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Selection of Herbal Medicines Requiring Quality Control for Loss on Drying, Total Ash, and Acid-insoluble Ash in Korea

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Abstract – The quality inspections items such as loss on drying, total ash, and acid-insoluble ash contents in herbal medicines, have a correlation with external sources of pollution, but are not themselves hazardous factors. Z-scores for standard normal distribution were used to investigate herbal medicines requiring quality control, which exceeds the regulatory limits of quality inspection. In total, 7,773 samples were analyzed based on plant parts. For the loss on drying, the numbers of items of herbal medicines requiring quality control are like these; 15 items for above-ground parts and 5 items for underground parts. For the total ash, 21 items for above-ground parts and 4 items for underground parts. For the acid-insoluble ash, 8 items for above-ground parts and 1 item for underground parts.
Keywords – herbal medicines, loss on drying, total ash, acid-insoluble ash, quality control

Introduction

Good manufacturing practice (GMP) guidelines for herbal medicines establish standards for the cultivation of medicinal plants, manufacture, and distribution of herbal medicines in order to produce 'Standardized Herbal Medicines' (WHO, 2007). A total of 548 raw materials of herbal medicines are registered in the Korean Pharmacopoeia (KP 9) and Korean Herbal Pharmacopoeia (KHP): 437 items of plant origin, 46 items of animal origin, 40 items of mineral origin, and 25 other items. The herbal material of plant origin accounts for about 80% of the registered materials in Korea (KFDA, 2007; 2008).

The objective of quality control of herbal medicines is to secure the quality of the customer's wants, which consists of two parts. First, quality control is aimed at preserving and strengthening effective components of medicinal plants during the course of cultivation and processing in terms of their original medicinal plants, loss on drying, total ash, acid-insoluble ash, essential oil, extract contents, and marker compounds. Second, quality control prevents contamination by dangerous heavy metals, pesticide residues, sulfur dioxide residues, and mycotoxins caused by external sources of pollution (Fort and Raman, 2000; Hong and Kim, 2004). At present, however, commercial herbal medicines in Korea are used both as food ingredients and as raw material for medicine with no relevant restriction. Hence, it cannot be guaranteed that herbal medicines from the same producing district have the same quality. For this reason, it is difficult to standardize herbal medicines. In addition, there are chances that faked products of different origin or cheap imported goods may enter the market due to various distribution networks (Choi *et al*., 2002; Chou *et al*., 2006).

There have been many reports on hazardous substance, including heavy metals (K. Chan, 2003), sulfur dioxide residues (Oh *et al*., 2007), pesticide residues (Cho *et al*., 2001), and mycotoxins (Klaus and Wolfgang, 1995), but there has been no report on the quality control of loss on drying, total ash, and acid-insoluble ash contents in commercial herbal medicines.

The moisture of herbal medicines influence quality deterioration due to toxigenic fungi and damage from insects if crude drugs are poorly dried and stored. The content of total ash shows how many minerals are physiologically contained in the medicinal plants and how many foreign materials are mixed during the course of processing (Cho *et al*., 2007; Ahmad *et al*, 2007). Finally, acid-insoluble ash content shows how many fine particles of soil and sand are present, which has a correlation with dangerous heavy metals (Kim *et al*., 2009).

This study investigates the contents of loss on drying, total ash, and acid-insoluble ash in the commercial herbal

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medicines, depending on the plant parts. In addition, this study also investigates the herbal medicines requiring quality control, which exceeds regulatory limits of quality inspection, in order to provide basic data for GMP guidelines for herbal medicines in Korea.

