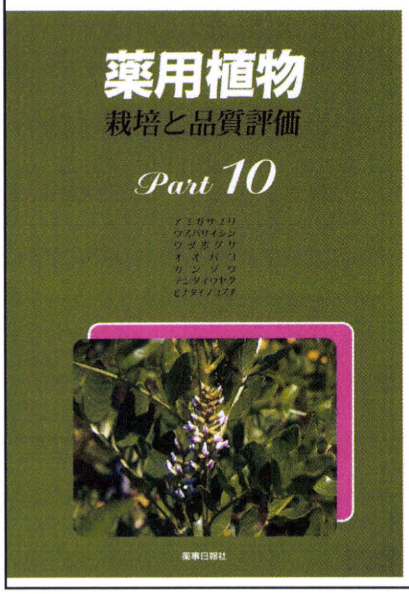
★ *Cassia angustifolia* Vahl
Cassia acutifolia Delile:(センナ)

★ *Plectranthus japonicus* (Burm.) Koidzumi:(延命草)

★ *Saussurea lappa* Clarke:(木香)

★ *Ephedra sinica* Stapf:(麻黄)

Part 10



★ *Fritillaria verticillata* Willd. var. *thunbergii* Baker:(貝母)

★ *Asiasarum sieboldii* F. Maekawa:(細辛)

★ *Prunella vulgaris* L. var. *lilacina* Nakai:(夏枯草)

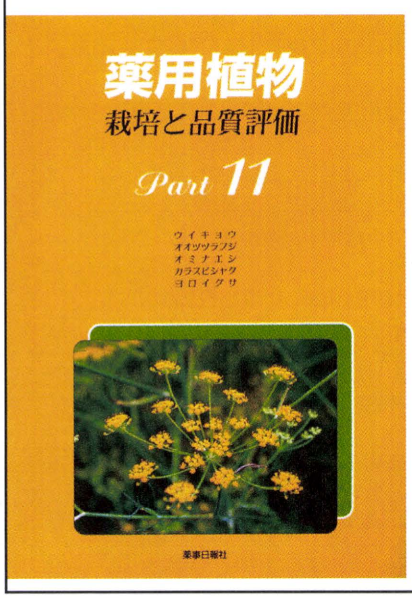
★ *Plantago asiatica* L.:(車前草, 車前子)

★ *Glycyrrhiza* glabra L.
Glycyrrhiza uralensia Fisher:(甘草)

★ *Lindera* strychnifolia F. Villars:(烏薬)

★ *Achyranthes* fauriei Leveillé et Vaniot
Achyranthes bidentata Blume:(牛膝)

Part 11



★ *Foeniculum vulgare* Miller :(茴香)

★ *Sinomenium acutum* Rehder et Wisson:(防已)

★ *Patrinia scabiosaefolia* Fischer:(敗醤根)

★ *Pinellia ternata* Breitenbach:(半夏)

