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Dermal mast cells play a central role in the incidence of scratching behavior in mice induced by multiple application of the hapten, 2,4,6-trinitrochlorobenzene

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Abstract: Repeated application of 1% 2,4,6-trinitrochlorobenzene (TNCB) in acetone solution causes chronic skin inflammation in BALB/c mice. Associated scratching behavior gradually appeared, and chronic scratching behavior was established over 40 days after the initial application of TNCB. In order to explore the possible involvement of T cells and mast cells in the appearance of pruritus, we examined the response of athymic nude mice and genetically mast-cell-deficient mice. We could not detect either severe skin inflammation or immunoglobulin (Ig)E production in T-cell-deficient BALB/c nu/nu mice even after 80 days of TNCB treatment, whereas typical severe skin inflammation and IgE production were observed in mast-cell-deficient WBB6F1-W/W^v and WBB6F1-Sl/Sl^d mice. Furthermore, we observed persistent scratching behavior in WBB6F1-W/W^v mice, but not in BALB/c nu/nu and WBB6F1-Sl/Sl^d mice. Histological examination of TNCB-treated animals revealed the development of dermal mast cells in W/W^v mice but not in Sl/Sl^d mice. Degranulation of dermal mast cells was observed in the WBB6F1-W/W^v genotype, but most mast cells remained intact in TNCB-treated BALB/c nu/nu mice. These results suggest that mast cells play a pivotal role in the incidence of scratching behavior in this chronic pruritus model.

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Introduction

Itch is an unpleasant cutaneous sensation which provokes the desire to scratch (1). An itch-scratch vicious cycle exists in inflammatory skin diseases such as atopic dermatitis (AD), in which scratching damage enhances the itching sensation.

The mainstay of therapy for pruritus, for example in AD patients, remains sedative antihistamines (2–4), although it has been suggested that histamine is not a major peripheral mediator of itch in AD (5). Topical steroids have reduced itching caused by inflamed skin (6,7), and phototherapy might also be effective in some patients (8,9). Tacrolimus can relieve the pruritus in some cases, as can other immunosuppressants such as cyclosporine A, although they have no primary antipruritic activities (10,11). At present, however, there is no single treatment that is effective in curing pruritus in all patients.

In order to better understand the molecular basis of pruritus in inflamed skin, appropriate experimental models are needed. Some murine models have been developed but these represent relatively acute models (12–15). Establishment of chronic models would be highly desirable for physiological and pharmacological studies on the underlying molecular process controlling the development of itching in chronic inflammatory skin diseases.

In this study, we demonstrated that persistent scratching behavior associated with chronic skin inflammation could be induced by repeated application of TNCB in mice. Furthermore, we explore the possible participation of T cells and

mast cells in the development of pruritus, using athymic nude mice and genetically mast-cell-deficient mice.

Materials and methods

Animals

Female BALB/c mice and female athymic nude BALB/c nu/nu mice were purchased from Charles River Japan, Inc. (Yokohama, Japan). Female genetically mast-cell-deficient WBB6F1-W/W^v and WBB6F1-Sl/Sl^d mice were obtained from the Shizuoka Laboratory Animal Center (Hamamatsu, Japan). The animals were housed in standard plastic cages in a temperature- and humidity-controlled environment, with food (CE-2, Clea Co., Tokyo, Japan) and water available *ad libitum*. A period of at least 7 days of acclimatization was allowed prior to experimentation. Experimental procedures were approved by the Animal Care Committee at Graduate School of Pharmaceutical Sciences, Nagoya City University, in accordance with the guidelines of the Japanese Council on Animal Care.

Chemicals

2,4,6-Trinitrochlorobenzene (TNCB) was obtained from Nacalai Tesque, Inc. (Kyoto, Japan). TNCB was dissolved in acetone-olive oil (4:1) as 1% w/v solutions and used for sensitization and elicitation. For enzyme-linked immunoadsorbent assay (ELISA), monoclonal antibodies for mouse immunoglobulin (Ig)E (R35-72) as the capture antibodies, biotin-conjugated monoclonal antibodies for IgE (R35-118) as detection antibodies, and streptoavidin-conjugated horseradish peroxidase were purchased from PharMingen (San Diego, CA, USA). All other reagents used were of analytical grade.

Application of TNCB

Mice were initially sensitized by painting 1% TNCB solution (20 µl) on each face of both ears. Starting 7 days later, they were then repeatedly challenged by painting 20 µl 1% TNCB solutions every 48 h. The thickness of the right ear was measured with a dial thickness gauge (G-1A, Ozaki MFG. Co., Ltd, Tokyo, Japan) prior to each topical application of TNCB.

Determination of total IgE level in serum

The serum concentrations of total IgE were measured by a sandwich ELISA using two kinds of rat antimouse IgE monoclonal antibody, according to the manufacturer's instruction. Purified mouse IgE (clone 27–74, PharMingen) was used as a standard.

Histological observation

Ears were removed from the mice 48 h after the final topical application of the vehicle or TNCB, fixed with 10% phosphate-buffered formalin (pH 7.2), and embedded in paraffin. Sections (3 µm) were stained with hematoxylin and eosin or with acidic toluidine blue (pH 4.0), and the number of dermal mast cells expressed as the number of cells per square millimeter of dermis was determined as previously described (16,17). The cells were classified into three categories: extensively degranulated (>50% of the cytoplasmic granules exhibiting fusion, staining alterations, and extrusion from the cell), slightly to moderately degranulated (10–50% of the granules exhibiting fusion or discharge), or normal (16,17).

Evaluation of scratching behavior

The following two methods were used for evaluation of scratching behavior:

Method 1. An 8-mm video camera (CCD-TR900, Sony, Tokyo, Japan) was used to record scratching behavior associated with repeated application of TNCB. Briefly, mice were put into one compartment of four-divided TPX cage (22.5 × 33.8 × 14 cm, CL-0104, Clea Japan Inc., Tokyo, Japan) for 60 min for acclimation. The behavior was then recorded for 10 min using the video camera under unmanned conditions. Scratching behavior was assessed according to the method of Kuraishi et al. (12). The number of event of scratching of both ears by the hind paws was counted. The mice generally displayed several scratches for about 1 s, and a series of the behavior was counted as one incident of scratching for 10 min.

Method 2. To record scratching behavior continuously for 24 h, we used the MicroAct system (Neuroscience, Tokyo, Japan), by which scratching behavior could be detected automatically and analyzed objectively (18). Briefly, a small ring-type magnet (1 mm inner diameter, 2.5 mm outer diameter ×2 mm height, 130–145 mT/cm^2) was attached to each hind ankle with a stainless wire (No. 34, TOHO Co. Ltd, Hiroshima, Japan) in the evening before the measurement. The mouse with attached magnets was placed for 60 min for acclimation in the plastic chamber (11 cm in diameter and 18 cm height) surrounded by a round coil. The electric current induced in the coil by the movement of the magnets was amplified and recorded. Then, characteristic signals were identified as scratching behavior using the parameters as follows: threshold, 0.12 V; event gap, 0.02 s; minimum duration, 0.4 s; maximum frequency, 18 Hz; and minimum frequency, 5 Hz.

Statistics

Results are given as the mean ± SEM. Mean values were compared by the two-tailed Student's or Aspin–Welch's *t*-test after the *F*-test to examine the homogeneity of the difference.

Results

Appearance of chronic scratching behavior caused by repeated application of TNCB in BALB/c mice

We confirmed that repeated epicutaneous application of 1% TNCB on ears every 48 h resulted in chronic skin inflammation and a marked increase in the serum IgE level. The ear thickness increased dramatically up to 50 days before reaching a plateau. Ninety days after the initial application, the ear thickness in TNCB-treated mice was 1226 ± 60 µm and then serum total IgE level was 355.9 ± 81.8 µg/ml, compared to 238.8 ± 1.3 µm thickness and 3.8 ± 1.0 µg/ml total IgE in vehicle-treated mice.

To examine the induction of itch sensation in this model, we scored the incidence of scratching behavior over time. As shown in Fig. 1(a), mice showed increased scratching behavior immediately after sensitization with 1% TNCB on their ears as did vehicle-treated mice. These scratching behaviors, however, were due to non-specific stimuli such as solvent rather than to antigen-specific stimulation, and they disappeared 48 h after the sensitization. Therefore, we decided to observe and to

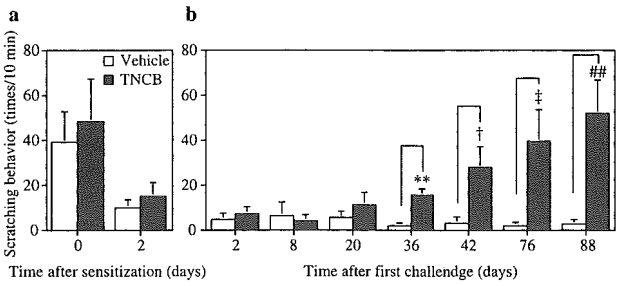

Figure 1. Scratching behavior caused by repeated application of 2,4,6-trinitrochlorobenzene (TNCB) in BALB/c mice. (a) Scratching behavior after the sensitization and (b) scratching behavior caused by repeated application of TNCB at indicated time. Scratching behavior was recorded for 10 min using a video camera under unmanned conditions. Scratching of ears by the hind paws was counted. The mice generally showed several scratches for about 1 s, and a series of the behavior was counted one incident of scratching for 10 min. Each column represents mean ± SEM of three to four mice. †$P < 0.1$; **$P < 0.01$ vs. the vehicle group (Student's t-test). ‡$P < 0.1$; ##$P < 0.05$ vs. the vehicle group (Welch's t-test).

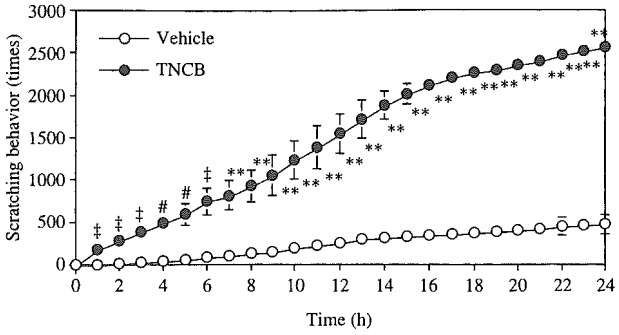

Figure 2. Changes of scratching behavior with time in 24 h. Scratching behavior was measured at day 86 after the first challenge. The incidence of scratching behavior was recorded and analyzed with MicroAct. Characteristic waves were identified as scratching behavior using the parameter as follows: threshold, 0.12 V; event gap, 0.02; minimum duration, 0.4 s; maximum frequency, 18 Hz; and minimum frequency, 5 Hz. Each point represents mean ± SEM of four mice. **$P < 0.01$ vs. the vehicle group (Student's t-test). ‡$P < 0.1$; #$P < 0.05$ vs. the vehicle group (Welch's t-test).

evaluate scratching behavior 48 h after each topical application of TNCB.

There were no differences in the frequency of scratching events between the control and TNCB-treated groups 48 h after the first challenge with 1% TNCB solution, as shown in Fig. 1(b). With increasing number of topical application of TNCB, the incidence of scratching behavior in the TNCB-treated group gradually increased, and within the relatively short time of 42 days, the increase in scratching rate was apparent even within the short time (10 min) observation procedure.

When scratching behavior was measured continuously for 24 h using the MicroAct system, 176.7 ± 45.4 scratching events were recorded in the first hour in TNCB-treated mice and the cumulative incidence of scratching behavior increased almost linearly thereafter (Fig. 2). These results indicated that scratching behavior induced in this model was persistent over a long time.

The roles of T cells and mast cells in the regulating scratching behavior induced by repeated application of TNCB

In order to test the hypothesis that mast cells and T cells might be involved in the induction of scratching behavior in this chronic dermatitis model, repeated application of 1% TNCB was also carried out in T-cell-deficient BALB/c nu/nu mice and in mast-cell-deficient WBB6F1-W/W^v and WBB6F1-Sl/Sl^d mice.

Neither ear swelling nor an increase in serum IgE level was observed in BALB/c nu/nu mice, even by 80 days after the initial application of TNCB (data not shown). On the other hand, in both mast-cell-deficient genotypes (WBB6F1-W/W^v and -Sl/Sl^d), both chronic ear swelling (ear thickness at day 80 in TNCB-treated W/W^v mice, 843.7 ± 93.0 μm; vs. 248.3 ± 7.6 μm in controls; ear thickness in TNCB-treated Sl/Sl^d mice, 1175 ± 153.6 μm; vs. 302.9 ± 34.8 μm in controls) and a significant increase in serum IgE levels at day 80 were observed (serum total IgE level in TNCB-treated W/W^v mice, 74.5 ± 18.1 μg/ml; vs. 14.7 ± 4.3 μg/ml in controls; serum total IgE level in TNCB-treated Sl/Sl^d mice, 83.2 ± 17.9 μg/ml; vs. 23.2 ± 0.9 μg/ml in controls).

