



Guideline for Assigning Titles to *USP* Dietary Supplement Monographs

INTRODUCTION

The purpose of this Guideline is to provide a systematic approach to the development of monograph titles for dietary ingredients and dietary supplement dosage forms admitted to the *United States Pharmacopeia–National Formulary (USP–NF)* published by the United States Pharmacopeial Convention (USP). There are many considerations made when naming dietary ingredient and dietary supplement (DS) monographs, including but not limited to: available scientific conventions, the practices of the DS industry, USP’s historical and scientific practices, international similarities and differences, environmental and agricultural practices, regulatory status, and the labeling requirements of applicable federal regulations.

The Guideline describes how either common names or scientific names for articles are selected for use in the monograph title. For complex articles of botanical or animal origin, this Guideline will explain which details should be in the monograph title versus in the *Definition* section with regard to species and subspecies or variety names and common synonyms, part of the organism and its processed form, type of extract and composition of partially purified natural complexes. The Guideline will also discuss assignment of titles for DS single chemical entity monographs and for DS monographs describing the article in a particular finished oral dosage form. Examples provided are drawn from monographs in the *USP–NF*, and recommended or new monograph titles are provided to illustrate the results of applying this guidance. However, it should be noted that this Guideline applies to *USP* DS monograph titles and not to *NF* or other non-DS monograph titles.

Each monograph shall have a title that is consistent with its *Definition* section and that avoids ambiguity as much as possible yet is concise. Dietary supplement monograph titles should also be reflective of how the article is best known in commerce and help guide manufacturers in meeting the identity aspects of dietary ingredient and finished dietary supplement product labeling. It is preferable that existing monograph titles that do not follow the new approach be revised only on an as-needed, case-by-case basis. This Guideline complements *USP* General Chapter <1121> *Nomenclature*.

This Guideline was developed with input from the USP Nomenclature and Labeling Expert Committee (NL EC), the Botanical Dietary Supplements and Herbal Medicines Expert Committee (DSHM EC) and the Non-Botanical Dietary Supplements Expert Committee (NBDS EC). All titles of dietary ingredient monographs and DS monographs are concurred with by the appropriate ECs, based on USP staff research and the best scientific judgment of the ECs.



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GENERAL CONSIDERATIONS

Historical Practice

The first *Pharmacopoeia of the United States of America*, published in 1820, included monographs of articles that today may be marketed as DSs, including some minerals (medicinal and in some cases also nutritional) and many botanicals. During its first 100 years, from 1820 through 1920, around 875 botanical monographs were published in the *USP*. Vitamin monographs were incorporated later – the USP established a Vitamin Advisory Board in 1932 and the very first USP reference standards distributed were Vitamins A & D in Cod Liver Oil. In 1993, in response to the Nutrition Labeling and Education Act (NLEA) of 1990, a separate compendium section titled *Nutritional Supplements* was created to contain monographs for vitamins and minerals. DS monographs were started in 1995 in response to the Dietary Supplement Health and Education Act of 1994 (DSHEA) and included some monographs for botanicals that were originally placed in the *NF*. The *Nutritional Supplements* section was active through the publication of *USP 26–NF 21* in 2003. In 2004, a new section, *Dietary Supplements*, was introduced into *USP 27–NF 22* to replace the *Nutritional Supplements* section and included monographs for ingredients and dosage forms of DSs as defined by DSHEA. Most monographs for botanical DSs originally in the *NF* were also migrated to this new DS section, which is a subsection of the *USP*.

It should be noted, however, that other botanical articles in the *USP–NF* are not necessarily DSs because they may be classified as drugs (prescription or non-prescription), medical devices or excipients. For example (indicating monograph titles in bold font), **Aloe**, **Belladonna Leaf**, **Digitalis**, **Elm**, **Ipecac**, **Opium**, **Podophyllum**, **Psyllium Husk**, **Rauwolfia Serpentina**, **Senna Leaf** and **Senna Pod** remain in the drug section of the *USP*. There is a *USP* monograph for **Gutta Percha**, which is used as a medical device material, e.g., for endodontic (root canal) treatment. Other articles, such as flavors, fragrances, and other excipients, e.g., **Rose Oil**, are placed in the *NF*.

Crafting monograph titles for vitamin and mineral articles has always been more straightforward than it is for botanical articles, as the former are mostly comprised of single ingredients with titles largely formulated in a manner similar to those for drugs. Guidance for developing botanical monograph titles was provided in the first *USP* in 1820 to adopt a nomenclature to "...be conformable to the present language of science, divested of as much of its prolixity as can be done consistently with clearness and distinctness. It is conceded that the essential properties of names ought to be expressiveness, brevity and dissimilarity." The intent was for the monograph title to "...expresses the medicine, and nothing else; ...needed to be short and explicit, and does not require to be mutilated in practical use, as long names will inevitably be" (1). Thus, a monograph title was to be brief and distinct; a single word sufficed if that word was expressive and unambiguous.



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DS Monograph Titles and DS Product Label Regulatory Requirements

DSHEA defines a DS as: “(1) a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) a herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).”¹ DSHEA also mandates that the label of a DS must bear a statement of identity.

As set out in the Code of Federal Regulations Title 21 (21 CFR) section 101.4 (h), the “common or usual names of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in *Herbs of Commerce*, 1992 edition” (*HoC1*) (2).

Since the incorporation of *HoC1* by reference into 21 CFR 101.4 (h), a second edition, *HoC2*, was published in 2000 (3). Some changes from *HoC1* to *HoC2*, beyond the addition of more herbs of commerce, include revisions to common names and Latin binomials and the dropping of hyphens from Pinyin Names. The revisions in *HoC2* and any subsequent editions will be taken into consideration for the creation of *DSC* monograph titles for botanicals.

The intent set out in *HoC1* was that there should be only one standardized common name (SCN) for a plant, and that name should apply to only one taxon. However, certain exceptions were noted.

Where a commodity is represented by more than one taxa in an official compendium such as the *USP*, the *European Pharmacopoeia (Ph. Eur.)* or the *European Medicines Agency (EMA)* monographs, the SCN could apply to all of the species in that one monograph with the correct Latin binomial being applied on the product label to clarify which species the product contains. For example, *HoC1* has only one species associated with the SCN “devil’s claw”, *Harpagophytum procumbens*, but a second species, *Harpagophytum zeyheri*, is included in the monographs of the *Ph. Eur.* and the *EMA*. Therefore, in the title for a DS monograph including both species the SCN could be applied, i.e., **Devil’s Claw**, with the Latin binomials of the two species set out in the

¹ See § 201(ff) of DSHEA, 108 Stat. 4325, Public Law 103-471, 103d Congress (1994) for additional details of the definition of a dietary supplement. These provisions are now codified in the Federal Food, Drug, and Cosmetic Act at 21 United States Code § 321(ff).



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Definition. The non-*HoC1* species could be distinguished on product labels as “devil’s claw (*Harpagophytum zeyheri*)”.

In cases where the plant has an established common name in the U.S. but it is imported from a country where a different common name is officially recognized, *HoC1* proposed that the foreign common name could follow in parentheses after the English common name, e.g., the SCN for *Astragalus membranaceus* is “astragalus” but it is well known in the Traditional Chinese Medicine trade as “huang qi”. Thus, a DS monograph title would be **Astragalus**, the monograph’s *Definition* could provide the Pinyin common name “huang qi”, and the article could be listed on a product label as “astragalus (huang qi)”.

The third exception noted in *HoC1* was that more than one SCN can be used for a single taxon if that plant produces more than one commodity in commerce. For example, *Myristica fragrans* has the SCN “nutmeg” for the seed and “mace” for the aril surrounding the seed, since they are used as separate spices. As a second example more applicable to monograph titles, *Siraitia grosvenorii* has the *HoC1* SCN “luo-han-guo” (without hyphens in *HoC2*), which is the common name best known for the article when used in Traditional Chinese Medicine. Thus, the title for a DS monograph should be **Luo Han Guo**. However, when used in foods and DSs as a natural low-calorie sweetener (i.e., meeting the exception set out in *HoC1* when the article represents a different commodity), *Siraitia grosvenorii* is better known as “monk fruit”, so an *NF* (i.e., for the sweetening agent purpose) monograph could have the title **Monk Fruit** even though the two monographs are describing the same botanical raw material and will both have the same Latin binomial in the monographs’ *Definition* section.

Although DS monograph titles are not subject to DSHEA and federal DS product labeling requirements, to make the monographs as useful as possible to DS stakeholders, the USP is assigning titles to DS monographs in a manner as consistent as possible with DSHEA and *HoC1*, including the use of SCNs of botanicals utilized in North American commerce.

It must be noted that later editions of *HoC* are not legally binding for DS labels. Therefore, guidance for DS monograph titles will also be taken from the U.S. regulations’ general principles for the naming of non-standardized foods, 21 CFR 102.5 (a): “The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.



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Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.”

Common names used in commerce change over time. For example, *Euterpe oleracea* had no SCN in *HoC1* but it has the SCN “cabbage palm” in *HoC2*. That DS ingredient is now better known as “açai palm”. In these cases using the most appropriate common name in the DS monograph title will facilitate the monograph’s use by industry, and the relationship between names can be clarified by adding other well-established common names and the Latin binomial to the monograph’s *Definition* and compendium *Index*.

