

## Guideline for Assigning Titles to USP *Herbal Medicines Compendium* Monographs Version 1.0: May 7, 2014

### INTRODUCTION

The United States Pharmacopeial Convention recently published the *Herbal Medicines Compendium* (*HMC*). The *HMC* includes standards for herbal articles approved by national regulatory authorities for use as ingredients of herbal medicines or included in national pharmacopeias throughout the world. The *HMC* does not include animal-origin, synthetic chemical, or biotechnology-derived medicines. An herbal article for the purpose of the *HMC* includes the plant (or fungal or algal) material in its intact form (e.g., whole plant, root, aerial parts, fruiting body, etc.), plant products (e.g., gums, latex, resins, etc.), or plant processed forms (e.g., powders, juices, extracts, and fractions) but does not include isolated pure compounds. This document provides guidelines for assigning titles to *HMC* monographs.

### HMC MONOGRAPH TITLES

Each monograph shall have a title that is consistent with its *Definition* section. The monograph title shall include the Latin binomial without the authority followed by the name of plant part(s) or plant product and, where applicable, the processed form. The plant part name, plant product name, and processed form name shall be written in English and in singular form. In cases where more than one species of a genus are represented in the monograph, the genus name shall be used followed by the word *Species*.<sup>1</sup> Additional information about the *HMC* article that is the subject of the monograph, e.g., the Latin binomial(s), with their corresponding author(s) and the family, identity and strength of solvent(s), range of ratios of crude plant material to extract, and range of concentration of marker compound(s), shall be included under its definition.

Below are examples indicating how monograph titles shall be developed for the different types of herbal articles in *HMC*.

#### Titles for Plant Material Monographs

For the purposes of the *HMC*, articles referred to as plant (or fungal or algal) materials include the whole plant or a specific part of the plant (e.g., leaf, fruiting body, root, stem bark, etc.). The examples provided below illustrate how titles for plant material monographs will be derived.

#### [LATIN BINOMIAL WITHOUT AUTHORITY] [PLANT PART(S)]

*Lagerstroemia speciosa* Leaf

*Salvia miltiorrhiza* Root and Rhizome

*Paeonia* Species Root

*Ganoderma lucidum* Fruiting Body

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<sup>1</sup> The Latin term *Species* with an uppercase S has a different meaning in monograph titles of some other currently valid national pharmacopeias, e.g., the pharmacopeias of Austria (ÖAB), Switzerland (PhHelv), Hungary (PhHg), and Formulae Normales (FoNo), wherein the term *Species* is used as a synonym for the German term *Teegemische*, meaning herbal teas composed of multiple species.

### Titles for Plant Product Monographs

For the purposes of the *HMC*, articles referred to as plant (or fungal or algal) products include substances produced naturally by a plant or plant part that do not require extensive processing to be obtained, such as gums, latex, resins, etc. The examples provided below illustrate how titles for plant product monographs will be derived.

#### [LATIN BINOMIAL WITHOUT AUTHORITY] [PLANT PRODUCT]

*Croton lechleri* Latex

*Commiphora wightii* Oleo-gum-resin

### Titles for Plant Processed Form Monographs

For the purposes of the *HMC*, articles referred to as plant (or fungal or algal) processed forms include plant powders, dry extracts, dry juices, liquid articles and fractions but do not include isolated pure compounds. The examples provided below illustrate how titles for plant processed form monographs will be derived.

#### [LATIN BINOMIAL WITHOUT AUTHORITY] [PLANT PART(S)] [POWDER]

*Lagerstroemia speciosa* Leaf Powder

*Salvia miltiorrhiza* Root and Rhizome Powder

*Trigonella foenum-graecum* Seed Powder

Paeonia Species Root Powder

#### [LATIN BINOMIAL WITHOUT AUTHORITY] {FRESH}<sup>2</sup> [PLANT PART(S) OR PLANT PRODUCT] [DRY {TYPE}]<sup>3</sup> EXTRACT