To assess scratching behavior in these mutants at day 80, we recorded their behavior for 8 h. As shown in Fig. 3, we could not detect any increase in scratching behavior in TNCB-treated BALB/c nu/nu mice. Moreover, we could not observe any change in scratching behavior in WBB6F1-Sl/Sl^d mice, whereas the increased scratching behavior was found in WBB6F1-W/W^v mice. To clarify the differences between the two mast-cell-deficient strains, a histological analysis was carried out. As shown in Fig. 4(a,b), TNCB-treated BALB/c mice skins exhibited features of chronic dermatitis, including acanthosis of the epidermis, hyperkeratosis with focal areas of parakeratosis, a prominent epidermal mononuclear cell infiltration, and massive dermal inflammatory cell infiltration. Furthermore, toluidine blue staining revealed an increase in the number of mast cells centering on stratum basale (Fig. 5a,b). On the other hand, those pathological changes were rarely observed in TNCB-treated T-cell-deficient BALB/c nu/nu mice (Fig. 4c,d and Fig. 5c,d). In both

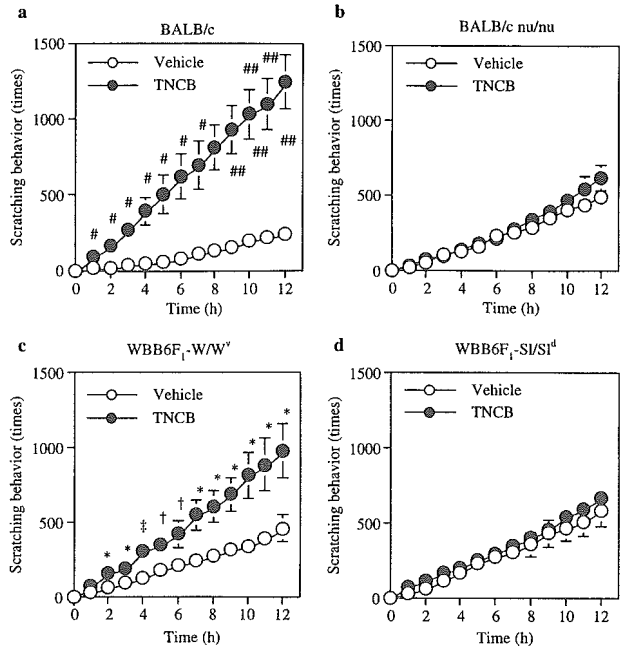

Figure 3. Scratching behavior caused by repeated application of 2,4,6-tri-nitrochlorobenzene in BALB/c nu/nu, WBB6F1-W/W^v, and WBB6F1-Sl/Sl^d mice. Scratching behavior was measured for 12 h at day 80 after the first challenge. The incidence of scratching behavior was recorded and analyzed with MicroAct. Characteristic waves were identified as scratching behavior using the parameter as follows: threshold, 0.12 V; event gap, 0.02; minimum duration, 0.4 s; maximum frequency, 18 Hz; and minimum frequency, 5 Hz. Each point represents mean ± SEM of four mice. †$P < 0.1$; *$P < 0.05$ vs. the vehicle group (Student's t-test). ‡$P < 0.1$; #$P < 0.05$; ##$P < 0.01$ vs. the vehicle group (Welch's t-test).

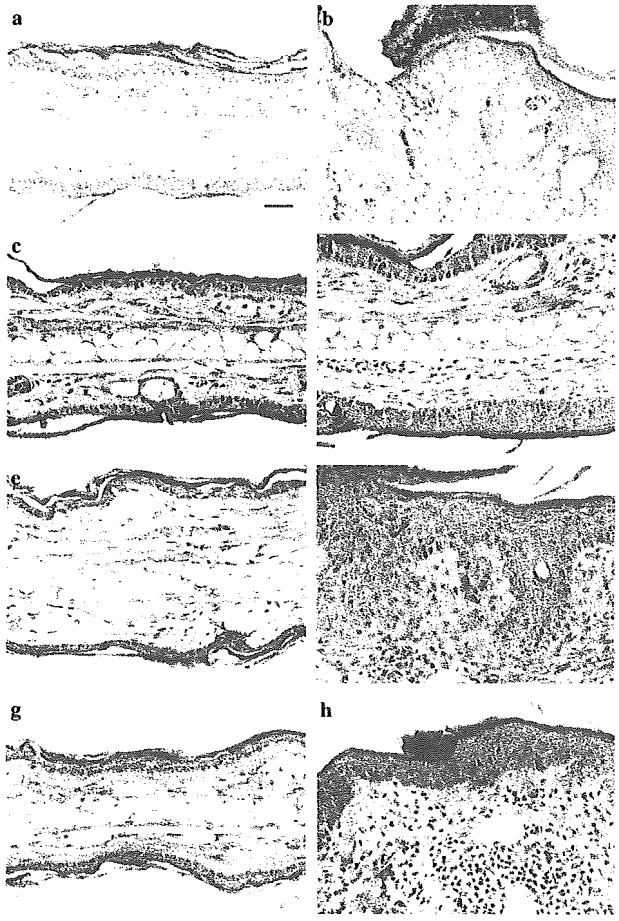

Figure 4. Histological feature of vehicle-treated or 2,4,6-trinitrochlorobenzene (TNCB)-treated skin lesion in BALB/c, BALB/c nu/nu, WBB6F1-W/W^v, and WBB6F1-Sl/Sl^d mice. (a) vehicle-treated BALB/c mice, (b) TNCB-treated BALB/c mice, (c) vehicle-treated BALB/c nu/nu mice, (d) TNCB-treated BALB/c nu/nu mice, (e) vehicle-treated WBB6F1-W/W^v mice, (f) TNCB-treated WBB6F1-W/W^v mice, (g) vehicle-treated WBB6F1-Sl/Sl^d mice, and (h) TNCB-treated WBB6F1-Sl/Sl^d mice. Formaldehyde-fixed and paraffin-embedded samples were stained with hematoxylin and eosin. Scale bar: 30 μm.

mast-cell-deficient genotypes, chronic skin inflammation responses comparable to those seen in BALB/c mice could be detected by hematoxylin and eosin staining (Fig. 4f,h). Toluidine blue staining also revealed the presence of increasing numbers of mast cells in WBB6F1-W/W^v mice, but we could not detect any development of dermal mast cells in WBB6F1-Sl/Sl^d mice (Fig. 5f,h). These histopathological changes were quantitatively evaluated, as summarized in Table 1. In BALB/c mice, the number of mast cells was increased almost ninefold in the TNCB-treated group. Twenty-six percent of the mast cells were extensively degranulated and 38% were moderately degranulated in TNCB-treated mice, whereas 90% of the mast cells in control mice were intact. In athymic nude mice, most mast cells were still intact, although the number of mast cells was increased almost 1.7-fold in TNCB-treated group. In WBB6F1-W/W^v mice, the number of mast cells was significantly increased in TNCB-treated mice and the percentage distribution of degranulated mast cells was almost identical to that seen in TNCB-treated BALB/c mice. On the other hand, we could not find any mast cells in ear tissue from the TNCB-treated WBB6F1-Sl/Sl^d mice.

Discussion

It has been reported that scratching behavior caused by a rostral back injection with pruritogenic agents such as compound 48/80 or substance P might be a response to itching rather than to pain (12). Other experimental scratching induction models involving intradermal injections of other human pruritogenic agents have since been reported (13,14), as well as induction of scratching behavior by passive cutaneous anaphylaxis in mice (15), which implied that an allergic reaction can also cause the sensation of itch in mice. Experimental

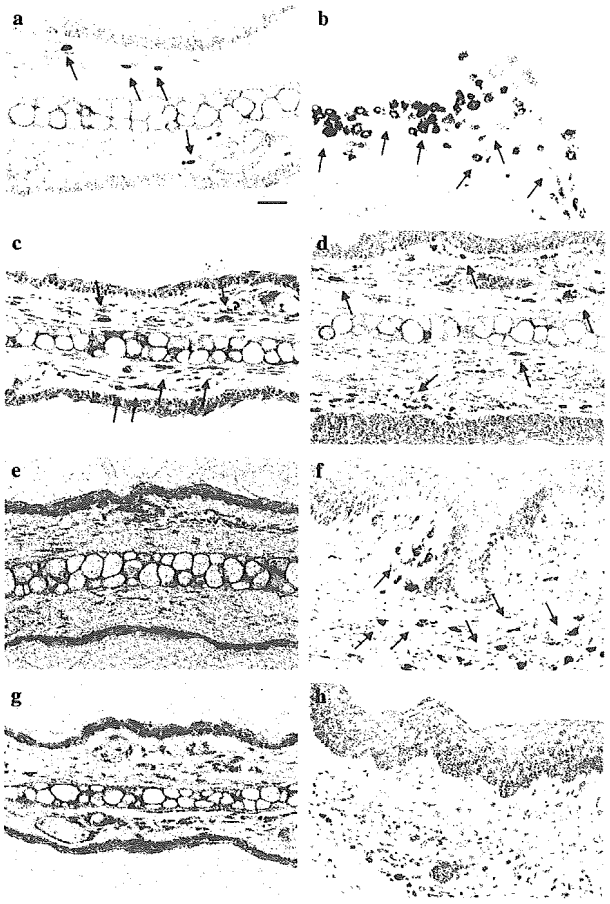

Figure 5. Histological feature of vehicle-treated or 2,4,6-trinitrochlorobenzene (TNCB)-treated skin lesion in BALB/c, BALB/c nu/nu, WBB6F1-W/W^v, and WBB6F1-Sl/Sl^d mice. (a) Vehicle-treated BALB/c mice, (b) TNCB-treated BALB/c mice, (c) vehicle-treated BALB/c nu/nu mice, (d) TNCB-treated BALB/c nu/nu mice, (e) vehicle-treated WBB6F1-W/W^v mice, (f) TNCB-treated WBB6F1-W/W^v mice, (g) vehicle-treated WBB6F1-Sl/Sl^d mice, and (h) TNCB-treated WBB6F1-Sl/Sl^d mice. Formaldehyde-fixed and paraffin-embedded samples were stained with toluidine blue. Scale bar: 30 μm. Arrows indicate the dermal mast cells.

dry skin has also been demonstrated to cause scratching behavior associated with itch (19). We had earlier observed that Nishiki-Cinnamon (NC) mice showed itch-associated responses and chronic dermatitis both spontaneously and following infestation with mites (20,21), but we could not demonstrate the same itch-associated response and dermatitis following infestation with mites in other strains (22). Recently, it has also been reported that over-expression of stratum corneum chymotryptic enzyme or interleukin-4 in transgenic mouse epidermis can cause pruritic dermatitis (23,24).

It has been reported that repeated application of TNCB causes AD-like immunological responses such as eczema and an increase in serum IgE levels (25,26). We subsequently noted the appearance of scratching behavior resulting from epicutaneous application of TNCB every 48 h for much longer periods. In the present study, we recorded any changes in behavior 48 h after topical application of TNCB in order to avoid non-specific responses. On day 86, the scratching behavior detected in TNCB-treated mice was significantly higher than that seen in control mice. The frequency of scratching events increased linearly over time. These results are consistent with the pattern associated with persistent pruritus caused by skin inflammation.

Repeated application of TNCB to ears of BALB/c nu/nu mice failed to cause severe skin inflammation or any marked increase in serum IgE level. In both of the mast-cell-deficient strains tested, WBB6F1-W/W^v and Sl/Sl^d mice, severe skin inflammation and increases of serum IgE level were observed. These data undoubtedly suggested that T cells play a critical role in the development of this skin inflammation and IgE production.

Scratching behavior was not induced in athymic nude mice by repeated application of TNCB. However, scratching behavior was induced in one mast-cell-deficient strain, WBB6F1-W/W^v, but not in another mast-cell-deficient strain, WBB6F1-Sl/Sl^d. Interestingly, we found that mast cells appeared at the chronic dermatitis lesions in WBB6F1-W/W^v mice, as they did in BALB/c mice, but we could not detect any development of dermal mast cells in WBB6F1-Sl/Sl^d mice. Induction of scratching behavior was therefore correlated with the development of dermal mast cells induced by repeated application of TNCB.

It is well known that the normal skin and other tissues of mature WBB6F1-W/W^v or WBB6F1-Sl/Sl^d mice contain far fewer (<1%) mast cells than do the corresponding tissues of congenic normal mice. WBB6F1-W/W^v mice lack the c-kit receptor that is involved the differentiation and proliferation of mast cells, whereas WBB6F1-Sl/Sl^d mice lack the membrane-associated c-kit ligand, stem cell factor (SCF). It is also known that mature dermal mast cells develop locally at sites of chronic idiopathic dermatitis in the skin of W/W^v, but not in Sl/Sl^d, mice (27). Repeated application of phorbol-12-myristate-13 acetate (PMA) to the ear skin of W/Wv has been shown to induce dermatitis and an increase in the number of dermal mast cells (28). Repeated application of PMA also caused chronic dermatitis in WCB6F1-Sl/Sl^d and in the corresponding normal congenic mice, but development of dermal mast cells were not detected in the ear skin of Sl/Sl^d mice. However, the incidence of scratching behavior in PMA-treated mice was not reported.

Our results suggested that the development of dermal mast cells is a key factor in the appearance

Table 1. Development and degranulation of mast cells in BALB/c, BALB/c nu/nu, WBB6F1-W/W^v, and WBB6F1-Sl/Sl^d at sites of repeated application of 1% 2,4,6-trinitrochlorobenzene (TNCB)

Mice	Treatment	Total mast cells (cells/mm^2)	Degranulation (% of total mast cells)		
			Extensive	Slight to moderate	None
BALB/c	Vehicle	143.6 ± 14.8	1.5 ± 1.5	8.0 ± 2.7	90.5 ± 3.7
	TNCB	1312.1 ± 215.5[1]	25.8 ± 3.8[1]	38.1 ± 3.5[2]	36.1 ± 3.2[1]
BALB/c nu/nu	Vehicle	289.8 ± 40.3	0.8 ± 0.8	8.3 ± 3.1	90.9 ± 3.3
	TNCB	485.0 ± 59.5[3]	3.9 ± 1.4	10.4 ± 1.4	85.6 ± 2.4[3]
WBB6F1-W/W^v	Vehicle	0 ± 0	–	–	–
	TNCB	472.4 ± 61.0[2]	24.2 ± 3.3[2]	31.9 ± 3.8[2]	43.8 ± 4.4[2]
WBB6F1-Sl/Sl^d	Vehicle	0 ± 0	–	–	–
	TNCB	0 ± 0	–	–	–

The number of dermal mast cells was counted under a light microscope and expressed as the number of cells per square millimeter of dermis. Mast cells were classified into three categories: extensively degranulated (> 50% of the cytoplasmic granules exhibiting fusion, staining alterations, and extrusion from the cell), slightly to moderately degranulated (10–50% of the granules exhibiting fusion or discharge), or normal. Data shown are mean ± S.E.M. of four mice.
[1] $P < 0.05$.
[2] $P < 0.01$ vs. the vehicle group (Welch's *t*-test).
[3] $P < 0.05$ vs. the vehicle group (Student's *t*-test).

of scratching behavior. Because we could not detect the development of dermal mast cells in WBB6F1-Sl/Sl^d mice, SCF is obviously essential for this process. This makes SCF as attractive target for the development of antipruritic agents in chronic skin inflammation.