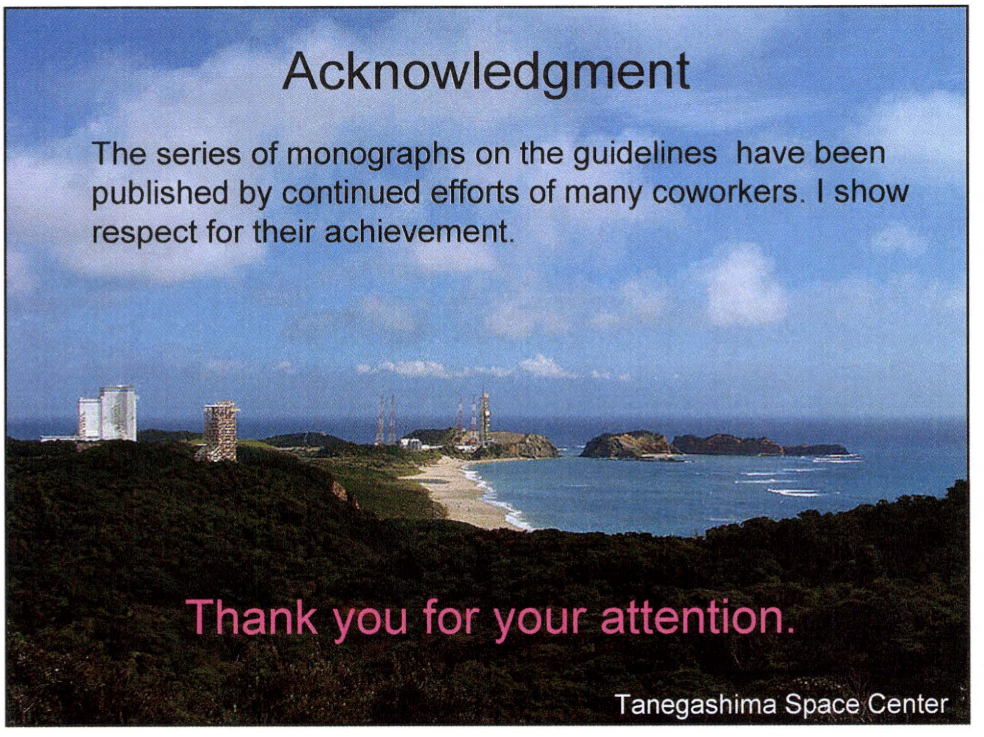
★ *Angelica dahurica* Bentham et Hooker:(白芷)

Part 12

1. *Artemisia annuua* :クソニンジン
2. *Benincasa cerifera* :冬瓜子
3. *Corydalis turtschaninovii* forma *yanhusuo* :延胡索
4. *Epimedium grandiflorum var. thunbergianum* :淫羊藿
5. *Glechoma hederacea* var. *grandis* :連銭草

Next

Acanthopanax senticosus, Cimicifuga simplex, Dioscorea japonica, Glehnia littoralis, Prunus persica, Evodia rutaecarpa, Sophora flavescens



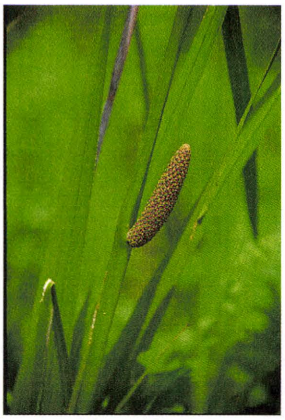
Myanmar Herbal Pharmacopoea

1. Synonyms +Local common names
2. Part used
3. Definition
4. Constituents
5. Description of the plant
6. Description of the part used
    1. Macroscopic
    2. Microscopic
7. Identification
    1. Colour reaction
    2. TLC
8. Moisture contents (Loss on drying)
9. Purity
    1. Foreign matter
    2. Chemical contamination
    3. Microbial contamination
    4. Heavy metal
10. Total ash
11. Acid insoluble ash
12. EtOH soluble extract
13. Water soluble extract
14. Volatile oil content
15. Important formulations
16. Traditional therapeutic uses
17. Dosage

Selected 20 Medicinal Plants

1. **Kyaung-pan-lay**
    - ***Vitex trifolia* Linn. (Leaves)**
2. **Kun ywet**
    - ***Piper betle* Linn. (Leaves)**
3. Kant gyoke ni
    - *Plumbago rosea* Linn. (Stems)
4. Kunzah gamon
    - *Kaempferia galanga* Linn. (Leaves)
5. Gyin
    - *Zingiber officinale* Rose. (Rhizome)
6. **Ngayok Kaung**
    - ***Piper nigrum* Linn. (Fruits)**
7. Hsin don ma nwe
    - *Tinospora cordifolia* Miers (Stem)
8. Zee phyu
    - *Emblica officinalis* Gaertn. (Fruits)
9. Hsay gah gyi
    - *Andrographidis paniculata* Nees (Whole plant)
10. **Zar deik pho**
    - ***Myristica fragrans* Houtt. (Fruits)**
11. Ta mar
    - *Azadirachta indica* A. Juss (Leaves)
12. **Mayagyi**
    - ***Adhatoda vasica* Nees. (Leaves)**
13. Sha zaung let pat
    - *Aloe vera* Linn. (Leaves)
14. Shan hsay gah
    - *Swertia purpurseince* (Whole plant)
15. Linlay
    - *Acorus calamus* Linn. (Rhizome)
16. Dant da luns ywet
    - *Moringa oleifera* Lamk. (Whole plant)
17. Hsan nwin
    - *Curcuma longa* Linn. (Rhisome)
18. **Myin khwa**
    - ***Centella asiatica* Linn. (Whole plant)**
19. **Yeyo**
    - ***Morinda citrifolia* Linn. (Fruits)**
20. Thet yin gynt
    - *Croton oblongifolis* Roxb. (Leaves)