*Lagerstroemia speciosa* Leaf Dry Extract

*Salvia miltiorrhiza* Root and Rhizome Dry Extract

*Trigonella foenum-graecum* Seed Dry Extract

Paeonia Species Root Dry Extract

*Commiphora wightii* Oleo-gum-resin Dry Extract

*Valeriana officinalis* Rhizome, Root, and Stolon Dry Aqueous Extract

*Valeriana officinalis* Rhizome, Root, and Stolon Dry Hydroalcoholic Extract

*Vaccinium myrtillus* Fresh Fruit Dry Extract

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<sup>2</sup> If fresh plant material is used to prepare the extract, the word “Fresh” is included after the Latin Binomial. Otherwise, dry material is assumed.

<sup>3</sup> “TYPE” is an additional term that further identifies the article. The solvent is specified when two articles need to be differentiated based on their chemical profile due to the solvent used. For example, the terms aqueous or hydroalcoholic specify the extraction solvent. Type may also include terms such as “enriched”, “purified” or “native” which specify the chemical nature of the extract; the word “native” has the same meaning as described in General Chapter <565> *Botanical Extracts* .

**[LATIN BINOMIAL WITHOUT AUTHORITY] [PLANT PART(S) OR PLANT PRODUCT] [DRY JUICE]**

*Echinacea purpurea* Aerial Parts Dry Juice

*Sambucus nigra* Fruit Dry Juice

**[LATIN BINOMIAL WITHOUT AUTHORITY] {FRESH} [PLANT PART(S) OR PLANT PRODUCT] [SOFT {TYPE}]<sup>3</sup> EXTRACT]**

*Lagerstroemia speciosa* Leaf Soft Extract

*Capsicum* Species Fruit Soft Extract

*Commiphora wightii* Oleo-gum-resin Soft Extract

*Valeriana officinalis* Root Soft Extract

*Valeriana officinalis* Fresh Root Soft Extract

**[LATIN BINOMIAL WITHOUT AUTHORITY] {FRESH} [PLANT PART(S) OR PLANT PRODUCT] [LIQUID EXTRACT] OR [OTHER LIQUID ARTICLES]<sup>4</sup>**

*Lagerstroemia speciosa* Leaf Liquid Extract

*Atropa belladonna* Leaf Liquid Extract

*Humulus lupulus* Strobile Fluidextract

*Eleutherococcus senticosus* Fluidextract

*Rhamnus purshiana* Bark Fluidextract

*Trigonella foenum-graecum* Seed Tincture

*Rhodiola rosea* Root and Rhizome Tincture

*Vaccinium macrocarpon* Fruit Juice Concentrate

*Prunus cerasus* Fruit Juice

*Mentha x piperita* Leaf Essential Oil

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<sup>4</sup> OTHER LIQUID ARTICLES include but are not limited to the following: [Fluidextract], [Tincture], [Juice], [Aqueous], [Essential Oil] and [Concentrate].

## GLOSSARY

This glossary does not include terms for plant (or fungal or algal) materials that are defined in standard textbooks. It focuses on terms specific to herbal medicine ingredients and processed forms whose definitions are not so readily available elsewhere, or have been defined differently in various sources.

