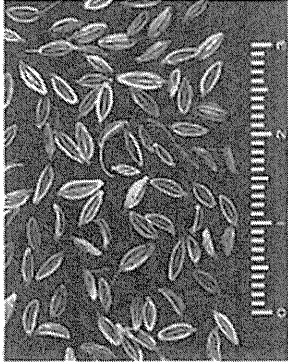
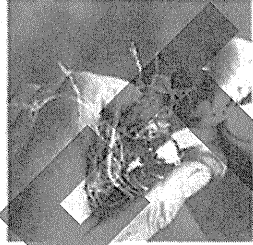


A. acutiloba Kitagawa seeds

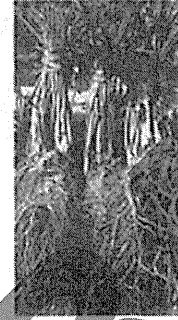


A. acutiloba Kitagawa bud hollowing



A. acutiloba Kitagawa flowers

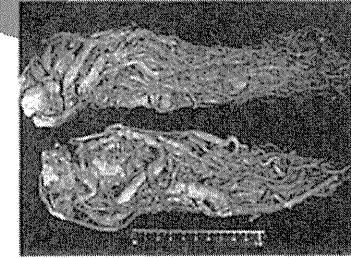
Drying harvested plants (drying poles)



Harvested plant preparation (washing in hot water)



Crude drug



A. acutiloba Kitagawa in peak growth



Bupleurum

DRAFT

1. Plant name Bupleurum
Crude drug name Saiko
Scientific name *Bupleurum falcatum* L.

2. Part used Root

3. Plant description

Bupleurum is a perennial herbaceous plant found in areas from Ibaragi prefecture and to the west in Japan. Glabrous stems grow upright, 40 to 100 cm high, with many thin branching. Leaves are linear to broad linear with 5 to 7 parallel veins. Yellow flowers bloom on August to October developing a number of small compound umbels. Florets have five petals and stamens, and two disks and styles. Fruits are oblong, approximately 3 mm long cremocarps.

4. Crude drug characteristics and places of production

1) Characteristics

Single or branched root of long cone or column shape, 10 to 20 cm in length, 0.5 to 1.5 cm in diameter; occasionally with remains of stem on the crown; externally light brown to brown and sometimes with deep wrinkles; easily broken, and fractured surface somewhat fibrous.

Odor, characteristic; taste, slightly bitter.

Under a microscope, a transverse section reveals the thickness of cortex reaching 1/3 to 1/2 of the radius, tangentially extended clefts in cortex; and cortex scattered with a good many intercellular schizogenous oil canals 15 to 35 μm in diameter; in xylem, vessels lined radially or stepwise, and fiber groups scattered; in the pith at the crown, the same oil canals as in the cortex; parenchyma cells containing starch grains and oil droplets.

Starch grains composed of simple grains, 2 to 10 μm in diameter, or compound grains.

2) Main places of production

Ibaraki, Gunma, Shizuoka, Kochi, and Miyazaki prefectures

5. Variety characteristics

Japanese varieties have many variations. Breeding of varieties has been performed in every area.

1) Morphological characteristics

The plant has a number of varieties with various length from short to tall.

The shape of leaves are racemose lanceolate to oblong.

Cultivated varieties have slightly thicker roots than wild varieties. The color of external surface

is brown to brownish in wild varieties and in light yellow-brown cultivated varieties.

2) Biological characteristics

Bupleurum is easy of bolting in most varieties. In some cultivated varieties, bolting may not occur in the first year.

3) Ingredients

Contains 15.0% of dilute ethanol extract content.

Cultivated varieties contain approximately 1% of saikosaponin a, c, and d, but some wild varieties, more than 25%.

4) Regional adaptability and growth characteristics

Grows in warm area from Kanto and to the west.

a) Climate classification

- | | | |
|-----------------|-----------------------------|-----------|
| (1) Temperature | (i) Coldness classification | III to V |
| | (ii) Warmth classification | 75 to 170 |

- | | |
|-------------------------|-----|
| (2) Sunshine conditions | III |
|-------------------------|-----|

b) Soil classification

- | | |
|---------------|-----------|
| (1) Soil type | II to III |
|---------------|-----------|

(2) Suitable soil

(i) Permeability and water retention condition suitability

Suitable for locations with good permeability

(ii) Soil properties and texture

Suitable for sandy to clay loams

Stagnant water are not favorable

(iii) Suitability to fertile soil

Suitable for fertile soil

(3) Need for light shielding

None

6 Cultivation

1) Varieties

Native varieties are cultivated.

2) Propagation

Uses seeds.

3) Cultivation

a) Suitability

Grows in grassland in mountains or hills from Kanto and to the west. Suitable for sandy to clay loams with good permeability.

a) Propagation

Uses seeds. Seeds are collected in the second year.

b) Sowing

Spring sowing is performed in from mid-May to early April in Kanto area, and half month earlier in warmer areas. Amount of seed should be 1 kg (2L) per 10 a. Seed of 500 g is sufficient, but too light sowing may not ensure enough number of plants. It is safe way to sow somewhat densely and thin out later.

