Nomenclature Guidelines

This document is referenced in USP General Chapter <1121> *Nomenclature*, and will be periodically updated by the USP Expert Committee on Nomenclature, Safety and Labeling

(last revision on: February 01, 2018)

Introduction

A consistent and logical approach to naming compendial articles including small molecule and large molecule drug substances, drug products, excipients, and dietary supplements is critical to the usefulness and integrity of the USP.[1,2] Standard naming approaches to developing monograph titles of articles appearing in the *USP-NF* are carried out by the Nomenclature, Safety and Labeling Expert Committee for consistency. These naming approaches are outlined in General Chapter <1121> *Nomenclature*. The purpose of the Guidelines is to provide supplemental information to the general approaches outlined in General Chapter <1121> *Nomenclature*.

In the United States under the Federal Food, Drug, and Cosmetic Act (FDCA), the official name given a drug plays a critical role. The FDCA defines the term 'official compendium' as the official *USP*, the official *NF*, or any supplement to them. A drug (which includes both FDCA drugs and Public Health Service Act biologics) with a name recognized in *USP-NF* must comply with compendial identity standards or be deemed adulterated and/or misbranded. Such drugs, whether substance or finished article, must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs. See FDCA 501(b) and 502(e)(3)(b), and the Food and Drug Administration (FDA) regulations at 21 CFR 299.5. The FDCA requires all drugs to have an "established name," which is a nonproprietary name, other than the applicable systematic chemical name. The established name is almost always tied to the drug name recognized in *USP-NF*. USP and FDA play an important role in creating established names, which in turn are a critical part not only for

[1] Sections on biologics, veterinary, etc. will be added to future revisions.

[2] The name of the committee was changed over the years and will be referred to as "nomenclature committee". Previous names include: Nomenclature Expert Committee, Nomenclature and Labeling Expert Committee and presently Nomenclature, Safety and Labeling Expert Committee.

enforceable compendial requirements, but also FDA regulations. Oversight of proprietary, or "brand" names, remains the responsibility of FDA, working with applicants in the course of reviewing and approving New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biologics License Applications (BLAs), New Animal Drug Applications (NADAs), and Abbreviated New Animal Drug Applications (ANADAs).

FDCA 502(e)(3) specifies how "established names" for drugs are created. FDA may designate such names by regulation under FDCA 508, but rarely does so. Instead, in the absence of a name specifically designated in a 508 rulemaking, the law recognizes the official title of a drug in *USP-NF* as the established name. Such recognition applies even if USP does not designate an established name until after FDA has approved a drug or biologic, which might necessitate a change in the nonproprietary name approved by FDA. As detailed in FDA regulations, the title of an article in a USP compendium is the primary pathway for deriving an official nonproprietary name. The USP usually adopts drug substance established names as recommended by the U.S. Adopted Names (USAN) Council. The USAN Council is made up of members representing the USP, American Medical Association (AMA), American Pharmacists Association (APhA), and the FDA. The regulated community and healthcare professionals may rely on the established name for any drug being the current compendial name or the USAN listed in the USP Dictionary of USAN and International Drug Names.[3]

USP has had a role in monograph naming since its inception in 1820. In 1986, a USP nomenclature committee was formed[2] to improve the process of creating official names. The role of a committee dedicated to nomenclature issues has helped advance consistency of naming compendial articles by developing nomenclature policies and addressing global aspects of nomenclature in a systematic manner. The nomenclature committee is responsible for developing and maintaining a *Pronunciation Guide* for

[3] See 21 CFR 299.4. The dictionary is now published under the title "USP Dictionary of USAN and International Drug Names," and includes names approved outside the US.

drug substances and excipients which is utilized by USAN. The activities of the committee are not limited to small molecule drugs. The committee also develops names for other compendial categories including:

- Biologics

  USP works with FDA and the USAN Council in establishing naming guidelines for biologics, vaccines, and tissue and gene therapy products.

- Excipients

  Excipient monographs are included in the *NF*. The nomenclature committee works with the excipient committee to provide consistent and informative names for excipients including polymers, products of plant and animal origin, and synthetic or semi-synthetic compounds.

- Dietary Supplements

  Names of dietary supplement products can be influenced by tradition, existing products in commerce, and international aspects of products and their common names that originate from traditional medicine. The nomenclature committee works with the dietary supplements committee to encourage and standardize the use of the Latin binomial names, standardized common names (as included in *Herbs of Commerce* published by the American Herbal Products Association), and to create naming conventions for extracts and their purified derivatives.

Drug Substances

USP, as one of the sponsoring organizations of the US Adopted Names (USAN) program, generally recognizes USAN names for drug substance monographs. However, final recommendations on compendial nomenclature reside with the nomenclature committee. In the vast majority of cases, USAN names are approved as monograph titles for drug substances. A complete listing of USAN and International Nonproprietary Names (INN) with supportive information is published in the USP Dictionary of USAN and International Drug Names.

“Concentrate” nomenclature

Some drug substances are available as concentrated solutions or mixture of solids (dispersions), and are intended to be used as intermediates for final formulations, e.g., Isosorbide Concentrate (used to prepare Isosorbide Oral Solution), and Glutaral Concentrate (used to prepare Glutaral Disinfectant Solution).

“Diluted” nomenclature

Another class of preparations that is not intended for direct administration to either humans or animals is the “diluted” products. In most cases dilution is necessary for safety reasons, e.g., Diluted Isosorbide Mononitrate, and Diluted Nitroglycerin.

“Hydrous” nomenclature

It is no longer preferred to use the term “hydrous,” in monograph titles.

Water of hydration in drug substances is not included in the name. Similarly, the term “anhydrous” is typically not preferred.