In some cases, two or more plant species may have the same SCN but can be distinguished from each other in the monograph title—if necessary to meet the requirements of the monograph—by using an Other Common Name (OCN) provided in *HoC2* in the monograph title. For example, “Labrador tea” was not included in *HoC1* but in *HoC2* it is the SCN for both *Ledum groenlandicum* (currently accepted name: *Ledum palustre* subsp. *groenlandicum*) and *Ledum palustre* subsp. *decumbens*. To have a separate DS monograph for each species, the OCNs “bog Labrador tea” and “marsh Labrador tea,” respectively, could be used in the monograph titles. *HoC2* explicitly noted the need for flexibility in the use of the exact SCN, giving the example of the SCN “common bean” for *Phaseolus vulgaris* but noting that specific naming of articles such as “kidney bean”, “pinto bean”, “green bean”, and “snap bean” is appropriate whenever such modifiers are applied accurately.

In cases where more than one species of a genus is represented in a single monograph, the genus name shall be used followed by the word Species² in the monograph title unless there is one SCN for all the included species and, for the purposes of the monograph, there is no need to distinguish among them. For example, *HoC2* has a separate SCN for each of 11 different species of willow, but in commerce the barks of various species of *Salix* are used alone or mixed to make “willow bark” or “willow bark extract” supplements. Due to substantial anatomical and chemical similarities and hybridization between species, distinguishing them by microscopic, chemical, or genetic tests is neither readily feasible nor necessary. Because use of any one “willow” SCN in the DS monograph title will not accurately reflect the composition of the article of commerce, a more appropriate title would be ***Salix* Species Bark**.

² 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), and Hungary (PhHg) as well as *Formulae Normales* (FoNo), wherein the term Species is used as a synonym for the German term Teegemische, meaning herbal teas composed of multiple species.



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DS Monograph Titles and Latin Binomial Names

The Latin binomial is required either in the DS monograph title or in the monograph's *Labeling* section, as well as in the *Definition*, for plants and other organisms that are not listed in *HoC1* or more recent editions, and thus have not been assigned an SCN, e.g., *Pelargonium sidoides* for that medicinal species of geranium, or *Lagerstroemia speciosa* for banaba. If the SCN applies to more than one species or there are no OCNs provided in *HoC* that distinguish those species, and a distinction is necessary for the purposes of the monograph, then the Latin binomial will be used in the monograph title.

Any Latin binomial shall be in accordance with internationally accepted rules on nomenclature, such as those in the *International Code of Nomenclature for algae, fungi, and plants (Melbourne Code)* (4), the 2011 edition of which replaced the *International Code of Botanical Nomenclature*, the *International Code of Zoological Nomenclature* (5), and the *International Code of Nomenclature of Bacteria* (6), the proposed revision of which has the title *International Code of Nomenclature of Prokaryotes* (7). For example, Latin binomials and subspecies or variety names must be italicized.

Inclusion of the variety or subspecies in the title of a DS monograph depends on whether or not it is relevant for an accurate definition of the article of commerce. Phytochemical and/or safety differences, which may arise in different ecotypes or chemotypes of the same species from different geographic regions, and traditional use differences at the variety or subspecies level should be evaluated to determine whether or not the variety or subspecies should be included in the monograph title. For example, there is an *Herbal Medicines Compendium (HMC)* monograph whose title includes the variety name, ***Ziziphus jujuba* var. *spinosa* Seed**, since only *Ziziphus jujube* var. *spinosa* (Bunge) Hu ex H.F.Chow is accepted as the source for the seeds that are the compendial article. Since the *HoC2* SCN “jujube” applies to both the species as a whole, *Ziziphus jujube* Mill., and the variety *Ziziphus jujube* var. *spinosa*, the title for a DS monograph for the same article as described in the *HMC* would also need to be ***Ziziphus jujuba* var. *spinosa* Seed** in order to accurately reflect the botanical source. The relationship of the DS article to the material with the SCN “jujube” would be explained in the *Definition*. When a variety or subspecies is not relevant to the article's definition and characterization, it should not be used in the title of the monograph.



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Use of Synonyms in DS Monograph Titles vs. *Definitions*

Both common names and Latin binomials may have synonyms used in commerce and in the literature on DSs. Use of well-established common name synonyms set out in *HoC1* and *HoC2* as OCNs have been discussed above.

The Latin binomial most widely known in commerce may be used in the monograph title even if it does not represent current accepted taxonomic nomenclature. For example, if a DS monograph were to be developed for the article *Scelletium tortuosum* aerial parts (which is currently an article in the *HMC*), the title would be the same, ***Scelletium tortuosum* Aerial Parts**, since the article is not listed in *HoC1* or *HoC2* and there is no SCN or OCN or a common name well known in commerce. According to the authoritative Kew Medicinal Plant Names Services (8), the currently accepted scientific name for this plant is *Mesembryanthemum tortuosum* L. but since the Latin binomial *Scelletium tortuosum* (L.) N.E. Br. is a synonym well established in commerce, it is the more appropriate choice for the monograph title. By providing appropriate details of synonymy in the monograph's *Definition*, the connection is maintained between the article of commerce and its current Latin binomial, which is always subject to revision by taxonomists.

Since there may be more than one commonly used synonym for an article of commerce, it is important to be pragmatic in selecting which other synonyms should be included in the monograph *Definition* to clarify the article's identity. Taxonomic web sites such as Kew's Medicinal Plant Names Services (8) and the U.S. Department of Agriculture, Agricultural Research Service, Germplasm Resources Information Network (GRIN) online database (9) can be consulted for a reasonably comprehensive list of Latin binomial synonyms, so it will not be necessary to duplicate all of that information in a DS monograph.

The following criteria may be helpful in deciding how to select Latin binomial synonyms for inclusion in the DS monograph *Definition* once the Latin binomial has been selected for the title:

1. If the Latin binomial selected for use in the DS monograph title or associated with the DS monograph title's SCN is a synonym according to the current nomenclature set out in Kew Medicinal Plant Names Services (8) or the USDA GRIN database (9), then clarification of the synonymy should be included in the DS monograph *Definition*. For example, *Polygonum multiflorum* Thunb. is the Latin binomial associated with the SCN "fo-ti" but it is a synonym for *Reynoutria multiflora* (Thunb.) Moldenke. Both this synonym and the current correct Latin binomial should be

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included in the **Fo-Ti** monograph. As another example, ***Garcinia cambogia*** (SCN “garcinia”) is a synonym used currently as a DS monograph title; both *Garcinia cambogia* (Gaertn.) Desr. and the accepted Latin binomial name *Garcinia gummi-gutta* (L.) Roxb. (but with the author N. Robson, which has since been revised to Roxb.) are included in the *Definition*. To determine which synonyms are well-established in commerce, references to consult include key compendia or pharmacopeias from authoritative sources (e.g., labeling standards or monographs published by the *European Medicines Agency*, or compendia such as the *Food Chemicals Codex*, *European Pharmacopoeia*, *Pharmacopoeia of the People’s Republic of China*, or the *Herbal Medicines Compendium*).

2. Where key compendia or pharmacopeias from authoritative sources provide multiple synonyms, the presence of a synonym in two or more compendia/pharmacopeias may be evidence that it is well-known enough to cite in the DS monograph *Definition* [e.g., *Momordica grosvenorii* Swingle and *Thladiantha grosvenorii* (Swingle) C. Jeffrey are commonly cited synonyms for *Siraitia grosvenorii* (Swingle) C. Jeffrey ex A.M. Lu & Zhi Y. Zhang]. It is possible that not all synonyms are used in commerce. Setting a criterion that synonyms must be found in two or more references may help avoid listing terms that are not used frequently. This criterion can be revisited if too long a list is obtained in too many cases.
3. If a synonym is not listed in one of these official compendia but other peer-reviewed literature suggests there is a risk of confusion, then this synonymy should be included in the monograph text. For example, the botanical with the SCN of “calamus”, used in both Traditional Chinese Medicine and in Ayurvedic medicine, has the Latin binomial *Acorus calamus* L. In North American traditional medicine, the related native plant is described in the literature either as *Acorus calamus* L. or as *Acorus americanus* (Raf.) Raf. The latter Latin binomial does not appear in most major compendia. The currently accepted Latin binomial for the North American plant is *Acorus calamus* var. *americanus* Raf. Belonging to the species *Acorus calamus*, the SCN applies so the monograph title should be **Calamus**, but there are phytochemical differences between the North American and Eurasian material that may be relevant to safety and quality standard-setting. For that reason, a DS monograph setting standards for the North American plant material should include this synonymy in the *Definition* to clarify its relationship to “calamus”.

Exclusion of Latin Binomial Authors from DS Monograph Titles

The citation of the author or authors who validly published the Latin binomial is a key part of the scientific name of an organism. For brevity, however, it is not necessary to



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include the author citation of a Latin binomial in the DS monograph title; it will be provided in the *Definition* section of the monograph.

The authors' names follow directly after the Latin binomial, e.g., *Andrographis paniculata* (Burm.f.) Nees. The reason the Latin binomial needs to be followed by the author citation is that the author citation helps in locating the original published plant description, which helps determine the “type species” (from which the original description was created), and the date (priority) of publication of the name; these are key criteria used to determine which name for a particular species is correct.

The author citation also helps trace changes in names. For example, the author citation for the plant name *Andrographis paniculata* (Burm.f.) Nees indicates that Christian Gottfried Daniel Nees von Esenbeck (internationally standardized abbreviation, “Nees”) transferred this species to the genus *Andrographis* after re-examining and reclassifying the same type specimen whose description was the basis for the original name *Justicia paniculata* Burm.f. published by Nicolaas Laurens Burman (“f.” stands for *filius* because he was the son of another botanist, Johannes Burman, whose abbreviation is “Burm”).