Perform fertilizing with 2000 kg of compost, plow and level the ground. Prepare rows for seeding (60 to 70 cm) and give basal fertilizer. Basal fertilizer mainly consists of manure and adjust the amount according to fertility of the field. Normally, poultry manure of 100 to 150kg, rapeseed oil cake of 50 to 100 kg, and chemical fertilizer (15-15-15) of 20 kg per 10 a. Sow the seeds on the rows, cover with approximately 5 mm soil, and lightly press them. Chaff can be used to prevent drying out.

c) Management

Germination usually begins 1 month after sowing and takes about 2 weeks to complete. Weeding in the early period is important and should be performed timely.

Thin out denser patches of plants twice or three times, from the time leaf length reaches 3 cm, to make it grid-like form with interval of 5 to 10 cm. Perform fertilizing and intertillage at the same time as weeding. These management operations should be performed by the end of the rainy season, because glowed stems are difficult to thin out and operations in hot dry climate can be harmful.

d) Fertilizing

Perform the first fertilizing at the time leaf length reaches 5 cm (mid- to late June). Fertilizers mainly consists of rapid-acting chemical fertilizer, with combined use of manure such as poultry manure. The amount is normally chemical fertilizer (15-15-15) of 40 to 50 kg and poultry manure of 100 to 150 kg per 10 a. The second fertilizing is performed in September at the half to same amount. Fertilizing in the second year can be performed similarly to that in the first year. The first fertilizing in the second year is performed earlier than that in the first year in mid- to late May. In the second fertilizing, nitrogen should be reduced, and phosphoric acid and potassium are mainly used.

e) Pest and disease damage

Root rot is typical disease of roots, which is caused by complex infection of *Phoma terrestris*, *Fusarium oxysporum*, and *Phomopsis sp.* and exhibit brown to blackish brown lesions with caving on the root collar at ground, invading gradually the entire root to dry-rot. Diseases in above-ground part include bitter rot. It occurs at the beginning of bolting, and lead to blackening death of apical area, stem, and branches. Mild disease does not affect roots, but in severe cases, growth of roots are inhibited and their harvesting is made impossible. Other diseases include leaf blight and southern blight caused by *Phomopsis*, and yellow dwarf by *Mycoplasma*. To control the diseases, prevent continuous cropping and select location with good permeability. For fertilizing, use mainly manure and avoid excessive use of nitrogen as chemical fertilizer.

f) Bud thinning

Cut the above-ground part at 70 cm from the ground, at the early period of blooming (in the bud). Bud thinning is performed twice or three times to promote growth of branches. Bud thinning is not necessary and should be done depending on the conditions of thickness.

g) Harvesting

Harvesting of roots had been performed in the second or third year, however, recently performed in the first year. November (after frost period) to February is appropriate for harvesting. Cut the above-ground part at 5 cm from the ground, and dig out the subterranean part. The roots are washed with water, cut off the stem, and dry in the sun.

h) Preparation

Cut off the stem on the top side and remove fibrous roots, and put into shape. To ease the removal of fibrous roots, rub the root before fully dried, which prevents braking the root. Prepared roots are stored in a dry cooled room.

i) Yield

The yield is approximately 30 to 50 kg, largely depending on cultivation and growth condition, up to 80 to 90 kg at the first year

7. Crude Drug Quality Evaluation

1) Japanese Pharmacopoeia test adequacy

- | | |
|---------------------------|--|
| a) Crude drug description | As in 4. 1) |
| b) Purity test | |
| (1) Stem and leaf | The amount of stem and leaf does not exceed 10.0%. |
| (2) Foreign matter | Other than stem and leaf, the amount of foreign matter does not exceed 1.0%. |
| c) Total ash | Not more than 6.5% |

d) Acid-insoluble ash Not more than 2.0%

e) Dilute ethanol extract content Not less than 11.0%

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8. Characteristic Classification

Bupleurum Characteristic Classification

Characteristic		Variety or strain name		
Category	Form or quality	Cultivated native varieties	Kochi wild varieties	Hirao-dai wild varieties
Plant	Plant length (First year, from ground to terminal flower at blooming period)	Medium (80 to 120 cm)	Medium (80 to 120 cm)	Medium (80 to 120 cm)
	Stem	Number of branches (First year, number of branches of main stem at blooming period)	Medium	Few
Leaf	Leaf form (First year, middle leaf of main stem at blooming period)	Narrow lanceolate	Linear lanceolate	Long elliptic
	Leaf length (First year, middle leaf of main stem at blooming period)	Medium (15 to 20 cm)	Slightly short (13 to 18 cm)	Short (8 to 13 cm)
	Leaf width (First year, largest leaf of main stem (excluding radical leaves) at blooming period)	Medium (1.2 to 1.8 cm)	Narrow (0.6 to 1.0 cm)	Broad (1.6 to 2.0 cm)
	Leaf blade color (First year, middle leaf of main stem at blooming period)	Green	Dark green	Yellow green
	Leaf coloration with anthocyanin (First year, middle leaf redness of main stem at blooming period)	Slightly colored	Seldom colored	Seldom colored
Root	Root thickness (First year, diameter of root collar in autumn)	Medium (7 to 11 mm)	Thin (4 to 8 mm)	Thin (4 to 8 mm)
	Root color (First year, color of root in autumn)	Light yellow-brown	Light yellow-brown	Light brown