However, an increase in the number of dermal mast cells alone can not account entirely for the appearance of scratching behavior induced by repeated application of TNCB, because we found a 1.7-fold increase in number of dermal mast cells in TNCB-treated BALB/c nu/nu mice without concomitant induction of scratching behavior. When we then observed morphological changes in dermal mast cells carefully, we found that total 56.1% of dermal mast cells were degranulated in TNCB-treated WBB6F1-W/W^v mice as total 63.9% of dermal mast cells were degranulated in TNCB-treated BALB/c mice, whereas most mast cells were intact in TNCB-treated BALB/c nu/nu mice. It is likely that IgE antibody plays a pivotal role in degranulation of mast cells, because 85.6% of the mast cells observed in TNCB-treated BALB/c nu/nu mice were still intact and we could not detect any increase in the levels of serum IgE.

The increased degranulation ratio in dermal mast cells in BALB/c and WBB6F1-W/W^v mice, not in BALB/c nu/nu mice, should therefore be associated with the incidence of scratching behavior. Not only degranulation but also secretion of chemical mediators in mast cells can be induced by IgE coupling. It is conceivable that the observation of degranulation provides evidence for the existence of IgE-coupled mast cells. Together with the serum IgE levels, inflamed skin milieu causes the development and degranulation of dermal mast cells to result in the induction of scratching behavior in this model. Although it is therefore probable that mast-cell-derived mediators are responsible for scratching behavior induced by repeated application of TNCB, we have not yet determined the mediator of pruritus. Itch upon degranulation of mast cells could not be suppressed by antihistamines in a recent study of pruritus in AD patients, indicating that mast cell mediators other than histamine could act as itch mediators in AD (29). Further work is needed to clarify when and how dermal mast cells are developed and degranulated, and what kinds of mediators are acting in this model.

In conclusion, we found that persistent scratching behavior was induced by repeated application of TNCB in mice and conclude that an increase in the number of dermal mast cells and mast cell degranulation are likely to be involved in the development of pruritus. We are presently examining more closely the putative roles of SCF and IgE in this model. In addition, it will be of great interest to identify the exact mediator of pruritus.

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西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方収載生薬の各種試験法並びに規格値の比較に関する研究

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Comparative Study on Testing Methods and Specification Values for Crude Drugs Used in Monographs Among Four Western Pacific Regional Countries (Japan, China, Korea and Vietnam)

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The Sub-committee I Meeting of the Western Pacific Regional Forum for the Harmonization of Herbal Medicine (FHH) nomenclature and standardization was held at the National Institute of Health Sciences, Tokyo, Japan. In the meeting, all the participants recognized the importance of comparing the descriptions for herbal medicines contained in member countries' pharmacopoeias or monograph standards as the first step in the harmonization of nomenclature and standardization and agreed to set up five expert working groups (EWG) to carry out the following specific tasks: 1) Nomenclature, 2) Testing Methods in Monographs, 3) List of Chemical Reference Standards (CRS) and Reference of Medicinal Plant Materials (RMPM), 4) List of Analytically Validated Methods, 5) Information on General Tests. The task of EWG2 is to list the testing methods in monographs. In this paper, we report on the preparation of a comparative table of testing methods and specification values for crude drugs used in monographs and to obtain some knowledge from this comparative table.

Keywords: FHH, Crude drug, Comparative table, Testing method, Pharmacopoeia

はじめに

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

1) Nomenclature

2) Testing Method in Monographs

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

4) List of Analytically Validated Method

5) Information on General Test

これらの専門部会では，それぞれの分野における各国薬局方の比較表を作成することが課題事項として議決された．EWG2 (Testing Method in Monographs) の責任者となった著者は試験法及び規格値に関する比較表の作成について担当することとなった．

本報では将来的な国際調和を踏まえ，各国の薬局方収載生薬について共通点と相違点を認識すること目的として，日本，中国，韓国，ベトナム４カ国の薬局方に収載された生薬の試験法並びに規格値について比較表を作成し，比較検討を行った．この結果，若干の知見が得られたので報告する．

方法

本研究では FHH 参加国及び地域のうち，独自の薬局方を保有している日本，中国，韓国，ベトナムの４カ国の生薬に関する試験法並びに規格値を精査し，著者の一人で，EWG1 (Nomenclature) の責任者でもある酒井が作成した共通生薬（103 種）の比較表 [1]をもとに各国の確認試験，純度試験，乾燥減量（水分），灰分，酸不溶性灰分，エキス含量及び定量法（精油含量を含む）の各項目について試験法の設定の有無，試験方法，規格値について比較表を作成した．なお，表中の共通生薬の基原植物は日本薬局方並びに日本薬局方外生薬規格に収載されている学名を中心に記載した．本比較表の作成に使用した各国薬局方を Table 1 に示す．

Table 1 Pharmacopoeias Used in Preparation of Comparative Table

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

結果

作成した比較表を Table 2 に示す．この結果，４カ国局方すべてにおいて共通の基原植物に由来する生薬は，No. 1 ゴシツより No. 56 キョウカツまでの 56 種であった．また，No. 57 テンナンショウより No.66 ゲンジンまでの 10 種は，生薬名としては４ヶ国の局方で共通に使用されているが，基原植物に関しては３カ国いずれかの局方においてのみ共通となっている生薬である．さらに，No. 67 ゲンノショウコ以降は，３カ国いずれかの局方において共通の基原植物に由来するが，残り１カ国に収載されていない生薬である．４カ国共通生薬 56 種に関して比較を行った場合，確認試験，純度試験，灰分の３項目についてはすべての局方においてほぼ設定がなされており，特に TLC 法を用いた確認試験が普及していることが明らかとなった．サイコ，ケイヒ，サンシシ，カンゾウ，コウボク，シャクヤク，ボタンピ，ニンジン，ダイオウ，ゴミシ，インヨウカク，ウコンの 12 生薬はすべての局方に TLC 法による確認試験が設定されている．これら 12 生薬のうちサイコ，ケイヒ，サンシシ，カンゾウ，ボタンピ，ダイオウ，ウコンはすべての局方で灰分の設定もなされており，さらにケイヒ，サンシシは灰分の規格値がすべての局方で同一であった．一方，乾燥減量，酸不溶性灰分，エキス含量等は設定されていない国が多かった．また定量法に関してはカンゾウ (Glycylrrhizinic acid)，ボタンピ (Paeonol)，ホミカ (Strychnine) において共通の指標成分が各局方に設定されていたが，試験法や規格値に相違点が認められた．

考察

今回の比較表作成より，東アジア地区４カ国の薬局方の共通点，相違点が明らかとなった．特にベトナム薬局方 (VP) と中華人民共和国薬典 (CP)，また日本薬局方 (JP) と大韓民国薬局方 (KP) との間にはそれぞれ共通点が多かった．これは局方作成に当り，VP は CP を KP は JP をそれぞれ参考にして作成されているため，このような結果が得られたものと推測された．また定量法に関して KP 及び JP は HPLC を用いた試験法が設定されているのに対し，CP 及び VP では TLC 法，吸光度法及び

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

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
1	*Achyranthes bidentata* Blume (ゴシツ)							
	CP RADIX ACHYRANTHIS BIDENTATAE	O (TLC)	X	O (↓ 15.0%, Water)	O (↓ 9.0%)	O (↓ 1.0%)	↑ 6.5% (1-Butanol-soluble extract)	X
	JP ACHYRANTHIS RADIX	O	O (Stem, Foreign matter)	O (↓ 17.0%)	O (↓ 10.0%)	O (↓ 1.5%)	X	X
	KP ACHYRANTHIS RADIX	O (TLC)	O (Stem, Foreign matter)	O (↓ 17.0%)	O (↓ 10.0%)	O (↓ 1.5%)	X	X
	VP RADIX ACHYRANTHIS BIDENTATAE	O (TLC)	O (Stem, Foreign matter)	O (↓ 15.0%)	O (↓ 9.0%)	X	X	X
2	*Alisma orientale* Juzepczuk (タクシャ)							
	CP RHIZOMA ALISMATIS	O	X	X	O (↓ 5.0%)	O (↓ 0.5%)	X	X
	JP ALISMATIS RHIZOMA	X	X	X	O (↓ 5.0%)	O (↓ 0.5%)	X	X
	KP ALISMATIS RHIZOMA	X	X	X	O (↓ 5.0%)	O (↓ 0.5%)	X	X
	VP RHIZOMA ALISMATIS	O (Powder)	X	O (↓ 12.0%)	O (↓ 5.0%)	X	X	X
3	*Alpinia oxyphylla* Miquel (ヤクチ)							
	CP FRUCTUS ALPINIAE OXYPHYLLAE	O (TLC)	X	X	X	X	X	↑ 1.0% (Essential oil content)
	JP ALPINIAE FRUCTUS	X	X	X	O (↓ 10.0%)	O (↓ 2.5%)	X	↑ 0.4 mL/50g (Essential oil content)
	KP ALPINIAE FRUCTUS	X	X	X	O (↓ 10.0%)	O (↓ 2.5%)	X	↑ 0.4 mL/50g (Essential oil content)
	VP FRUCTUS ALPINIAE OXYPHYLLAE	O (TLC)	O (Foreign matter)	O (↓ 11.0%, Water)	X	X	X	↑ 1.0% (Essential oil content)
4	*Anemarrhena asphodeloides* Bunge (チモ)							
	CP RHIZOMA ANEMARRHENAE	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 8.5%)	O (↓ 4.0%)	X	Diosgenin ↑ 1.0% (TLC)
	JP ANEMARRHENAE RHIZOMA	O	O (Foreign matter)	X	O (↓ 7.0%)	O (↓ 2.5%)	X	X
	KP ANEMARRHENAE RHIZOMA	O (TLC)	O (Foreign matter)	X	O (↓ 7.0%)	O (↓ 2.5%)	X	X
	VP RHIZOMA ANEMARRHENAE	O (TLC)	O (Foreign matter)	O (↓ 12.0%)	O (↓ 8.5%)	X	X	X
5	*Angelica dahurica* Bentham et Hooker fil (ビャクシ)							
	CP RADIX ANGELICA DAHURICAE	O (TLC)	X	O (↓ 14.0%, Water)	O (↓ 6.0%)	O (↓ 1.5%)	↑ 15.0% (Dilute ethanol-soluble extract)	Imperatorin ↑ 0.080% (HPLC)
	JP ANGELICAE DAHURICAE RADIX	O	O (Leaf sheath, Foreign matter)	X	O (↓ 7.0%)	O (↓ 2.0%)	↑ 25.0% (Dilute ethanol-soluble extract)	X
	KP ANGELICAE DAHURICAE RADIX	O	O (Leaf sheath, Foreign matter)	X	O (↓ 7.0%)	O (↓ 2.0%)	↑ 25.0% (Dilute ethanol-soluble extract)	X
	VP RADIX ANGELICA DAHURICAE	O (TLC)	O (Foreign matter)	O (↓ 13.0%, Water)	O (↓ 6.0%)	O (↓ 2.0%)	X	X
6	*Astragalus membranaceus* Bunge (オウギ)							
	CP RADIX ASTRAGALI	O (TLC)	O (Heavy metals, Arsenic, Total BHC, DDT, PCNB)	X	O (↓ 5.0%)	O (↓ 1.0%)	↑ 17.0% (Water-soluble extract)	Astrogaroside ↑ 0.04% (TLC)
	JP ASTRAGALI RADIX	X	O (Root of Hedysarum species and others)	O (↓ 13.0%)	O (↓ 5.0%)	O (↓ 1.0%)	X	X
	KP ASTRAGALI RADIX	X	O (Root of Hedysarum species and others)	O (↓ 13.0%)	O (↓ 5.0%)	O (↓ 1.0%)	X	X
	VP RADIX ASTRAGALI MEMBRANACI	O (TLC)	X	O (↓ 12.0%)	O (↓ 5.0%)	X	X	X
7	*Atractylodes lancea* De Candolle, *A. chinensis* Koidzumi (ソウジュツ)							
	CP RHIZOMA ATRACTILODIS	O (TLC)	X	X	O (↓ 7.0%)	X	X	X
	JP ATRACTYLODIS LANCEAE RHIZOMA	X	O (Atractylodis rhizome)	X	O (↓ 7.0%)	O (↓ 1.5%)	X	↑ 0.7 mL/50g (Essential oil content)
	KP ATRACTYLODIS RHIZOMA	X	O (Atractylodis rhizome)	X	O (↓ 7.0%)	O (↓ 1.5%)	X	↑ 0.7 mL/50g (Essential oil content)
	VP RHIZOMA ATRACTILODIS	O (TLC)	X	X	O (↓ 7.0%)	X	X	X
8	*Atractylodes ovata* De Candolle (ビャクジュツ)							
	CP RHIZOMA ATRACTYLODIS MACROCEPHALAE	O (TLC)	O (Degree of colouration)	X	O (↓ 5.0%)	O (↓ 1.0%)	X	X
	JP ATRACTYLODIS RHIZOMA	O	O (Atractylodis lancea rhizome)	X	O (↓ 7.0%)	O (↓ 1.0%)	X	↑ 0.5 mL/50g (Essential oil content)
	KP ATRACTYLODIS RHIZOMA ALBA	O	O (Atractylodis lancea rhizome)	X	O (↓ 7.0%)	O (↓ 1.0%)	X	↑ 0.7 mL/50g (Essential oil content)
	VP RHIZOMA ATRACTYLODIS MACROCEPHALAE	O (TLC)	O (Foreign matter)	O(↓ 14.0%)	O (↓ 5.0%)	X	X	X
9	*Bupleurum falcatum* Linne (サイコ)							
	CP RADIX BUPLEURI	O (TLC)	X	X	O (↓ 8.0%)	X	↑ 11.0% (Dilute ethanol-soluble extract)	X
	JP BUPLEURI RADIX	O (TLC)	O (Stem and leaf, Foreign matter)	X	O (↓ 6.5%)	O (↓ 2.0%)	↑ 11.0% (Dilute ethanol-soluble extract)	X
	KP BUPLEURI RADIX	O (TLC)	O (Stem and leaf, Foreign matter)	X	O (↓ 6.5%)	O (↓ 2.0%)	X	Saikosaponin a ↑ 0.3% (HPLC)
	VP RADIX BUPLEURI	O (TLC)	O (Stem and leaf, Foreign matter)	O (↓ 12.0%)	O (↓ 8.0%)	X	↑ 11.0% (Dilute ethanol-soluble extract)	X
10	*Carthamus tinctorius* Linne (コウカ)							
	CP FLOS CARTHAMI	O (TLC)	O (Foreign matter)	O (↓ 13.0%, Water)	O (↓ 15.0%)	O (↓ 5.0%)	↑ 30.0% (Water-soluble extract)	Hydroxysafflor A ↑ 1.0% (HPLC), Kaempferide ↑ 0.05% (HPLC)
	JP CARTHAMI FLOS	O	O (Foreign matter)	X	O (↓ 18.0%)	X	X	X
	KP CARTHAMI FLOS	O	O (Foreign matter)	X	O (↓ 18.0%)	X	X	X
	VP FLOS CARTHAMI TINCTORII	O (TLC)	O (Change of colouration, Foreign matter)	O (↓ 13.0%, Water)	O (↓ 15.0%)	X	X	X
11	*Cimicifuga heracleifolia* Komarov (ショウマ)							
	CP RHIZOMA CIMICIFUGAE	O (TLC)	O (Foreign matter)	O (↓ 13.0%, Water)	O (↓ 8.0%)	O (↓ 4.0%)	↑ 17.0% (Dilute ethanol-soluble extract)	Ferulic acid ↑ 0.1% (HPLC)
	JP CIMICIFUGAE RHIZOMA	X	O (Rhizome of Astilbe thunbergii Miquel)	X	O (↓ 9.0%)	O (↓ 1.5%)	↑ 18.0% (Dilute ethanol-soluble extract)	X
	KP CIMICIFUGAE RHIZOMA	X	O (Rhizome of Astilbe thunbergii Miquel)	X	O (↓ 9.0%)	O (↓ 1.5%)	↑ 18.0% (Dilute ethanol-soluble extract)	X
	VP RHIZOMA CIMICIFUGAE	X	X	O (↓ 12.0%)	O (↓ 8.0%)	X	X	X