The author citation becomes critical in tracing the source of the Latin binomial to prevent confusion over duplicate names and confirm the correct nomenclature of an article. A good example of this is the case of two different species which have been described in the literature with the same Latin binomial, *Illicium anisatum*. Only the author distinguishes the two names: *Illicium anisatum* L. is the correct Latin binomial for toxic Japanese star anise, and *Illicium anisatum* Lour. is an incorrect Latin binomial for edible Chinese star anise, for which the currently accepted Latin binomial is *Illicium verum* Hook.f. Correct nomenclature will be an issue on a product label, on a raw material order form, or in a master formula. Thus, the level of detail in the DS monograph *Definition* section will be consistent with the labeling regulations that require inclusion of the designation of the author or authors who published the Latin name.

A detailed explanation of how authors are cited and the meaning of terms such as “ex” or “in” found within the author citation is provided in Chapter VI of the *International Code of Nomenclature for algae, fungi, and plants* (4).

Use of Plant Parts in DS Monograph Titles

The 1820 edition of the *USP* deliberately omitted the plant part except where two parts of the plant had different uses, not just for brevity but because the names of botanical drugs and medicines were well known to be associated with a specific plant part (1).



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Thus, plant parts were not included previously in *USP* botanical monograph titles except where multiple monographs were developed for different plant parts of the same species, in which case the plant part was included to distinguish the monographs from each other by title.

The USP staff followed this format when formulating monograph titles until the enactment of DSHEA in 1994. Current regulations, i.e., 21 CFR101.4(h)(1), require the DS label to list the part of the plant (e.g., root, leaf) from which the dietary ingredient is derived [e.g., “Garlic bulb” or “Garlic (bulb)”] and there is a great diversity of both botanical species and parts finding use in modern dietary supplements. Therefore, in the DS monograph title, the name of the plant part (in singular form unless including multiple plant parts) follows the name (common or Latin binomial) of the article. For example, ***Echinacea purpurea* Aerial Parts** is a separate monograph from ***Echinacea purpurea* Root**.

The name of the part of the plant shall be expressed in English, e.g., “flower” rather than in Latin, e.g., “flos” as is used in some pharmacopeias.

An exception to including multiple plant parts in the DS monograph title may be made where that would result in a monograph title that is not brief. Generally, when there are three or more plant parts, it may be preferable to use in the monograph title the part best known to industry or used in monograph titles of other pharmacopeias, or alternatively, leaving the listing of plant parts to the *Definition*. For example, the current edition of the *Ph. Eur.* has a monograph for **Valerian Root (*Valerianae radix*)** for which the *Definition* is: “Dried, whole or fragmented underground parts of *Valeriana officinalis* L. *s.l.*, including the rhizome surrounded by the roots and stolons.” Therefore, rather than creating a DS monograph title **Valerian Rhizome Root and Stolon** that will become very cumbersome when extract types and dosage forms are added, it can be shortened to the internationally accepted **Valerian Root** with the additional plant parts set out in the *Definition*. As an example of the other situation, **Norway Spruce Lignans** may be obtained from multiple parts of the Norway spruce tree. In such cases, the necessary details of plant parts will be included in the monograph’s *Definition*.

Where several plant parts are included in the DS monograph title, the order of the plant parts currently is simply the order in which they are listed in the monograph’s *Definition*. This may or may not be in order of descending quantity in the article. While that would be a logical order that could be followed for titles of new DS monographs, it would be impractically labor-intensive to try to verify that for existing monographs. Where it exists, a collective term such as “aerial parts” or “flowering top” that accurately reflects the composition of the article should be used rather than listing plant parts separately, which

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could make DS monograph titles too cumbersome. For example, the article **Hawthorn Leaf with Flower** consists of the dried tips of the flower-bearing branches up to 7 cm in length. While this article will obviously also contain some stem and stem bark material, the *Definition* limits that by specifying the terminal 7 cm portion of the branch. Therefore, “Leaf with Flower” is sufficiently descriptive for the parts of the plant that are important for characterization of the article. On the other hand, the article ***Echinacea purpurea* Aerial Parts** consists of all plant parts above ground level, as described in the *Specific Tests – Botanic Characteristics – Macroscopic* section, and it would be too cumbersome to name them all in the title, so the use of a collective term is appropriate.

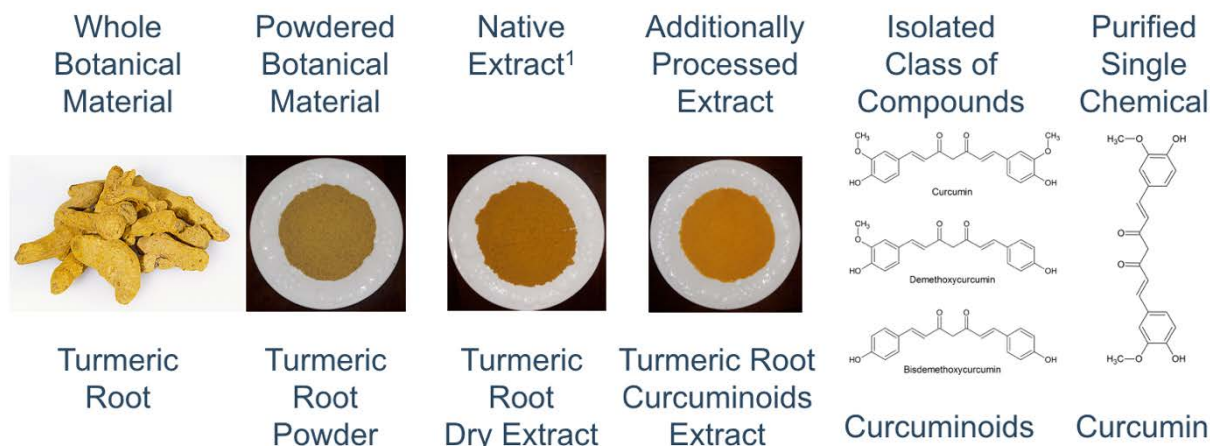
Organization of this Guideline

In order to provide organization and a logical flow to this guidance on assigning titles to DS monographs, the information is presented in a progression from the most complex articles to more refined articles. This is accomplished within the following categories: complex articles of botanical origin (including plants, fungi and algae), complex articles of animal origin, complex articles of bacterial origin, single chemical entities or combinations of single chemical entities, including vitamins, minerals, and amino acids, and finished oral dosage form articles.

For example, a family of DS monographs that would reflect this progressive level of refinement (and thus decrease in complexity) would be assigned names as follows. **Turmeric Rhizome** is the unprocessed botanical raw material DS article, from which grinding will produce the DS article **Turmeric Rhizome Powder**, which can be extracted with aqueous ethanol to make the extract DS article **Turmeric Rhizome Dry Extract**. This could be subject to additional processing to make a partially purified natural complex DS article **Turmeric Rhizome Curcuminoids Extract**, from which could be isolated the **Curcuminoids** class of compounds as another DS article. This could be further purified to provide **Curcumin** as a single isolated chemical entity DS article. Any of the preceding articles, except the unprocessed raw material, could be formulated into a finished oral dosage form DS article such as **Turmeric Rhizome Powder Capsules** or **Curcumin Tablets** (see *Figure 1*).

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Articles of Botanical Origin



Degree of Complexity

Intact plant material → Single chemical entity

Degree of Purification

¹ Extract with no added inert substances and no processing beyond extraction (*USP* General Chapter <565> *Botanical Extracts*)

Figure 1. A family of DS monographs

DIETARY INGREDIENT MONOGRAPH TITLES

A “dietary ingredient”, as defined by DSHEA, is a substance intended for use in the manufacture of DS finished dosage forms. Dietary ingredient monographs define and characterize plant, fungal, and algal materials, some of which may in fact be raw materials (crude herb is a synonymous term) as described in the *USP* General Chapter <563> *Identification of Articles of Botanical Origin*). They may also be dietary ingredients used directly in the manufacture of DSs. There are dietary ingredient monographs that describe botanical raw materials that have been processed to a limited extent, such as by drying and milling (cutting, sifting, particle sizing, and density adjustment). Other dietary ingredient monographs describe complex botanical extracts, extracts subjected



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to additional processing, partially purified natural complexes, single chemical entities and mixtures of single chemical entities.

Titles for DS Monographs of Complex Articles of Botanical Origin

Articles of botanical origin in this Guideline include plant, fungal, algal, and cyanobacterial articles. Each monograph shall have a title that is consistent with its *Definition* and *Identification* sections. The monograph title shall include the SCN (or OCN in the cases explained above) from *HoC1* or its subsequent editions or the Latin binomial where necessary (in the cases explained above). The organism's name will be followed by the name of the botanical part(s), except in the case of single-celled or colonial organisms such as yeasts (e.g., ***Saccharomyces cerevisiae*, Red Yeast**), certain algae (e.g., ***Chlorella***), and cyanobacteria (also known as blue-green algae, e.g., ***Spirulina***), which have no parts. The part name is followed, where applicable, by the processed form. The botanical part or material name and processed form name shall be written in English and in singular form unless multiple parts are included (e.g., aerial parts to represent all of the above-ground parts of the plant including the stems, leaves and flowers).

Additional information about the article that is the subject of the monograph, such as the Latin binomial(s) with their corresponding author(s) and the family, other common name(s), identity, strength (range of ratios of crude plant material to extract), composition (range of concentration of one or more marker compounds) and extraction solvent, shall generally be included under its *Definition*.