Characteristic		Variety or strain name		
Category	Form or quality	Cultivated native varieties	Kochi wild varieties	Hirao-dai wild varieties
Flower	Number of umbel (Umbel consisting of compound umbel at the terminal)	Medium (7 to 10)	Medium (7 to 10)	Medium (7 to 10)
	Number of floret (Floret per umbel at the terminal)	Medium (10 to 12)	Medium (10 to 12)	Medium (10 to 12)
Fruit	Fruit length (Second year, 100 grains in full maturity)	Medium (2.5 to 2.8 cm)	Slightly long (2.9 to 3.1 cm)	Slightly short (2.1 to 2.4cm)
	Grain weight (Second year, 100 grains in full maturity)	Medium (200 to 250 mg)	Slightly heavy (300 mg)	Medium (200 to 250mg)
Bolting	Difficulty of bolting (First year, bolting in autumn)	Easy (Bolting almost all)	Easy (Bolting almost all)	Easy (Bolting almost all)
Blooming period	Earliness of blooming (First year, at the time 50% of blooming)	Medium	Medium	Medium
Environmental tolerance	Cold tolerance (Second year, judged from germination)	Medium	Medium	Medium
	Heat tolerance (First year, leaf dying in Summer)	Medium	Weak	Medium
Lodging resistance	Lodging resistance (First year, lodging in autumn)	Medium	Weak	Medium
Ingredient	Dilute ethanol-soluble extract in dry root	Medium (12% to 15%)	Medium (12% to 15%)	Medium (12% to 15%)

10. Background Materials

- 1) Propagation material origins
 - a) Cultivated varieties
 - (1) Cultivated in Gotemba, Shizuoka prefecture (in the present, widely cultivated in various areas).
 - (2) Cultivated in north of Miyazaki prefecture.
 - b) Wild varieties
 - (1) Kochi wild varieties

Grows in north of Kochi prefecture (serpentinite area) in the wild.
 - (2) Hirao-dai wild varieties

Grows in Hirao-dai (limestone area) in Fukuoka prefecture in the wild.
- 2) Trial cultivation
 - a) Plot area

3 m² or more (60 to 70 cm interval between rows
(5 to 10 cm interval between plants))
 - b) No. trial plants

At least 20
 - c) No. repetitions

At least 2
- 3) Usage

Antipyretic, tonic, etc.
- 4) Kampo formulae containing Bupleurum

Daisaikoto, otsujito, shosaikoto, kami gedokuto, etc.

9. Cultivation Calendar

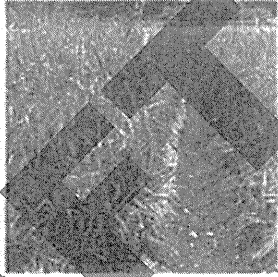
Bupleurum Cultivation Calendar

Month Time of Month	3		4		5		6		7		8		9		10		11		12		1		2																																																																																					
	E	M	L	E	M	L	E	M	L	E	M	L	E	M	L	E	M	L	E	M	L	E	M																																																																																					
Growth phase and work	Sowing period												Germination												Thinning												Weeding Pest and disease control												Fertilizing												Bud thinning												Blooming period												Fertilizing												Harvesting period											
Operations	☆*Basal fertilizer (per 10 a) Manure: 1000-2000 kg Poultry manure: 100-150 kg Rapessed oil cake: 50-100 kg Chemical (15-15-15): 20 kg ☆*Seed pretreatment 24-hour running water dipping ☆*Sowing (per 10 a) 800-1,000 g ☆*Sowing Stripe sowing with interval of 60 to 70 cm ☆*Thinning (2-3 per period) 5 cm interval (grid-like) Abbreviations: E: early; M: mid; L: late ☆*Post and disease control Root rot: rainy seasons (June and autumn) Bitter rot: harvesting period Aphid: all periods ☆*Fertilizing (twice a year) 1 st time (mid- to late June) Chemical (15-15-15): 40-50 kg Poultry manure: 100-150 kg 2 nd time (early Sep) Chemical: half to same as 1 st ☆*Bud thinning (bud formation) Thickness: in above-ground part Cut at 50-70 cm from the ground 2 or 3 times in the bud thinning period ☆*Harvesting Perform at above-ground part blight after frost period Cut the above-ground part at 5 cm, and dig out the subterranean part Wash the roots with water and remove sand ☆*Preparation Remove fibrous roots before washed roots fully dried Cut off the stem on the top side Dry out up to 10% of water ☆*Yield 30-50 kg per 10 a ☆*Seed production Collected from 2 nd year plant																																																																																																											

Bupleurum seeds



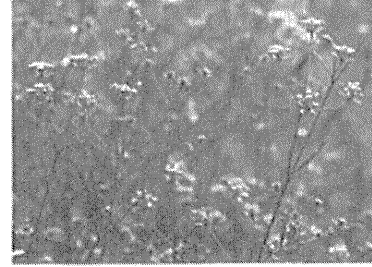
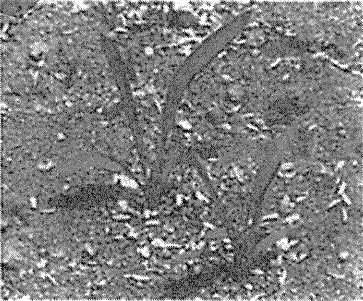
Bupleurum in rapid-growth-term