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
12	***Cinnamomum cassia*** **Blume(ケイヒ)**							
	CP CORTEX CINNAMOMI	O (TLC)	X	O (↓ 15.0%, Water)	O (↓ 6.0%)	X	X	↑ 1.2% (Essential oil content), Cinnamic acid ↑ 1.5% (HPLC)
	JP CINNAMOMI CORTEX	O (TLC)	X	O (↓ 15.5%)	O (↓ 5.0%)	X	X	↑ 0.5 mL/50g (Essential oil content)
	KP CINNAMOMI CORTEX	O (TLC)	X	O (↓ 15.5%)	O (↓ 5.0%)	X	X	Cinnamic acid ↑ 0.03% (HPLC)
	VP CORTEX CINNAMOMI	O (TLC)	O (Foreign matter)	O (↓ 14.0%, Water)	O (↓ 5.0%)	X	X	↑ 1.0% (Essential oil content)
13	***Cornus officinalis*** **Siebold et Zuccarini(サンシュユ)**							
	CP FRUCTUS CORNI	O (TLC)	O (Foreign matter)	O (↓ 16.0%, Water)	O (↓ 6.0%)	O (↓ 0.5%)	↑ 50.0% (Water-soluble extract)	Loganin ↑ 0.60% (HPLC)
	JP CORNI FRUCTUS	O (TLC)	O (Foreign matter)	X	O (↓ 5.0%)	X	↑ 35.0% (Dilute ethanol-soluble extract)	X
	KP CORNI FRUCTUS	O (TLC)	O (Foreign matter)	X	O (↓ 5.0%)	X	X	Loganin ↑ 0.5% (HPLC)
	VP FRUCTUS CORNI OFFICINALIS	O (TLC)	O (Seed and stem, Foreign matter)	O (↓ 12.0%, Water)	X	X	X	X
14	***Cyperus rotundus*** **Linne(コウブシ)**							
	CP RHIZOMA CYPERI	O (TLC)	X	X	O (↓ 4.0%)	X	X	X
	JP CYPERI RHIZOMA	X	X	X	O (↓ 3.0%)	X	X	↑ 0.3 mL/50g (Essential oil content)
	KP CYPERI RHIZOMA	X	X	X	O (↓ 3.0%)	O (↓ 1.5%)	X	↑ 0.3 mL/50g (Essential oil content)
	VP RHIZOMA CYPERI	O	O (Stem, Black burned, Foreign matter)	O (↓ 13.0%, Water)	X	X	X	↑ 0.35% (Essential oil content)
15	***Euphoria longana*** **Lamarck.(リュウガンニク、局外)**							
	CP ARILLUS LONGAN	O	X	O (↓ 15.0%, Water)	O (↓ 4.0%)	X	↑ 70.0% (Water-soluble extract)	X
*	JP LONGAN ARILLUS	O	X	O (↓ 15.0%)	O (↓ 5.0%)	X	X	X
	KP LONGANAE ARILLUS	O	X	O (↓ 15.0%)	O (↓ 5.0%)	X	X	X
	VP ARILLUS LONGAN	X	O (Dark brown)	O (↓ 18.0%, Water)	X	X	X	X
16	***Ephedra sinica*** **Stapf(マオウ)**							
	CP HERBA EPHEDRAE	O (TLC)	O (Foreign matter)	O (↓ 9.0%, Water)	O (↓ 10.0%)	X	X	Ephedorine hydrochloride ↑ 1.0% (HPLC)
	JP EPHEDRAE HERBA	O (TLC)	O (Woody stem, Foreign matter)	X	O (↓ 11.0%)	O (↓ 2.0%)	X	Total alkaroids ↑ 0.7% (HPLC)
	KP EPHEDRAE HERBA	O (TLC)	O (Woody stem, Foreign matter)	X	O (↓ 11.0%)	O (↓ 2.0%)	X	Total alkaroids (Ephedrine+ Psheudoephedrine) ↑ 0.7% (HPLC)
	VP HERBA EPHEDRAE	O (TLC)	O (Foreign matter)	O (↓ 10.0%)	O (↓ 10.0%)	O (↓ 2.0%)	X	Total alkaroids ↑ 0.8% (Titration)
17	***Eucommia ulmoides*** **Oliver(トチュウ)**							
	CP CORTEX EUCOMMIAE	O	X	X	X	X	↑ 11.0% (Dilute ethanol-soluble extract)	Pinoresinol-di-glucopyranoside ↑ 0.10% (HPLC)
	JP EUCOMMIAE CORTEX	O	X	O (↓ 12.0%)	O (↓ 8.0%)	O (↓ 5.0%)	↑ 7.0% (Dilute ethanol-soluble extract)	X
	KP EUCOMMIAE CORTEX	X	X	O (↓ 10.0%)	O (↓ 8.0%)	O (↓ 6.0%)	↑ 9.0% (Dilute ethanol-soluble extract)	X
	VP CORTEX EUCOMMIAE	O	O (Foreign matter)	O (↓ 10.0%)	X	X	↑ 11.0% (Dilute ethanol-soluble extract)	X
18	***Evodia rutaecarpa*** **Bentham(ゴシュユ)**							
	CP FRUCTUS EVODIAE	O (TLC)	O (Foreign matter)	O (↓ 15.0%, Water)	O (↓ 10.0%)	O (↓ 1.0%)	↑ 30.0% (Dilute ethanol-soluble extract)	Evodiamine+Rutaecarpine ↑ 0.15% (HPLC)
	JP EVODIAE FRUCTUS	O	O (Peduncle, Foreign matter)	X	O (↓ 8.0%)	X	X	X
	KP EVODIAE FRUCTUS	O (TLC)	O (Peduncle, Foreign matter)	X	O (↓ 8.0%)	X	X	X
	VP FRUCTUS EVODIAE RUTAECARPAE	O	O (Peduncle, Foreign matter)	O (↓ 5.0%, Water)	X	X	X	↑ 0.25% (Essential oil content)
19	***Foeniculum vulgare*** **Miller(ウイキョウ)**							
	CP FRUCTUS FOENICULI	O (TLC)	O (Foreign matter)	X	O (↓ 10.0%)	X	X	↑ 1.5% (Essential oil content)
	JP FOENICULI FRUCTUS	O (TLC)	O (Peduncle, Foreign matter)	X	O (↓ 10.0%)	O (↓ 1.5%)	X	↑ 0.7 mL/50g (Essential oil content)
	KP FOENICULI FRUCTUS	O (TLC)	O (Peduncle, Foreign matter)	X	O (↓ 10.0%)	O (↓ 1.5%)	X	↑ 0.7 mL/50g (Essential oil content)
	VP FRUCTUS FOENICULI	O	O (Foreign matter)	O (↓ 13.0%, Water)	O (↓ 10.0%)	X	X	↑ 1.5% (Essential oil content)
20	***Forsythia suspensa*** **Vahl(レンギョウ)**							
	CP FRUCTUS FORSYTHIAE	O (TLC)	O (Foreign matter)	O (↓ 10.0%, Water)	O (↓ 4.0%)	X	↑ 16.0% (Dilute ethanol-soluble extract)	Forsythiaside ↑ 0.15% (HPLC)
	JP FORSYTHIAE FRUCTUS	O	O (Blanchlet, Foreign matter)	X	O (↓ 5.0%)	X	↑ 10.0% (Dilute ethanol-soluble extract)	X
	KP FORSYTHIAE FRUCTUS	O	O (Blanchlet, Foreign matter)	X	O (↓ 5.0%)	X	↑ 10.0% (Dilute ethanol-soluble extract)	X
	VP FRUCTUS FORSYTHIAE	O (TLC)	O (Foreign matter)	O (↓ 10.0%)	O (↓ 4.0%)	X	↑ 16.0% (Dilute ethanol-soluble extract)	X
21	***Fritillaria verticillata*** **Willdenow var. *thunbergii*** **Baker(バイモ)**							
	CP BULBUS FRITILLAIAE THUNBERGII	O (TLC)	X	O (↓ 18.0%, Water)	O (↓ 6.0%)	O (↓ 1.0%)	↑ 8.0% (Dilute ethanol-soluble extract)	Peimine+Peimenine ↑ 0.080% (HPLC)
	JP FRITILLARIAE BULBUS	O (TLC)	X	O (↓ 16.0%)	O (↓ 6.5%)	O (↓ 1.0%)	↑ 8.0% (Dilute ethanol-soluble extract)	X
	KP FRITILLARIAE THUNBERGII BULBUS	O	X	O (↓ 15.0%)	O (↓ 5.0%)	X	↑ 9.0% (Dilute ethanol-soluble extract)	X
	VP BULBUS FRITILLAIAE THUNBERGII	O (TLC)	O (Foreign matter)	O (↓ 12.0%)	X	X	X	X
22	***Gardenia jasminoides*** **Ellis(サンシシ)**							
	CP FRUCTUS GARDENIAE	O (TLC)	X	O (↓ 8.5%, Water)	O (↓ 6.0%)	X	X	Geniposide ↑ 1.8% (HPLC)
	JP GARDENIAE FRUCTUS	O (TLC)	X	O (↓ 13.0%)	O (↓ 6.0%)	X	X	Geniposide ↑ 3.0% (HPLC)
	KP GARDENIAE FRUCTUS	O (TLC)	X	X	O (↓ 6.0%)	X	X	X
	VP FRUCTUS GARDENIAE	O (TLC)	O (Young, broken, black, Foreign matter)	O (↓ 13.0%, Water)	O (↓ 6.0%)	X	X	X
23	***Glycyrrhiza uralensis*** **Fisher, *G. glabra*** **Linne(カンゾウ)**							
	CP RADIX ET RHIZOMA GLYCYRRHIZAE	O (TLC)	O (Heavy metals, Arsenic, Total BHC, DDT, PCNB)	O (↓ 12.0%, Water)	O (↓ 7.0%)	O (↓ 2.0%)	X	Glycyrrhizinic acid ↑ 2.0% (HPLC)
	JP GLYCYRRHIZAE RADIX	O (TLC)	X	O (↓ 12.0%)	O (↓ 7.0%)	O (↓ 2.0%)	↑ 25.0% (Dilute ethanol-soluble extract)	Glycyrrhizinic acid ↑ 2.5% (HPLC)
	KP GLYCYRRHIZAE RADIX	O (TLC)	X	O (↓ 12.0%)	O (↓ 7.0%)	O (↓ 2.0%)	X	Glycyrrhizinic acid ↑ 2.5% (HPLC)
	VP RADIX GLYCYRRHIZAE	O (TLC)	O (Foreign matter)	O (↓ 12.0%)	O (↓ 10.0%)	O (↓ 2.5%)	X	Glycyrrhizinic acid ↑ 6.0% (Weight)