Drug Products

Entries in this section constitute an alphabetic listing of dosage forms with considerations and examples as well as general nomenclature practices. Dosage forms are addressed within USP General Chapter <1151> *Pharmaceutical Dosage Forms.* The approach taken in <1151> *Pharmaceutical Dosage Forms* is to classify dosage forms by physical characteristic. For example, solution dosage forms have certain attributes in common regardless of the route of administration. This guideline recognizes the necessity, when naming official articles, of indicating information beyond the physical form. Every attempt is made to accommodate these differences in approach by including entries in <1151> *Pharmaceutical Dosage Forms* corresponding to names of official articles with reference to appropriate entries representing physical characteristics for those dosage forms within the chapter. Chapter <1151> *Pharmaceutical Dosage Forms* includes a glossary providing a compilation of definitions relating to

dosage form terminology. The glossary serves as a source not only of preferred terms but of nomenclature not preferred in the naming of compendial articles. Generally, the dosage form title appears in the following format:

[DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM]

Many monograph titles were adopted before the establishment of the title formats and nomenclature policies. Pre-existing monograph titles have been aligned with current nomenclature practices in many instances. However, alignment with current nomenclature practices has not always occurred for various reasons. Therefore, existing monograph titles that do not comply with current nomenclature practices should not be interpreted as precedents for other monograph titles.

General Nomenclature Practices

- The [ROUTE OF ADMINISTRATION] is omitted from dosage form titles for which the route of administration is understood. The general form then becomes [DRUG] [DOSAGE FORM]. Some examples are provided below; please also refer to the specific dosage form entries for more detailed considerations.
    - The term "oral" will not be included as the route of administration for orally administered capsules, tablets, and lozenges. However, if some other route of administration is intended (e.g., sublingual) the route will be included in the monograph title.
    - The route of administration is omitted for drugs that are injected, because the route (e.g., intravenous, intramuscular, subcutaneous) must appear on labels and in labeling.
    - The route of administration is omitted for topically applied products - creams, ointments, lotions, and pastes. However, if some other route of administration is intended (e.g., ophthalmic) the route will be included in the monograph title.

    - Some products intended for buccal administration were subsequently approved for sublingual administration. The original name of the product will remain unchanged and an additional route of administration will be addressed in the labeling. This practice may be applied to any product with new permitted route of administration as long as the original route is still valid.

- The term "for" is included in names of solid preparations which must be dissolved or suspended in a suitable liquid to obtain a dosage form suitable for administration, and the general format becomes [DRUG] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM] e.g. Ampicillin for Oral Suspension, Cytarabine for Injection.
- In some instances, the drug is supplied in one dosage form for the preparation of the intended dosage form. In such cases the dosage form provided in the container is named first and the word "for" appears, followed by the final dosage form that is suitable for administration. The general format becomes [DRUG] [DOSAGE FORM] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM], e.g., Aspirin Effervescent Tablets for Oral Solution.

The term "Vaginal Inserts", rather than "Vaginal Tablets", "Vaginal Capsules", or "Vaginal Suppositories" is used in the title of this general type of vaginal preparation to decrease the potential for misadministration of these products. The term "Vaginal" is also preferred rather than "Intravaginal" as defining term for the administration route.

- The term "Suppositories" is used in the titles of solid preparations that are intended for rectal administration.

Modified Release in Dosage Forms

Dosage forms may be formulated such that the drug release is modified. There are two types of modified-release products: Delayed-Release, and Extended-Release.

Delayed-Release — Delayed-Release products are deliberately modified to delay release of the drug substance for some period of time after initial administration. Oral products sometimes are formulated with acid-resistant or enteric coatings to protect acid-labile drug substances from the gastric environment or to prevent adverse events such as irritation. Delayed release of the drug substance may also occur by means of formulation such as gastroretentive technology.

Extended-Release — Extended-release products are formulated in such a manner as to make the drug substance available over an extended period of time following administration. Expressions such as "prolonged-release", "repeat-action", "controlled-release", "sustained-release", and their corresponding acronyms should not be used to describe such dosage forms. The term "extended-release" is used for compendial nomenclature. [See USP General Chapter <1151> *Pharmaceutical Dosage Forms*]

In cases of drug products exhibiting more than one release characteristic the following nomenclature practices are applicable:

- The term Immediate-Release is never used in drug product nomenclature
- Combination of Immediate-Release and Extended-Release is referred to as Extended-Release
- Combination of immediate-release and delayed-release with at least one ingredient exhibiting both release characteristics is referred to as Extended-release
- Combination of immediate-release and delayed-release where no ingredient exhibits both release characteristics is referred to as Delayed-release
- Combination of Extended-Release and Delayed-Release is referred to as Extended-Release

The use of the term "prompt" in monograph titles, as in the official monograph "Prompt Phenytoin Sodium Capsules," is no longer preferred.

Miscellaneous

- Any specific instructions for administration, e.g., opening and sprinkling the content of the capsule on soft food, shall be included in the labeling, but are not part of the compendial name.
- Products using recombinant DNA – [to come]
- Natural and synthetic products – [to come]
- Products containing components with the same counterion are named using a plural form of the salt, e.g., sulfates, hydrochlorides.
- In names of products that are salts of polyvalent acids or bases: prefixes indicating stoichiometry, e.g., “di-” or “tri-”, etc… are not preferred.
- Water of hydration in drug substances is not included in the drug product name.
- The use of the term “and”, and the term “in”. Where all drug substances are active the term “and” is used (e.g. Acetaminophen and Codeine Phosphate Tablets). Where one substance is merely the carrier for administering the therapeutic agent the word "in" is used in the monograph title (e.g., Potassium Chloride in Dextrose Injection). Where the vehicle is therapeutically active or equivalent to another component, the word "and" is used in the monograph title (e.g., Dextrose and Sodium Chloride Injection).
- Rules for listing ingredients in Fixed-Combination Drug Products [to come]
- The monograph title for an official compounded preparation uses the following convention:
  [DRUG SUBSTANCE] Compounded [ROUTE OF ADMINISTRATION] [DOSAGE FORM]
  e.g. Baclofen Compounded Oral Suspension
- The monograph title for an official compounded preparation for use in only animal patients uses the following convention:
  [DRUG SUBSTANCE] Compounded [ROUTE OF ADMINISTRATION] [DOSAGE FORM], Veterinary
  e.g. Atenolol Compounded Oral Suspension, Veterinary

Lipid Complexes

Lipid complexes are chemically and physically defined nonvesicular associations of drugs with certain lipids. The general format used when naming a lipid complex is [DRUG] Lipid Complex Type X [DOSAGE FORM].