Bupleurum in early growth term

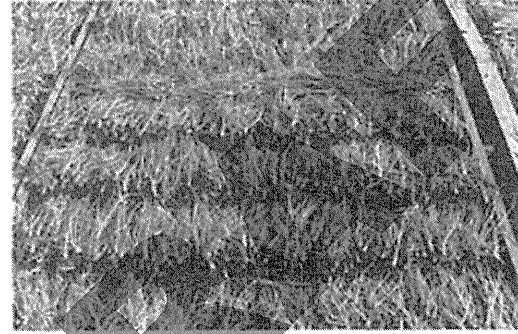


Bupleurum in early growth term



Bupleurum flowers

Drying of harvested Bupleurum



Crude drug

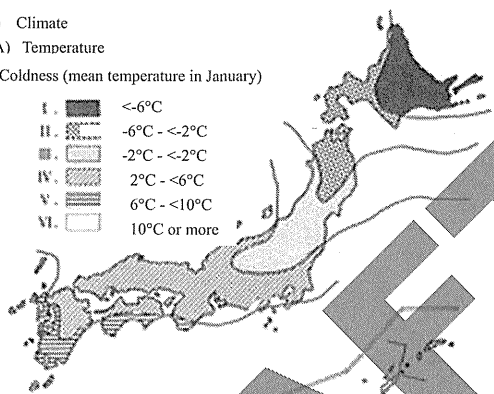
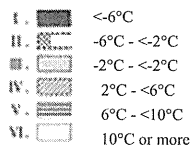


Area suitable for cultivation

1) Climate

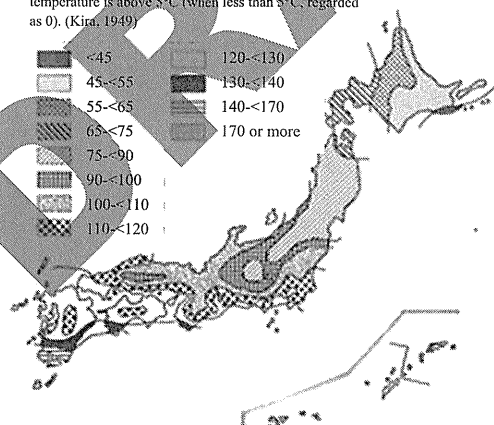
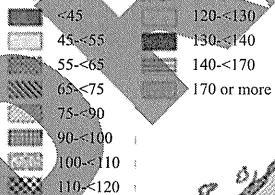
A) Temperature

Coldness (mean temperature in January)

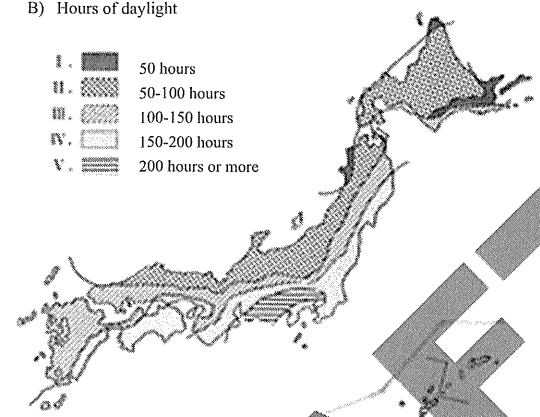
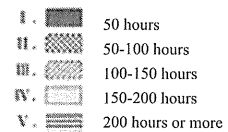


Warmness (warmness index, WI)

Sum of (monthly mean temperature degree-5) when temperature is above 5°C (when less than 5°C, regarded as 0). (Kira, 1949)

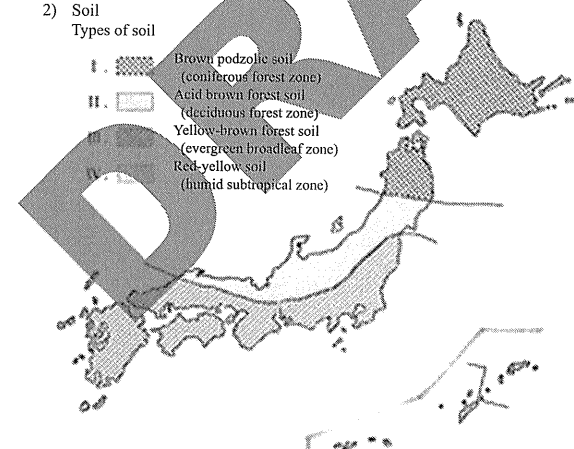
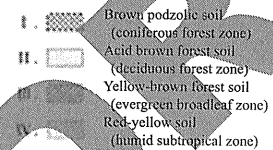


B) Hours of daylight



2) Soil

Types of soil



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Reference number of working document: **ISO/TC 249 N XXX**

Date: 2015-02-26

Reference number of document: **ISO/NP 19617**

Committee identification: ISO/TC 249/WG 2

Secretariat: SAC

General requirements for manufacturing process of natural products used in and as Traditional Chinese Medicine (Provisional)* —

* At such time as ISO/TC 249 adopts a permanent title the terms, “traditional Chinese medicine (TCM)” and “TCM” should be replaced with whatever permanent title or appropriate abbreviation is adopted for ISO/TC 249

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Document subtype: non
Document stage: (20) Preparation
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ISO/NP 19617

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Contents		Page
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Assurance of manufacturing process	6
4.1	Premises	6
4.2	Sanitation and hygiene	8
4.3	Documentation	8
4.4	Personnel	11
4.5	Manufacturing control	12
4.6	Quality control	14
4.7	Change control	16
4.8	Deviation Control	16
4.9	Self-inspections	16
	Bibliography	17

ISO/NP 19617**Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

ISO/NP 19617 was prepared by Technical Committee ISO/TC 249, Traditional Chinese Medicine (Provisional), WG2, Quality and safety of manufactured TCM products.