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
24	***Leonurus sibiricus* Linne.(ヤクモソウ、局外)**							
	CP HERBA LEONURI	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 11.0%)	O (↓ 1.0%)	↑ 15.0% (Water-soluble extract)	Stachydrine ↑ 0.50% (TLC)
*	JP LEONURI HERBA	O	X	O (↓ 13.0%)	O (↓ 10.0%)	O (↓ 2.0%)	↑ 8.0% (Dilute ethanol-soluble extract)	X
	KP LEONURI HERBA	O	X	O (↓ 13.0%)	O (↓ 10.0%)	O (↓ 2.0%)	↑ 8.0% (Dilute ethanol-soluble extract)	X
	VP HERBA LEONURI JAPONICI	O (PC)	O (Herba > 40cm, Foreign matter)	O (↓ 13.0%, Water)	O (↓ 10.0%)	X	↑ 20.0% (Water-soluble extract)	X
25	***Lonicera japonica* Thunberg(キンギンカ、局外)**							
	CP FLOS LONICERAE JAPONICAE	O (TLC)	O (Heavy metals, Arsenic)	O (↓ 12.0%, Water)	O (↓ 10.0%)	O (↓ 3.0%)	X	Chlorogenic acid ↑ 1.5% (HPLC)
*	JP LONICERAE FLOS	O	O (Stems and leaves)	O (↓ 15.0%)	O (↓ 9.0%)	X	↑ 32.0% (Dilute ethanol-soluble extract)	X
	KP LONICERAE FLOS	O	O (Stems and leaves)	O (↓ 15.0%)	O (↓ 9.0%)	X	↑ 16.0% (Dilute ethanol-soluble extract)	X
	VP FLOS LONICERAE	O	O (Stems and leaves, Foreign matter)	O (↓ 12.0%)	O (↓ 9.0%)	O (↓ 1.5%)	X	X
26	***Magnolia officinalis* Rehder et Wilson var. *biloba* Rehder et Wilson(コウボク)**							
	CP CORTEX MAGNOLIAE OFFICINALIS	O (TLC)	X	X	X	X	X	Magnolol+Honokiol ↑ 2.0% (HPLC)
	JP MAGNOLIAE CORTEX	O (TLC)	X	X	O (↓ 6.0%)	X	↑ 11.0% (Dilute ethanol-soluble extract)	Magnolol ↑ 0.8% (HPLC)
	KP MAGNOLIAE CORTEX	O (TLC)	X	X	O (↓ 6.0%)	X	X	Magnolol ↑ 0.8% (HPLC)
	VP CORTEX MAGNOLIAE OFFICINALIS	O (TLC)	O (Cork bark, Foreign matter)	O (↓ 15.0%, Water)	O (↓ 6.0%)	X	X	X
27	***Morus alba* Linne(ソウハクヒ)**							
	CP CORTEX MORI	O (TLC)	X	X	X	X	X	X
	JP MORI CORTEX	O	O (Foreign matter)	X	O (↓ 11.0%)	O (↓ 1.0%)	X	X
	KP MORI CORTEX	O	O (Foreign matter)	X	O (↓ 11.0%)	O (↓ 1.0%)	X	X
	VP CORTEX MORI ALBAE	O	O (Foreign matter)	O (↓ 12.0%)	O (↓ 9.0%)	X	X	X
28	***Myristica fragrans* Houttuyn(ニクズク、局外)**							
	CP SEMEN MYRISTICAE	O (TLC)	X	O (↓ 10.0%, Water)	X	X	X	↑ 6.0% (Essential oil content)
*	JP MYRISTICAE SEMEN	O	X	X	O (↓ 3.0%)	X	X	↑ 0.5 mL/50g (Essential oil content)
	KP MYRISTICAE SEMEN	O (TLC)	X	X	O (↓ 3.0%)	O (↓ 0.5%)	X	↑ 0.5 mL/50g (Essential oil content)
	VP SEMEN MYRISTICAE	O (TLC)	X	O (↓ 12.0%, Water)	X	X	X	↑ 6.0% (Essential oil content)
29	***Nelumbo nucifera* Gaertner(レンニク、局外)**							
	CP SEMEN NELUMBINIS	O (TLC)	X	O (↓ 14.0%, Water)	X	X	X	X
*	JP NELUMBIS SEMEN	O	X	X	O (↓ 5.5%)	X	↑ 12.0% (Dilute ethanol-soluble extract)	X
	KP NELUMBINIS SEMEN	O	X	X	O (↓ 5.5%)	X	↑ 12.0% (Dilute ethanol-soluble extract)	X
	VP SEMEN NELUMBINIS	O	O (Foreign matter)	O (↓ 11.0%)	O (↓ 5.0%)	X	X	X
30	***Paeonia lactiflora* Pallas(シャクヤク)**							
	CP RADIX PAEONIAE ALBA	O (TLC)	O (Heavy metals, Arsenic)	X	X	X	X	Paeoniflorin ↑ 1.6% (HPLC)
	JP PAEONIAE RADIX	O (TLC)	X	O (↓ 14.0%)	O (↓ 6.5%)	O (↓ 0.5%)	X	Paeoniflorin ↑ 2.0% (HPLC)
	KP PAEONIAE RADIX	O (TLC)	X	X	O (↓ 6.5%)	O (↓ 0.5%)	X	Paeoniflorin ↑ 2.0% (HPLC)
	VP RADIX PAEONIAE	O (TLC)	X	X	X	X	X	X
31	***Paeonia suffruticosa* Andrews (ボタンピ)**							
	CP CORTEX MOUTAN	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 5.0%)	O (↓ 1.0%)	↑ 15.0% (Ethanol-soluble extract)	Paeonol ↑ 1.2% (HPLC)
	JP MOUTAN CORTEX	O (TLC)	O (Xylem, Foreign matter)	X	O (↓ 6.0%)	O (↓ 1.0%)	X	Paeonol ↑ 1.0% (HPLC)
	KP MOUTAN CORTEX RADICIS	O (TLC)	O (Xylem, Foreign matter)	X	O (↓ 6.0%)	O (↓ 1.0%)	X	Paeonol ↑ 1.0% (HPLC)
	VP CORTEX PAEONIA SUFFURUTICOSAE	O (TLC)	O (Wood, Foreign matter)	O (↓ 13.0%)	O (↓ 5.0%)	X	X	Paeonol ↑ 1.2% (Absorption)
32	***Panax ginseng* C. A. Meyer(ニンジン)**							
	CP RADIX ET RHIZOMA GINSENG	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 5.0%)	O (↓ 1.0%)	X	Ginsenoside Rg_1+Re ↑ 0.30% , Ginsenoside Rb_1 ↑ 0.20% (HPLC)
	JP GINSENG RADIX	O (TLC)	O (Foreign matter, Heavy metals, Arsenic, Total BHC, Total DDT)	X	O (↓ 4.2%)	X	↑ 14.0% (Dilute ethanol-soluble extract)	X
	KP GINSENG RADIX ALBA	O (TLC)	O (Foreign matter)	X	O (↓ 4.2%)	X	↑ 14.0% (Dilute ethanol-soluble extract)	X
	VP RADIX GINSENG	O (TLC)	X	X	X	X	X	X
33	***Platycodon grandiflorum* A. De Candolle(キキョウ)**							
	CP RADIX PLATYCODONIS	O (TLC)	X	X	X	X	X	Total saponin ↑ 6.0% (Dry weight)
	JP PLATYCODI RADIX	O	X	X	O (↓ 4.0%)	X	↑ 25.0% (Dilute ethanol-soluble extract)	X
	KP PLATYCODI RADIX	O	X	X	O (↓ 4.0%)	X	↑ 25.0% (Dilute ethanol-soluble extract)	X
	VP RADIX PLATYCODI GRANDIFLORI	O	O (Foreign matter)	O (↓ 9.0%)	O (↓ 4.0%)	O (↓ 1.0%)	X	Total saponin ↑ 5.0%
34	***Pogostemon cablin* Bentham(カッコウ、局外)**							
	CP HERBA POGOSTEMONIS	O (TLC)	O (Foreign matter, Leaves)	O (↓ 14.0%, Water)	O (↓ 11.0%)	O (↓ 4.0%)	↑ 2.5% (Ethanol-soluble extract)	Patchouli alcohol ↑ 0.10% (GC)
*	JP POGOSTEMONI HERBA	O	X	O (↓ 13.0%)	O (↓ 13.0%)	O (↓ 3.0%)	X	↑ 0.3 mL/50g (Essential oil content)
	KP POGOSTEMONIS HERBA	O	X	O (↓ 13.0%)	O (↓ 3.0%)	X	X	↑ 0.3 mL/50g (Essential oil content)
	VP HERBA POGOSTEMONIS	O (TLC)	O (Foreign matter)	O (↓ 12.0%, Water)	X	X	X	↑ 3% (Essential oil content)
35	***Polygonatum sibiricum* Redoute(オウセイ、局外)**							
	CP RHIZOMA POLYGONATI	O	X	O (↓ 18.0%, Water)	O (↓ 4.0%)	O (↓ 1.0%)	↑ 45.0% (Dilute ethanol-soluble extract)	Glucose ↑ 7.0% (Absorption)
*	JP POLYGONATI RHIZOMA	X	X	X	O (↓ 5.0%)	O (↓ 1.5%)	X	X
	KP POLYGONATI RHIZOMA	X	X	O (↓ 15.0%)	O (↓ 3.0%)	X	↑ 14.0% (Dilute ethanol-soluble extract)	X
	VP RHIZOMA POLYGONATI	X	O (Stems and rhizomes, other foreign matter)	O (↓ 14.0%, Water)	X	X	X	X

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
36	*Polyporus umbellatus* Fries(チョレイ)							
	CP POLYPORUS	O	X	X	O (↓ 12.0%)	X	X	X
	JP POLYPORUS	O	X	X	O (↓ 16.0%)	O (↓ 4.0%)	X	X
	KP POLYPORUS	O	X	X	O (↓ 16.0%)	O (↓ 4.0%)	X	X
	VP POLYPORUS	O	X	O (↓ 13.0%)	O (↓ 12.0%)	X	X	X
37	*Poria cocos* Wolf(ブクリョウ)							
	CP PORIA	O	X	O (↓ 15.0%, Water)	O (↓ 4.0%)	O (↓ 2.0%)	X	X
	JP PORIA	O	X	X	O (↓ 1.0%)	X	X	X
	KP HOELEN	O	X	X	O (↓ 1.0%)	X	X	X
	VP PORIA	O	O (Foreign matter)	O (↓ 12.0%)	X	X	X	X
38	*Prunus armeniaca* Linne, *P. armeniaca* Linne var. *ansu* Maximowicz(キョウニン)							
	CP SEMEN ARMENIACAE AMARUM	O (TLC)	O (Rancidity)	X	X	X	X	Amygdalin ↑ 3.0% (Titration)
	JP ARMENIACAE SEMEN	O (TLC)	O (Rancidity, Foreign matter)	X	X	X	X	X
	KP ARMENIACAE SEMEN	O (TLC)	O (Rancidity, Foreign matter)	X	X	X	X	Amygdalin ↑ 3.0% (HPLC)
	VP SEMEN ARMENIACAE AMARUM	O (TLC)	O (Foreign matter, inner pericarp)	O (↓ 7.0%, Water)	X	X	X	Amygdalin ↑ 3.0% (Titration)
39	*Prunus persica* Batsch, *P. persica* Batsch var *davidiana* Maximowicz(トウニン)							
	CP SEMEN PERSICAE	O	O (Rancidity)	X	X	X	X	X
	JP PERSICAE SEMEN	O (TLC)	O (Rancidity, Foreign matter)	X	X	X	X	X
	KP PERSICAE SEMEN	O (TLC)	O (Rancidity, Foreign matter)	X	X	X	X	Amygdalin ↑ 0.5% (HPLC)
	VP SEMEN PRUNI	X	O (Foreign matter)	O (↓ 7.0%, Water)	X	X	X	X
40	*Rheum palmatum* Linne(ダイオウ)							
	CP RADIX ET RHIZOMA RHEI	O (TLC)	O (Raponticin)	O (↓ 15.0%)	O (↓ 10.0%)	O (↓ 0.8%)	↑ 25.0% (Water-soluble extract)	Aloeemodin+Rhein+Emodin+Chrysophanol+Physcion ↑ 1.5% (HPLC)
	JP RHEI RHIZOMA	O (TLC)	O (Raponticin)	O (↓ 13.0%)	O (↓ 13.0%)	X	↑ 30.0% (Dilute ethanol-soluble extract)	Sennoside A ↑ 0.25% (HPLC)
	KP RHEI RHIZOMA	O (TLC)	O (Raponticin)	O (↓ 13.0%)	O (↓ 13.0%)	O (↓ 2.0%)	X	Sennoside A ↑ 0.25% (HPLC)
	VP RHIZOMA RHEI	O (TLC)	O	O (↓ 12.0%)	O (↓ 13.0%)	O (↓ 2.0%)	X	Hydroxy anthracen ↑ 2.2% (Absorption)
41	*Schisandra chinensis* Baillon(ゴミシ)							
	CP FRUCTUS SCHISANDRAE CHINENSIS	O (TLC)	O (Foreign matter)	X	X	X	X	Schizandrin ↑ 0.40% (HPLC)
	JP SCHISANDRAE FRUCTUS	O (TLC)	O (Foreign matter)	X	O (↓ 5.0%)	X	X	X
	KP SCHIZANDRAE FRUCTUS	O (TLC)	O (Foreign matter)	X	O (↓ 5.0%)	X	X	X
	VP FRUCTUS SCHISANDRAE	O (TLC)	O (Foreign matter)	O (↓ 13.0%, Water)	X	X	X	X
42	*Scutellaria baicalensis* Georgi(オウゴン)							
	CP RADIX SCUTELLARIAE	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 6.0%)	X	↑ 40.0% (Dilute ethanol-soluble extract)	Baicalin ↑ 9.0% (HPLC)
	JP SCUTELLARIAE RADIX	O (TLC)	X	O (↓ 12.0%)	O (↓ 6.0%)	X	X	Baicalin ↑ 10.0% (HPLC)
	KP SCUTELLARIAE RADIX	O (TLC)	X	O (↓ 15.0%)	O (↓ 6.0%)	O (↓ 1.0%)	X	Baicalin ↑ 10.0% (HPLC)
	VP RADIX SCUTELLARIAE	O	X	O (↓ 12.0%)	O (↓ 6.0%)	X	X	Flavonoid calculated as Baicalin ↑ 4.0% (Absorption)
43	*Strychnos nux-vomica* Linne(ホミカ)							
	CP SEMEN STRYCHNI	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 2.0%)	X	X	Strychnine 1.20-2.20%, Brucine ↑ 0.80% (HPLC)
	JP STRYCHNI SEMEN	O	X	X	O (↓ 3.0%)	X	X	Strychnine ↑ 1.07% (HPLC)
	KP STRYCHNI SEMEN	O	X	X	O (↓ 3.0%)	X	X	Strychnine ↑ 1.05% (HPLC)
	VP SEMEN STRYCHNI	O (TLC)	O (Flat and black seed, Foreign matter)	O (↓ 12.0%)	O (↓ 3.5%)	O (↓ 0.6%)	X	Strychnine ↑ 1.2% (Absorption)
44	*Trichosanthes kirilowii* Maximowicz(カロコン)							
	CP RADIX TRICHOSANTHIS	O (TLC)	X	X	X	X	X	X
	JP TRICHOSANTHIS RADIX	X	X	X	O (↓ 4.0%)	X	X	X
	KP TRICHOSANTHIS RADIX	X	X	X	O (↓ 4.0%)	X	X	X
	VP RADIX TRICHOSANTHIS	O (TLC)	O (Foreign matter)	O (↓ 11.0%)	X	X	X	X
45	*Trichosanthes kirilowii* Maximowicz(カロニン、局外)							
	CP SEMEN TRICHOSANTHIS	X	X	O (↓ 10.0%, Water)	O (↓ 3.0%)	X	↑ 4.0% (Petoleum ether-soluble extract)	X
*	JP TRICHOSANTHIS SEMEN	O	X	X	O (↓ 4.0%)	X	X	X
	KP TRICHOSANTHIS SEMEN	O	O (Unriped seed)	O (↓ 6.0%)	O (↓ 3.0%)	X	↑ 6.0% (Water-soluble extract)	X
	VP SEMEN TRICHOSANTHIS	X	O (Rotten and thin seeds)	O (↓ 10.0%, Water)	X	X	X	X
46	*Zingiber officinale* Roscoe(ショウキョウ)							
	CP RHIZOMA ZINGIBERIS RECENS	X	X	X	X	X	X	X
	JP ZINGIBERIS RHIZOMA	O (TLC)	X	X	O (↓ 8.0%)	X	X	X
	KP ZINGIBERIS RHIZOMA	O (TLC)	X	X	O (↓ 8.0%)	X	X	6-Gingerol ↑ 0.4% (HPLC)
	VP RHIZOMA ZINGIBERIS	O	O (Young, Foreign matter)	O (↓ 13.0%, Water)	O (↓ 6.0%)	O (↓ 3.0%)	↑ 10.0% (Water-soluble extract)	↑ 1.5% (Essential oil content)
47	*Zizyphus jujuba* Miller var. *spinosa* (Bunge) Hu ex H. F. Chou(サンソウニン)							
	CP SEMEN ZIZIPHI SPINOSAE	O (TLC)	O (Foreign matter)	X	X	X	X	X
	JP ZIZYPHI SEMEN	O (TLC)	O (Foreign matter)	O (↓ 11.0%)	O (↓ 5.0%)	X	↑ 9.0% (Dilute ethanol-soluble extract)	X
	KP ZIZYPHI SEMEN	O	O (Foreign matter)	X	O (↓ 7.0%)	X	X	X
	VP SEMEN ZIZIPHI MAURITIANAE	O (TLC)	O (Broken seed)	O (↓ 8.0%, Water)	X	X	X	X