Experimental

Herbal medicines – Herbal medicines were purchased by an individual packing unit from a market in Seoul. The nomenclature and classification of crude drugs are important information for determining properties and efficacy of herbal medicines, and they can be classified based on shape, producing district, efficacy, color, and medicinal parts (Seo *et al*., 2006). In this study, samples are classified by the plant parts (Table 1). A total of 7,773 samples of 172 items were analyzed based on nine plant parts: cortex, flos, fructus, herba, perithecium, semen, caulis, radix, and rhizoma. The samples were mixed, and crushed by a crusher (DA-280 Gold.A, Daesung ARTLON Co., Korea) which was washed with purified water then, the crushed samples were passed though a No. 50

Table 1. Classification of herbal medicines used in the experiment

Parts	N (n)[1)]	Latin name
Cortex	14 (827)	*Acanthopanacis Cortex, Betulae Cortex, Cinnamomi Cortex, Dictamni Cortex, Eucommiae Cortex, Kalopanacis Cortex, Lycii Cortex, Magnoliae Cortex, Mori Cortex, Moutan Cortex, Myrrha, Olibanum , Phellodendri Cortex, Ulmi Cortex*
Flos	9 (276)	*Carthami Flos, Chrysanthemi Flos, Farfarae Flos, Lonicerae Flos, Magnoliae Flos, Prunellae Spika, Schizonepetae Spika, Syzygii Flos, Typhae Pollen*
Fructus	34 (1354)	*Alpiniae Oxyphyllae, Amomi Fructus Rotundus, Amomi Fructus, Amomi Tsao-ko Fructus, Anethi Fructus, Arecae Pericarpium, Aurantii Fructus Immaturus, Chaenomelis Fructus, Citri Unshius Pericarpium, Citrii Unshius Pericarpium Immaturus, Cnidii Fructus, Corni Fructus, Crataegi Fructus, Evodiae Fructus, Foeniculi Fructus, Forsythiae Fructus, Gardeniae Fructus, Hordei Fructus Germinatus, Illici Veri Fructus, Kochiae Fructus, Ligustri Fructus, Longan Arillus, Lycii Fructus, Meliae Fructus, Mume Fructus, Piperis Longi Fructus, Ponciri Fructus Immaturus, Rubi Fructus, Schisandrae Fructus, Terminaliae Fructus, Tribuli Fructus, Viticis Fructus, Xanthii Fructus, Zizyphi Fructus*
Herba	20 (484)	*Agastachis Herba, Artemisiae Argyi Folium, Artemisiae Capillaris Herba, Chrysanthemi Zawadskii Herba, Cistanchis Herba, Cynomorii Herba, Dendrobii Herba, Dianthi Herba, Elsholtziae Herba, Ephedrae Herba, Epimedii Herba, Equiseti Herba, Geranii Herba, Leonuri Herba, Melandrii Herba, Menthae Herba, Perillae Folium, Pogostemonis Herba, Sennae Folium, Taraxaci Herba*
Perithecium	3 (259)	*Hoelen Cum Radix, Polyporus, Poria Sclerotium*
Semen	19 (614)	*Alpiniae Katsumadaii Semen, Arecae Semen, Carthami Tinctorii Seed Fructus, Cassiae Semen, Coicis Semen, Cuscutae Semen, Dolichoris Semen , Euryales Semen, Massa Medicata Fermentata, Myristicae Semen, Nelumbinis Semen, Perillae Semen, Plantaginis Semen, Psoraleae Semen, Raphani Semen, Sinapis Semen, Thujae Semen, Trichosanthis Semen, Zizyphi Semen*
Caulis	7 (287)	*Akebia Caulis, Bambusae Caulis In Taeniam, Cinnamomi Ramulus, Gleditsiae Spina, Lonicerae Folium et Caulis, Sappan Lignum, Uncariae Ramulus et Uncus*
Radix	35 (2227)	*Achyranthis Radix, Adenophorae Radix, Angelicae Dahuricae Radix, Angelicae Decursivae Radix, Angelicae Gigantis Radix, Angelicae Tenuissimae Radix, Araliae Continentalis Radix, Arctii Radix, Astragali Radix, Aucklandiae Radix, Bupleuri Radix, Clematidis Radix , Codonopsis Pilosulae Radix, Curcumae Radix, Cynanchi Wilfordii Radix, Glehniae Radix, Glycyrrhizae Radix et Rhizoma, Linderae Radix, Morindae Radix, Osterici Radix, Paeoniae Radix, Peucedani Radix, Platycodonis Radix, Polygalae Radix, Polygoni multiflori Radix, Puerariae Radix, Rehmanniae Radix Preparata, Rhei Radix et Rhizoma, Salviae Miltiorrhizae Radix, Sanguisorbae Radix, Saposhnikoviae Radix, Scrophulariae Radix, Scutellariae Radix, Sophorae Radix, Trichosanthis Radix*
Rhizoma	31 (1445)	*Acori Gramineri Rhizoma, Alismatis Rhizoma, Alpiniae Officinari Rhizoma, Anemarrhenae Rhizoma, Arisaematis Rhizoma, Asiasari Radix et Rhizoma, Asparagi Tuber, Atractylodis Rhizoma Alba, Atractylodis Rhizoma, Cibotii Rhizoma, Cimicifugae Rhizoma, Cnidii Rhizoma, Coptidis Rhizoma, Corydalis Tuber, Curcumae Longae Rhizoma, Curcumae Rhizoma, Cyperi Rhizoma, Dioscoreae Rhizoma , Fritillariae Thunbergii Bulbus, Gastrodiae Rhizoma, Gentianae scabrae Radix et Rhizoma, Imperatae Rhizoma, Liriopis Tuber, Phragmitis Rhizoma, Pinelliae Tuber, Polygonati Odorati Rhizoma, Rhei Undulatai Rhizoma, Sinomeni Caulis et Rhizoma, Smilacis Rhizoma, SparganiiRhizoma, zingiberis Rhizoma*
Total	172 (7773)	