The first lipid complex approved for a particular drug and dosage form is assumed to be type A and the type is not given (i.e. “Type A” is not included). For subsequent products of the same drug and dosage form, the type is listed and “X” is replaced sequentially with B, C, D...Z.

Liposomes

Liposomes are microvesicles composed of a bilayer and/or a concentric series of multiple bilayers separated by aqueous compartments formed by amphipathic molecules such as phospholipids which enclose a central aqueous compartment. The general format used when naming a lipid complex is [DRUG] Liposome Type X [DOSAGE FORM] or [DRUG] Pegylated Liposome Type X [DOSAGE FORM].

The first liposomal product approved for a particular drug and dosage form is assumed to be type A and the type is not given (i.e. “Type A” is not included). For subsequent products of the same drug and dosage form, the type is listed and “X” is replaced sequentially with B, C, D...Z.

Radiopharmaceuticals

Radiopharmaceuticals are drug products labeled with a radioisotope. They are used for diagnostic imaging or therapy. Standard nomenclature practices for dosage forms apply to radiopharmaceuticals. The following discussion describes aspects unique to this class of products.

Each name must specify the substance, the isotope, and the dosage form. The route of administration is also included when appropriate for a dosage form. Many radiopharmaceuticals contain a ligand

(sometimes an antibody conjugated with a ligand that directs the isotope to accumulate in a selected organ or tissue), which forms a complex with the isotope upon reconstitution and mixing in the vehicle. USP monograph titles are established for the product which is administered. However, the products which are marketed are frequently available as "kits" which require the addition of the radioisotope and other manipulation to produce the final dosage form; USP does not develop monograph titles for kits.

Radiopharmaceuticals Nomenclature

[DRUG] [ISOTOPE] [ROUTE OF ADMINISTRATION] [DOSAGE FORM]

[DRUG] [ISOTOPE] Capsules (Urea C 14 Capsules)

[DRUG] [ISOTOPE] Injection (Fludeoxyglucose F 18 Injection)

[DRUG] [ISOTOPE] [LIGAND] [ROUTE OF ADMINISTRATION] [DOSAGE FORM]

[DRUG] [ISOTOPE] [LIGAND] Injection (Indium In 111 Pentetate Injection, Technetium Tc 99m Sestamibi Injection)

A radiopharmaceutical intended for ex-vivo radiolabeling with subsequent administration of the labeled product will not include the ultimate route of administration in the monograph title. Instead the drug product is named according to the format:

[DRUG] [ISOTOPE] [DOSAGE FORM] (Indium In 111 Oxyquinoline Solution)

The term used for the dosage form portion of the title will describe the physical dosage form. The phrase "for radiolabeling" will also appear elsewhere in the product labeling.

Drug products containing salts

The titles of USP monographs for drug products and compounded preparations formulated with a salt of an acid or base use the name of the active moiety. The strength of the product or preparation is also expressed in terms of the active moiety.

An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be a salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule.

Quaternary ammonium salts are exceptional chemical entities, because they cannot exist without the counterion, but the pharmacological activity is usually provided by the charged cation.

Drug products containing such salts shall be named, and the strength shall be expressed, in terms of this charged cation. Generally, the title appears in the following format:

[DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM] (Umeclidinium Inhalation Powder)

This Policy is followed by USP in naming drug products and compounded preparations that are newly recognized in the USP . Revising existing monographs to conform to this Policy is not intended, except where the USP Council of Experts determines that, for reasons such as safety, a nomenclature change is warranted.

Nomenclature Guidelines for Specific Dosage Forms

The following presents a brief description of the particular dosage-form type and specific naming examples for each.

Aerosols

Aerosols are dosage forms packaged under pressure and contain therapeutic agent(s) and a propellant that are released upon actuation of an appropriate valve system.

Aerosols are intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols). These products may be fitted with valves enabling either continuous or metered-dose delivery. All aerosols are assumed to be metered

except for the topical aerosols which are not metered. Details pertaining to metering are part of the labeling and are not included in the name.

Aerosols Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Aerosol

[DRUG] Inhalation Aerosol (i.e., for oral inhalation)

[DRUG] Lingual Aerosol

[DRUG] Nasal Aerosol

[DRUG] Topical Aerosol (Tolnaftate Topical Aerosol)

Beads

Not preferred, see **Pellets**

Capsules

Capsules are solid dosage forms in which the drug substance and any excipients are enclosed within a soluble container or shell or coated on the capsule shell. Capsules are assumed to be for oral administration so there is no need to include the route of administration in the monograph title. The capsule shell may be composed of two pieces (usually hard shell), or it may be composed of a single piece (usually soft gelatin). The composition of the shell or the physical form of the capsule contents (liquid or solid) is not conveyed in the monograph title.

Capsules Nomenclature

[DRUG] {RELEASE CHARACTERISTICS}[4] Capsules

[DRUG] Capsules (Tamsulosin Hydrochloride Capsules, Rifampin and Isoniazid Capsules)

[DRUG] Delayed-Release Capsules (Omeprazole Delayed-Release Capsules)

[4] Terms enclosed in the braces "{}" are included in the name when applicable.

[DRUG] Extended-Release Capsules (Chlorpheniramine Maleate Extended-Release Capsules, Propranolol Hydrochloride and Hydrochlorothiazide Extended-Release Capsules)

Caplets

Not preferred, see **Tablets**

Collodions

Not preferred, see **Solutions**

The term is reserved for Pyroxilin in Alcohol and Ether.