Myanmar Herbal Pharmacopoea



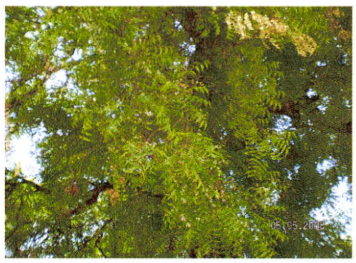
Acorus calamus Linn.
(Rhizome)

Curcuma longa Linn.
(Rhisome)

Piper betle **Linn**.
(Leaves)

Myanmar Herbal Pharmacopoea

Centella asiatica (L) Urb. (Whole plant)



Azadirachta indica A.Juss (Leaves)

Aloe vera Linn. (Leaves)

Andrographis paniculata Nees. (Whole plant)

Myanmar Herbal Pharmacopoea

Myristica fragrans Houtt. (Fruits)

Moringa oleifera Lam. (Whole plant)

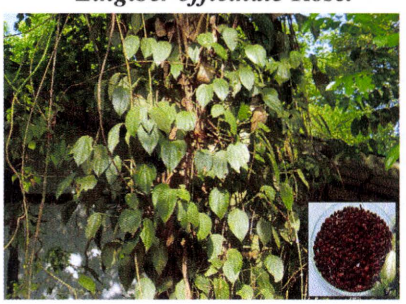
Vitex trifolia Linn. (Leaves)

Tinospora cordifolia Miers. (Stem)

Myanmar Herbal Pharmacopoea

Zingiber officinale **Rose.**

Adhatoda vasica **Nees. (Leaves)**



Piper nigrum **Linn. (Fruits)**

TLC conditions for 7 medicinal Plants

Vitex trifolia
- **Extraction**: 1 g of powder was first extracted with 10 ml of petroleum ether and this extract was removed. The marc was then extracted with ethanol.
- **TLC**: Silicagel, $CHCl_3$ /EtOH (5/1)
- **Detection**: Iodine

Piper betle
- **Extraction**: n-hexane, successively MeOH
- **TLC**: Silicagel, Tolene:EtOAc (95/5)
- **Detection**: Vaniline/H_2SO_4

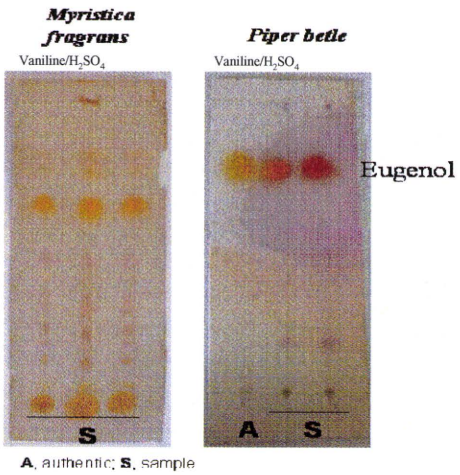
Piper nigrum
- (see below)

Myristica fragrans
- **Extraction**: petroleum ethe
- **TLC**: Silicagel, n-Hexane/ EtOAc (19/1)
- **Detection**: Vaniline/H_2SO_4

Adhatoda vasica
- (see below)