Introduction

Natural products used in TCM (provisional)*, including medicinal products, dietary supplements and health foods, are manufactured from materials of natural origin which have a variety of quality according to geographical, climatic and seasonal conditions. For quality assurance of final products, quality evaluation on starting materials for natural products used in TCM (provisional)* is important. On the other hand, it is also important to handle these natural materials properly and to control manufacturing processes for natural products used in TCM (provisional)*.

The management of manufacturing process under Good Manufacturing Practice (GMP) is indispensable to ensure quality of medicinal products. International GMP was issued by WHO in 1967, and numbers of regional and international GMPs have subsequently been established. Recently, Pharmaceutical Inspection Convention (PIC)/Pharmaceutical Inspection Cooperation Scheme (PIC/S) has been disseminated widely across the world. Actually, two-thirds of member bodies of ISO/TC249 are affiliated with PIC/S and some more countries are waiting for review of their application.

These general GMPs were extensively applied to different fields and enriched with special supplements for herbal medicines in some countries and organizations. However, these herbal GMPs are focusing on European herbal medicines, and those of China, Japan and Korea are covering traditional medicines in the East Asian regions.

For example, rules and requirements in herbal GMPs of WHO, EU or PIC/S are mainly premised on medicinal products consisting of a single herb, and products made with more than one herb were stipulated as special cases; however, multi-herbal products are more common than single-herbal products in the East Asian regions. Further, raw materials in herbal GMPs of WHO, EU or PIC/S are exclusively of plant origin, while traditional medicines in East Asian often include animal and mineral materials. In order to use correctly identified materials, it is important to identify the starting materials not only by physical/chemical examinations but also by perceptive identification by well-trained experts, though the experts with particular skills on natural materials are not described in the above international herbal GMPs. For the better safety and quality control of TCM products, conventional GMPs for the manufacturing of herbal medicines are in need of enrichment with standards proposed in this work.

Consequently, this proposed standard specifies general requirements for manufacturing process that are particular to the natural products used in TCM (provisional)* based on Chinese, Japanese and Korean herbal GMPs and with reference to international GMPs. Employment of this standard with conventional GMPs for general pharmaceutical products will make manufacturers possible to manufacture safety- and quality-guaranteed natural products used in TCM (provisional)*, and concurrently prevent people in the consuming countries from health hazards caused by products with low quality. It will allow people to enjoy benefits of natural products used in TCM (provisional)* for treatments of diseases as well as health promotion. This standard will also benefit countries of non-members of PIC/S to request quality assurance of the products to manufacturers and manufacturing countries with quotation of this standard. Finally, this standard will make it possible to complement and/or amend WHO's, EU's, and PIC/S' herbal GMPs.

* At such time as ISO/TC 249 adopts a permanent title the terms, "traditional Chinese medicine (TCM)" and "TCM" should be replaced with whatever permanent title or appropriate abbreviation is adopted for ISO/TC 249.

General requirements for manufacturing process of natural products used in and as Traditional Chinese Medicine (Provisional)* —

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1 Scope

This standard specifies the general requirements for manufacturing process to assure the quality of finished products used in Traditional Chinese Medicine (TCM) (provisional)*. This standard covers premises, documentation, personnel, training, manufacturing control and quality control. This standard applies to the manufacturing of natural products used in TCM such as medicinal products, dietary supplements and health foods.

This standard does not conflict with general pharmaceutical GMPs and is not targeting to the management system standard.

This standard applies to all materials of natural product origin: medicinal plants, medicinal animals, medicinal minerals, crude drugs or crude drug preparations.

2 Normative references

The following referenced documents regarding GMPs for herbal medicines are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

WHO guidelines on good manufacturing practices [GMP] for herbal medicines, World Health Organization, 2007.

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3 Terms and definitions

The definitions given below apply to the terms used in this document. They may have different meanings in other contexts.

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「ISO/TC249 における国際規格策定に資する科学的研究と調査 および統合医療の一翼としての漢方・鍼灸の基盤研究」

業務項目③ 「鍼領域の機器の規格と安全性に関する研究」報告

国内外の鍼電極低周波治療器の基本特性の計測・評価

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要旨：鍼電極低周波治療器に関する国際規格策定は、ISO/TC249 の WG4 における重要案件に位置づけられ、今日に至るまで様々な提案と議論が積み重ねられてきている。我が国においては、先般策定された医療機器としての認証基準と内容的に齟齬を来さないようにすることに加え、世界各国で使用されている機器の実状、および主要製造国における基準等を理解し、global relevance の立場からこれら製品・仕様をむやみに排除する規格とならないよう提言を続けていく必要があると思われる。そこで本年度は、情報収集を目的として国外で流通している主要な鍼電極低周波治療器の基本的性能の計測、評価を行い、国内流通品との比較も行った。

A. 目的

平成 19 年の薬事改正に伴う医療機器のカテゴリ分類において、鍼電極低周波治療器はクラス II に指定され、いわゆる第三者認証基準は平成 25 年 11 月に告示に至っている。この認証基準では、他の低周波治療器とは異なり、刺激電極としての鍼を体内に刺入するという機器の特性から、通電量（最大 1 C 以下）や使用する鍼の材質や直径（ステンレス製ディスポーザブル鍼で直径 0.20 mm 以上）など、鍼の電気分解に伴うリスクに関する特段の配慮がなされている。