Concentrates

Historically "concentrate" had two meanings: one was simply reflecting a high concentration sometimes referred to as "high potency", and the other 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 recommended that the term "concentrate" no longer be included in human drug product names, but instead the statement "must be diluted" be displayed prominently on the label. The term "concentrate" is being phased out of nomenclature for human drug products. Instead, the appropriate dosage form terms, e.g., solution or suspension, should be used. USP general chapter <1121> Nomenclature, currently limits use of "concentrate" to drug substances that are not intended for direct administration to humans or animals.[5] However, there are several historical exceptions. Other than those historical exceptions, use of the word "Concentrate" for human drug products is restricted to one specific monograph: Potassium Chloride for Injection Concentrate.

For additional information pertaining to the use of "concentrate" in a monograph title see the **Drug Substances** section.

[5] Section on veterinary products will be added at later date.

Creams

Creams are semisolid emulsion dosage forms (see **Emulsions** for additional information) that often contain more than 20% water and volatiles and/or less than 50% hydrocarbons, waxes or polyols as the vehicle for the drug substance. Creams are generally intended to be applied topically to the skin or to a mucous membrane. Typically, any other administration route shall be reflected in the compendial name. However, rectally administered creams can often be applied topically as well, and would not include the rectal route in the name even if labeling is targeted to rectal use.

Creams Nomenclature

[DRUG] {ROUTE OF ADMINISTRATION} Cream

[DRUG] Cream (Clotrimazole Cream)

[DRUG] Vaginal Cream (Estradiol Vaginal Cream)

Elixirs

Not preferred, see **Solutions**

Emulsions

A dosage form consisting of a two-phase system composed of at least two immiscible liquids, one which is dispersed as droplets (internal or dispersed phase) within the other liquid (external or continuous phase) and generally stabilized with one or more emulsifying agents. Emulsion is not used as a dosage form term if a more specific term is applicable (e.g., Cream, Lotion, or Ointment).

For Injectable Emulsions see **Injections**

Emulsions Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Emulsion

[DRUG] Oral Emulsion

Films

Films are thin sheets that are placed in the oral cavity. They contain one or more layers. A layer may or may not contain a drug substance.

Films Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Film

[DRUG] Buccal Film (Fentanyl Buccal Film)

[DRUG] Oral Film

[DRUG] Sublingual Film

Foams

[to come]

Gases (Medical Gases)

Medical gases are products that are administered directly as a gas. A medical gas has a direct pharmacological action or acts as a diluent for another medical gas.

The name of the specific gas is to be used without the term “gas”.

Gases Nomenclature

[GAS] (Oxygen)

Gels

Gels are semisolid systems consisting either of suspensions of small inorganic particles or of organic molecules interpenetrated by a liquid. Gels can be used to administer drugs by topical or mucosal routes.

The nomenclature committee recommended that from January 11, 2010 forward, the administration route shall be specified in the title (Topical, Vaginal, Periodontal, etc.).

Although the term “Jelly” has been historically used, it is no longer acceptable to use this term in a pharmaceutical context because it has been associated with medication errors related to misadministration of the product. Existing monograph (Lidocaine Hydrochloride Jelly) became official before 1985 and will not be renamed but it is understood that in the future the term “Gel” is to be used.

In a two-phase system, if the particle size of the dispersed phase is relatively large, the gel mass is sometimes referred to as a magma (e.g., Bentonite Magma). Magma is a historical name, and it is no longer preferred.

Both gels and magmas may be thixotropic, forming semisolids on standing and becoming less viscous on agitation.

Gels Nomenclature

Gel (singular) is understood to be a continuous dosage form.

[DRUG] [ROUTE OF ADMINISTRATION] Gel

[DRUG] Dental Gel

[DRUG] Nasal Gel

[DRUG] Ophthalmic Gel

[DRUG] Oral Gel

[DRUG] Periodontal Gel

[DRUG] Topical Gel (Erythromycin Topical Gel, Erythromycin and Benzoyl Peroxide Topical Gel)

[DRUG] Vaginal Gel

Chewable Gels

Chewable gels are used to deliver drug substances or dietary supplement ingredients via the oral route. Chewable gels can consist of all or some of the following components—gelling agent(s), sugars, water, sweeteners, and flavoring agents. The sweeteners and flavoring are intended to enhance consumer acceptance and mask the taste of the delivered labeled drug substance. Chewable gels maintain their molded shape, are elastic, and yield to mastication. They are intended to be chewed before swallowing. Chewable gels are also known as "gummies" in the confectionary and dietary supplement industries but that term is not used in official article titles.

Chewable Gels Nomenclature

Gels (plural) is understood to refer to products formulated as discrete dosage units.

[DRUG] Chewable Gels (Ascorbic Acid Chewable Gels)

Granules

Granules are a solid dosage form composed of dry aggregates of powder particles that may contain one or more drug substances, with or without excipients. This term should be used in drug product nomenclature when the drug is administered as granules, e.g. product is packaged as granules intended to be sprinkled on soft food prior to administration. The route of administration shall be specified in the title.

For granules that are reconstituted to make the administered dosage form, use the final dosage form in the title and the term "for" in front of it, e.g. in the case of granules reconstituted to make an oral solution, the appropriate nomenclature would be [DRUG] for Oral Solution.

Granules Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Granules

[DRUG] Oral Granules

Gums

A medicated gum is a semisolid dosage form designed to be chewed rather than swallowed. Medicated gums release the drug substance(s) into the saliva. Medicated gums can deliver therapeutic agents and are generally for systemic absorption via the buccal or gastrointestinal routes (e.g., nicotine or aspirin). Because gums are intended to be chewed there is no need to include the route of administration, oral, in the monograph title. The singular form, gum, is used in the title.

Gums Nomenclature

[DRUG] Gum (Nicotine Polacrilex Gum)

Implants

Implants are long-acting dosage forms that provide continuous release of the drug substance often for periods of months to years. Implants are usually administered by means of a surgical incision or by a suitable special injector (e.g., trocar).

Implants are available in a variety of shapes, sizes and materials: pellets, resorbable microparticles, polymer implants (biodegradable or non-biodegradable), metal or metal/plastic implants (osmotic pumps and stents). An implant can have systemic or local effect. The specific route of administration is typically not included in the monograph title, unless there is only a single anatomical location for the implant. Generally the plural form, Implants, is used in the monograph titles. However, depending on how it is packaged, the singular form, Implant, may be appropriate when labeling the product.