Moringa oleifera
- **Extraction**: EtOH
- **TLC**: Silicagel, Benzene/EtOH (9/1)
- **Detection**: Iodine

Centella asiatica
- **Extraction**: 70% ethanol
- **TLC**: Silicagel, HCl_3/EtOH (5/0.1)
- **Detection**: Anisealdehayde/H_2SO_4 or Rhodamine B



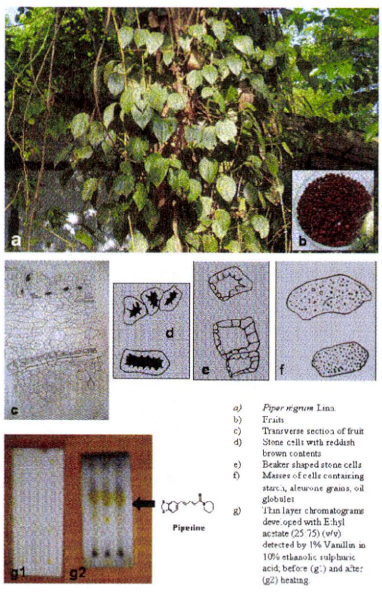
A, authentic; **S**, sample

Fig. Examples of TLC results

Example of a monograph for *Piper nigrum*

Black pepper Fructus
Piper nigrum **Linn. (Piperaceae)**

1. **Synonym(s)**- *Piper trioicum, Piper malabaronse, Piper baccatum, Muldora multiserris.* **Local name(s)** - Black pepper (English), Nga yok kaung (Myanmar), Sayome (dyarmar)
2. **Part(s) used** – Fruits
3. **Constituents** - Alkaloid, amino acid, flavonoid, phenolic compounds
4. **Definition**- Black pepper fructus consists of the dried mature fruit of *Piper nigrum* L. (Family Piperaceae)
5. **Description of the plants**
6. **Description of the part used**
   - 6.1. **Macroscopic** - Fruits are globose or ovoid, 3.0-5.0 mm in diam. Externally brownish to black with wrinkled surface. Single seeded, white in colour. Odour aromatic and characteristic, taste strongly pungent.
   - 6.2. **Microscopic** Transverse section of fruit shows 1) Epicarp composed of a single layered, tubular shaped epidermis having a distinct cuticle with dark brown to blackish contents. 2) Two to three layers of thin-walled parenchyma present below the epidermis intermingle with 1-3 layers of radially elongated lignified stone cells. 3) A broad zone of mesocarp filled with a big band of tangentially elongated parenchymatous cells, containing a few isolated, tangentially elongated oil cells in outer region. Collateral fibrovascular bundles and a regular row of oil cells present in the inner region of mesocarp. 4) A row of beaker shaped stone cells lie in endocarp. 5) A single layer of yellow coloured testa composed of a thick walled sclerenchymatous cells. 6) Perisperm consists of parenchymatous cells containing oil globules, abundant starch and a few aleurone grains.
7. **Identification**
   - 7.1. **Colour reaction** - Dissolve a few mg of alcoholic extract of *Piper nigrum* in 5 ml of distilled water, add 2 M HCl until an acid reaction occurs, then add 1m. of dragendroff's reagent, an orange precipitate is produced immediately.
   - 7.2. **Thin layer chromatographic identification** - To 2 g of Powder of *Piper nigrum* add 20 ml of 95% EtOH, shake for 30 mins, allow to stand for overnight, filter and filtrate is used for chromatography.
8. **Moisture contents** Loss on drying at 105°C) 12.5 % (w/w)
9. **Purity**
   - 9.1 **Foreign matter** Not more than 2 %
10. **Total ash** Not more than 4.7 % (w/w)
11. **Acid-insoluble ash** Not more than 0.8 % (w/w)
12. **Ethanol soluble extract**. Not less than 3.5 % (w/w)
13. **Water soluble extract**. Not less than 11.5% (w/w)
14. **Important Formulations** TMF-1, TMF-9, TMF-23, TMF-24, TMF-29, TMF-34, TMF-38, TMF-40, TMF-42, TMF-45
15. **Traditional therapeutic uses**
16. **Dosage**



a) *Piper nigrum* Linn.
b) Fruits
c) Transverse section of fruit
d) Stone cells with reddish brown contents
e) Beaker shaped stone cells
f) Masses of cells containing starch, aleurone grains, oil globules
g) Thin layer chromatograms developed with Ethyl acetate (25:75) (v/v) detected by 1% Vanillin in 10% ethanolic sulphuric acid, before (g1) and after (g2) heating