Below are examples indicating how monograph titles shall be developed for the different types of complex dietary ingredients of botanical origin including raw botanical materials and various types of botanical processed forms. Following this Guideline will allow a family of monographs to have a consistent title format, e.g., a botanical raw material monograph for **Gymnema Leaf** (in *Table 1*), a processed botanical material monograph for **Gymnema Leaf Powder** (in *Table 2*), a botanical dry extract monograph for **Gymnema Leaf Dry Extract** (in *Table 3*) and an additionally processed botanical extract monograph for **Gymnema Leaf Gymnemic Acids Dry Extract** (in *Table 8*).

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Titles for Botanical Material Monographs

Botanical materials include the whole plant or a specific part of the plant (or fungus or alga), with the exception noted above for single-celled or colonial organisms. Botanical materials also include some natural gums, resins, oleo-gum-resins, mucilages and latexes that occur as exudates of the plant, e.g., aloe latex or guggul oleo-gum-resin.³ Other examples of these types of materials are obtained by extraction, e.g., guar gum, Capsicum oleoresin and marshmallow root mucilage. In either case these terms are descriptive of the article, so to keep the DS monograph title concise, the details will be captured in the *Definition*.

The examples provided in *Table 1* illustrate how titles for botanical material monographs will be derived when following the new Guideline, compared to how current monograph titles were derived. Two particularly complicated cases, regarding kelp and spirulina, are explained in footnotes as further guidance on how titles are assigned.

Table 1. Current and Recommended Nomenclature Formats for Botanical Material Monograph Titles

Current Examples	Recommended Examples ^a
[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] ^d {BOTANICAL MATERIAL(S)}	[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)]
Aloe	<i>Aloe</i> Species Latex
Andrographis	Andrographis Stem and Leaf
Asian Ginseng	Asian Ginseng Root
<i>Boswellia serrata</i>	Indian Frankincense Oleo-gum-resin
Capsicum	<i>Capsicum</i> Species Fruit
<i>Centella asiatica</i>	Gotu Kola Aerial Parts
Chamomile	Chamomile Flower
NA^c	Clubmoss Spore

³ The *Guideline for Assigning Titles to USP Herbal Medicines Compendium Monographs*, Version 1.0: May 7, 2014, used the term “plant product” to describe a gum, latex, resin, or oleo-gum-resin produced naturally by a plant or plant part that does not require extensive processing to be obtained. In this Guideline these will be included as botanical materials and not described as plant products to avoid confusion with discussion of DS finished products.

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Current Examples	Recommended Examples ^a
[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] ^b {BOTANICAL MATERIAL(S)}	[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)]
Ganoderma Lucidum Fruiting Body	Reishi Fruiting Body
Guggul	Guggul Oleo-gum-resin
Gymnema	Gymnema Leaf
NA	Kelp Thallus^d
Myrrh	Myrrh Oleo-gum-resin
NA	White Pine Pollen
<i>Rhodiola rosea</i>	<i>Rhodiola rosea</i> Root and Rhizome
Senna Leaf	Senna Leaf
Senna Pods	Senna Pod
Spirulina	<i>Spirulina</i> Species^e
Valerian	Valerian Root
Wheat Bran	Wheat Bran

^a Some examples provided are hypothetical, solely to show what the new titles would look like.

^b Items within brackets [] are required, whereas those within braces { } are to be used as appropriate, e.g., one should use {SCN} where an unambiguous SCN is provided in *Herbs of Commerce* but use {Latin binomial} in other cases as explained above.

^c **NA**: title not available because currently no USP monograph exists for this article.

^d As an example of an unusual case, “kelp” is the SCN for various species of brown algae: *Alaria marginata*, *Ascophyllum nodosum*, *Laminaria digitata*, *L. hyperborea* (synonym *L. cloustonii*), *L. setchellii*, *L. sinclairii*, and *Macrocystis pyrifera*. Not all of these species have assigned OCNs. Another species, *L. saccharina*, has “sugar kelp” as the SCN. Kelp is defined in 21CFR172.365 as the dehydrated, ground product prepared from *Macrocystis pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni* [sic] for special dietary and nutritional additives as a source of the essential mineral iodine. Therefore, using the SCN in a DS monograph title, **Kelp**, might be interpreted to capture only three of the four species set out in 21 CFR 172.365, and could include other genera and species not permitted as Kelp under the conditions set out in this regulation. To resolve this rare exception to the general approach, a DS monograph entitled **Kelp Thallus** could specify the four species from 21CFR172.365 in the *Definition*, while a monograph for *Ascophyllum nodosum* could have the title **Kelp (*Ascophyllum nodosum*) Thallus** to include the SCN and be distinguishable from the other monograph.

^e The DS article ***Spirulina* Species** consists of the dried, whole, blue-green microalgae *Arthrospira platensis* (Nordstedt) Gomont, synonym *Spirulina platensis* (Nordstedt) Geitler; *Arthrospira maxima* Setchell & Gardner, synonym *Spirulina maxima* (Setchell & Gardner) Geitler in Rabenhorst (illegitimate); or *Arthrospira fusiformis* (Voronichin) J. Komarek & J.W.G. Lund, synonym *Spirulina fusiformis* Voronichin. Although all three species of *Arthrospira* have a *Spirulina* synonym, only the first two of these species have the SCN “spirulina”. They constitute most of the article on the market so using the synonym ***Spirulina*** rather than the currently accepted ***Arthrospira*** followed by **Species** in the title is a compromise



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Current Examples	Recommended Examples ^a
[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] ^d {BOTANICAL MATERIAL(S)}	[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)]
<p>that allows the monograph title to use the SCN with which industry and consumers are very familiar. The <i>Definition</i> section will provide details that may be needed for an understanding of the DS article composition. In some cases the monograph will also include a labeling requirement related to these additional details.</p>	

Titles for Botanical Processed Form Monographs

Articles referred to as plant (or fungal, algal, or cyanobacterial) processed forms include plant powders, dry extracts, soft extracts, liquid extracts, juices (liquid or dry), other liquid articles such as fixed oils and essential oils, and fractions of extracts, but do not include isolated pure compounds. The examples provided below illustrate how titles for plant processed article monographs will be derived following this Guideline, compared to how current monograph titles were derived.

Titles for Botanical Powder Monographs:

The term “powder” indicates that the botanical material has been milled (comminuted) into a powder. Some materials such as spores and pollen are powder-sized but spores and pollen are botanical parts so their DS monograph titles will follow the format and examples shown in *Table 1*. Botanical powders (see *Table 2* for examples) include powdered botanical materials but are not meant to include other botanically derived articles that may be powdered or present in powder form, such as dry extracts and dry juices, the monograph title formats for which are discussed below.

Table 2. Current and Recommended Nomenclature Formats for Botanical Powders

Current Examples	Recommended Examples
{PROCESS } [{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] {BOTANICAL MATERIAL(S)}	[{SCN}] OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)] [POWDER]
Powdered Andrographis	Andrographis Stem and Leaf Powder
Powdered Ashwagandha Root	Ashwagandha Root Powder
Powdered Black Cohosh	Black Cohosh Rhizome and Root Powder

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Current Examples	Recommended Examples
{PROCESS } [{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] {BOTANICAL MATERIAL(S)}	[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)] [POWDER]
Powdered <i>Centella asiatica</i>	Gotu Kola Aerial Parts Powder
Powdered Garlic	Garlic Bulb Powder
Powdered Gymnema	Gymnema Leaf Powder
Powdered Hawthorn Leaf with Flower	Hawthorn Leaf with Flower Powder
Powdered Horse Chestnut	Horse Chestnut Seed Powder

Titles for Botanical Extract Monographs:

Titles for monographs for extracts obtained from botanical materials are derived from the source plant raw material identity, the extract's physical state or consistency, such as liquid (liquid extracts), semisolid (soft extracts), or dry (extracts in solid form, e.g., powders, granules, or flakes), whether or not the plant raw material was fresh or dried, and which extraction solvent was used in cases where two or more articles need to be differentiated based on their chemical profile due to the extraction solvent used (see General Chapter <565> *Botanical Extracts*). The examples provided in *Tables 3, 4* and *5* illustrate how titles for botanical extract monographs will be derived when following the new Guideline compared to how current monograph titles were derived.

For the sake of clarity, in the following tables the format terms: **[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] [BOTANICAL MATERIAL(S)]** used above to describe botanical materials and powders will be simplified to **[SOURCE MATERIAL]**, which incorporates all of the above terms.

Table 3. Current and Recommended Nomenclature Formats for Botanical Dry Extracts

Current Examples	Recommended Examples
[{PROCESS} {TYPE}] [SOURCE MATERIAL ^a] [EXTRACT]	[SOURCE MATERIAL {FRESH} ^b] [{TYPE} ^c DRY EXTRACT]
Powdered Andrographis Extract	Andrographis Stem and Leaf Dry Extract
Powdered Asian Ginseng Extract	Asian Ginseng Root Dry Extract
Powdered <i>Centella asiatica</i> Extract	Gotu Kola Aerial Parts Dry Extract

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Current Examples	Recommended Examples
[{PROCESS} {TYPE}] [SOURCE MATERIAL ^a] [EXTRACT]	[SOURCE MATERIAL {FRESH} ^b] [{TYPE} ^c DRY EXTRACT]
Powdered Goldenseal Extract	Goldenseal Root and Rhizome Dry Extract
Native Gymnema Extract	Gymnema Leaf Dry Extract
NA	Oat Fresh Seed Dry Extract
Rosemary Leaf Dry Aqueous Extract	Rosemary Leaf Aqueous Dry Extract
NA	Rosemary Leaf Hydroalcoholic Dry Extract
Saw Palmetto Extract (in part) ^d	Saw Palmetto Fruit Hydroalcoholic Dry Extract
Yeast Extract	Yeast Dry Extract

^a Source material refers to the unprocessed botanical material used to prepare an extract or other processed botanical materials, the naming of which is exemplified in *Tables 1* and *2*.