一方、ISO/TC249 においては、鍼以外の TCM 領域医療機器を取り扱う WG4 の第 1 回会議（2011 年 9 月、韓国）において、鍼電極低周波治療器の国際規格策定の必要性が各国から指摘され、灸（moxibustion）に続く 2 番目の優先順位で検討していくことが議決された。

その後、今日に至るまで様々な提案と議論が積み重ねられてきており、現在は 2 つの規格案が WD ステージで審議されている。その一つが韓国と日本をプロジェクトリーダーとして進

めている WD 18586 であり、鍼電極低周波治療器の安全のための一般的な要求事項を規定することを目的として掲げている。もう一つは、中国とカナダが提案する WD 18663 であり、鍼通電療治療に使用する鍼電極低周波治療器の臨床上の効果を達成するための基本性能（essential performance）を規定することが scope に盛り込まれている。

通常、1 つの医療機器のために 2 種の規格文書（案）が存在するのは不自然であり、実際、両者間で用語の定義が必ずしも一致していないことや、両者の文書中で共通の項目（たとえば、出力制限値や許容周波数など）に対する規定が存在し、かつそれらの規定値が異なっていること、さらには機器の試験方法が異なっていることなど、2 種の規格案が存在することに起因する混乱が生じているのが実状である。今後、両者の統合化、あるいは明確な役割分担に関する合意が形成される必要があると思われるが、その際に我が国においては、(1)先般策定された鍼電極低周波治療器の医療機器認証基準と内容的

に齟齬を来さないようにすること、(2)世界各国で現在流通・使用されている鍼電極低周波治療器の実状、および主要製造国における基準等を理解し、global relevance の立場からこれら製品・仕様をむやみに排除する規格とならないよう提言を続けていく必要があると思われる。

そこで本年度は、上記(2)に関する情報収集を目的として、国外で流通している主要な鍼電極低周波治療器を入手し、基本的性能の計測、評価を行い、国内流通品との比較もふまえて実態を把握することを目的とした。

B. 研究方法

B-1 代表的な鍼電極低周波治療器サンプル (日本国内) の基本的特性の計測、評価

検討1では、検討2で入手、検討する海外製鍼電極低周波治療器との比較対照のため、現在我が国において流通している日本製治療器の基本特性の調査のための通電試験を行った。

調査対象は全医療器製 LFP-4000 (以下 J1)、鈴木医療器製 PG-505 (以下 J2)、カナケン製ラスパー A (以下 J3)、全医療器製 LFP-2000 (以下 J4) の4機種とした。また、通電試験は 500 Ω の固定抵抗負荷条件において、最大出力かつ最大周波数設定で出力される通電波形をデジタルデータロガー (HIOKI 製 8870) にてサンプリング周波数 10 μs で 100 ms 取り込んだ後、(1)パルス波形、(2)パルス幅、(3)ピーク出力値、(4)実効値、(5)100 ms 間の平均電流値について評価を行った。

B-2 代表的な鍼電極低周波治療器サンプル (日本国外) の入手および基本的特性の計測、評価

現在世界各国で広く使用されている海外製鍼電極低周波治療器を入手し、基本性能等の調査を行った。調査対象として、現在アメリカ、イギリス、ドイツ、オーストラリア等欧米諸国において販売されていることが確認可能な機器7品目を選定した。調査に当たっては、現地業者

へのコンタクト、および販売業者の WWW ページからの確認等の手法を用いた。

当該機器は、香港の医療機器販売会社 (MAYFAIR MEDICAL SUPPLIES) にて購入後、試験研究用として薬監証明を取得し、国内に輸入した。

入手した機器について、仕様およびマニュアル記載事項の調査を行った後、B-1 と同様の方法で出力波形の計測と評価を実施した。

C. 結果

C-1 代表的な鍼電極低周波治療器サンプル (日本国内) の基本的特性の計測、評価

500 Ω 固定抵抗負荷時の J1~J4 の出力波形を図1に示す。すべての機種で双極性非対称パルスとなっており、パルス幅については J3 が約 80 μs と最も短く、それ以外の機種は近似した値 (約 250 μs) であった。

J1~J4 の波形データから算出したパルスのピーク値、実効値、および平均値を表1に示す。すべての機種で出力モードが2段階となっており、低出力モードを鍼電極低周波治療器に、高出力モードを経皮電極治療に用いるようマニュアルに記載されていた。鍼電極に用いられることが想定され

表1：国内機種の最大出力計測結果 (500 Ω固定抵抗負荷時)

低出力(Low)モード	電圧(V)			電流(mA)		
	機種(パルス幅)	実測値	実効値	平均値	実測値	実効値
J1(250 μs)	27.4	4.5	-0.101	53.2	8.7	-0.145
J2(250 μs)	10.5	1.4	-0.012	20.4	2.8	-0.079
J3(80 μs)	27.9	2.7	-0.086	54.2	5.3	-0.150
J4(250 μs)	24.8	3.9	-0.108	48.2	7.6	-0.169

高出力(High)モード	電圧(V)			電流(mA)		
	機種(パルス幅)	実測値	実効値	平均値	実測値	実効値
J1(250 μs)	47.0	7.2	-0.177	91.5	13.9	-0.352
J2(250 μs)	19.9	2.8	-0.012	38.6	5.4	-0.078
J3(80 μs)	67.8	6.5	-0.189	132.0	12.5	-0.324
J4(250 μs)	47.7	7.2	-0.120	92.6	14.0	-0.182