An example of a monograph for *Piper nigrum*

Vasaka Folium
***Adhatoda vasica* Nees (Acanthaceae)**

1. **Synonym(s)** - *Adhatoda zeylanica* Medicus, *Justicia adhatoda* Linn; Local name(s) - Vasaka (English), Ma-ya-gyi (Myanmar)
2. **Part(s) used** – Leaves
3. **Constituents** - Alkaloid, Amino acid, Flavonoid, Phenolic compounds, Tannin, Saponin, Steroid, Reducing sugars and Anthraquinones
4. **Definition** - Vasaka folium consists of the mature leaves of *Adhatoda vasica* Nees. (Family Acanthaceae)
5. **Description of the plants**
6. **Description of the part used**

6.1. Macroscopic - Upper surface dull brown and paler beneath, lanceolate or ovate-lanceolate, apex acuminate, base tapering, margin entire. (9-15)cm long and (3-5)cm broad, 9-10 pairs of veins, pinnate venation, few hairs present on the midrib, petiole (0.7-1.5)cm long glabrous. Slightly characteristic odour and bitter taste.

6.2. Microscopic –

6.2.1. Transverse section of the leaf shows 1) large central midrib region and long wings of the lamina on both side. 2) In surface with two layers of palisade cells under the upper epidermis. 3) Epidermal cells sinuous with anomocytic stomata on both surfaces, more numerous on lower surface. 4) Clothing trichomes and glandular trichomes are present on both surfaces. 5) Prismatic calcium oxalate crystals and elongated cystoliths are found in the mesophyll layer. 6) In the midrib region 4-6 layers of collenchyma cells occurring beneath the epidermis.

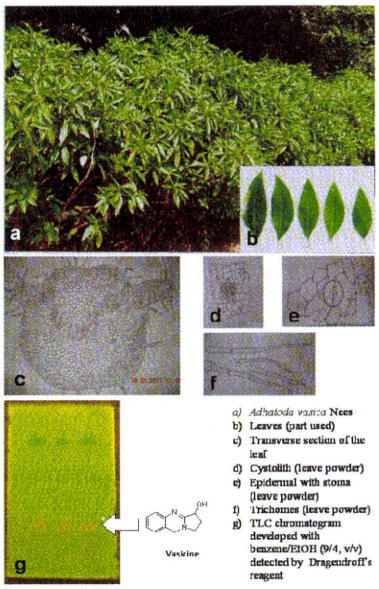
6.2.2. Characteristic particles of *Adhatoda vasica* leaves powder: the powdered drug is greenish in colour, characteristic odour and bitter taste. The diagnostic characters of the powdered drug are 1) trichomes more or less with base. 2) Sinuous epidermal cell with anomocytic stomata in surface view. 3) Elongated cystolith in mesophyll layer.

7. **Identification**

7.1. Colour reaction - a) Dissolve a few mg of alcoholic extract of *Adhatoda vasica* in 5 ml of distilled water, add 2 M HCl until an acid reaction occurs, then add 1ml of dragendorff's reagent, an orange precipitate is produced immediately. b) In a test tube containing 0.5 ml of alcoholic extract of the *Adhatoda vasica* , add 5 drops of dil. HCl followed by a small piece of magnesium. Boil the solution for few mints. Pink colour is produced.

7.2. Thin layer chromatographic identification - Powder of *A vasica* (1g) was mixed thoroughly with 10% ammonia solution and then extracted for 10 min with 5 ml MeOH under reflux. The filtrate was used for TLC analysis.