^b If fresh plant material is used to prepare the extract, the word **Fresh** is included after the SCN or Latin binomial and before the plant part. Otherwise, dry material is assumed.

^c **TYPE** is an additional term that further identifies the article. The solvent is specified when two or more articles need to be differentiated based on their chemical profile due to the solvent used.

^d The current **Saw Palmetto Extract** monograph describes extracts obtained by extraction with hydroalcoholic mixtures, hexane, or supercritical carbon dioxide. In future this may be divided into three separate monographs, one for the dry extract and two for the soft extracts, due to the differences in physical form and composition of the extracts produced by using different extraction solvents.

Table 4. Current and Recommended Nomenclature Formats for Botanical Soft Extracts

Current Examples	Recommended Examples
[SOURCE MATERIAL] [EXTRACT]	[SOURCE MATERIAL {FRESH}] [{TYPE} {SOFT EXTRACT}] OR [{MUCILAGE}] OR [{OLEORESIN}]
Capsicum Oleoresin	<i>Capsicum</i> Species Fruit Oleoresin
NA	Turmeric Rhizome Ethanol Oleoresin
NA	Ginger Rhizome Carbon Dioxide Soft Extract
NA	Lemon Balm Leaf Soft Extract
NA	Marshmallow Root Mucilage
Saw Palmetto Extract (in	Saw Palmetto Fruit Lipophilic Soft Extract

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Current Examples	Recommended Examples
[SOURCE MATERIAL] [EXTRACT]	[SOURCE MATERIAL {FRESH}] [{TYPE} {SOFT EXTRACT} OR {MUCILAGE} OR {OLEORESIN}]
part) ^a	Saw Palmetto Fruit Carbon Dioxide Soft Extract
NA	Valerian Fresh Root Soft Extract
^a The current Saw Palmetto Extract monograph describes extracts obtained by extraction with hydroalcoholic mixtures, hexane, or supercritical carbon dioxide. In future this may be divided into three separate monographs, one for the dry extract and two for the soft extracts, due to the differences in physical form and composition of the extracts produced by using different extraction solvents.	

Table 5. Current and Recommended Nomenclature Formats for Botanical Liquid Extracts

Current Examples	Recommended Examples
[SOURCE MATERIAL] [EXTRACT]	[SOURCE MATERIAL {FRESH}] [LIQUID EXTRACT]
Aromatic Cascara Fluidextract	Cascara Sagrada Bark Aromatic^a Fluidextract
Black Cohosh Fluidextract	Black Cohosh Root and Rhizome Fluidextract
Garlic Fluidextract	Garlic Bulb Fluidextract
Ginger Tincture	Ginger Rhizome Tincture
Licorice Fluidextract	Licorice Root Fluidextract
NA	Oat Fresh Seed Tincture
<i>Rhodiola rosea</i> Tincture	<i>Rhodiola rosea</i> Root and Rhizome Tincture
Valerian Tincture	Valerian Root Tincture
^a See the Glossary for an explanation of “aromatic”	

Titles for Botanical Fatty Oil and Essential Oil Monographs:

Articles such as fatty (fixed) oils, essential (volatile) oils, essential oil spirits, and essential oil waters may be obtained by solvent extraction as described in General Chapter <565> *Botanical Extracts*. However, they may also be obtained by other methods such as expression (e.g., cold press) of fatty oils and steam distillation of essential oils. The type of oil (e.g., fatty vs. essential) is not differentiated in the DS monograph title but in the *Definition*. Examples of botanical fatty oil and essential oil article monograph titles are provided in *Table 6*.

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Table 6. Current and Recommended Nomenclature Formats for Botanical Fatty Oils and Essential Oils

Current Examples	Recommended Examples
[SOURCE MATERIAL] [{OIL} OR {SPIRIT} OR {WATER}]	[SOURCE MATERIAL {FRESH}] [{OIL} OR {OIL SPIRIT} OR {OIL WATER}]
Castor Oil	Castor Seed Oil
Aromatic Castor Oil	Castor Seed Aromatic ^a Oil
<i>Cryptocodinium cohnii</i> Oil	<i>Cryptocodinium cohnii</i> Oil
Evening Primrose Oil	Evening Primrose Seed Oil
Flax Seed Oil	Flax Seed Oil
Peppermint Oil	Peppermint Leaf Oil
Peppermint Spirit	Peppermint Leaf Oil Spirit ^a
Peppermint Water	Peppermint Leaf Oil Water ^a
Schizochytrium Oil	<i>Schizochytrium</i> Species Oil

^a See the Glossary for an explanation of terms such as “aromatic”, “aromatic oil water”, and “spirit”

Titles for Botanical Juice Monographs:

Juices are distinguished from other botanical liquid articles because while they are liquid to start (pure, concentrated, or preserved with alcohol or another suitable vehicle as set out in the *Definition*), they may be dried subsequently to make the article of commerce, i.e., a “dry juice”. The ability to extract a juice depends upon the plant material being fresh since they are obtained by expression, so {FRESH} is assumed. Examples are provided in *Table 7*.

Table 7. Current and Recommended Nomenclature Formats for Plant Juices

Current Examples	Recommended Examples
[SOURCE MATERIAL] [EXTRACT]	[SOURCE MATERIAL] [{JUICE} OR {DRY JUICE}]
Cranberry Liquid Preparation ^a	Cranberry Fruit Juice ^b
NA	<i>Echinacea purpurea</i> Aerial Parts Juice
NA	<i>Echinacea purpurea</i> Aerial Parts Dry Juice



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Current Examples	Recommended Examples
[SOURCE MATERIAL] [EXTRACT]	[SOURCE MATERIAL] [{JUICE} OR {DRY JUICE}]
NA	European Elder Fruit Dry Juice
NA	Stinging Nettle Aerial Parts Juice
<p>^a Use of the term “Preparation” is discussed below.</p> <p>^b The Cranberry Liquid Preparation monograph <i>Definition</i> allows for two species, <i>Vaccinium macrocarpon</i> or <i>Vaccinium oxycoccus</i>, but both have the same SCN “cranberry” and there is no need to distinguish them in the monograph, so the title Cranberry Fruit Juice follows the recommended format.</p>	

Use of the Term “Native Extract” in Monograph Titles:

General Chapter <565> states that certain botanical extracts are “native extracts”, which it describes as “extracts with no added inert substances and no processing beyond the extraction” (except for solvent removal in the case of dry or soft extracts). The only DS monographs with the word “native” in the title currently are **Native Guggul Extract** (recommended title: **Guggul Oleo-gum-resin Extract**) and **Native Gymnema Extract** (recommended title: **Gymnema Leaf Dry Extract**). Note that both of these monographs have a contrasting monograph, **Purified Guggul Extract** (recommended title: **Guggul Oleo-gum-resin Guggulsterones Soft or Dry Extract**), where the *Definition* states that “It may be a semisolid extract with no added substances or powder extract containing suitable added substances”, and **Purified Gymnema Extract** (recommended title: **Gymnema Leaf Gymnemic Acids Dry Extract**), where the *Definition* states that “It may contain suitable added substances as carriers”.

Most other botanical extract monographs indicate in the *Definition* rather than by the use of the term “native” in the title whether or not suitable inert substances may be added (e.g., carriers in the monograph for **Powdered Holy Basil Leaf Extract**, recommended title: **Holy Basil Leaf Dry Extract**) or the *Definition* may say nothing about the presence or absence of added substances (e.g., in the monograph for **Maritime Pine Extract** (recommended title: **Maritime Pine Stem Bark Dry Extract**)). Note that many aspects of product formulation are not specified in the *Definition* of botanical extract articles, such as the use of excipients as diluents for producing normalized or standardized content extracts or the use of flow agents in powders such as dry extracts.

Since the *Definition* is an appropriate location to describe the acceptability of the use of certain excipients in the article, for example to dilute a native extract in order to standardize quantified content, there is no need to add qualifiers to monograph titles



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denoting that the article is excipient-free, e.g., “native”. DS monographs that currently have “native” in the title will be reviewed and appropriate changes will be made as part of the normal monograph revision cycle.

The DS monograph title term “purified” relates to botanical extracts subjected to additional processing, which is discussed in the next section.

Titles for Monographs for Botanical Extracts Subjected to Additional Processing:

Some extracts are subjected to additional processing that increases the content of characterized constituents, decreases the content of unwanted constituents, or both. The percentage of characterized or unwanted constituents in a processed extract may vary and will be specified in the *Definition* of the article. For example, the current **Powdered Garcinia Hydroxycitrate Extract** monograph (recommended title: **Garcinia Pericarp Hydroxycitrate Dry Extract**) specifies NLT 40% (-)-hydroxycitric acid.