[1)]Number of items (number of analyzed samples)

(300 μm) sieve. Subsequently, the samples were placed in an airtight container, stored in a refrigerator, and used in the experiments.

Analysis of loss on drying, total ash, and acid-insoluble ash – The Seoul Metropolitan Government Research Institute of Public Health and Environment (SIHE), under the Seoul City Government, is conducting research on quality inspection items related to herbal medicines, in accordance with KP 9 and KHP. Experiments were conducted to determine the content of loss on drying, total ash, and acid-insoluble ash based on Standard Operation Procedure (SOP). Loss on drying test is designed to measure the amount of moisture and volatile matters in a sample. Place 2 to 6 g of the sample into a weighing bottle which has been accurately weighed, and weigh it accurately. Then, dry it at 105 °C for 5 - 6 hours and cool it in desiccators with silica gel. When the material is dried to a constant weight, the percent of loss on drying is determined. The percent of total ash is the content obtained when the sample was exposed to a high temperature and turned into white ash to constant weight. Place 2 to 4 g of the sample in a crucible, which is previously dried and weighed. Heat it slowly and expose it to the temperature of 550 °C for about 4 hours until readily carbonizable substances disappear. It is then cooled in desiccators and weighed. Then, obtain the percent of total ash from the weight. In the case of acid-insoluble ash content, 25 mL of dilute hydrochloric acid is added to the total ash obtained and the mixture is boiled for 5 minutes. It is then filtered through a quantitative filter paper (No. 5A, Toyo Co., Japan). The residue is thoroughly washed with hot water. The filter paper is dried and burned to obtain the amount of acid-insoluble ash.

Selection of herbal medicines requiring quality control – Herbal medicines requiring quality control, which exceeds the limits of quality inspection, are selected in accordance with the methods below as the means of statistical quality control (Kim *et al.*, 2009). Random variable z-scores for standard normal distribution N(0,1) were used to obtain P(z), and items are selected as herbal medicines requiring intensive quality control when the z-value is less than or equal to 1 based on [1 – P(z ≤ 1) = 0.1587] (Table 2).

$$z = (X - \mu) / \sigma$$

X: Herbal standard value in quality inspection announced by KFDA

μ: Mean value obtained after quality test

σ: Standard deviation

Table 2. Standard normal distribution chart

z	P(z)	1-P(z)	z	P(z)	1-P(z)
-3.0	0.0013	0.9987	0.0	0.5000	0.5000
-2.5	0.0062	0.9938	0.5	0.6915	0.3085
-2.0	0.0228	0.9772	**1.0**	**0.8413**	**0.1587**
-1.5	0.0668	0.9332	1.5	0.9332	0.0668
-1.0	0.1587	0.8413	2.0	0.9772	0.0228
-0.5	0.3085	0.6915	2.5	0.9938	0.0062
0.0	0.5000	0.5000	3.0	0.9987	0.0013

Statistical analysis – PASW statistics (version 17.0 KO) was used to compute mean, standard deviation, and range values. The independent-samples t-test and the one-way ANOVA-test were used for analysis of significant differences. Duncan's multiple range test was conducted for post hoc comparison ($p < 0.05$).