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
48	*Coix lacryma-jobi* Linne var. *ma-yuen* Stapf(ヨクイニン)							
	CP SEMEN COICIS	O	X	O (↓ 15.0%, Water)	O (↓ 3.0%)	X	↑ 5.5% (1-Butanol-soluble extract)	Glycerin trioleate ↑ 0.50% (HPLC)
	JP COICIS SEMEN	O	X	O (↓ 14.0%)	O (↓ 3.0%)	X	X	X
	KP COICIS SEMEN	O	X	O (↓ 14.0%)	O (↓ 3.0%)	X	X	X
	VP SEMEN COICIS	O (Powder)	O (Foreign matter)	O (↓ 12.0%)	O (↓ 2.0%)	X	X	X
49	*Imperata cylindrica* Beauvois(ボウコン)							
	CP RHIZOMA IMPERATAE	O	X	X	O (↓ 5.0%)	X	X	X
	JP IMPERATAE RHIZOMA	O	O (Rootlet and scaly leaf, Foreign matter)	X	O (↓ 5.0%)	O (↓ 1.5%)	X	X
	KP IMPERATAE RHIZOMA	O	O (Rootlet and scaly leaf, Foreign matter)	X	O (↓ 5.0%)	O (↓ 1.5%)	X	X
	VP RHIZOMA IMPERATAE CYLINDRICAE	O	X	O (↓ 12.0%)	O (↓ 6.0%)	O (↓ 3.0%)	X	X
50	*Mentha arvensis* Linne var. *piperascens* Malinvaud(ハッカ)							
	CP HERBA MENTHAE	O (TLC)	O (Leaves)	X	X	X	X	↑ 0.80% (Essential oil content)
	JP MENTHAE HERBA	O	O (Foreign matter)	O (↓ 15.0%)	O (↓ 11.0%)	O (↓ 2.5%)	X	↑ 0.4 mL/50g (Essential oil content)
	KP MENTHAE HERBA	O	O (Foreign matter)	O (↓ 15.0%)	O (↓ 11.0%)	O (↓ 2.5%)	X	↑ 0.4 mL/50g (Essential oil content)
	VP HERBA MENTHAE ARVENSIS	O (TLC)	O (Inorganic, Organic foreign matter, Stem)	O (↓ 13.0%, Water)	O (↓ 13.0%)	X	X	↑ 0.5% (Essential oil content)
51	*Prunella vulgaris* Linne var. *lilacina* Nakai(カゴソウ)							
	CP SPICA PRUNELLAE	O (TLC)	X	O (↓ 14.0%, Water)	O (↓ 12.0%)	O (↓ 4.0%)	↑ 10.0% (Water-soluble extract)	Ursoric acid ↑ 0.12% (HPLC)
	JP PRUNELLAE SPICA	X	O (Stem, Foreign matter)	X	O (↓ 13.0%)	O (↓ 5.0%)	X	X
	KP PRUNELLAE SPICA	X	O (Stem, Foreign matter)	X	O (↓ 13.0%)	O (↓ 5.0%)	X	X
	VP SPICA PRUNELLAE	O (TLC)	O (Stem, Foreign matter)	O (↓ 12.0%)	O (↓ 10.0%)	X	X	X
52	*Zizyphus jujuba* Miller var. *inermis* Rehder(タイソウ)							
	CP FRUCTUS JUJUBAE	O (TLC)	X	X	O (↓ 2.0%)	X	X	X
	JP ZIZYPHI FRUCTUS	X	O (Rancidity)	X	O (↓ 3.0%)	X	X	X
	KP ZIZYPHI FRUCTUS	X	O (Rancidity)	X	O (↓ 3.0%)	X	X	X
	VP FRUCTUS ZIZIPHI JUJUBAE	X	X	O (↓ 13.0%, Water)	O (↓ 2.0%)	X	X	X
53	*Aconitum carmichaeli* Debeaux(ブシ)							
	CP RADIX ACONITI LATERALIS PREPARATA	O	O (Limit test for acontine)	X	X	X	X	X
	JP PROCESSI ACONITI RADIX	O (TLC)	O (Limit test for acontine, jesaconitine, hypaconitine, mesaconitine)	O (↓ 15.0%)	O (Type 1 ↓ 4.0%, Type 2 ↓ 12.0%, Type 3 ↓ 19.0%)	O (↓ 0.9%)	X	Total alkaroid Type 1: 0.7–1.5%, Type 2: 0.1–0.6%, Type 3: 0.5–0.9% (Titration)
	KP ACONITI LATERALIS RADIX PREPARATA	O	O (Acontine)	X	X	X	X	X
	VP RADIX ACONITI LATERALIS PREPARATA	O	O (Limit test for acontine)	X	X	X	X	X
54	*Epimedium koreanum* Nakai(インヨウカク)							
	CP HERBA EPIMEDII	O (TLC)	O (Foreign matter)	O (↓ 12.0%, Water)	O (↓ 8.0%)	O (↓ 1.0%)	↑ 15.0% (Dilute ethanol-soluble extract)	Icariin ↑ 0.50% (HPLC)
	JP EPIMEDII HERBA	O (TLC)	X	O (↓ 12.5%)	O (↓ 8.5%)	O (↓ 2.0%)	↑ 17.0% (Dilute ethanol-soluble extract)	X
	KP EPIMEDII HERBA	O (TLC)	X	O (↓ 13.0%)	O (↓ 8.0%)	O (↓ 0.9%)	↑ 17.0% (Dilute ethanol-soluble extract)	X
	VP HERBA EPIMEDII	O (TLC)	X	O (↓ 13.0%)	X	X	X	X
55	*Curcuma longa* Linne(ウコン)							
	CP RHIZOMA CURUCUMAE LONGAE	O (TLC)	X	O (↓ 16.0%, Water)	O (↓ 7.0%)	O (↓ 1.0%)	↑ 12.0% (Dilute ethanol-soluble extract)	↑ 7.0% (Essential oil content), Curcumin ↑ 1.0% (HPLC)
	JP CURCUMAE RHIZOMA	O (TLC)	X	O (↓ 17.0%)	O (↓ 7.5%)	O (↓ 1.0%)	↑ 9.0% (Dilute ethanol-soluble extract)	X
	KP CURCUMAE LONGAE RHIZOMA	O (TLC)	O (Artificial coloring)	O (↓ 16.0%)	O (↓ 9.0%)	X	X	X
	VP RHIZOMA CURUCUMAE LONGAE	O (TLC)	O (Foreign matter)	O (↓ 12.0%, Water)	O (↓ 8.0%)	X	↑ 8.0% (Ethanol-soluble extract)	X
56	*Notopterygium incisum* Ting ex H. T. Chang, *N. forbesii* Boissieu(キョウカツ)							
	CP RHIZOMA ET RADIX NOTOPTERYGII	X	X	X	X	X	↑ 15.0% (Ethanol-soluble extract)	↑ 2.8% (Essential oil content)
	JP NOTOPTERYGII RHIZOMA	O (TLC)	X	O (↓ 13.0%)	O (↓ 6.5%)	O (↓ 1.5%)	↑ 20.0% (Dilute ethanol-soluble extract)	X
	KP OSTERICI RADIX	O	O (Foreign matter)	O (↓ 12.0%)	O (↓ 10.0%)	O (↓ 2.0%)	↑ 20.0% (Dilute ethanol-soluble extract)	↑ 0.2 mL/50g (Essential oil content)
	VP RHIZOMA SEU RADIX NOTOPTERYGII	O (Powder)	O (Foreign matter)	O (↓ 15.0%, Water)	X	X	X	X
57	*Arisaema erubescens* Schott, *A. heterophyllum* Blume(テンナンショウ、局外)							
	CP RHIZOMA ARISAEMATIS	O	X	X	X	X	X	X
*	JP ARISAEMATIS TUBER	O	X	O (↓ 13.0%)	O (↓ 5.0%)	X	X	X
	KP ARISAEMATIS RHIZOMA	O	X	O (↓ 15.0%)	O (↓ 5.0%)	O (↓ 1.0%)	X	X
	VP RHIZOMA ARISAEMATIS	O (Powder)	O (Foreign matter)	O (↓ 14.0%)	X	X	X	X
58	*Cassia obtusifolia* Linne, *C. tora* Linne(ケツメイシ)							
	CP SEMEN CASSIAE	O (TLC)	X	X	O (↓ 5.0%)	X	X	Crysophanol ↑ 0.080% (HPLC)
	JP CASSIAE SEMEN	O	O (Foreign matter)	X	O (↓ 5.0%)	X	X	X
	KP CASSIAE SEMEN	O	O (Foreign matter)	X	O (↓ 5.0%)	X	X	X
	VP SEMEN CASSIAE TORAE	O	O (Thin seeds, Foreign matter)	O (↓ 12.0%, Water)	O (↓ 7.0%)	X	X	X

