

UNIFICATION OF PHARMACOPŒIAL FORMULAS FOR POTENT DRUGS

*Agreement and procès-verbal of signature signed at Brussels
November 29, 1906*

Entered into force December 29, 1906

Terminated by protocol of May 20, 1952¹

Treaty Series 510

[TRANSLATION]

AGREEMENT RESPECTING THE UNIFICATION OF THE PHARMACOPŒIAL FORMULAS FOR POTENT DRUGS

The Governments of Germany, Austria and Hungary, Belgium, Bulgaria, Denmark, Spain, the United States of America, France, Great Britain, Greece, Italy, the Grand Duchy of Luxemburg, Norway, the Netherlands, Portugal, Russia, Servia, Sweden, and Switzerland, having recognized the utility of concluding an Agreement with a view to the unification of the Pharmacopœial formulas for potent drugs on the basis indicated in the Final Protocol signed on the 20th September, 1902, as a result of the Conference held at Brussels,² the Undersigned, duly authorized thereto, have agreed upon the following stipulations:

ARTICLE 1

The medicinal substances inscribed in the Table given below shall be designated, in the Pharmacopœia published by each of the Contracting Governments, by the Latin names employed in this Table, and shall conform with the directions indicated in the column opposite.

¹ 3 UST 5067; TIAS 2692.

² The 1902 conference, composed of delegates from nearly every civilized country, was held for the purpose of formulating standards for potent remedies which would be adopted by the various pharmacopœias of the world and would thus secure the principal object of an international pharmacopœia.

Latin names and synonyms of drugs and preparations	Pharmaceutical directions
Aconitum Napellus. L. Aconiti tuber seu Tuber Aconiti.	Use only the tuber of the current year, dried. Powdered drug to be used entire, without separation of residue.
Aconiti tinctura seu Tinctura Aconiti.	Prepare by percolation with alcohol (70 per cent. by volume). Tincture to be standardized to 0.05 per cent. of total alkaloids.
Atropa Belladonna. L. Belladonnæ folium seu Folium Belladonnæ.	Use only the leaf, dried. Powdered drug to be used entire.
Belladonnæ tinctura seu Tinctura Belladonnæ.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Belladonnæ extractum seu Extractum Belladonnæ.	Prepare a solid extract (containing about 10 per cent. of water) by means of alcohol (70 per cent.).
Colchicum autumnale. L. Colchici semen seu Semen Colchici. Colchici tinctura seu Tinctura Colchici.	Use only the seed. Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Digitalis purpurea. L. Digitalis folium seu Folium Digitalis.	Use the leaf of the second year. Powdered drug to be used entire.
Digitalis tinctura seu Tinctura Digitalis.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Uragoga Ipecacuanha. <i>Baill.</i> Ipecacuanhæ radix seu Radix Ipecacuanhæ.	Powder only the root-bark, rejecting the woody portion. The powder should have an alkaloidal strength of 2 per cent.
Ipecacuanhæ tinctura seu Tinctura Ipecacuanhæ.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Ipecacuanhæ sirupus seu Sirupus Ipecacuanhæ.	Prepare with 10 per cent. of the tincture.
Hyoscyamus niger. L. Hyoscyami folium seu Folium Hyoscyami. Hyoscyami tinctura seu Tinctura Hyoscyami.	Use only the leaf. Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Hyoscyami extractum seu Extractum Hyoscyami.	Prepare a solid extract (containing about 10 per cent. of water) by means of alcohol (70 per cent.).
Strychnos Nux vomica. L. Strychni semen seu Semen Strychni seu Nux vomica.	Alkaloidal strength (of powdered drug) 2.5 per cent.
Strychni tinctura seu Tinctura Strychni; Nucis vomicæ tinctura seu Tinctura Nucis vomicæ.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.). Alkaloidal strength 0.25 per cent.
Strychni extractum seu Extractum Strychni; Nucis vomicæ extractum seu Extractum Nucis vomicæ.	Prepare by means of alcohol (70 per cent.). Alkaloidal strength 16 per cent.
Opium pulvis seu Pulvis Opii.	Powder to be dried at 60° C. Strength in morphine 10 per cent.
Opium extractum seu Extractum Opii.	Strength in morphine 20 per cent.
Opium tinctura seu Tinctura Opii.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.). Strength in morphine 1 per cent.
Opium tinctura crocata seu Tinctura Opii crocata seu Laudanum Sydenhami.	Strength in morphine 1 per cent.
Opium et Ipecacuanhæ pulvis compositus seu Pulvis Doveri.	To contain 10 per cent. of Pulvis Opii.
Opium tinctura benzoica seu Tinctura Opii benzoica.	Strength in morphine 0.05 per cent.