Results and discussion

The contents of loss on drying, total ash, and acid-insoluble ash depending on plant parts and the herbal medicines requiring quality control are given in Tables 3 and 4, respectively.

For the content of loss on drying, 4,143 samples (106 types) were analyzed. The percent (%) of cortex was 9.8, flos 9.1, fructus 10.2, herba 9.5, perithecium 11.7, semen 7.6, caulis 9.2, radix 9.8, and rhizoma 10.6. These results were similar to the report by Yu (Yu, 2006) that, for medicinal plants, the moisture content is higher in the fruit and lower in the root, seed, and epidermis. There was a significant difference between the above-ground parts (9.6) and the underground parts (10.0) ($p < 0.05$). The number of samples exceeding regulatory limits per analyzed samples was higher in the above-ground parts (72/2158) than in the underground parts (21/1985). The herbal medicines requiring quality control include, for fructus (6 items): *Mume Fructus*, *Amomi Fructus Rotundus*, *Illici Veri Fructus*, *Xanthii Fructus*, *Citri Unshius Pericarpium*, and *Citrii Unshius Pericarpium Immaturus*; for radix (4 items): *Codonopsis Pilosulae Radix*, *Peucedani Radix*, *Morindae Radix*, and *Clematidis Radix*; for flos (3 items): *Farfarae Flos*, *Typhae Pollen*, and *Chrysanthemi Flos*; for herba (2 items): *Cistanchis Herba* and *Equiseti Herba*; for cortex (1 item): *Betulae Cortex*; for perithecium (1 item): *Hoelen Cum Radix*; for semen (1 item): *Alpiniae Katsumadaii Semen*; for caulis (1 item): *Cinnamomi Ramulus*; and for rhizoma (1 item):

Table 3. The contents of loss on drying, total ash, and acid-insoluble ash, depending on the plant parts

Parts	Loss on drying				Total ash				Acid-insoluble ash			
	N[1)]	n[2)]	%[3)]		N[1)]	n[2)]	%[3)]		N[1)]	n[2)]	%[3)]	
Above-ground parts	70	72/2158	9.6 ± 2.7*	(2.1-22.3)	102	104/3935	5.2 ± 3.6*	(0.1-39.3)	57	28/1696	1.0 ± 1.7*	(0.1-31.8)
Underground parts	36	21/1985	10.0 ± 2.4	(1.9-29.2)	66	25/3672	4.4 ± 1.7	(0.1-18.2)	47	5/2573	0.6 ± 0.5	(0.0-4.0)
Total	106	93/4143	9.8 ± 2.6	(1.9-29.2)	168	129/7607	4.8 ± 2.9	(0.1-39.3)	104	33/4269	0.7 ± 1.2	(0.0-31.8)
Cortex	9	1/409	9.8 ± 3.2^{cd}	(2.3-15.7)	12	12/722	5.8 ± 3.4^{f}	(0.5-39.3)	8	7/355	1.2 ± 2.9^{e}	(0.1-31.8)
Flos	5	14/127	9.1 ± 2.3^{b}	(3.0-15.9)	9	28/276	8.6 ± 6.4^{g}	(1.0-38.7)	6	2/157	0.7 ± 0.6^{ab}	(0.1-4.4)
Fructus	21	39/737	10.2 ± 2.8^{de}	(2.1-22.3)	33	27/1308	4.5 ± 1.9^{e}	(0.2-15.2)	15	0/409	1.0 ± 0.9^{bc}	(0.1-4.6)
Herba	18	10/387	9.5 ± 2.0^{bc}	(2.7-17.6)	20	24/484	8.7 ± 3.2^{g}	(1.9-30.4)	17	16/446	1.1 ± 1.6^{c}	(0.1-16.3)
Perithecium	1	2/29	11.7 ± 2.2^{f}	(7.6-18.5)	3	0/259	2.1 ± 4.3^{a}	(0.1-15.4)	1	0/40	2.5 ± 1.0^{d}	(0.1-11.2)
Semen	10	0/261	7.6 ± 2.7^{a}	(2.1-13.5)	18	5/599	3.6 ± 1.5^{c}	(0.8-15.3)	8	3/246	0.7 ± 1.0^{ab}	(0.2-3.7)
Caulis	6	6/208	9.2 ± 1.6^{bc}	(5.5-17.9)	7	8/287	3.2 ± 2.1^{b}	(0.4-11.4)	2	0/43	0.5 ± 0.4^{a}	(0.1-1.4)
Radix	24	16/1473	9.8 ± 2.3^{cd}	(2.5-20.5)	35	3/2227	4.5 ± 1.6^{e}	(0.1-14.0)	26	2/1571	0.6 ± 0.6^{a}	(0.0-3.7)
Rhizoma	12	5/512	10.6 ± 2.6^{e}	(1.9-29.2)	31	22/1445	4.1 ± 1.9^{d}	(0.4-18.2)	21	3/1002	0.5 ± 0.4^{a}	(0.0-4.0)