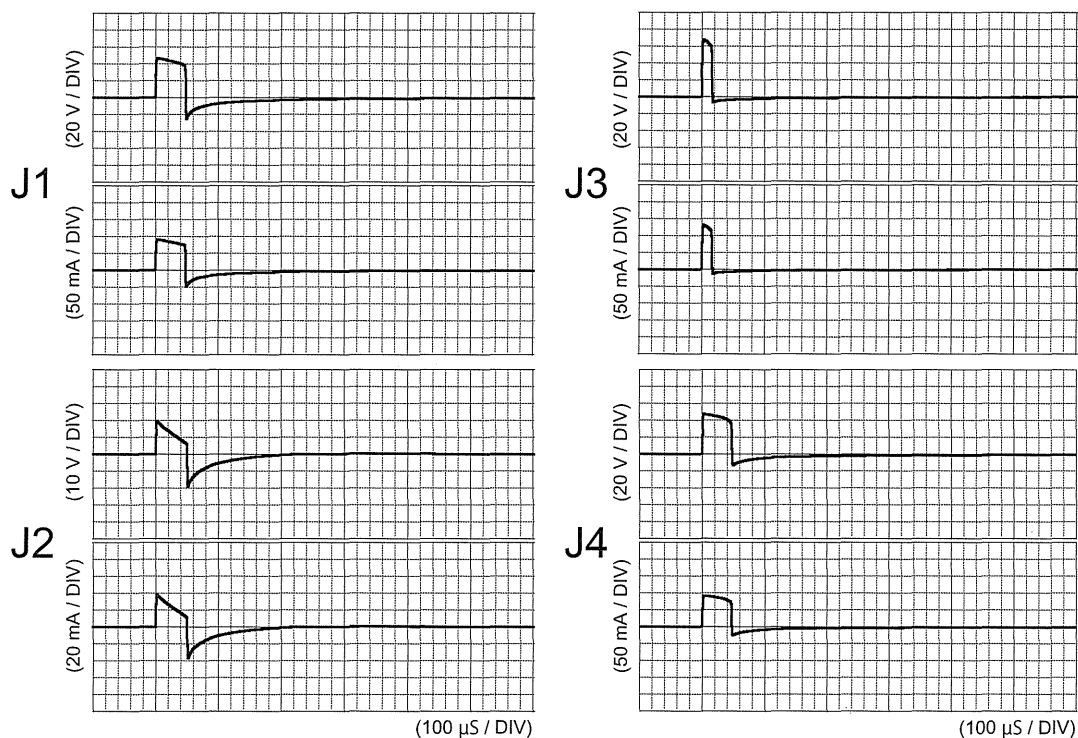


図1 国内機種の実出力波形 (500 Ω固定抵抗負荷時)

たLowモードでは、ピーク値は、J1、J3、J4で30 V/50 mA程度、J2はやや低出力で10 V/20 mAであった。電流実効値はすべての機種で10 mA以下、平均値は最大の機種で $-169 \mu A$ であった。

C-2 代表的な鍼電極低周波治療器サンプル (日本国外)の入手および基本的特性の計測、評価
今回選定入手した機種の一覧、および外観を表2、図2に示す。

C7を除いてすべての機種がオーストラリア、ドイツ、イギリス、アメリカで輸入販売されていた。ことに、中国製のC5、6は、包装にCEマーク取得済であること、IEC60601-2-10適合品であることを明記されており、輸出を強く意識した製品であることがうかがえた。

操作系から判断される内部回路の構成については、タイマーを含み完全なアナログ回路で構成されていると思われるのはC1、C5、C7であり、C2、C3、C6ではタイマー回路や周波数カウンタなど、一部デジタル回路を含む構成、C4に至っては出力調整も含め完全なデジタル回路による構成と考えられた。なお、電源はす

べて乾電池を基本としており、C1、2では006P角形電池、C3以降はすべて単2型電池を6本使用する仕様となっていた。

各製品に添付されていた製品マニュアルに記載されていた基本スペックの一覧を表3に示す。出力波形については5機種において記載されており、矩形波+三角波による双極性パルス(C1、C3)、双極性矩形波(C4)、非対称性双方向パルス(C5、C6)など記載方法は一定していなかった。また、2機種(C2、C7)においては、

表2 海外機種 (選定機種一覧)

機種番号	型式番号	製造業者	製造国	販売国
C1	E-STIM II	TENS PLUS INDUSTRIAL COMPANY	中国 (香港)	AU DE GB US
C2	AWQ-104L	TENS PLUS INDUSTRIAL COMPANY	中国 (香港)	AU DE GB US
C3	AWQ-105	TENS PLUS INDUSTRIAL COMPANY	中国 (香港)	AU DE GB US
C4	E600 HAN	TENS PLUS INDUSTRIAL COMPANY	中国 (香港)	AU DE GB US
C5	SDZ-II	SUZHOU MEDICAL APPLICANCE FACTORY	中国	AU DE GB US
C6	SDZ-III	SUZHOU MEDICAL APPLICANCE FACTORY	中国	AU DE GB US
C7	KWD-808 I	CHANGZHOU WUJIN GREAT WALL MEDICAL DEVICE CO LTD	中国	AU GB US