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
59	***Gentiana scabra*** **Bunge (ゲンチアナ)**							
	CP RADIX ET RHIZOMA GENTIANAE	O (TLC)	X	X	O (↓ 7.0%)	X	X	Gentiopicrin ↑ 1.0% (HPLC)
	JP GENTIANAE SCABRAE RADIX	O (TLC)	X	X	O (↓ 6.0%)	O (↓ 3.0%)	X	X
	KP GENTIANAE SCABRAE RADIX	O (TLC)	X	X	O (↓ 7.0%)	O (↓ 3.0%)	X	X
	VP RADIX GENTIANAE	O	O (Seeds, Foreign matter)	O (↓ 12.0%, Water)	X	X	X	X
60	***Lycium barbarum*** **Linne, *L. chinense* Miller (クコシ)**							
	CP FRUCTUS LYCII	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 5.0%)	X	↑ 55.0% (Water-soluble extract)	Glucose ↑ 1.8% (Absorption), Betaine ↑ 0.30% (HPLC)
	JP LYCII FRUCTUS	O (TLC)	O (Foreign matter)	X	O (↓ 8.0%)	O (↓ 1.0%)	↑ 35.0% (Dilute ethanol-soluble extract)	X
	KP LYCII FRUCTUS	O	O (Foreign matter)	X	O (↓ 6.0%)	X	X	Betaine ↑ 0.5% (HPLC)
	VP FRUCTUS LYCII	O (Powder)	O (Foreign matter)	O (↓ 15.0%, Water)	X	X	X	X
61	***Phellodendron amurense*** **Ruprecht, *P. chinense* Schneider (オウバク)**							
	CP CORTEX PHELLODENDRI AMURENSIS	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 8.5%)	X	X	Berberine ↑ 0.6% (HPLC)
	CORTEX PHELLODENDRI CHINENSIS	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 8.0%)	X	↑ 14.0% (Dilute ethanol-soluble extract)	Berberine ↑ 3.0% (HPLC)
	JP PHELLODENDRI CORTEX	O (TLC)	X	O (↓ 9.0%)	O (↓ 7.5%)	O (↓ 0.5%)	X	Berberine ↑ 1.2% (HPLC)
	KP PHELLODENDRI CORTEX	O (TLC)	X	O (↓ 9.0%)	O (↓ 7.5%)	X	X	Berberine ↑ 0.6% (HPLC)
	VP CORTEX PHELLODENDRI	O	O (Foreign matter)	O (↓ 13.0%)	X	X	X	Berberine ↑ 2.5% (Absorption)
62	***Plantago asiatica*** **Linne (シャゼンシ)**							
	CP SEMEN PLANTAGINIS	O	O (Swelling capacity)	O (↓ 12.0%, Water)	O (↓ 6.0%)	O (↓ 2.0%)	X	X
	JP PLANTAGINIS SEMEN	O	O (Foreign matter)	X	O (↓ 5.5%)	O (↓ 2.0%)	X	X
	KP PLANTAGINIS SEMEN	O	O (Foreign matter)	X	O (↓ 5.5%)	O (↓ 2.0%)	X	X
	VP SEMEN PLANTAGINIS	O (Powder)	O (Flat seeds, Swelling capacity)	O (↓ 10.0%, Water)	X	X	X	X
63	***Polygala tenuifolia*** **Willdenow (オンジ)**							
	CP RADIX POLYGALAE	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 6.0%)	O (↓ 1.5%)	↑ 20.0% (70% ethanol-soluble extract)	Polygalic acid ↑ 0.70% (HPLC)
	JP POLYGALAE RADIX	O	O (Stem, Foreign matter)	X	O (↓ 6.0%)	X	X	X
	KP POLYGALAE RADIX	O	O (Stem, Foreign matter)	X	O (↓ 6.0%)	X	X	X
	VP RADIX POLYGALAE	O	O (Core-wood, Stem, Foreign matter)	O (↓ 14.0%, Water)	O (↓ 6.0%)	X	X	X
64	***Pueraria lobata*** **Ohwi (カッコン)**							
	CP RADIX PUERARIAE LOBATAE	O (TLC)	X	O (↓ 14.0%, Water)	O (↓ 7.0%)	X	X	Puerarin ↑ 2.4% (HPLC)
	JP PUERARIAE RADIX	O (TLC)	X	O (↓ 13.0%)	O (↓ 6.0%)	X	X	Puerarin ↑ 2.0% (HPLC)
	KP PUERARIAE RADIX	O (TLC)	X	O (↓ 13.0%)	O (↓ 6.0%)	X	X	Puerarin ↑ 2.0% (HPLC)
	VP RADIX PUERARIAE	O (Powder)	O (Foreign matter)	O (↓ 12.0%)	O (↓ 5.0%)	X	X	X
65	***Rehmannia glutinosa*** **Liboschitz (ジオウ)**							
	CP RADIX REHMANNIAE	O (TLC)	X	O (↓ 15.0%, Water)	O (↓ 6.0%)	O (↓ 2.0%)	↑ 65.0% (Water-soluble extract)	Catalnol ↑ 0.20%
	JP REHMANNIAE RADIX	X	X	X	O (↓ 6.0%)	O (↓ 2.5%)	X	X
	KP REHMANNIAE RADIX	X	O (Foreign matter)	X	O (↓ 6.0%)	O (↓ 2.0%)	X	X
	VP RADIX REHMANNIAE GLUTINOSAE	O (TLC)	O (Foreign matter)	O (↓ 18.0%, Water)	O (↓ 5.0%)	X	X	X
66	***Scrophularia ningpoensis*** **Hemsley, *S. buergeriana* Miquel (ゲンジン、局外)**							
	CP RADIX SCROPHULARIAE	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 5.0%)	O (↓ 1.8%)	↑ 60.0% (Water-soluble extract)	Harpagoside ↑ 0.050% (HPLC)
*	JP SCROPHULARIAE RADIX	O	X	O (↓ 17.0%)	O (↓ 6.0%)	O (↓ 2.0%)	X	X
	KP SCROPHULARIAE RADIX	O	X	O (↓ 17.0%)	O (↓ 6.0%)	O (↓ 2.0%)	↑ 24.0% (Dilute ethanol-soluble extract)	X
	VP RADIX SCROPHULARIAE	O	X	O (↓ 14.0%)	O (↓ 4.0%)	X	X	X
67	***Geranium thunbergii*** **Siboid et Zuccarini (ゲンノショウコ)**							
	CP							
	JP GERANII HERBA	O	O (Foreign matter)	X	O (↓ 10.0%)	O (↓ 1.5%)	↑ 15.0% (Dilute ethanol-soluble extract)	X
	KP GERANII HERBA	O	O (Foreign matter)	X	O (↓ 10.0%)	O (↓ 1.5%)	↑ 15.0% (Dilute ethanol-soluble extract)	X
	VP HERBA GERANII THUNBERGII	O	O (Root, Foreign matter)	O (↓ 12.0%)	O (↓ 10.0%)	O (↓ 6.0%)	X	↑ 13.0% (tannin)
68	***Curcuma zedoaria*** **Roscoe (ガジュツ)**							
	CP							
	JP ZEDOARIAE RHIZOMA	X	X	X	O (↓ 7.0%)	X	X	↑ 0.5 mL/50g (Essential oil content)
	KP ZEDOARIAE RHIZOMA	X	X	X	O (↓ 7.0%)	X	X	↑ 0.5 mL/50g (Essential oil content)
	VP RHIZOMA CURUCUMAE ZEDOARIAE	X	O (Stem and pericladia, Foreign matter)	O (↓ 13.0%, Water)	O (↓ 7.0%)	X	X	↑ 1.0% (Essential oil content)
69	***Piper nigrum*** **Linne (コショウ)**							
	CP FRUCTUS PIPERIS	O (TLC)	X	X	X	X	X	Piperine ↑ 3.0% (HPLC)
	JP							
	KP PIPERIS NIGRI FRUCTUS	X	O (Foreign matter)	X	O (↓ 7.0%)	X	X	X
	VP FRUCTUS PIPERIS NIGRI	O (TLC)	X	O (↓ 11.0%, Water)	X	X	X	↑ 1.0% (Essential oil content)

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
70	***Salvia miltiorrhiza*** **Bunge (タンジン)**							
	CP RADIX ET RHIZOMA SALVIAE MILTIORRHIZAE	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 10.0%)	O (↓ 3.0%)	↑ 35.0% (Water-soluble extract), ↑ 15.0% (Ethanol-soluble extract)	Tanshinone IIA ↑ 0.20%, Salvinolic acid B ↑ 3.0% (HPLC)
	JP							
	KP SALVIAE MILTIORRHIZAE RADIX	O (TLC)	X	O (↓ 12.0%)	O (↓ 7.0%)	X	↑ 25.0% (Dilute ethanol-soluble extract)	X
	VP RADIX SALVIAE MILTIORRHIZAE	O	O (Foreign matter)	O (↓ 12.0%)	X	X	X	X
71	***Crataegus pinnatifida*** **Bunge var. *major* N.E. Brown (サンザシ、局外)**							
	CP FRUCTUS CRATAEGI	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 3.0%)	X	↑ 21.0% (Ethanol-soluble extract)	Citric acid ↑ 5.0% (Titration)
*	JP CRATAEGI FRUCTUS	O	X	X	O (↓ 6.0%)	X	X	X
	KP CRATAEGI FRUCTUS	O	X	X	O (↓ 6.0%)	X	X	X
	VP							
72	***Areca catechu*** **Linne (ビンロウジ)**							
	CP SEMEN ARECAE	O (TLC)	X	O (↓ 10.0%, Water)	X	X	X	Arecoline ↑ 0.30% (Titration)
	JP ARECAE SEMEN	O (TLC)	O (Pericarp, Foreign matter)	X	O (↓ 2.5%)	X	X	X
	KP ARECAE SEMEN	O (TLC)	O (Pericarp, Foreign matter)	X	O (↓ 2.5%)	X	X	X
	VP							
73	***Cassia angustifolia*** **Vahl, *C. acutifolia*** **Delile (センナ)**							
	CP FOLIUM SENNAE	O (TLC)	O (Foreign matter)	O (↓ 10.0%, Water)	X	X	X	Sennoside B ↑ 2.5% (Absorption)
	JP SENNAE FOLIUM	O (TLC)	O (Rachis and fruit, Foreign matter, Total BHC and DDT)	O (↓ 12.0%)	O (↓ 12.0%)	O (↓ 2.0%)	X	Total Sennoside ↑ 1.0% (HPLC)
	KP SENNAE FOLIUM	O (TLC)	O (Rachis and fruit, Foreign matter)	O (↓ 12.0%)	O (↓ 12.0%)	O (↓ 2.0%)	X	Total Sennoside ↑ 1.0% (HPLC)
	VP							
74	***Crocus sativus*** **Linne (サフラン)**							
	CP STIGMA CROCI	O (TLC)	O (Absorbance)	O (↓ 12.0%)	O (↓ 7.5%)	O (↓ 1.5%)	↑ 55.0% (30%Ethanol-soluble extract)	Crocin I+II ↑ 10.0%, (HPLC)
	JP CROCUS	O	O (Aniline dyes, Glycerol, Sugar or honey, Yellow style)	O (↓ 12.0%)	O (↓ 7.5%)	X	X	Crocin (Content)
	KP CROCUS	O (Crocin)	O (Aniline dyes, Glycerol, Sugar or honey, Yellow style)	O (↓ 12.0%)	O (↓ 7.5%)	X	X	X
	VP							
75	***Dioscorea batatas*** **Decaisne (サンヤク)**							
	CP RHIZOMA DIOSCOREAE	X	X	X	X	X	X	X
	JP DIOSCOREAE RHIZOMA	O	X	O (↓ 14.0%)	O (↓ 6.0%)	O (↓ 0.5%)	X	X
	KP DIOSCOREAE RHIZOMA	O	X	O (↓ 14.0%)	O (↓ 6.0%)	O (↓ 0.5%)	X	X
	VP							
76	***Syzygium aromaticum*** **Merrill et Perry (チョウジ)**							
	CP FLOS CARYOPHYLLI	O (TLC)	O (Foreign matter)	O (↓ 12.0%, Water)	X	X	X	Eugenol ↑ 11.0% (GC)
	JP CARYOPHYLLI FLOS	O	O (Stem, Foreign matter)	X	O (↓ 7.0%)	O (↓ 0.5%)	X	↑ 1.6 mL/50g (Essential oil content)
	KP SYZYGII FLOS	O	O (Stem, Foreign matter)	X	O (↓ 7.0%)	O (↓ 0.5%)	X	↑ 1.6 mL/10g (Essential oil content)
	VP							
77	***Pharbitis nil*** **Choisy (ケンゴシ)**							
	CP SEMEN PHARBITIDIS	O (TLC)	X	O (↓ 10.0%, Water)	O (↓ 5.0%)	O (↓ 1.0%)	↑ 15.0% (Ethanol-soluble extract)	Caffeic acid+Caffeic acid ethyl ester ↑ 0.20% (HPLC)
	JP PHARBITIDIS SEMEN	X	X	X	O (↓ 6.0%)	X	X	X
	KP PHARBITIDIS SEMEN	X	X	X	O (↓ 6.0%)	X	X	X
	VP							
78	***Saposhnikovia divaricata*** **Schiskin (ボウフウ)**							
	CP RADIX SAPOSHNIKOVIAE	O (TLC)	X	O (↓ 10.0%, Water)	O (↓ 6.5%)	O (↓ 1.5%)	↑ 13.0% (Ethanol-soluble extract)	Cimicifugoside+5-Methoxyvisaminol ↑ 0.24% (HPLC)
	JP SAPOSHNIKOVIAE RADIX	X	O (Foreign matter)	X	O (↓ 7.0%)	O (↓ 1.5%)	↑ 20.0% (Dilute ethanol-soluble extract)	X
	KP SAPOSHNIKOVIAE RADIX	X	O (Foreign matter)	X	O (↓ 7.0%)	O (↓ 1.5%)	↑ 20.0% (Dilute ethanol-soluble extract)	X
	VP							
79	***Sophora flavescens*** **Aiton (クジン)**							
	CP RADIX SOPHORAE FLAVESCENTIS	O (TLC)	X	O (↓ 11.0%, Water)	O (↓ 8.0%)	O (↓ 1.5%)	↑ 20.0% (Water-soluble extract)	Matrine+Oxymatrine ↑ 1.2% (HPLC)
	JP SOPHORAE RADIX	O	O (Stem, Foreign matter)	X	O (↓ 6.0%)	O (↓ 1.5%)	X	X
	KP SOPHORAE RADIX	O	O (Stem, Foreign matter)	X	O (↓ 6.0%)	O (↓ 1.5%)	X	X
	VP							
80	***Sophora japonica*** **Linne (カイカ、局外)**							
	CP FLOS SOPHORAE	O (TLC)	X	X	X	X	↑ 37.0% (30% Methanol-soluble extract)	Rutin ↑ 6.0% (HPLC)
*	JP SOPHORAE FLOS	O (TLC)	X	O (↓ 10.0%)	X	O (↓ 1.5%)	X	X
	KP SOPHORAE FLOS	O (TLC)	O (Foreign matter, Rutin)	X	O (↓ 9.0%)	X	X	X
	VP							