[1)] Number of items
[2)] Number of samples exceeding regulatory limits of quality inspection/number of analyzed samples
[3)] Mean ± standard deviation. The same letters (**a-c**) in the same column are not significantly different ($p < 0.05$). Numbers in parenthesis are range.
[4)] * shows a significant difference depending on the above-ground parts and the underground parts (t-test, $p < 0.05$).

Sparganii Rhizoma. The results of this experiment indicate that samples with higher contents of loss on drying than regulatory limits may not been dried sufficiently in the course of processing, and may have been affected by the humidity in the storage and distribution.

For the total ash, 7,607 samples (168 types) were analyzed. The content (%) of the cortex was 5.8, flos 8.6, fructus 4.5, herba 8.7, perithecium 2.1, semen 3.6, caulis 3.2, radix 4.5, and rhizoma 4.1. The content was higher in the case of the above-ground parts (5.2) than in the underground parts (4.4) ($p < 0.05$). In the significance test among the parts used, the number of sample groups for ash (a-g) was higher than that for acid-insoluble ash (a-d) or for loss on drying (a-f) (ANOVA-test, $p < 0.05$). The number of samples exceeding regulatory limits per analyzed samples was higher in the above-ground parts (104/3935) than in the underground parts (25/3672). The herbal medicines requiring quality control include, for herba (5 items): *Melandrii Herba*, *Dianthi Herba*, *Equiseti Herba*, *Cistanchis Herba*, and *Taraxaci Herba*; for cortex (4 items): *Myrrha*, *Dictamni Cortex*, *Kalopanacis Cortex*, and *Phellodendri Cortex*; for flos (4 items): *Typhae Pollen*, *Farfarae Flos*, *Carthami Flos*, and *Lonicerae Flos*; for fructus (4 items): *Amomi Tsao-ko Fructus*, *Meliae Fructus*, *Terminaliae Fructus*, and *Piperis Longi Fructus*; for rhizoma (3 items): *Phragmitis Rhizoma*, *Rhei Undulatai Rhizoma*, and *Pinelliae Tuber*; for semen (2 items): *Thujae Semen* and *Plantaginis Semen*; for caulis (2 items): *Gleditsiae Spina* and *Akebia Caulis*; for radix (1 item): *Peucedani Radix*; and for perithecium, no items. In the case of *Melandrii Herba* and *Myrrha*, all analyzed samples exceeded regulatory limits of total ash. It is believed that regulatory limits established by the Korea Food and Drug Administration (KFDA) may be wrong or that the different medicinal plants of different origin have been distributed for these items in Korea.