Latin names and synonyms of drugs and preparations	Pharmaceutical directions
Strophanthi tinctura seu Tinctura Strophanthi.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.). Seeds not to be freed from fat.
Sclerotium clavicepitis purpureæ Tul. seu Clavicepitis purpureæ Tul. Sclerotium.	
Secale cornutum seu Ergotum secale.	Ergot to be not more than one year old, and kept whole.
Secalis cornuti extractum seu Extractum Secalis cornuti; Ergoti extractum seu Extractum Ergoti.	Prepare a watery extract and make up with alcohol (60 per cent.).
Secalis cornuti extractum fluidum seu Extractum fluidum Secalis cornuti; Ergoti extractum fluidum seu Extractum fluidum Ergoti.	Strength 100 per cent.
Acidum hydrocyanicum dilutum.	Strength 2 per cent.
Laurocerasi aqua seu Aqua Laurocerasi.	Strength 0.10 per cent.
Amygdalæ amaræ aqua seu Aqua Amygdalæ amaræ.	Strength 0.10 per cent.
Phenoli solutio seu Aqua phenolata.	Strength 2 per cent.
Arsenas sodii seu Sodii arsenas; Arsenicum natrium seu Natrium arsenicum.	The crystalized salt, containing 36.85 per cent. of arsenic acid.
Arsenicalis liquor Fowleri seu Liquor arsenicalis Fowleri seu Kalii arsenicosi liquor.	Strength in arsenious acid 1 per cent.
Ferri iodidi sirupus seu Sirupus iodeti ferrosi seu Sirupus ferri iodati.	Strength in anhydrous ferrous iodide 5 per cent.
Cantharidis tinctura seu Tinctura Cantharidis.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Iodi tinctura seu Tinctura Iodi.	Strength 10 per cent. Prepare with alcohol (95 per cent.).
Lobelizæ tinctura seu Tinctura Lobelizæ.	Strength 10 per cent. Prepare by percolation with alcohol (70 per cent.).
Cocainum hydrochloricum.	The anhydrous salt.
Hydrargyri unguentum seu Unguentum Hydrargyri.	Strength 30 per cent.
Antimoniale vinum seu Vinum antimoniale; Stibiatum vinum seu Vinum stibiatum.	Strength in tartar emetic 0.40 per cent.

ARTICLE 2

So far as regards substances other than those which appear in the Table contained in Article 1, and which may hereafter be included in the Pharmacopœias, the Contracting Governments undertake that the following rules shall apply:

(a) No potent drug shall be directed to be prepared in the form of a medicinal wine (*vinum*);

(b) Tinctures of potent drugs shall be directed to be prepared of the strength of 10 per cent. and by percolation;

(c) Fluid extracts of potent drugs shall be prepared of the strength of 100 per cent.

ARTICLE 3

The Contracting Governments shall adopt a normal drop-measure, the external diameter of whose outlet tube shall be exactly 3 millimetres, that is

to say, which, at a temperature of 15 degrees centigrade and with distilled water, shall yield 20 drops to the gramme.

ARTICLE 4

Governments which have not taken part in the present Agreement shall be allowed at their own request to signify their adhesion to it. Such adhesion shall be notified, through the proper diplomatic channel, to the Belgian Government, and by it to the other Signatory Governments.

ARTICLE 5

The present Agreement shall come into force one month after the date of its signature. It is understood, nevertheless, that the stipulations of Articles 1, 2, and 3 shall not become binding upon any one of the Contracting Parties until the publication of a new issue, or of a supplement, of its Pharmacopœia.

ARTICLE 6

In case one or other of the Contracting Parties shall denounce the present Agreement, such denunciation shall take effect only so far as regards itself, and then only six months after the day upon which such denunciation shall have been notified to the Belgian Government.

In witness whereof the Undersigned have signed the present Agreement. Done at Brussels, the 29th November, 1906, in a single instrument, of which an exact copy shall be delivered to each of the Signatory Governments.