Aqueous Extract	Articles prepared by extracting materials with water.
Concentrate	A liquid or solid preparation of higher concentration and smaller volume than the final dosage form; usually intended to be diluted prior to administration.
Dry Extract	Solid preparations obtained by evaporation of the solvent used in their production.
Dry Juice	Dry material obtained by, for example, freeze-drying, or spray drying juice.
Essential Oil	Natural aromatic complex mixtures of compounds (there may be 200 or more in one essential oil) belonging mainly to two chemical classes, terpenoids such as menthol or limonene, and phenylpropanoids such as cinnamaldehyde or safrole. However, there may also be some phenols such as methyl salicylate (oil of wintergreen) or vanillin, sulphur-containing compounds such as allyl isothiocyanate in mustard oil, or aldehydes such as benzaldehyde in bitter almond essential oil. They are called “essential” because they represent the “essence” of the plant in terms of fragrance. Since they evaporate when exposed to the air at room temperature, they are also called volatile oils or ethereal oils. They may be present in the leaf, seed, bark, stem, root, flower, and other plant parts, and may be obtained by steam distillation or by extraction using various solvents.
Extract	Preparations with liquid, solid, or semisolid consistency obtained from plant material using solvents (such as ethanol, methanol, etc.) to separate constituents of interest from the plant material. Types of extracts are namely: Dry Extract, Soft Extract, and Liquid Extract; each is defined in this Glossary.
Fluidextract	A type of Liquid Extract preparation of plant matter, containing ethanol as a solvent or as a preservative, or both, so made that each 1 mL contains the extracted constituents of 1 g of the crude dry material that it represents, unless otherwise specified in the individual monograph. For example, fluidextracts of <i>Eleutherococcus senticosus</i> with a 2:1 or 1:2 ratio are articles of commerce so an <i>HMC</i> monograph with that specification is possible.
Fraction	Processed extracts that consist of a specific class of compounds, for example, sennosides from <i>Senna</i> , oligomeric proanthocyanidins from Grape Seed, and triterpenes from <i>Centella asiatica</i> .
Gum	A water-soluble carbohydrate derivative in the form of a hydrocolloid comprised of an anionic or nonionic polysaccharide or salts of polysaccharides, e.g. tragacanth, arabic (a.k.a. acacia), ghatti, guar, karaya, locust bean, or xanthan.
Latin Binomial	A system of nomenclature of animals, plants, and other life forms (developed by Linnaeus) that assigns a two-part Latinized name, the generic and specific epithets, to each species, such as <i>Harpagophytum procumbens</i> or <i>Harpagophytum zeyheri</i> for the two species of Devil’s Claw included in the <i>Harpagophytum</i> Species Root monograph.

Latin Binomial Authority	The author of the Latin binomial, i.e. the individual(s) who first named, or later revised the name of the plant and validly published that binomial. The author information immediately follows the specific epithet, e.g. <i>Harpagophytum procumbens</i> (Burch.) DC. ex Meisn. or <i>Harpagophytum zeyheri</i> Decne.
Liquid Extract	Liquid preparations of plant matter containing ethanol, water, vinegar, vegetable oil, or glycerin (or a mixture e.g. aqueous ethanol) as a solvent. The term liquid indicates a material that is pourable and conforms to its container at room temperature.
Preparation	Mixtures of one or more ingredients with suitable vehicles. The vehicles are used to facilitate dilution of a botanical ingredient in order to achieve desired concentrations. Preparations should be homogeneous. It is essential that materials of suitable fineness be used and that thorough mixing be achieved at all stages of their preparation. They may be prepared as liquids (e.g. suspensions, emulsions, or solutions in the case of a soluble fraction), powders, pellets, or in granulated form. The granulated form is free flowing and free from aggregates.
Oleo-gum-resin	A mixture of an oleoresin and a gum, e.g. myrrh.
Plant Processed Forms	Plant material that has been subjected to processing e.g. grinding to powder. Examples of processed plant forms are powders, juices, extracts and fractions, but not isolated pure compounds.
Plant Product	Substance produced naturally by a plant or plant part that does not require extensive processing to be obtained. Examples include gums, latex, resins, etc.
Resin	An amorphous complex mixture of resin acids, resin alcohols, resinotannols, esters and resins, usually hard and transparent or translucent at room temperature, and insoluble in water, e.g. rosin, guaiac, and mastic.
Soft Extract	Preparations having consistencies between those of liquid extracts and those of dry extracts, and are obtained by partial evaporation of the solvent (e.g., water, alcohol, or hydroalcoholic mixture) used for extraction.
Tincture	Liquid preparations usually prepared by extracting plant materials with alcohol or hydroalcoholic mixtures. Traditionally, tinctures of potent articles of botanical origin represent the activity of 1 g of the drug in each 10 mL of tincture, the strength being adjusted following the test for content of active principles or marker compounds.