For the acid-insoluble ash, 4,269 samples (104 types) were analyzed. The content (%) of cortex was 1.2, flos 0.7, fructus 1.0, herba 1.1, perithecium 2.5, semen 0.7, caulis 0.5, radix 0.6, and rhizoma 0.5. The content was higher in the case of the above-ground parts (1.0) than in the underground parts (0.6) ($p < 0.05$). The number of samples exceeding regulatory limits per analyzed samples was higher in the above-ground parts (28/1696) than in the underground parts (5/2573). It was reported that the use of water in washing can decrease acid-insoluble ash content by 0.4 - 2.2%, so as to enhance the quality of oriental herbal medicines, but clean and cold water should be used as quickly as possible in order to ensure that

Table 4. The herbal medicines requiring quality control, which exceeded the regulatory limits of quality inspection

Parts / Latin name	n1[1]	Loss on drying				Total ash				Acid-insoluble ash			
		n2[2]	z[3]	%[4]	KFDA[5]	n2[2]	z[3]	%[4]	KFDA[5]	n2[2]	z[3]	%[4]	KFDA[5]
Cortex													
Betulae Cortex	8	0	**0.8**	6.0 ± 1.3	7.0	0	2.5	4.8 ± 2.5	11.0	- [6]	-	-	-
Dictamni Cortex	12	0	2.5	8.2 ± 1.5	12.0	1	**0.5**	7.4 ± 1.3	8.0	0	2.0	0.6 ± 0.2	1.0
Kalopanacis Cortex	45	0	1.6	7.9 ± 0.7	9.0	0	**0.9**	8.5 ± 1.7	10.0	-	-	-	-
Myrrha	9	-	-	-	-	9	**-2.3**	25.8 ± 7.2	9.0	6	**-0.9**	14.7 ± 10.9	5.0
Phellodendri Cortex	94	0	2.4	7.0 ± 1.7	11.0	0	**1.0**	6.6 ± 0.9	7.5	0	2.0	0.3 ± 0.1	0.5
Flos													
Carthami Flos	59	-	-	-	-	9	**0.4**	14.8 ± 8.7	18.0	-	-	-	-
Chrysanthemi Flos	49	4	**0.3**	9.6 ± 1.6	10.0	0	2.8	6.3 ± 1.3	10.0	0	2.7	0.7 ± 0.3	1.5
Farfarae Flos	18	6	**-0.4**	9.2 ± 2.8	8.0	4	**-0.1**	5.3 ± 1.8	5.0	2	**0.4**	1.3 ± 0.5	1.5
Lonicerae Flos	44	0	2.5	9.7 ± 2.1	15.0	1	**0.6**	7.7 ± 2.2	9.0	-	-	-	-
Typhae Pollen	16	4	**0.0**	6.1 ± 2.1	6.0	14	**-1.5**	17.5 ± 8.3	5.0	-	-	-	-
Fructus													
Amomi Fructus Rotundus	46	22	**-0.5**	14.2 ± 4.2	12.0	-	-	-	-	0	4.7	2.2 ± 0.6	5.0
Amomi Tsao-ko Fructus	25	0	1.4	9.4 ± 1.8	12.0	15	**-0.9**	5.7 ± 2.0	4.0	0	1.8	1.3 ± 0.4	2.0
Citri Unshius Pericarpium	131	4	**0.8**	11.5 ± 1.9	13.0	0	4.7	2.6 ± 0.3	4.0	-	-	-	-
Citrii Unshius Pericarpium Immaturus	67	1	**0.9**	10.8 ± 1.4	12.0	0	3.3	4.0 ± 0.3	5.0	0	3.5	0.3 ± 0.2	1.0
Illici Veri Fructus	14	6	**-0.5**	12.8 ± 3.2	11.0	0	5.0	3.0 ± 0.2	4.0	-	-	-	-