In other articles, the specifications in the *Definition* are based on a labeled amount rather than a concentration in the extract. The **Purified Guggul Extract** (recommended title: **Guggul Oleo-gum-resin Guggulsterones Soft or Dry Extract**) monograph specifies NLT 90.0% and NMT 110.0% of the labeled amount of the sum of guggulsterones *E* and *Z* calculated as guggulsterone *Z*. The article is explicitly described in the *Definition* as a “semisolid extract” with no added substances or a “powder extract” containing suitable added substances. Similarly, in the **Purified Gymnema Extract** (recommended title: **Gymnema Leaf Gymnemic Acids Dry Extract**) monograph the *Definition* specifies an extract with NLT 90.0% and NMT 110.0% of the labeled amount of gymnemic acids, calculated as gymnemagenin on the dried basis.

Powdered Decaffeinated Green Tea Extract (recommended title: **Green Tea Leaf Decaffeinated Dry Extract**) serves as an example of a current monograph for an article with a reduction of the level of a constituent, by its caffeine specification of NMT 0.1%. Please note that the order of terms in the monograph title is intended to follow the standard pattern set out in *Table 8*; it is not intended to reflect the order in which steps in the processing of the article are done. For example, the decaffeination of green tea is done by extraction of the leaf material with supercritical carbon dioxide; or with water at a high temperature for a short extraction time followed by carbon filtration to remove most of the caffeine and then reuse of the filtered water with the remaining flavor ingredients for preparation of the extract; or with organic solvents such as methylene chloride or ethyl acetate. The decaffeinated leaf material is then used in the production



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of the dry extract rather than the green tea leaf extract being subsequently decaffeinated. Another potential example of reduction of the level of a constituent would be **Licorice Root Deglycyrrhizinated Soft Extract** which has been processed to remove glycyrrhizin (glycyrrhizic acid or glycyrrhizinic acid).

Table 8. Current and Recommended Nomenclature Formats for Botanical Extracts Subjected to Additional Processing

Current Examples	Recommended Examples
[[{PROCESS} {TYPE}]] [SOURCE MATERIAL] [{CONSTITUENT OR CLASS OF COMPOUNDS} {EXTRACT}]	[SOURCE MATERIAL] [CONSTITUENT OR CLASS OF COMPOUNDS] [{TYPE} {DRY EXTRACT} OR {SOFT EXTRACT} OR {LIQUID EXTRACT} OR {OIL}]
Powdered Garcinia Hydroxycitrate Extract	Garcinia Pericarp Hydroxycitrate Dry Extract
Powdered Decaffeinated Green Tea Extract	Green Tea Leaf Decaffeinated Dry Extract
Purified Guggul Extract	Guggul Oleo-gum-resin Guggulsterones Soft or Dry Extract^a
Purified Gymnema Extract	Gymnema Leaf Gymnemic Acids Dry Extract
NA	Licorice Root Deglycyrrhizinated Soft Extract
Powdered Soy Isoflavones Extract	Soy Seed Isoflavones Dry Extract
Tomato Extract Containing Lycopene	Tomato Fruit Lycopene Soft Extract

^a The monograph's *Definition* explicitly includes both a soft extract and a dry extract.

At a higher level along the continuum of refinement, in some current monographs, the specification in the monograph's *Definition* is for a class of compounds isolated as a fraction from a particular botanical material's extract. For example, **Centella asiatica Triterpenes** (recommended title: **Gotu Kola Aerial Parts Triterpenes**) is described as a fraction that contains NLT 90.0% *Centella asiatica* triterpene derivatives; **Grape Seeds Oligomeric Proanthocyanidins** (recommended title: **Grape Seed Oligomeric Proanthocyanidins**) is described as a fraction that contains NLT 75.0% oligomeric proanthocyanidins.

Since triterpenes and oligomeric proanthocyanidins are both diverse and widespread classes of compounds, it is necessary to include the source botanical material in the

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monograph title. *Table 9* provides some examples of current and recommended monograph titles for articles that consist of classes of compounds obtained as fractions of botanical material extracts.

Table 9. Current and Recommended Nomenclature Formats for Classes of Compounds Obtained as a Fraction of a Botanical Material Extract

Current Examples	Recommended Examples
[{PROCESS} {TYPE}] [SOURCE MATERIAL] [CONSTITUENT OR CLASS OF COMPOUNDS]	[SOURCE MATERIAL] [CONSTITUENT OR CLASS OF COMPOUNDS]
<i>Centella asiatica</i> Triterpenes	Gotu Kola Aerial Parts Triterpenes
Grape Seeds Oligomeric Proanthocyanidins	Grape Seed Oligomeric Proanthocyanidins
Psyllium Hemicellulose	Psyllium Seed Husk Hemicellulose

There are also DS monographs that set standards for “partially purified natural complexes” as opposed to the processed/semi-purified extracts and fractions just described. The format for DS monograph titles for partially purified natural complexes is simply [CLASS OF COMPOUNDS]. For example, **Sennosides** is defined as a partially purified natural complex of anthraquinone glucosides isolated from senna leaf and/or senna pod as the calcium salts. The specifications are for NLT 90.0% and NMT 110.0% of the labeled amount of sennosides, and the labeled amount of sennosides should be NLT 60.0% (w/w) calculated on the dried basis. **Curcuminoids** is defined as a partially purified natural complex of diaryl heptanoid derivatives isolated from turmeric, with NLT 95.0% of curcuminoids, calculated on the dried basis, as a sum of curcumin (70.0%–80.0%), desmethoxycurcumin (15.0%–25.0%), and bisdesmethoxycurcumin (2.5%–6.5%). Note that the name for the class of compounds is sufficiently distinctive that the source botanical material does not need to be in the monograph title, only in the *Definition*.

With regard to extracts subjected to additional processing to be enriched or depleted in a particular substance vs. fractions of extracts vs. partially purified natural complexes, it would be arbitrary to set any numerical concentration threshold to distinguish between them. Note that the current DS monograph for **Sennosides** specifies an amount of NLT 60% while **Gotu Kola Aerial Parts Triterpenes** monograph specifies NLT 90.0% *Centella asiatica* triterpene derivatives, so concentration ranges overlap; they are all complex articles along a continuum of refinement.



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In practice, while the degree of purification of natural complexes may overlap with that of extracts subjected to additional processing, the intent of a monograph for a partially purified natural complex is to provide quality specifications for a complex article that is more akin to a single chemical entity than a botanical extract. The characterized constituents may be isolated as salts or other derivatives not found in the source plant material, or the ratios of the congeners may be very different from what is found in the source plant material. The *Definition* section of each monograph provides the necessary details.

While these are general principles that may help to distinguish *DSC* monograph titles that specify the name of the source plant material as well as the class of compounds from those that mention only the class of compounds, the decision on how to title these very similar categories of monographs will have to be made on a case-by-case basis with input from the appropriate Expert Committees.

Titles for Monographs of Complex Articles of Animal Origin

Monograph titles for dietary ingredients of animal origin should follow the directives in 21 CFR 101.4 *Food; designation of ingredients*, which is consistent with DSHEA with respect to the requirement to use common or usual English names where available. Nomenclature at the appropriate level of detail will be provided in the article's *Definition*. For example, **Krill Oil** is extracted primarily from a single species of Antarctic krill identified in the monograph's *Definition* as *Euphausia superba* Dana.

The general nomenclature convention for titles of monographs of complex articles of animal origin is **[ANIMAL NAME] [{ANIMAL ORGAN(S)} {ANIMAL MATERIAL}]**. Current examples include **Cod Liver Oil** and **Krill Oil**, and potential examples could be **Oyster Shell** and **Shark Cartilage**.

Just as with botanical material extracts subjected to additional processing to increase the content of characterized constituents, decrease the content of unwanted constituents, or both, an example of a complex article of animal origin subject to further processing would be the **Fish Oil Containing Omega-3 Acids** monograph (recommended title: **Fish Oil Omega-3 Acids**). Note that the several families of fish that can be used to produce fish oil omega-3 acids (families Engraulidae, Carangidae, Clupeidae, Osmeridae, Scombroideae, and Ammodytidae) are listed in the **Fish Oil Omega-3 Acids** monograph's *Definition* because it is not feasible to identify each individual species in the monograph title or *Definition*.



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An example of a DS monograph for an article of animal origin that sets standards for a “partially purified natural complex” would be **Omega-3 Acid Triglycerides**, the *Definition* of which specifies that the omega-3 acids must come from fish body oil and sets out the families of fish that are acceptable sources of the body oil, the omega-3 acids that comprise the triglycerides, and that the article contains NLT 58.0% of total omega-3 acids expressed as triglycerides and NLT the labeled amount of EPA and DHA, expressed as the free fatty acids. The format for monograph titles for partially purified natural complexes from animal source materials, as with that type of botanical monograph title, is simply [**CLASS OF COMPOUNDS**]. Another example is the **Pancreatin** monograph, in which the source material name (hog pancreas or ox pancreas) is provided in the *Definition* and can be specified in labeling, e.g., to allow consumers to make informed choices with respect to kosher or halal products.

Titles for Monographs of Complex Articles of Bacterial Origin

Monographs for complex articles of bacterial origin such as probiotics should follow the format [**LATIN BINOMIAL w/o AUTHORITY**] [**STRAIN IDENTIFIER**]. For example, draft *USP* monographs for ***Lactobacillus acidophilus* La-14**, ***Lactobacillus acidophilus* NCFM**, ***Lactobacillus paracasei* LPC-37**, and ***Lactobacillus rhamnosus* HN001** have been posted for comment in *Pharmacopeial Forum* 42(2) (March 1, 2016) and a monograph for ***Bifidobacterium animalis* ssp. *lactis*** strains Bi-07 (ATCC SD5220), Bi-04 (ATCC SD5219), and HN019 (ATCC SD5674) has been posted for comment in PF 42(3) (May 2, 2016). Note that where a subspecies is included in the monograph title, the preferred abbreviation will be “subsp.” rather than “ssp.”, in accordance with the *International Code of Nomenclature of Prokaryotes* (7), as it is for plant, fungal and algal subspecies as per the *International Code of Nomenclature for algae, fungi, and plants* (4).