Implants Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Implants

[DRUG] Implants

[DRUG] Intravitreal Implants

Infusions

For human drug products which are infused, see **Injections** for appropriate nomenclature.

Inhalants

[to come]

Injections

For compendial naming purposes, injections are preparations intended for parenteral administration or for constituting or diluting a parenteral article prior to administration. Drugs that are injected may be administered via various target tissues, e.g., intravenous, intramuscular, subcutaneous, or intrathecal. USP and FDA agree that the target tissue is specified on the container label and in labeling and should not be in the compendial name (21 CFR 201.100(b)(3)). Further, many drugs have more than one target tissue for administration and multiple routes could not reasonably be cited in the name. The USP currently recognizes seven categories of injections:

1. **[DRUG] Injection** — Liquid preparations that are drug substances or solutions thereof.
2. **[DRUG] for Injection** — Dry solids that upon the addition of a suitable vehicle yield solutions conforming in all respects to the requirements for Injections.
3. **[DRUG] Injectable Emulsion** — Liquid preparations of drug substances dissolved or dispersed in a suitable emulsion medium.
4. **[DRUG] Injectable Suspension** — Liquid preparations of solids suspended in a suitable liquid medium.
5. **[DRUG] for Injectable Suspension** — Dry solids that upon the addition of a suitable vehicle yield preparations conforming in all respects to the requirements for Injectable Suspensions.

6. **[DRUG] Extended-Release Injectable Suspension** — Liquid preparations of solids suspended in a suitable liquid medium and formulated in a manner that allows the contained drug substance to be available over an extended period of time.
7. **[DRUG] for Extended-Release Injectable Suspension** — Dry solids that upon the addition of a suitable vehicle yield preparations conforming in all respects to the requirements for Extended-Release Injectable Suspensions.

Injectable products that are formulated as a solution or suspension, and are intended to be diluted before being injected (including addition to intravenous fluids) shall be named either "injection" or "injectable suspension." Dilution instructions are to be included in the labeling of the product. For products intended for parenteral administration, use of the word "Concentrate" in the monograph title is restricted to one specific monograph, Potassium Chloride for Injection Concentrate.

For more information on concentrates – see **Drug Substances** section.

Injectable products intended to be infused (commonly marketed in containers of 50 mL to 1000 mL)) shall have the vehicle specified in the compendial name, and the general form becomes **[DRUG] in [VEHICLE] Injection** (Dobutamine in Dextrose Injection, Cimetidine in Sodium Chloride Injection)

For these parenteral solutions, the concentration of each vehicle named in the official title is labeled as if part of the official title, e.g., Dextrose Injection 5%, or Dextrose (5%) and Sodium Chloride (0.2%) Injection. The same principle of naming official titles for these parenteral solutions applies when the marketed products contain additional drug substances.

Examples of Vehicle formats which currently appear in USP monographs titles are:

1. [DRUG] in Dextrose Injection
2. [DRUG] in Dextrose and Sodium Chloride Injection

3. [DRUG] in Lactated Ringer's and Dextrose Injection
4. [DRUG] in Sodium Chloride Injection

For injectable Lipid Complexes – see **Lipid Complexes**

For injectable Liposomes – see **Liposomes**

Injections Nomenclature

[DRUG] Injection (Epinephrine Injection, Fluorouracil Injection)

[DRUG] for Injection (Nafcillin for Injection)

[DRUG] Injectable Emulsion (Propofol Injectable Emulsion)

[DRUG] Injectable Suspension (Medroxyprogesterone Acetate Injectable Suspension, Triamcinolone Acetonide Injectable Suspension)

[DRUG] for Injectable Suspension (Spectinomycin for Injectable Suspension)

[DRUG] Extended-Release Injectable Suspension

[DRUG] for Extended-Release Injectable Suspension

Inserts

Inserts are solid dosage forms intended to be placed in a naturally occurring body cavity other than the mouth or rectum.

In 2007, due to instances of misadministration of products named vaginal tablets and vaginal capsules, the nomenclature committee approved use of "insert" rather than the more specific descriptor of the dosage form (i.e., tablets, capsules) for all routes other than rectal. Drug products inserted rectally are called suppositories (see **Suppositories**).

Inserts Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Inserts

[DRUG] Urethral Inserts

[DRUG] Vaginal Inserts (Clindamycin Phosphate Vaginal Inserts, Estradiol Vaginal Inserts)

Irrigations

Irrigations are sterile solutions intended to bathe or flush open wounds or body cavities. Irrigations are used to rinse body surfaces other than the mouth. (see **Rinse**)

Historically the route of administration for irrigations has not been included in the monograph titles since they were understood to be used for wounds or body cavities. However, highly specific routes of administration should be defined.

Irrigations Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Irrigation

[DRUG] Irrigation (Sodium Chloride Irrigation)

[DRUG] for Irrigation

[DRUG] Intraocular Irrigation

Jelly

Non-preferred term – see **Gels**

Liquids

A liquid dosage form consists of a pure chemical in its liquid state. Examples include mineral oil, isoflurane, and desflurane. This dosage form term is not applied to solutions. Typically the term “liquid” is not used in drug product monograph titles.

Lotions

Lotions are emulsified (see **Emulsions** for additional information) liquids intended to be applied topically on the skin. The topical route of administration is understood and is not indicated in the compendial name. Lotions share many characteristics with creams, but are more fluid and pourable. They can be more easily applied to large surfaces of the skin than semisolid preparations. Historically some topical suspensions, such as Calamine Lotion, have been called lotions, but this nomenclature is no longer preferred.

Lotions Nomenclature

[DRUG] Lotion (Betamethasone Valerate Lotion, Triamcinolone Acetonide Lotion)

Lozenges

Lozenges are solid oral dosage forms designed to dissolve or disintegrate slowly in the mouth. Therefore there is no need to include the route of administration in the title. Lozenges contain one or more drug substances that are slowly liberated from the typically flavored and sweetened base. Their therapeutic action can be local or systemic. There are a number of historically used terms for molded lozenges, which are now classified as non-preferred terms by the nomenclature committee: [cough] drops, pastilles, lollipops, and troches.