8. **Moisture contents** (Loss on drying at 105 °C): 7.2 % (w/w)
9. **Purity**
   - **9.1. Foreign matter**: Not more than 3 %
10. **Total ash**: Not more than 19.9 %(w/w)
11. **Acid-insoluble ash**: Not more than 0.4 % (w/w)
12. **Ethanol soluble extract**: Not less than 6.3 % (w/w)
13. **Water soluble extract**: Not less than 16.7 % (w/w)
14. **Volatile oil content**
15. **Important Formulations**: TMF -20 and Some private traditional medicine formulation
16. **Traditional therapeutic uses**:
17. **Dosage**:



a) *Adhatoda vasica* Nees
b) Leaves (part used)
c) Transverse section of the leaf
d) Cystolith (leave powder)
e) Epidermal with stoma (leave powder)
f) Trichomes (leave powder)
g) TLC chromatogram developed with benzene/EtOH (9/4, v/v) detected by Dragendroff's reagent

Vasaka Folium
***Adhatoda vasica* Nees (Acanthaceae)**

1. **Synonym(s)** - *Adhatoda zeylanica* Medicus, *Justicia adhatoda* Linn; Local name(s) - Vasaka (English), Ma-ya-gyi (Myanmar)
2. **Part(s) used** – Leaves
3. **Constituents** - Alkaloid, Amino acid, Flavonoid, Phenolic compounds, Tannin, Saponin, Steroid, Reducing sugars and Anthraquinones
4. **Definition** - Vasaka folium consists of the mature leaves of *Adhatoda vasica* Nees. (Family Acanthaceae)
5. **Description of the plants**
6. **Description of the part used**

6.1. Macroscopic - Upper surface dull brown and paler beneath, lanceolate or ovate-lanceolate, apex acuminate, base tapering, margin entire. (9-15)cm long and (3-5)cm broad, 9-10 pairs of veins, pinnate venation, few hairs present on the midrib, petiole (0.7-1.5)cm long glabrous. Slightly characteristic odour and bitter taste.

6.2. Microscopic –

6.2.1. Transverse section of the leaf shows 1) large central midrib region and long wings of the lamina on both side. 2) In surface with two layers of palisade cells under the upper epidermis. 3) Epidermal cells sinuous with anomocytic stomata on both surfaces, more numerous on lower surface. 4) Clothing trichomes and glandular trichomes are present on both surfaces. 5) Prismatic calcium oxalate crystals and elongated cystoliths are found in the mesophyll layer. 6) In the midrib region 4-6 layers of collenchyma cells occurring beneath the epidermis.

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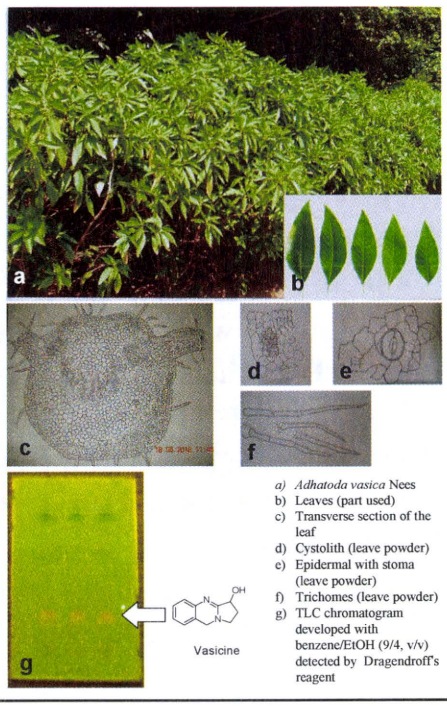
13. **Water soluble extract**: Not less than 16.7 % (w/w)
14. **Volatile oil content**
15. **Important Formulations**: TMF -20 and Some private traditional medicine formulation
16. **Traditional therapeutic uses**:
17. **Dosage**:



a) *Adhatoda vasica* Nees
b) Leaves (part used)
c) Transverse section of the leaf
d) Cystolith (leave powder)
e) Epidermal with stoma (leave powder)
f) Trichomes (leave powder)
g) TLC chromatogram developed with benzene/EtOH (9/4, v/v) detected by Dragendroff's reagent