For Germany:

GRAF VON WALLWITZ

For Austria and for Hungary:

COMTE CLARY ET ALDRINGEN, *Minister of Austria-Hungary*

For Belgium:

FAVEREAU

For Bulgaria:

DR. ZOLOTOVITZ

For Denmark:

W. GREVENKOP CASTENKIOLD

For Spain:

ARTURO DE BAGUER

For the United States of America:

HENRY LANE WILSON

For France:

ETIENNE GANDERAX

For Great Britain:

ARTHUR H. HARDINGE

For Greece:

A. CHARALAMBY

For Italy:

PCE MARIO RUSPOLI DE POGGIO SUASA

For the Grand Duchy of Luxemburg:

LE COMTE D'ANSEMBOURG

For Norway:

W. CHRISTOPHERSEN

For the Netherlands:

VAN DER STAAL VAN PIERSHIL

For Portugal:

For Russia:

N. DE GIERS

For Servia:

M. BOGHITCHÉVITCH

For Sweden:

FALKENBERG

For Switzerland:

JULES BOREL

PROCÈS-VERBAL OF SIGNATURE

The Undersigned, duly authorized, have met together on the 29th November, 1906, at the Belgian Ministry for Foreign Affairs, in order to proceed to the signature of the Act intended to give diplomatic sanction to the Resolutions adopted by the Conference which assembled at Brussels in the month of September 1902, with a view to the unification of the Pharmacopœial formulas for potent drugs.

At the moment of affixing their signatures to the said Act, the Representatives of Germany, Austria-Hungary, the United States of America, Great Britain, Portugal, and Sweden have formulated, in the name of their respective Governments, the following reservations:

I. RESERVATIONS FORMULATED BY THE GERMAN GOVERNMENT.—

“The Imperial Government does not impose upon itself, by the fact of signing the present Agreement, any other obligation beyond that of exercising its influence, when the proper time arrives, that is to say, at the date of the next revision of the German Pharmacopœia, in order to bring the latter into conformity with the present Agreement.

“At the same time the Imperial Government reserves to itself the right of introducing into the stipulations of this Agreement any modifications which, on the one hand, appear necessary in order to take account of the progress of medical and pharmaceutical science, and which, on the other hand, may be desirable from the point of view of the unification of the German Pharmacopœia.”

II. RESERVATIONS FORMULATED BY THE AUSTRIAN GOVERNMENT.—

“So far as regards *opii pulvis* the Austrian Government reserves to itself the right of permitting the sale of the pure drug containing, as a maximum, 12 per cent. of morphine.”

III. RESERVATIONS FORMULATED BY THE GOVERNMENT OF THE UNITED STATES OF AMERICA.—

“The Government of the United States does not assume, by the fact of signing the present Agreement, any other obligation beyond that of exercising its influence in order that, at the next revision of the American Pharmacopœia, the latter may be brought into harmony with the said Agreement.”

IV. RESERVATIONS FORMULATED BY THE GOVERNMENT OF HIS BRITANNIC MAJESTY.—

“The Government of His Britannic Majesty declares that it reserves the right of introducing into the stipulations of the present Agreement such modifications in detail as the progress of medical and pharmaceutical science may render necessary from time to time.

“The Government of His Britannic Majesty further declares that it reserves the right of adhering to the Agreement, and of denouncing it, with reference to each of the British Colonies or Possessions, separately.”

V. RESERVATIONS FORMULATED BY THE PORTUGUESE GOVERNMENT.—
 “The Resolutions of the International Conference held at Brussels for the unification of the Pharmacopœial formulas of potent drugs shall be applied in Portugal. Nevertheless, the vernacular Portuguese name of each substance shall appear in the text of the Pharmacopœia, and shall be adopted as the primary denomination; one of the Latin names inscribed in the Table contained in Article 1 of the present Agreement shall be used as the first synonymous denomination.”

VI. RESERVATIONS FORMULATED BY THE SWEDISH GOVERNMENT.—“1. The denominations of the potent drugs enumerated in the present Agreement, differing entirely from those employed in the Swedish Pharmacopœia, shall not be inscribed in the text itself of that Pharmacopœia, but shall appear in a special supplement to the new issue of the Pharmacopœia which is in course of preparation;

“2. The denomination of the medicinal wine *vinum glycyrrhizæ opiatum* shall be maintained in Sweden;

“3. As the preparation of tinctures of drugs by percolation involves an increase in the price of these products, this method seems not altogether suitable for employment in a general manner.”

At the moment of proceeding to the signature of the present procès-verbal the Undersigned declare themselves in accord in recognizing that the right referred to in the first reservation formulated by the Government of His Britannic Majesty is acquired by all the Signatory Governments.

It is understood that the Contracting Parties which exercise this right will inform each other, reciprocally, through the intermediary of the Belgian Government, of any modifications introduced into the stipulations of the Agreement.

In witness whereof the Undersigned have drawn up the present procès-verbal.

Done at Brussels, the 29th November, 1906, in a single instrument, of which an exact copy shall be delivered to each of the Signatory Governments.

For Germany:

GRAF VON WALLWITZ

For Austria and for Hungary:

COMTE CLARY ET ALDRINGEN, *Minister of Austria-Hungary*

For Belgium:

FAVEREAU

For Bulgaria:

DR. ZOLOTOVITZ

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