Titles for Single Chemical Entity Monographs

The nomenclature for single chemical entities (e.g., vitamins, mineral nutrients, amino acids, enzymes, and isolated or synthetic substances) is the same as for drug substances, as described in the *USP Nomenclature Guidelines* (8) cited in *USP General Chapter <1121> Nomenclature*. Some examples include **Alanine**, **Ascorbic Acid**, **N-Acetylglucosamine**, **Chromium Picolinate**, **Cyanocobalamin**, **Ergocalciferol**, **Glutathione**, **Lactase**, **Lycopene**, **Magnesium Sulfate**, **Melatonin**, **Quercetin**, **Rutin**, and **S-Adenosyl-L-methionine Disulfate Tosylate**.



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In some cases, “single” chemical entities may in fact be comprised of isomers or derivatives. For example, the **Phytonadione** monograph contains a purity specification of NLT 97.0% and NMT 103.0%, but it is a mixture of the *E*- and *Z*-isomers, of which it contains NMT 21.0% of the *Z*-isomer. To be compliant with the **Vitamin A** monograph, the article must possess NLT 95.0% of the vitamin A activity declared on the label but it may consist of retinol or esters of retinol formed from edible fatty acids, principally acetic and palmitic acids. The **Vitamin E** article consists of alpha-tocopherol and its alpha-tocopheryl acetate or alpha-tocopheryl acid succinate derivatives, and it may be the *RRR*- (previously referred to as *d*-) isomer or the all-racemic (*d,l*-) form. Other tocopherols and tocotrienols are not included in the **Vitamin E Definition**—a potential separate monograph could cover mixed tocopherols and tocotrienols. Although most mineral DS are single chemical entity articles of high purity, the current **Ground Limestone** monograph describes a more complex article in which the main constituent, calcium carbonate (NLT 94.0% and NMT 100.5% CaCO₃), is accompanied by other trace minerals (e.g., magnesium and alkali salts, and fluoride).

Titles for Monographs of DS Manufacturing Intermediates

In the DS industry, some of the ingredients used for manufacturing are mixtures containing active substances and excipients. These mixtures are intended to increase uniformity in the resulting dosage forms, such as in cases where ingredients are included in minute (e.g., microgram) quantities, or to help increase dispersability of lipophilic substances in water for better dissolution profiles, or to increase the stability of some substances that are known to interact with other ingredients and thus require protection.

Historically, the titles of DS monographs setting out standards for such manufacturing intermediate mixtures of one or more dietary ingredients and excipients included the term “Preparation”. The first example was when the vitamin E family of monographs was created. It became necessary to distinguish pure vitamin E substances from different articles containing vitamin E forms such as the acetate or the succinate that were used as ingredients for the Vitamin E capsules. Following the recommendation of the American Pharmacists Association, the term “Preparation” was introduced to accomplish this purpose.

Subsequently, use of the term “Preparation” was extended to botanical ingredients and has been applied to nine current monograph titles to distinguish DS ingredients from more complex articles incorporating that DS ingredient. However, the use of this term has not been very consistent with the original intended meaning. Also, this is different



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from how the term is used in some other pharmacopeias such as the *European Pharmacopoeia* where “preparation” is used to describe herbal extracts, fractions and other processed forms.

For example, the **Cranberry Liquid Preparation** (recommended title: **Cranberry Fruit Juice**) monograph specifies cranberry juice and no added substances, so the term “Preparation” in the title is not necessary. Many current DS monographs that do not contain the word “Preparation” in the title include provisions in the *Definition* section that allow for the addition of “suitable added substances” (excipients, e.g., **Powdered Andrographis Extract**, recommended title: **Andrographis Stem and Leaf Dry Extract**). Some allow for the addition of “suitable antioxidants” (e.g., **Cryptocodium Oil**).

In contrast, for vitamins and carotenoids, the term “Preparation” in the monograph title still serves to distinguish a more complex article from the relevant DS ingredient article that generally has a separate monograph.

For example, **Dexpanthenol Preparation** contains NLT 94.5% and NMT 98.5% of dexpanthenol, and NLT 2.7% and NMT 4.2% of pantolactone as ingredients. In this case, there is no separate **Dexpanthenol** or **Pantolactone** monograph.

Vitamin A Oral Liquid Preparation consists of an emulsion, suspension, or solution that contains either retinyl acetate or retinyl palmitate in an amount equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of vitamin A as retinol, while the **Vitamin A** monograph defines the article as a suitable form of retinol (retinol itself or esters of retinol formed from edible fatty acids, principally acetic and palmitic acids) that may be diluted with edible oils; incorporated in solid, edible carriers, or excipients; and it may contain suitable antimicrobial agents, dispersants and antioxidants. The tolerance limit is set to vitamin A activity equivalent to NLT 95.0% of that declared on the label.

Vitamin E Preparation combines a single form of vitamin E (*d*- or *dl*-alpha tocopherol or their acetate or succinate esters) with one or more inert substances in a liquid or solid form. It contains NLT 95.0% and NMT 120.0% of the labeled amount of vitamin E. In contrast, in the **Vitamin E** monograph, the article is one of the above forms of vitamin E that contains NLT 96.0% and NMT 102.0% of that form of vitamin E. Thus, there are specific and narrow quantitative tolerances for the purity of the DS ingredient set out in the **Vitamin E** monograph compared to broader tolerances for the labeled amount in the **Vitamin E Preparation** monograph.



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Similarly, **Menaquinone-7 Preparation, Beta Carotene Preparation, Lutein Preparation, Lycopene Preparation, and *meso*-Zeaxanthin Preparation** monographs describe a combination of the DS ingredient with one or more inert substances and/or antioxidants and the “Preparation” monographs specify tolerance limits for the labeled amount of DS ingredient, while the related but separate DS ingredient monographs describe the article as a substance with tolerance limits for the content of that ingredient.

TITLES FOR DIETARY SUPPLEMENT MONOGRAPHS

Dietary supplements are finished oral dosage forms manufactured to include dietary ingredients. Most commonly, DSs are available as tablets, capsules, liquid extracts (e.g., fluidextracts and tinctures), juices, syrups, teas for infusion, and powders to be reconstituted for ingestion or sprinkled on food. DS dosage form nomenclature typically follows the same rules as those for drug products (see the *USP Nomenclature Guidelines* and General Chapter <1151> *Pharmaceutical Dosage Forms*).

Some examples are provided below (note that some examples are hypothetical and are provided only to illustrate how titles should be derived). For the sake of clarity, the terms: **[{SCN} OR {LATIN BINOMIAL W/O AUTHORITY}] [{BOTANICAL MATERIAL(S)} {FRESH}] [{TYPE} {DRY EXTRACT} OR {SOFT EXTRACT} OR {OLEORESIN} OR {LIQUID EXTRACT} OR {JUICE} OR {DRY JUICE} AND/OR {CONSTITUENT OR CLASS OF COMPOUNDS}]** used above to describe botanical materials (or animal materials) and processed form will be simplified to **[DIETARY INGREDIENT]** which incorporates all of the above terms.

The general form is as follows: **[DIETARY INGREDIENT] {RELEASE CHARACTERISTIC} [DOSAGE FORM]**

Capsules:

Asian Ginseng Root Powder Capsules, Cod Liver Oil Capsules, Fish Oil Omega-3 Acids Delayed-Release Capsules, Krill Oil Delayed-Release Capsules, Milk Thistle Fruit Dry Extract Capsules

Lozenges:

Calcium Carbonate Lozenges, Zinc and Vitamin C Lozenges

Tablets:

Black Cohosh Rhizome and Root Fluidextract Tablets, Cat’s Claw Stem Bark Dry Extract Tablets, Chondroitin Sulfate Sodium Tablets, Glucosamine Tablets,



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Gymnema Leaf Dry Extract Tablets, Methylsulfonylmethane Tablets, Niacin Extended-Release Tablets

Oral emulsions:

Castor Oil Emulsion

Oral solutions:

Ascorbic Acid Oral Solution, Cholecalciferol Solution, Oil-Soluble Vitamins with Minerals Oral Solution, Water-Soluble Vitamins with Minerals Oral Solution, Oil- and Water-Soluble Vitamins with Minerals Oral Solution, Zinc Acetate Oral Solution

Oral suspensions:

Calcium Carbonate Oral Suspension

Powders for oral suspension:

Psyllium Hydrophilic Mucilloid for Oral Suspension

DRUG VERSUS DIETARY SUPPLEMENT NAMES FOR ARTICLES

In the United States, drugs and DSs conform to different standards and require different testing procedures for identity, purity, strength, and composition. Occasionally, the same substance is used in a drug and in a DS. When used in a drug, the substance is given a US Adopted Name (USAN) or an International Nonproprietary Name (INN), but when the same substance is used in a DS, it may be referred to by a different scientific name, SCN or other common name. Because the articles (drug vs. DS) may have to meet different standards, the use of different names may be important. *Table 10* provides some examples of such multiple names.

