

TABLE 1

SUMMARY OF RESULTS OF ANALYSIS AND PHARMACEUTICAL ACTIVITY OF CRUDE DRUG EXTRACTS																
EXAMPLE	EXTRACTION METHOD	QUANTITATIVE TEST $\mu\text{gSi/ml}$	ACTIVITY TEST	CONFIRMATION TEST												
				1	2	3	4	5	6	7	8	9	10	11	12	13
1-1	1	0.65	0.772			p	p			p	p	p	p	p	p	p
1-2	2	0.737	1.44			p	p			p	p	p	p	p	p	p
1-3	3	0.682	0.608			p	p			p	p	p	p	p	p	p
1-4	5(3)	0.627	0.824			p	p			p	p	p	p	p	p	p
2	5(1)	0.388	1.184	p	p					p	p	p	p	p	p	p
3-1	1	0.304	1.848		p			p		p	p	p	p	p	p	p
3-2	2	0.347	2.268		p	p		p		p	p	p	p	p	p	p
4-1	1	2.7	0.716		p				p	p	p	p	p	p	p	p
4-2	2	2.728	0.876		p				p	p	p	p	p	p	p	p
4-3	5(1)	15.93	0.996		p				p	p	p	p	p	p	p	p
5-1	1	1.276	0.688		p		p			p	p	p	p	p	p	p
5-2	2	1.805	0.88		p	p	p			p	p	p	p	p	p	p
6	5(1)	0.809	0.78		p	p				p	p	p	p	p	p	p
7	2	0.392	0.752		p		p	p		p	p	p	p	p	p	p
8-1	1	0.725	0.189		p	p				p	p		p		p	p
8-2	2	0.964	0.573		p	p	p	p			p		p		p	p
9	2	0.281	0.434		p	p					p	p	p	p	p	p
10	2	0.077	0.164		p						p	p	p		p	p
11-1	3	0.203	0.09		p	p					p	p	p	p	p	p
11-2	5(3)	0.227	0.063		p	p					p	p	p	p	p	p
12-1	1	0.969	0.055		p	p	p			p	p				p	p
12-2	2	1.711	0.084		p	p	p				p		p	p	p	p
13-1	1	0.118	0.071		p	p		p	p			p	p	p	p	p
13-2	2	0.122	0.078		p	p		p	p			p		p	p	p
14	1	0.536	0.074		p			p			p				p	p
15	1	0.087	0.051		p	p	p			p	p			p	p	p

It is apparent from the results of the above-mentioned Examples where various crude drugs were used that, when soluble silicon compounds are contained in more than certain amounts, the crude drug extracts exhibit a pharmaceutical effect. The method of the present invention establishes a standardization for crude drugs which has been ambiguous up to now. The silicon compounds contained in the crude drug extracts include various kinds of compounds. In the present invention, they are wholly standardized in terms of amount calculated as silicon measured by a molybdenum blue method. Depending upon the type of the crude drug, substances therein other than the silicon compounds are varied. However, when coloring reaction tests, etc. for such substances are appropriately used together with the silicon content determination, more precise standardization of crude drugs can be established.

As shown in Table 1, the Examples indicate a tendency for an increase in the extracting efficiency of the soluble silicon compounds when the extracting operation is conducted using a solution where the pH is adjusted to an alkaline region (e.g. pH being around 9.5), as for example in extraction method 2. Accordingly, extraction using a solution where the pH is adjusted to the alkaline region (e.g. pH about 9.5) is an example of a preferred extracting method.

As such, in accordance with the present invention, when soluble silicon compounds which provide a pharmaceutical effect, such as inhibition of plasma kallikrein, are used as an index, the quality of various crude drugs and extracts thereof can be standardized. Accordingly, the present invention achieves crude drug extracts having a stable quality and greatly contributes to the appropriate standardization of pharmaceuticals.

What is claimed is:

1. A method for standardizing or evaluating plant drugs for pharmaceutical effectiveness comprising subjecting a plant drug to extraction to obtain an extract solution, drying

the extract solution to obtain a dry drug extract, determining the amount of soluble silicon compounds calculated as silicon per gram of dry drug extract, and comparing the determined amount of soluble silicon compounds to a minimal amount needed to obtain inhibition of plasma kallikrein production.

2. A method as claimed in claim 1 wherein the plant drug is subjected to extraction with water or an aqueous solvent to obtain an extract solution and the extract solution is dried to obtain a drug extract in powder form.

3. A method as claimed in claim 2 wherein the pH of said water or aqueous solvent for extraction is adjusted to 8.5 to 10.5.

4. A method as claimed in claim 1 wherein the amount of soluble silicon compounds is determined by a molybdenum blue method.

5. A method as claimed in claim 1 wherein the amount of soluble silicon is determined by dissolving the dry drug extract, removing insoluble matter to obtain a filtrate, admixing the filtrate with ammonium molybdate tetrahydrate, and measuring absorbance at a wavelength of 820 nm.

6. A method as claimed in claim 1 wherein the standardization or evaluation further comprises measuring inhibiting action of the drug extract against plasma kallikrein production.

7. A method as claimed in claim 1 wherein the standardization or evaluation further comprises subjecting said drug extract to a plurality of coloring reactions.

8. A method for standardizing plant drug extracts comprising determining the amount of soluble silicon compounds calculated as silicon per gram of dry drug extract, measuring inhibiting action of the drug extract against plasma kallikrein production, and subjecting said drug extract to a plurality of coloring reactions.

9. A method as claimed in claim 8 wherein said plant drug extracts are obtained by subjecting a plant drug to extraction