Lozenge Nomenclature

[DRUG] Lozenges (Clotrimazole Lozenges)

Mouthwash

Not preferred, see **Rinse**

Ointments

Ointments are semisolid preparations usually containing less than 20% water and volatiles, and more than 50% hydrocarbons, waxes, or polyols as the vehicle. Ointments are generally intended to be applied topically to the skin or to a mucous membrane. Any other administration route shall typically be reflected in the compendial name. However, rectally administered ointments can often be applied topically as well, and would not include the rectal route in the name even if labeling is targeted for rectal use.

Ointments Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Ointment

[DRUG] Ointment (Bacitracin Ointment, Fluocinolone Acetonide Ointment)

[DRUG] Nasal Ointment (Mupirocin Nasal Ointment)

[DRUG] Ophthalmic Ointment (Neomycin and Polymyxin B Sulfates and Bacitracin Ophthalmic Ointment, Vidarabine Ophthalmic Ointment)

Pastes

Pastes are semisolid dosage forms containing a high percentage (e.g., 20–50%) of finely dispersed solids, have a stiff consistency, are intended for topical application, and serve as a protective coating over body areas to which they are applied. Pastes are assumed to be topical unless specified otherwise. Typically, any other administration route shall be reflected in the compendial name.

Pastes Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Paste

[DRUG] Paste (Zinc Oxide Paste)

Patch

Not preferred, see **Transdermal System**

Pellets

Pellets are small solid masses consisting of a drug substance (with or without excipients) made by compression or molding. Existing official monographs for pellets are historical, as this term is no longer used in compendial names.

For pellets that are administered by implantation see **Implants**

For pellets that are encapsulated see **Capsules**

Plasters

Not preferred, see **Transdermal System**

Pledgets

This historical term means a small compress or tuft, usually of cotton or cotton wool, used to apply disinfectant or medicament to the skin. There is currently one example in the USP - Erythromycin Pledgets. This term is no longer preferred.

Powders

Powders are a dosage form defined as a solid or a mixture of solids in a finely divided state intended for internal or external use. The word “Powder” will only be included in the compendial name when the product is directly administered, such as a powder that is dusted on the skin or one that is inhaled.

Powders Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Powder

[DRUG] Inhalation Powder (Cromolyn Sodium Inhalation Powder)

Inhalation powders are assumed to be for oral inhalation. Inhalation powders can be packaged in a variety of ways, e.g., capsules, blisters, electro spray devices. All these products are named inhalation powders.

[DRUG] Nasal Powder

[DRUG] Topical Powder (Nystatin Topical Powder)

Powders can also be reconstituted with an appropriate vehicle to provide a final dosage form. Because the product will not be administered as a powder, the word "Powder" shall not appear in the compendial name. Instead, the word "for" is used to indicate that the product is intended for reconstitution, such as Ampicillin for Oral Suspension.

[DRUG] for Injection – see **Injections**

[DRUG] for [ROUTE OF ADMINISTRATION] Solution – see **Solutions**

[DRUG] for [ROUTE OF ADMINISTRATION] Suspension – see **Suspensions**

The term "soluble" is used in some official USP monographs for veterinary products, but is no longer preferred (e.g., Tetracycline Hydrochloride Soluble Powder).

The historical monograph for Absorbable Dusting Powder was introduced in the USP XV (1955). The term "dusting" is non-preferred for use in monograph titles.

Rinses

Rinses are liquid preparations used to cleanse by flushing. This dosage form is generally swished in the mouth and then expectorated. A rinse has sometimes been called by the non-preferred term "mouthwash." See **Irrigations** for information on preparations used to flush body surfaces other than the mouth.

Rinses Nomenclature

[DRUG] Rinse

Shampoos (Medicated)

A shampoo is a solution or suspension dosage form used to clean the hair and scalp. It may contain a drug substance intended for topical application to the scalp followed by rinsing with water. Topical administration is understood, therefore there is no need to specify the route in the title.

Shampoos Nomenclature

[DRUG] Shampoo (Lindane Shampoo)

Occasionally a Topical Suspension (or Solution) may also be labeled for use as a Shampoo (e.g., Selenium Sulfide Topical Suspension).

Soaps (Medicated)

Soap is the alkali salt(s) of a fatty acid or mixture of fatty acids used to cleanse the skin. Soaps used as dosage forms may contain a drug substance intended for topical application to the skin followed by rinsing with water.

[DRUG] Soap (Green Soap)

Solutions

Solutions are liquid preparations containing one or more drug substances dissolved in a suitable solvent or mixture of mutually miscible solvents. Solutions may be administered by various routes of administration including: Inhalation, Intraocular, Intravesical, Nasal, Oral, Ophthalmic, Otic, Parenteral (Injection), Rectal, and Topical. Nasal solutions, e.g., Tetrahydrozoline Hydrochloride Nasal Solution, are intended to be instilled into the nostril and are typically non-metered.

In some cases drug products are dispensed as soluble solids or soluble mixtures of solids in the form of the powder or granules, with the intent of dissolving them in a solvent prior to administration. The name of such products shall be in the format [DRUG] for [ROUTE OF ADMINISTRATION] Solution. Solutions can also be prepared from other dosage forms, such as tablets, and the name of such products shall be in the format [DRUG] [DOSAGE FORM] for [ROUTE OF ADMINISTRATION] Solution (e.g., Aspirin Effervescent Tablets for Oral Solution)

The drug and excipients must all go into solution for the final product to be called a solution. If the drug is soluble, but the excipients are not, the final dosage form is a Suspension.