Table 10. USAN Names vs. DS Names

USAN Name	DS Name
Ademetionine	S-Adenosyl-L-methionine
Ubidecarenone	Coenzyme Q₁₀
Sinecatechins (topical drug)	Green Tea Leaf Catechins Extract



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The number of cases in which a product that has a USAN as a drug ingredient is also a DS ingredient is limited by the regulations governing DSs. For example, the plant with the *HoC2* SCN “dragon’s blood croton” (*Croton lechleri* Müll.Arg., family Euphorbiaceae) is the source of a red latex article with the USAN Crofelemer (trade name Fulyzaq) which has been approved in the U.S. as a prescription botanical drug for the treatment of diarrhea associated with anti-HIV drugs. According to the FDA’s *Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues* (11), an ingredient that has been approved as a new drug or licensed as a biologic can be a dietary ingredient for use in a DS if, and only if, prior to such approval or licensing, the ingredient was marketed as a DS or as a food. Similarly, an article that has been authorized for investigation as a new drug or as a biologic before being marketed as a food or as a DS cannot be marketed as a DS if substantial clinical investigations of the article have begun and the existence of such investigations has been made public.

Nevertheless, there are many botanicals with a long history of use as both DSs and as OTC or prescription drug ingredients, which may also lead to differences in names. For example, “elm bark” is the name for the demulcent ingredient from the plant *Ulmus rubra* Muhl. (family Ulmaceae) in the FDA’s Oral Health Care drug products monograph (12), while the current DS monograph title is **Elm** and the recommended title based on this Guideline and the SCN is **Slippery Elm Inner Bark**.

GLOSSARY

This glossary does not include terms for plant (or fungal, algal, bacterial, or animal) materials that are defined in standard textbooks. It focuses on terms specific to DS products and ingredients whose definitions are not so readily available elsewhere or that have been defined differently in various sources. Readers are also encouraged to consult *USP* General Chapters (563) *Identification of Articles of Botanical Origin* and (565) *Botanical Extracts* for additional information on DS terminology.

Aqueous extract: Articles prepared by extracting materials with water.

Aromatic: An aromatic botanical article is created by the addition of essential oils to the extract (e.g., **Cascara Sagrada Bark Aromatic Fluidextract**) or other type of article (e.g., **Castor Seed Aromatic Oil**) as flavoring agents, so the DS monograph title follows the recommended format with the addition of the adjective **Aromatic**.



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Aromatic oil water: a clear, saturated, aqueous solution of essential oils or other aromatic or volatile substances. For example, **Peppermint Leaf Oil Water** is prepared as a clear, saturated solution of **Peppermint Leaf Oil** in **Purified Water**.

Concentrate: Historically, “concentrate” had two meanings. One was simply reflecting a liquid or solid article of higher concentration sometimes referred to as “high potency”. The other meaning was that the product must be diluted before administration. Not all “high potency” products had to be diluted, so the word “concentrate” lost its definitive meaning and created confusion. The nomenclature committee has recommended that the term “concentrate” be phased out of nomenclature. Instead, for DSs, the appropriate dosage form terms, e.g., fluidextract or tincture, with the extraction or concentration ratio in the *Definition* and on the label, can be used to indicate strength. If applicable, the statement “must be diluted” should be displayed prominently on the label.

Dry extract: Solid articles obtained by evaporation of the solvent used in their production. Excipients such as carriers or flow agents may be needed in some cases to prepare a dry extract.

Dry juice: Dry material obtained by, for example, freeze drying or spray drying plant juice into a 100% juice solids form or diluted with use of excipients such as carriers or flow agents.

Essential oil: Natural aromatic complex mixtures of compounds (there may be 200 or more in one essential oil) belonging mainly to two chemical classes: 1) terpenoids (e.g., monoterpenoid ketones, alcohols, hydrocarbons, and esters such as carvone, menthol, α -pinene, and thymol acetate; sesquiterpenoids such as α -bisabolol and caryophyllene; and less commonly, diterpenoids such as phyllocladene and (+)-kaurene); and 2) phenylpropanoids (e.g., anethole, cinnamaldehyde, coniferyl alcohol). However, there may also be other volatile compounds such as phenols (e.g., methyl salicylate or vanillin), non-terpene alcohols, non-terpene alkanes, alkenes, alkynes, spiro-ethers, coumarin, sulfur-containing compounds such as allyl isothiocyanate in mustard oil, or aldehydes such as benzaldehyde in bitter almond essential oil. They are liquid at room temperature and generally immiscible in water but are soluble in alcohol or other organic solvents, so they act like oils. 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, extraction using various solvents, or other techniques.

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Extract: an article with liquid, solid, or semisolid consistency in which the constituents of interest are completely or partially separated from other components with the aid of water, alcohol, alcohol-water mixtures, or other suitable solvents. This extraction process involves the removal of the desired constituents from the plant matter with suitable menstrua, the evaporation of all or nearly all of the solvent, and the adjustment of the residual fluids, masses, or powders to the prescribed standards. Suitable inert substances may be added as carriers or diluents to improve physical characteristics. Suitable antimicrobials and other preservatives may be added to preserve the integrity. Extracts may be subjected to processes that increase the content of characterized constituents, decrease the content of unwanted constituents, or both. Extracts with no added inert substances and no processing beyond the extraction are called native extracts. In some articles, the plant matter may be pretreated by inactivation of enzymes and microbial contaminants, grinding, defatting, or a similar procedure. Types of extracts are namely: *Dry extract*, *Soft extract*, and *Liquid extract*, each is defined in this *Glossary*.

Fluidextract: A type of *Liquid extract* 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 (e.g., 1:2) in the individual monograph.

Fraction: Extracts subjected to additional processing to produce an article that may consist of one or more specific classes of compounds. Single chemical class examples include sennosides from Senna, oligomeric proanthocyanidins from Grape Seed, and triterpenes from Gotu Kola (*Centella asiatica*) while multiple classes are included in **Saw Palmetto Fruit Lipophilic Soft Extract**, which contains a combination of fractions of fatty acids, sterols and long-chain alcohols.

Granules: As defined in General Chapter <1151>, granules are solid dosage forms that are composed of agglomerations of smaller particles. These multicomponent compositions are prepared for oral administration and are used to facilitate flexible dosing regimens as granules or as suspensions, address stability challenges, allow taste masking, or facilitate flexibility in administration (for instance, to pediatric or geriatric patients). A marketed product example would be encapsulated granules of pancreatin. Note that some DS raw materials may also be in the form of granules.

Gum: A water-soluble carbohydrate derivative in the form of a hydrocolloid comprised of an anionic or nonionic polysaccharide or salts of polysaccharides. Some, such as gum tragacanth, gum arabic (also known as acacia), gum karaya (sterculia gum), and gum ghatti are exudate gums obtained by tapping (wounding) the plant, while guar gum



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and locust bean (carob) gum are extractive gums obtained from seeds, and xanthan gum is obtained by bacterial fermentation of glucose, sucrose, or lactose.

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 *Urtica dioica* and *Urtica urens* for the two species of Stinging Nettle that are included in the current **Stinging Nettle** monograph. Following the new system for monograph titles it would be named **Urtica Species Root and Rhizome** since the two species have different SCNs in *HoC2*.

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., *Arthrospira platensis* (Nordstedt) Gomont, *Arthrospira maxima* Setchell & Gardner, and *Arthrospira fusiformis* (Voronichin) J. Komarek & J.W.G. Lund, the three species included in the **Spirulina** monograph.

Liquid extract: Liquid articles prepared from plant matter containing ethanol, water, vinegar, vegetable oil, or glycerin (or a mixture, e.g., aqueous ethanol) as a solvent or vehicle. The term liquid indicates a material that is pourable and conforms to its container at room temperature.

Native extract: An extract that contains only those constituents native to the botanical material from which the extract was made, with no added inert substances and no processing beyond the extraction and solvent removal.

Oleo-gum-resin: A naturally occurring exudate obtained by incision or by spontaneous exudation, e.g., myrrh, frankincense, and guggul. The term “oleo-gum-resin” reflects their complex composition.

Plant processed forms: Plant material that has been subjected to processing, e.g., comminution to a powder. Examples of processed plant forms include powders, juices, extracts and fractions, but not isolated pure compounds.

Resin: An amorphous complex mixture of resin acids, resin alcohols, resinoannols, esters and resins, usually hard and transparent or translucent at room temperature, and insoluble in water, e.g., rosin, guaiac, and mastic.

Soft extract: Soft extracts are articles having consistencies between those of liquid extracts and those of dry extracts, and are obtained by partial evaporation of the solvent

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(e.g., alcohol, or hydroalcoholic mixture) used for extraction. Soft, thickly viscous extracts can also be produced by supercritical carbon dioxide extraction.

Spirit: A spirit is created by the addition of alcohol to essential oils or other aromatic substances. For example, **Peppermint Oil Spirit** is a *USP* article created by adding alcohol to peppermint leaf oil and the alcohol extract produced from peppermint leaf powder that was macerated in water, strongly expressed, then macerated in alcohol and filtered. **Compound Orange Spirit** is an *NF* article prepared by adding alcohol to a combination (compounding) of orange oil, lemon oil, coriander oil and anise oil.

Camphor Spirit is a *USP* article consisting of alcohol added to the monoterpene substance camphor. **Aromatic Ammonia Spirit** is a *USP* article for which alcohol is added to ammonia and ammonium carbonate.

Tincture: Tinctures are liquid articles usually prepared by extracting plant materials with alcohol or hydroalcoholic mixtures by maceration or percolation. Traditionally, tinctures of potent articles of botanical origin represent the activity of 1 g of the plant material in each 10 mL of tincture but tinctures with other ratios (e.g., 1:5) are also prepared.

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