Meliae Fructus	12	0	1.1	9.1 ± 0.8	10.0	6	**-0.5**	2.6 ± 1.3	2.0	-	-	-	-
Mume Fructus	6	5	**-1.6**	11.8 ± 3.6	6.0	0	2.5	4.0 ± 0.4	5.0	0	11.0	0.4 ± 0.1	1.5
Piperis Longi Fructus	5	0	2.5	9.5 ± 0.2	10.0	0	**0.9**	4.0 ± 1.1	5.0	-	-	-	-
Terminaliae Fructus	18	0	1.6	9.7 ± 1.4	12.0	6	**0.0**	2.0 ± 1.1	2.0	0	3.0	0.1 ± 0.1	0.4
Xanthii Fructus	15	1	**0.3**	6.5 ± 1.5	7.0	0	4.8	4.1 ± 0.6	7.0	0	4.0	0.2 ± 0.2	1.0
Herba													
Cistanchis Herba	20	10	**-0.7**	11.4 ± 3.5	9.0	2	**0.0**	10.1 ± 4.6	10.0	0	1.8	1.3 ± 0.4	2.0
Dianthi Herba	9	0	1.1	8.7 ± 1.2	10.0	7	**-1.3**	8.5 ± 3.5	4.0	3	**-0.3**	0.8 ± 1.1	0.5
Equiseti Herba	10	0	**0.9**	8.8 ± 1.4	10.0	5	**-0.4**	11.9 ± 2.1	11.0	7	**-1.2**	6.1 ± 4.0	1.5
Melandrii Herba	7	0	1.4	7.0 ± 0.7	8.0	7	**-3.8**	7.6 ± 1.2	3.0	1	**1.0**	0.8 ± 0.2	1.0
Taraxaci Herba	29	0	1.8	10.8 ± 2.3	15.0	3	**0.1**	16.5 ± 3.7	17.0	4	**0.0**	4.1 ± 3.4	4.0
Perithecium													
Hoelen Cum Radix	29	2	**0.6**	11.7 ± 2.2	13.0	0	12.0	0.3 ± 0.1	1.5	-	-	-	-
Semen													
Alpiniae Katsumadaii Semen	15	0	**0.8**	10.6 ± 1.7	12.0	-	-	-	-	-	-	-	-
Plantaginis Semen	63	-	-	-	-	2	**0.5**	4.9 ± 1.3	5.5	2	**0.9**	1.0 ± 1.1	2.0
Thujae Semen	26	0	2.2	4.4 ± 1.2	7.0	2	**0.3**	5.3 ± 2.3	6.0	1	**0.0**	1.0 ± 2.1	1.0
Caulis													
Akebia Caulis	79	-	-	-	-	6	**0.5**	6.3 ± 1.4	7.0	-	-	-	-
Cinnamomi Ramulus	103	6	**0.6**	10.0 ± 1.7	11.0	0	3.0	2.1 ± 0.3	3.0	-	-	-	-
Gleditsiae Spina	7	0	1.3	8.8 ± 0.9	10.0	2	**0.0**	2.0 ± 0.9	2.0	-	-	-	-
Radix													
Clematidis Radix	62	2	**0.6**	9.0 ± 1.6	10.0	0	1.9	5.9 ± 1.4	8.5	0	2.1	2.1 ± 0.9	4.0
Codonopsis Pilosulae Radix	34	6	**0.0**	13.0 ± 2.6	13.0	0	2.7	4.4 ± 0.6	6.0	0	3.0	1.1 ± 0.3	2.0
Morindae Radix	24	6	**0.4**	11.7 ± 3.1	13.0	0	4.2	3.9 ± 0.5	6.0	0	4.0	0.6 ± 0.1	1.0
Peucedani Radix	14	1	**0.2**	9.5 ± 2.2	10.0	0	**0.8**	3.3 ± 0.9	4.0	0	3.0	0.8 ± 0.4	2.0
Rhizoma													
Phragmitis Rhizoma	12	-	-	-	-	11	**-2.7**	5.5 ± 1.5	1.4	-	-	-	-
Pinelliae Tuber	39	0	2.3	9.2 ± 2.1	14.0	7	**0.2**	3.3 ± 0.9	3.5	-	-	-	-
Rhei Undulatai Rhizoma	21	-	-	-	-	3	**0.1**	9.6 ± 3.0	10.0	-	-	-	-
Smilacis Rhizoma	15	0	1.8	8.7 ± 1.8	12.0	2	4.7	2.2 ± 0.6	5.0	0	**0.0**	0.5 ± 0.6	0.5
Sparganii Rhizoma	33	1	**0.6**	9.1 ± 1.5	10.0	0	4.3	3.3 ± 0.4	5.0	0	7.0	0.3 ± 0.1	1.0