Solutions Nomenclature

[DRUG] {FOR} [ROUTE OF ADMINISTRATION] Solution

[DRUG] for Effervescent Oral Solution

[DRUG] Effervescent Tablets for Oral Solution (Aspirin Effervescent Tablets for Oral Solution)

[DRUG] Inhalation Solution (Isoproterenol Sulfate Inhalation Solution)

[DRUG] for Inhalation Solution (Ribavirin for Inhalation Solution)

[DRUG] Solution for Inhalation (This is an atypical use of the term "for". Solution for Inhalation is a solution to be diluted before administration using a nebulization system.)

[DRUG] Intraocular Solution (Carbachol Intraocular Solution)

[DRUG] Intravesical Solution (Valrubicin Intravesical Solution)

[DRUG] Nasal Solution (Cromolyn Sodium Nasal Solution)

[DRUG] Ophthalmic Solution (Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, Methylcellulose Ophthalmic Solution, Tobramycin Ophthalmic Solution)

[DRUG] for Ophthalmic Solution (Echothiophate Iodide for Ophthalmic Solution)

[DRUG] Oral Solution (Guaifenesin Oral Solution, Oxycodone Hydrochloride Oral Solution, Potassium Chloride Oral Solution)

[DRUG] for Oral Solution (Penicillin V Potassium for Oral Solution, Vancomycin Hydrochloride for Oral Solution)

[DRUG] Otic Solution (Acetic Acid Otic Solution, Carbamide Peroxide Otic Solution, Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution)

[DRUG] for Otic Solution

[DRUG] Rectal Solution (Sodium Phosphates Rectal Solution)

[DRUG] Topical Solution (Clotrimazole Topical Solution, Coal Tar Topical Solution, Hydrogen Peroxide Topical Solution, Lidocaine Hydrochloride Topical Solution)

[DRUG] for Topical Solution (Mafenide Acetate for Topical Solution)

Occasionally products will be named to accommodate their special use, e.g., Lidocaine Hydrochloride Oral Topical Solution was coined to indicate that the drug's action takes place in the lining of the mouth rather than in the gastrointestinal tract.

Circumstances may call for specifying a special use unrelated to the route of administration. Such products will be named according to the format:

[DRUG]{FOR} {QUALIFIER} Solution

[DRUG] Cleansing Solution (Povidone-Iodine Cleansing Solution)

Solution may appear without the route of administration in unique circumstances such as when the solution is:

a. A disinfectant, because it is not intended for use on the human body. (e.g., Glutaral Disinfectant Solution)
b. For ex-vivo use (e.g., to radiolabel blood cells that will subsequently be administered to the patient). (e.g., Indium In 111 Chloride Solution)
c. Specifically labeled for oral and rectal administration (e.g., Lactulose Solution), where it would be misleading as either Oral Solution or Rectal Solution.

See also – Injections, Irrigations, Rinses, Soaps, Shampoos, Sprays.

Spirits

Spirits were described in the first USP in the year 1820. Spirits are a liquid dosage form composed of an alcoholic or hydroalcoholic solution of volatile substances. This historical name is a non-preferred dosage form term. Instead the term "solution" should be used. However, the term "spirit" remains in the title of the monographs: Camphor Spirit, Aromatic Ammonia Spirit, Peppermint Spirit and Compound Orange Spirit.

Sponges

[to come]

Sprays

A spray is a preparation that contains drug substance(s) in the liquid state and is intended for administration as a fine mist, generated by means other than the use of a volatile propellant (see **Aerosols**). Most sprays are generated by manually squeezing a flexible container or actuation of a pump that generates a mist by extruding it through a nozzle.

The intended routes of administration include: Inhalation, Lingual, Nasal, Oral and Topical. Sprays intended for the first four routes are assumed to be metered. Topical sprays may or may not be metered, but are typically not metered. Details pertaining to metering are part of the labeling and are not included in the name.

Sprays Nomenclature

[DRUG] [ROUTE OF ADMINISTRATION] Spray

[DRUG] Inhalation Spray

[DRUG] Lingual Spray (Nitroglycerin Lingual Spray)

[DRUG] Nasal Spray (Fluticasone Propionate Nasal Spray, Sumatriptan Nasal Spray)

[DRUG] Oral Spray

[DRUG] Topical Spray

Strips

[to come]

Suppositories

Suppositories are solid bodies of various sizes and shapes adapted for introduction into the rectum. They are formulated to melt, soften, or dissolve at body temperature. The drug substance contained in the suppository may act locally or be systemically absorbed. The term "suppository" shall not be used for products inserted into other body cavities. Instead the term "insert" should be used (see **Inserts**).

Suppositories Nomenclature

[DRUG] Suppositories (Acetaminophen Suppositories, Glycerin Suppositories, Prochlorperazine Suppositories)

Suspensions

Suspensions are liquid preparations containing drug substance(s) and consist of solid particles dispersed throughout a liquid phase in which the particles are present in excess of the solubility. Dosage forms categorized as "Suspensions" should always have the intended route of administration included, such as ophthalmic, oral, otic, topical. Some suspensions are prepared and ready for use, while others are solid mixtures intended for constitution before use with an appropriate vehicle. Such products are designated "for [ROUTE OF ADMINISTRATION] Suspension."

Suspensions Nomenclature

[DRUG] {FOR} [ROUTE OF ADMINISTRATION] Suspension

[DRUG] Suspension for Inhalation (This is an atypical use of the term "for". Suspension for Inhalation is a suspension to be diluted before administration using a nebulization system.)

[DRUG] Ophthalmic Suspension

[DRUG] for Ophthalmic Suspension

[DRUG] Oral Suspension

[DRUG] Delayed-Release Oral Suspension

[DRUG] Extended-Release Oral Suspension

[DRUG] for Oral Suspension

[DRUG] for Delayed-Release Oral Suspension

[DRUG] for Extended-Release Oral Suspension

[DRUG] Otic Suspension

[DRUG] for Otic Suspension

[DRUG] Rectal Suspension

[DRUG] Topical Suspension

[DRUG] for Topical Suspension

Suspension may appear without the route of administration in unique circumstances such as when the suspension is specifically labeled for oral and rectal administration (e.g., Barium sulfate Suspension), where it would be misleading as either Oral Solution or Rectal Solution.