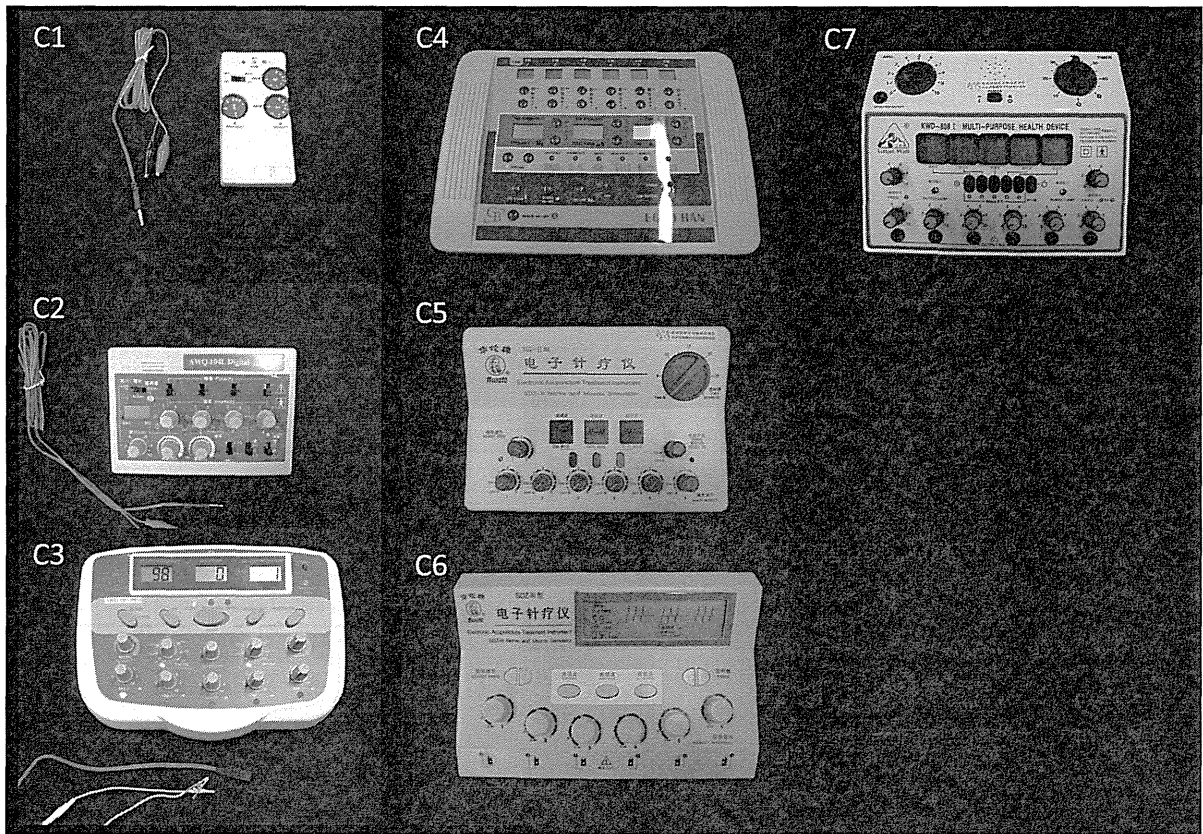


図2 海外機種外観

波形に関する記載そのものが存在しなかった。

周波数については、7機種中3機種(C2、C3、C4)で100 Hzを超える周波数設定が可能であった。なお、これらの機種では100 Hzを超える設定時にパルス幅が自動的に短縮し総出力を減じる対策がなされていた。全ての機種を通じてみると、パルス幅は最短10 μm 、最長600 μm であった。

出力値は、C1～C4までの機種では2段階の最大出力モードを切り替える機能を持っていたが、いずれの機種においても鍼電極を用いる際の出力モード指定はなされていなかった。また、最大出力値についての記載方法は、機種ごとに大きく異なっていた。固定抵抗負荷500 Ω を採用した例では、ピーク電流値と電圧値が併記されているもの(C3、C4)、ピーク電流値のみ

表3 海外機種マニュアル掲載スペック

機種番号	CH	出力モード数	波形数	波 形	周波数	出 力	パルス幅
C1	2	2	1	biphasic square wave with negative peak	2-100 Hz($\pm 20\%$)	0-40 mA rms($\pm 20\%$) 0-2 mA rms($\pm 20\%$)	260 μm
C2	4	2	1	-	1-100 Hz($\times 1$ モード) 10-999 Hz($\times 10$ モード)	0-40 mA 0-18 mA	350 μm ($\times 1$ モード) 40 μm ($\times 10$ モード)
C3	5	2	1	正方形波及負三角形波	1-100 Hz($\times 1$ モード) 5-500 Hz($\times 5$ モード)	0-45 mA / 0-22.5 V 0-20 mA / 0-10 V	50-500 μm ($\times 1$ モード) 10-100 μm ($\times 5$ モード)
C4	6	2	2	biphasic square wave HAN wave	0.5-500 Hz	0-30 mA / 0-15 V 0-10 mA / 0-5 V	50-400 μm
C5	6	1	1	Un-symmetry bi-directional pulse	1-100 Hz	≤ 10 mA (load 250 ohm), Output DC amount 0	200 μm
C6	6	1	1	Un-symmetry bi-directional pulse	1-100 Hz	≤ 10 mA (load 250 ohm)	200 μm
C7	6	1	1	-	1.2-55 Hz	0-50 V($\pm 30\%$)	600 μm