[1] n1: number of analyzed samples, [2] n2: number of samples exceeding regulatory limits of quality inspection in KP 9 and KHP, [3] Z-score = (herbal standard value in quality inspection – mean value obtained after quality test) / standard deviation Herbal medicines requiring intensive quality control whose z value is less than or equal to 1 ($z \leq 1$) expressed in bold type, [4] Mean ± standard deviation, [5] Regulatory limits of quality inspection announced by KFDA, [6] Herbal medicines without established regulatory limits in KP9 and KHP

Table 5. Correlation between total ash and acid-insoluble ash contents of herbal medicines

Parts	n (*r*) [1)]
Above-ground parts	1580 (0.614**)
Underground parts	2573 (0.517**)
Total	4153 (0.602**)
Cortex	285 (0.714**)
Flos	157 (0.575**)
Fructus	363 (0.463**)
Herba	446 (0.676**)
Perithecium	40 (0.468**)
Semen	246 (0.701**)
Caulis	43 (NS)
Radix	1571 (0.523**)
Rhizoma	1002 (0.511**)

[1)] Number of analyzed samples (correlation coefficient)
** = $p < 0.01$, NS: Not significant

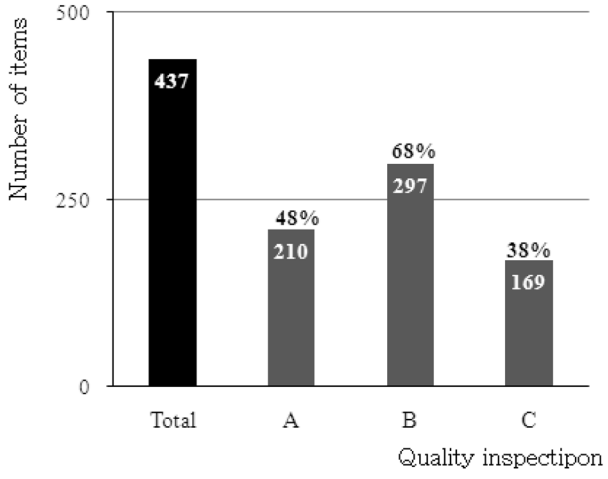

Fig. 1. The items of herbal medicines covered by KP9 and KHP (**Total** - the total number of herbal medicines of plant origin, **A**- the number of items with established regulatory limits for loss on drying, **B** - the number of items with established regulatory limits for total ash, **C** - the number of items with established regulatory limits for acid-insoluble ash).

effective elements are not washed out (Park and Kang, 2006). The herbal medicines requiring quality control include, for herba (4 items): *Equiseti Herba*, *Dianthi Herba*, *Taraxaci Herba*, and *Melandrii Herba*; for semen (2 items): *Thujae Semen* and *Plantaginis Semen*; for cortex (1 item): *Myrrha*; for flos (1 item): *Farfarae Flos*, for rhizoma (1 item): *Smilacis Rhizoma*, and for fructus, perithecium, caulis, and radix, no items.

A correlation between the total ash and acid-insoluble ash contents depending on plant parts is given in Table 5. It showed a positive correlation in the above-ground parts (n = 1580, r = 0.614) and underground parts (n = 2573, r = 0.517) ($p < 0.01$).

Loss on drying, total ash, and acid-insoluble ash are basic factors for evaluating the state of quality control of commercial herbal medicines (Kim *et al.*, 2009). However, as of yet, regulatory limits regarding loss on drying, total ash, and acid-insoluble ash contents have been established, only for 210 items (48%), 297 items (68%), and 169 items (39%), respectively out of 437 items of herbal medicines covered by KP 9 and KHP (Fig. 1). Therefore, regulatory limits should be established for other items in order to properly control the quality of commercial herbal medicines.

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