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
81	*Perilla frutescens* Britton var. *acuta* Kudo (シソシ、局外)							
	CP FRUCTUS PERILLAE	X	X	X	X	X	X	X
*	JP PERILLAE FRUCTUS	O	X	X	O (↓ 10.0%)	O (↓ 6.0%)	X	X
	KP							
	VP FRUCTUS PERILLAE	X	O (Foreign matter)	O (↓ 12.0%, Water)	X	X	X	X
82	*Aloe ferox* Miller (アロエ)							
	CP ALOE	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 4.0%)	O (↓ 1.0%)	↑ 60.0% (Ethanol-soluble extract)	Barbaloin ↑ 6.0% (HPLC)
	JP ALOE	O (TLC)	O (Resin, Ethanol-insoluble substances)	O (↓ 12.0%)	O (↓ 2.0%)	X	↑ 40.0% (Water-soluble extract)	Barbaloin ↑ 4.0% (HPLC)
	KP							
	VP ALOE	O	X	X	X	X	X	Hydroxyanthoracen ↑ 28.0% (Absorption)
83	*Alpinia officinarum* Hance (リョウキョウ)							
	CP RHIZOMA ALPINIAE OFFICINARUM	O	X	O (↓ 16.0%, Water)	O (↓ 4.0%)	O (↓ 1.0%)	X	Cineol ↑ 0.15% (GC)
	JP ALPINIAE OFFICINARI RHIZOMA	O (TLC)	X	O (↓ 15.0%)	O (↓ 7.5%)	O (↓ 1.5%)	↑ 14.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP RHIZOMA ALPINIAE OFFICINARUM	X	X	X	X	X	X	X
84	*Angelica pubescens* Maximowicz (トウドッカツ)							
	CP RADIX ANGELICAE PUBESCENTIS	O (TLC)	X	X	O (↓ 8.0%)	X	↑ 3.0% (Ether-soluble extract)	Osthol ↑ 0.50% (HPLC)
*	JP ANGELICAE PUBESCENTIS RADIX	O	O (Stone cork cell, Calcium oxalate)	O (↓ 15.0%)	O (↓ 9.0%)	O (↓ 1.0%)	X	X
	KP							
	VP RADIX ANGELICAE PUBESCENTIS	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 8.0%)	X	↑ 3.0% (Ether-soluble extract)	X
85	*Arctium lappa* Linne (ゴボウシ)							
	CP FRUCTUS ARCTII	O (TLC)	X	X	O (↓ 7.0%)	O (↓ 2.0%)	X	Arctiin ↑ 5.0% (HPLC)
	JP ARCTII FRUCTUS	O (TLC)	X	O (↓ 12.0%)	O (↓ 7.0%)	O (↓ 1.0%)	↑ 15.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP FRUCTUS ARCTII	O	X	O (↓ 12.0%)	O (↓ 7.0%)	X	X	X
86	*Areca catechu* Linne (ダイフクヒ、局外)							
	CP PERICARPIUM ARECAE	O	X	O (↓ 12.0%, Water)	X	X	X	X
*	JP ARECAE PERICARPIUM	O	X	O (↓ 11.0%)	O (↓ 6.0%)	X	X	X
	KP							
	VP PERICARPIUM ARECAE CATECHI	O (Powder)	O (Foreign matter)	O (↓ 12.0%)	X	X	X	X
87	*Aster tataricus* Linne fil. (シオン、局外)							
	CP RADIX ET RHIZOMA ASTERIS	O (TLC)	X	X	O (↓ 15.0%)	O (↓ 8.0%)	X	Friedelin ↑ 0.10% (HPLC)
*	JP ASTERIS RADIX	O	X	O (↓ 18.0%)	O (↓ 12.0%)	O (↓ 6.0%)	↑ 30.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP RADIX ASTERIS	O	X	O (↓ 12.0%)	O (↓ 15.0%)	O (↓ 8.0%)	X	X
88	*Saussurea lappa* Clarke (モッコウ)							
	CP RADIX AUCKLANDIAE	O (TLC)	X	X	O (↓ 4.0%)	X	X	Costunolide+Dehydrocostunolide ↑ 1.8% (HPLC)
	JP SAUSSUREAE RADIX	O	O (Foreign matter)	X	O (↓ 4.0%)	X	↑ 17.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP RADIX SAUSSUREAE LAPPAE	O	O (Foreign matter)	O (↓ 15.0%, Water)	X	X	X	↑ 0.4% (Essential oil content)
89	*Chrysanthemum indicum* Linne (キクカ)							
	CP FLOS CHRYSANTHEMI INDICI	O (TLC)	X	O (↓ 14.0%, Water)	O (↓ 9.0%)	O (↓ 2.0%)	X	Buddoleoside ↑ 0.80% (HPLC)
	JP CHRYSANTHEMI FLOS	O (TLC)	X	O (↓ 15.0%)	O (↓ 8.5%)	O (↓ 1.0%)	↑ 30.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP FLOS CHRYSANTHEMI INDICI	O (TLC)	X	O (↓ 13.0%)	X	X	X	X
90	*Citrus aurantium* Linne (キジツ)							
	CP FRUCTUS AURANTII IMMATURUS	O (TLC)	X	O (↓ 15.0%, Water)	O (↓ 7.0%)	O (↓ 1.0%)	↑ 12.0% (70%Ethanol-soluble extract)	Synephrine ↑ 0.30% (HPLC)
	JP AURANTII FRUCUTUS IMMATURUS	O	X	X	O (↓ 7.0%)	X	X	X
	KP							
	VP FRUCTUS AURANTII IMMATURUS	O (TLC)	O (Foreign matter)	O (↓ 12.0%, Water)	O (↓ 7.0%)	X	X	X
91	*Clematis chinensis* Osbeck, *C. manshurica* Ruprecht, *C. hexapetala* Pallas (イレイセン)							
	CP RADIX ET RHIZOMA CLEMATIDIS	O (TLC)	X	O (↓ 15.0%, Water)	O (↓ 10.0%)	X	↑ 15.0% (Ethanol-soluble extract)	X
	JP CLEMATIDIS RADIX	O	X	O (↓ 13.0%)	O (↓ 8.5%)	O (↓ 3.0%)	↑ 15.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP RADIX CLEMATIDIS	X	X	O (↓ 12.0%)	O (↓ 10.0%)	X	↑ 15.0% (Ethanol-soluble extract)	X
92	*Cnidium monnieri* Cusson (ジャショウシ)							
	CP FRUCTUS CNIDII	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 13.0%)	O (↓ 6.0%)	↑ 7.0% (Ethanol-soluble extract)	Osthol ↑ 1.0% (HPLC)
	JP CNIDII MONNIERIS FRUCTUS	O (TLC)	X	O (↓ 12.0%)	O (↓ 17.0%)	O (↓ 6.0%)	↑ 8.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP FRUCTUS CNIDII	O (TLC)	O (Foreign matter)	O (↓ 13.0%, Water)	X	X	X	↑ 1.0% (Essential oil content)

No.	Latin name	Identification	Purification	Loss on drying	Total ash	Acid insoluble ash	Extract content	Assay (Essential oil content)
		(O: Established, X: Not established, ↓ : Not more than, ↑ : Not less than)						
93	*Diospyros kaki* Thunberg (シテイ、局外)							
	CP CALYX KAKI	O (TLC)	X	X	X	X	X	X
*	JP KAKI CALYX	O	X	O (↓ 15.0%)	O (↓ 8.0%)	O (↓ 1.0%)	↑ 12.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP CALYX KAKI	X	X	O (↓ 12.0%)	X	X	X	X
94	*Eriobotrya japonica* Lindley (ビワヨウ)							
	CP FOLIUM ERIOBOTRYAE	O	X	X	X	X	↑ 10.0% (Water-soluble extract)	X
	JP ERIOBOTRYAE FOLIUM	O (TLC)	X	O (↓ 15.0%)	O (↓ 10.0%)	X	↑ 16.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP FOLIUM ERIOBOTRYAE JAPONICAE	X	O (Foreign matter)	O (↓ 13.0%)	O (↓ 7.0%)	X	↑ 10.0% (Water-soluble extract)	X
95	*Houttuynia cordata* Thunberg (ジュウヤク)							
	CP HERBA HOUTTUYNIAE	O (TLC)	X	O (↓ 15.0%, Water)	X	O (↓ 2.5%)	↑ 10.0% (Water-soluble extract)	X
	JP HOUTTUYNIAE HERBA	O	O (Foreign matter)	X	O (↓ 14.0%)	O (↓ 3.0%)	↑ 10.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP HERBA HOUTTUYNIAE CORDATAE	O	O (Foreign matter)	O (↓ 13.0%, Water)	O (↓ 14.0%)	X	X	↑ 0.08% (Essential oil content)
96	*Lindera strychnifolia* Fernabdez-Villar (ウヤク)							
	CP RADIX LINDERAE	O (TLC)	X	X	X	X	X	Linderane ↑ 0.030% (HPLC)
	JP LINDERAE RADIX	O (TLC)	X	O (↓ 14.0%)	O (↓ 2.5%)	X	↑ 6.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP RADIX LINDERAE	O (Powder)	O (Old hard, Fibrous roots)	O (↓ 12.0%, Water)	X	X	X	X
97	*Lycium chinense* Miller (ジコッピ)							
	CP CORTEX LYCII	O	X	X	O (↓ 11.0%)	X	X	X
	JP LYCII CORTEX	O (TLC)	X	O (↓ 11.5%)	O (↓ 20.0%)	O (↓ 3.0%)	↑ 10.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP CORTEX LYCII	X	X	O (↓ 11.0%)	X	X	X	X
98	*Peucedanum praeruptorum* Dunn, *Angelica decursiva* Franchet et Savatier (ゼンコ、局外)							
	CP RADIX PEUCEDANI	O (TLC)	X	O (↓ 12.0%, Water)	O (↓ 8.0%)	O (↓ 2.0%)	↑ 20.0% (Dilute ethanol-soluble extract)	Praeruptorin A ↑ 0.90% (HPLC)
*	JP PEUCEDANI RADIX	O	X	O (↓ 13.0%)	O (↓ 7.5%)	O (↓ 2.0%)	↑ 20.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP RADIX PEUCEDANI	O	X	O (↓ 13.0%, Water)	X	X	↑ 20.0% (Ethanol-soluble extract)	X
99	*Prunus mume* Siebold et Zuccarini (ウバイ、局外)							
	CP FRUCTUS MUME	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 5.0%)	O (↓ 0.5%)	↑ 24.0% (Water-soluble extract),	Citric acid ↑ 15.0% (Titration)
*	JP MUME FRUCTUS	O	X	O (↓ 19.0%)	O (↓ 5.0%)	X	↑ 25.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP FRUCTUS MUME PRAEPARATUS	X	X	O (↓ 15.0%)	X	X	X	X
100	*Smilax glabra* Roxburgh (サンキライ)							
	CP RHIZOMA SMILACIS GLABRAE	O	X	O (↓ 15.0%, Water)	O (↓ 5.0%)	O (↓ 1.0%)	↑ 15.0% (Dilute ethanol-soluble extract)	X
	JP SMILACIS RHIZOMA	X	X	X	O (↓ 5.0%)	X	X	X
	KP							
	VP RHIZOMA SMILACIS GLABRAE	O (Powder)	O (Tender rhizomes, Foreign matter)	O (↓ 13.0%)	O (↓ 5.0%)	X	X	X
101	*Terminalia chebula* Retzius (カシ、局外)							
	CP FRUCTUS CHEBULAE	O (TLC)	X	O (↓ 13.0%, Water)	O (↓ 5.0%)	O (↓ 1.0%)	↑ 30.0% (Water-soluble extract),	X
*	JP CHEBULAE FRUCTUS	O	X	O (↓ 14.0%)	O (↓ 5.0%)	X	↑ 30.0% (Dilute ethanol-soluble extract)	X
	KP							
	VP FRUCTUS TERMINALIAE CHEBULAE	O	X	O (↓ 13.0%)	X	X	X	X
102	*Tribulus terrestris* Linne (シツリシ)							
	CP FRUCTUS TRIBULI	O (TLC)	X	O (↓ 9.0%, Water)	O (↓ 12.0%)	X	X	X
	JP TRIBULI FRUCTUS	O (TLC)	O (Peduncle, Foreign matter)	O (↓ 11.0%)	O (↓ 13.0%)	O (↓ 1.5%)	↑ 8.5% (Dilute ethanol-soluble extract)	X
	KP							
	VP FRUCTUS TRIBULI TERRESTRIS	O (Powder)	X	O (↓ 13.0%)	X	X	X	X
103	*Vitex trifolia* Linne (マンケイシ、局外)							
	CP FRUCTUS VITICIS	O (TLC)	O (Foreign matter)	O (↓ 14.0%, Water)	O (↓ 7.0%)	X	↑ 8.0% (Methanol-soluble extract)	Vitexicarpin ↑ 0.030% (HPLC)
*	JP VITICIS FRUCTUS	O	O (Peduncle, Foreign matter)	O (↓ 12.0%)	O (↓ 9.0%)	O (↓ 3.5%)	X	X
	KP							
	VP FRUCTUS VITICIS TRIFOLIAE	O (Powder)	O (Young thin fruit, Foreign matter)	O (↓ 11.0%, Water)	X	X	X	X

* Registered in the Japanese Herbal Medicine Codex (JHMC) 1989.

滴定法を用いた試験法も多く設定されており，今後の調和へ向けたテーマとなりうるものと考えられた．さらに今回は詳細な検討を行わなかったが，TLC 法を用いた確認試験において CP 及び VP ではクロロホルム，ベンゼン等の有害試薬が展開溶媒として設定されており，今後はクリーンアナリシスの観点からも検討が必要であると考えられた．また本報では各国薬局方の運用状況等については考慮せず，試験法並びに規格値ついて一元的に比較表を作成し，検討を行った．しかし，各国それぞれの法制度下では薬局方の運用状況が異なるため，今後は各国における運用面の調査も必要と考えられた．

結論

将来的な国際調和を踏まえ，各国の薬局方について共通点と相違点を認識すること目的として，日本，中国，韓国，ベトナム４カ国の薬局方に収載された試験法並びに規格値ついて比較表の作成を試みた．この結果，確認試験，純度試験，灰分の設定に関して共通点が多く認められたが，定量法に関しては試験法及びその規格値に相違点が認められ，今後の調和へ向けての課題が改めて示された．今回は検討事項とならなかった２カ国に共通な生薬についても比較を行う必要があると考えられた．現在，４カ国に共通設定されている各種試験に関して，その詳細な試験方法（TLC に関しては展開溶媒、標準物質等、定量法に関しては分析条件等）についても比較表の作成を行っている．

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漢方処方名ローマ字表記法

Standard Kampo Formula Nomenclature

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