See also **Injections**, **Shampoos**, **Soaps**, **Sprays**.

Swabs

[to come]

Syrups

Non-preferred term. See Oral Solutions, Oral Suspensions.

Systems

Systems are preparations of drug substance(s) in carrier devices, often containing adhesive backing that are applied topically or inserted into body cavities from which drugs are released in a controlled manner over a specified period of time or the drug substance is released based on its concentration in the formulation, after which the carrier device is removed unless otherwise stated in the labeling.

The primary notation of strength is defined in terms of the rate of release of the drug substance from the system, e.g., x mg/y hours. Various routes of administration are possible, so the route must always be indicated in the compendial name. For example, absorption of the drug substance may take place through the dermis without specifying the region of the body to which the device is applied, so the route is named "transdermal." When a specific location for application is essential for proper use, the name shall indicate the place or organ where the system is applied, e.g., "intrauterine," or "ocular," as the route of administration. The term "patch" has sometimes been used but is not preferred for use in drug product monograph nomenclature when referring to a system.

Systems Nomenclature

[DRUG] {SITE OF APPLICATION} System

[DRUG] Intrauterine System

[DRUG] Ocular System (Pilocarpine Ocular System)

[DRUG] Oral Mucosal System

[DRUG] Periodontal System (Minocycline Periodontal System)

[DRUG] Transdermal System (Clonidine Transdermal System, Estradiol Transdermal System)

Tablets

Tablets are oral solid dosage forms containing drug substance(s) with or without excipients. Tablets can be produced in a variety of sizes and shapes. In addition, tablets may be formulated to obtain a desired method of administration, targeted site of delivery, or performance characteristics; these unique characteristics may be reflected in the compendial name. The following nomenclature conventions have been approved:

1. The format "[DRUG] Tablets" will be used for tablets that are swallowed whole or that MAY be chewed or crushed AND for which there is no intended alternative method of administration. When appropriate, there will also be a labeling statement indicating that the tablets MAY be chewed.
2. The format "[DRUG] Chewable Tablets" will be used for tablets that MUST be chewed or crushed AND for which there is no intended alternative method of administration. There will also be a labeling statement indicating that the tablets MUST be chewed.
3. The format "[DRUG] Tablets for Oral Suspension" or "[DRUG] Tablets for Oral Solution" will be used for tablets intended to be dispersed in a liquid before administration. This title will be used even if the tablet may also be chewed or swallowed whole. There will also be a labeling statement indicating all methods of administration. For example: “Tablets may be swallowed whole, chewed, or dispersed in water or fruit juice.”

Crushing a tablet and sprinkling the resulting powder over food prior to administration or crushing the tablet and making a slurry or solution to enable administration via a nasogastric (NG) tube is an option for many immediate release solid oral dosage forms, so these will not be included in the considerations of other intended alternative methods of administration for item 1, 2, and 3 above.

If a Tablet for Oral Solution contains components, usually citric acid or tartaric acid and carbonates or bicarbonates, to produce an effervescent solution for oral administration, the name shall be [DRUG] Effervescent Tablets for Oral Solution.

4. Tablets formulated to provide very rapid disintegration upon contact with saliva shall be named [DRUG] Orally Disintegrating Tablets.
5. Tablets may be intended to be absorbed in a specific location in the mouth rather than in other parts of the gastrointestinal tract. Such location shall be indicated in the name, e.g., [DRUG] Buccal Tablets, [DRUG] Sublingual Tablets.
6. Tablets may be formulated such that the release is modified. Currently there are two types of modified-release tablets: Delayed-Release Tablets, and Extended-Release Tablets (the term Delayed-Release or Extended-Release is to be substituted for Release Characteristics in the examples below). It is unacceptable to use other descriptors, e.g., "Controlled Release," "Enteric Coated," or corresponding acronyms, in compendial names. (see **General Nomenclature Practices** section)

Tablets Nomenclature

[DRUG] {RELEASE CHARACTERISTICS} {UNIQUE DESCRIPTOR} {SITE OF DELIVERY} Tablets

The terms noted above are described below:

{RELEASE CHARACTERISTICS}: extended-release, delayed-release

{UNIQUE DESCRIPTOR}: chewable, orally disintegrating

{SITE OF DELIVERY}: buccal, sublingual etc.

[DRUG] Tablets (Hydrochlorothiazide Tablets)

[DRUG] Buccal Tablets (Nitroglycerin Buccal Tablets)

[DRUG] Chewable Tablets (Cefaclor Chewable Tablets)

[DRUG] Delayed-Release Tablets (Bisacodyl Delayed-Release Tablets)

[DRUG] Extended-Release Tablets (Zolpidem Tartrate Extended-Release Tablets)

[DRUG] Orally Disintegrating Tablets (Clonazepam Orally Disintegrating Tablets, Vardenafil Hydrochloride Orally Disintegrating Tablets)

[DRUG] Delayed Release Orally Disintegrating Tablets

[DRUG] Sublingual Tablets (Nitroglycerin Sublingual Tablets)

[DRUG] Tablets for Oral Solution (Sodium Chloride Tablets for Oral Solution)

[DRUG] Effervescent Tablets for Oral Solution (Aspirin Effervescent Tablets for Oral Solution)

[DRUG] Tablets for Topical Solution (Cocaine Hydrochloride Tablets for Topical Solution)

[DRUG] Tablets for Oral Suspension (Cephalexin Tablets for Oral Suspension)

Tape

Not preferred, see **Transdermal System**

Tinctures

Not preferred, see **Solutions**

Troche

Not preferred, see **Lozenges**

References

1. *USP 35-NF 30*. General Chapter <1121> *Nomenclature*, U.S. Pharmacopeial Convention, Rockville, MD, 2009.

2. *USP 35-NF 30*. General Chapter <1151> *Pharmaceutical Dosage Forms*, U.S. Pharmacopeial Convention, Rockville, MD, 2009.

3. *AHFS Drug Information, 2009*. American Society of Health System Pharmacists, Bethesda, MD, February 1, 2009.