Vietnam Pharmacopoeia

Fourth Edition 2010

1157 monographs (Standards)

356 chemical monographs,

260 monographs of their formulated preparation,

314 monographs of materia medica and vietnamese traditional medicines,

25 monographs of vaccines and medical bio-products

202 general monographs of quality control methods and general notices with moree than 500 chemicals and reagents

Safety of herbal products (Vietnam)

+ **The test for microbial contamination limits is very necessary for all the traditional medicines except the specific traditional medicines (tinture, volatile oils).**
+ **Aflatoxins and pestiside residues in the medicinal plants as well as their finished products because they are highly dangerous contaminants.**
+ **Regulatory limits and determination method of toxic metals such as copper, lead , arsenic and mercury in traditional medicines.**
+ **Testing for abnormal toxicity of the finished products, in which there is the toxic medicinal plant.**

2. GACP

WHO Guideline on Good Agricultural and Collection Practices for Medicinal Plants

(GACP)

Ottawa Meeting 2001
Methodologies for Quality Control of Finished Herbal Products

One of the recommendations was to immediately develop a guideline to ensure the quality of source raw medicinal plant materials through Good Agriculture Practice (GAP) and Good Field Collection Practice (GFCP).

Good Agricultural and Field Collection Practices GACP

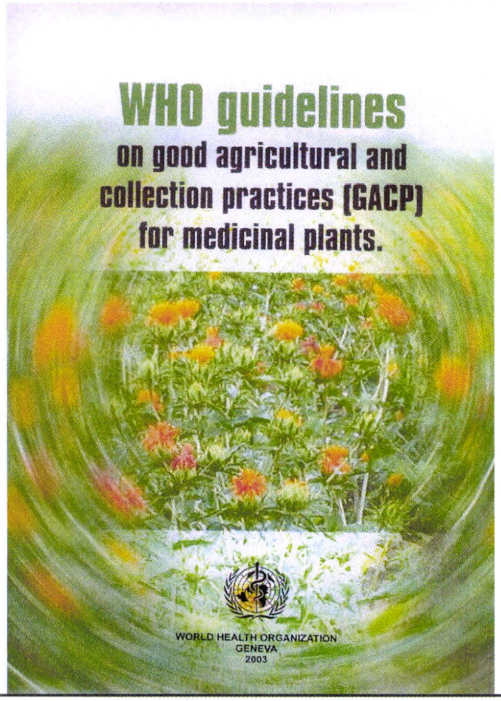
November 2002

Draft WHO Guideline on

Good Agricultural and Field

Collection Practices (GACP)

for Medicinal Plants



Good Agricultural and Collection Practices (GACP) for medicinal plants (2003)

Good Agricultural Practices of medicinal plants (GAP)

Good Field Collection Practices of medicinal plants (GFCP)

Draft WHO Guideline on Good Agricultural and Field Collection Practices (GACP) for Medicinal Plants 2002

1. General Introduction
2. Objectives
   - A. Good Agriculture Practices (GAP) for Medicinal Plants
   - B. Good Field Collection Practices (GFCP) for Medicinal Plants
   - C. Common Technical Aspects for both GAP and GFCP
   - D. Other Issues or Consideration Relating to GAP and GFCP

- Annex 1. Template for cultivated medicinal plants record
- Annex 2: Japanese Good Agriculture Practice Monograph on Medicinal Plants

Towards the safety of herbal medicines

- *Regulation and registration for herbal medicines*
  - *Safety assessment - Research /Evaluation methodology*
- *Quality assurance and control of herbal medicines*
  - *GACP*
  - *GMP*
- *Proper use of herbal medicines*
  - *Education/training of health professionals*
  - *Education of public*
- *Surveillance system - Pharmacovigilance*