



## Nomenclature Guidelines

This document is referenced in USP General Chapter <1121> *Nomenclature*, and will be periodically updated by the USP Expert Committee on Nomenclature and Labeling  
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### 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 *United States Pharmacopeia–National Formulary (USP–NF)*. To achieve this consistency, standard naming approaches for developing monograph titles appearing in the *USP–NF* are carried out by the Nomenclature and Labeling Expert Committee.<sup>a</sup> These naming approaches are outlined in General Chapter <1121> *Nomenclature*. The purpose of these Guidelines is to provide supplemental information to the general approaches outlined in General Chapter <1121>.

In the United States under the Federal Food, Drug, and Cosmetic Act (FDCA), the official name given to a drug plays a critical role. The FDCA defines the term “official compendium,” in part, as the official *USP*, the official *NF*, or any supplement to either of 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 a drug 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 have a critical role, not only for enforceable compendial requirements but also for FDA regulations. Oversight of proprietary or “brand” names remains the responsibility of FDA, working with applicants in the

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<sup>a</sup> The name of the committee has changed over the years and will be referred to as “nomenclature committee” in the remainder of this document.

Previous names include: Nomenclature Expert Committee; Nomenclature, Safety, and Labeling Expert Committee; and presently Nomenclature and Labeling Expert Committee.



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. USP usually adopts drug substance established names as recommended by the United States Adopted Names (USAN) Council. The USAN Council is comprised of members representing USP, the American Medical Association (AMA), the American Pharmacists Association (APhA), FDA, and one member-at-large. 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*.<sup>b</sup>

USP has had a role in monograph naming since its inception in 1820. In 1986, a USP nomenclature committee was formed to improve the process of creating official names. The role of a committee dedicated to nomenclature issues has helped advance consistency in 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 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

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<sup>b</sup> 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 U.S.



USP works with FDA and the USAN Council in establishing naming guidelines for biologics, vaccines, tissue and gene therapy products, and others. USP assigns titles to biologic products according to the “core name.”

- Excipients

Excipient monographs are included in the *NF*. The nomenclature committee works with the excipient committees 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 committees to encourage and standardize the use of the Latin binomials 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. The term “dietary supplement,” as legally defined by the Dietary Supplement and Health Education Act (DSHEA), applies to human products, but not animal products. The Dietary Supplements Herbal Medicines Nomenclature Joint Subcommittee developed the *Guideline for Assigning Titles to USP Dietary Supplements Monographs*, which is also used as a basis for decisions by the Nomenclature and Labeling Expert Committee.

## **Drug Substances**

USP generally recognizes USAN names for drug substance monographs. However, final recommendations on compendial nomenclature reside with the nomenclature committee. 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 mixtures of solids (dispersions) and are intended to be used as intermediates for making final formulations. Examples include 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” articles. In most cases, dilution is necessary for safety reasons; examples include Diluted Isosorbide Mononitrate and Diluted Nitroglycerin.

### **“Hydrous” nomenclature**

It is no longer preferred to use the term “hydrous” in monograph titles for drug substances. 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, including considerations and examples, as well as general nomenclature practices. Dosage forms in this section are also addressed in USP General Chapter <1151> *Pharmaceutical Dosage Forms*. The approach taken in General Chapter <1151> 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 General Chapter <1151> corresponding to names of official articles with reference to appropriate entries representing physical characteristics for those dosage forms within the chapter. General Chapter <1151> 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 also of nomenclature not preferred in the naming of compendial articles.

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

### Dosage Form in Nomenclature

- Generally, the dosage form title appears in the following format:

**[DRUG] [ROUTE OF ADMINISTRATION]<sup>c</sup> [DOSAGE FORM]**

### Route of Administration in Nomenclature

- The [ROUTE OF ADMINISTRATION] is omitted from dosage form titles in which the route of administration is understood. The general form of the monograph title 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 most topically applied products, i.e., 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. For animal drug products that are topically applied to the skin and intended to achieve a systemic effect, “transdermal” is typically included as the route of administration in the monograph title.
  - Some products intended for buccal administration were subsequently approved for sublingual administration. The current 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 a new permitted route of administration as long as the original route is still valid.

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<sup>c</sup> Where applicable



### Terms used in Nomenclature: “for,” “in,” or “and”

- Use of the term “for”:
  - The term “for” is included in names of solid preparations that must be dissolved or suspended in a suitable liquid to obtain a dosage form suitable for administration. The general format becomes [DRUG] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM], e.g., Ampicillin for Oral Suspension, Aminolevulinic Acid Hydrochloride for Topical Solution.
  - In some instances, the drug is supplied in one dosage form for the preparation of the intended dosage form (e.g., a tablet is used to make a suspension). 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., Everolimus Tablets for Oral Suspension. See the **Solutions** and **Suspensions** sections for further information on this nomenclature practice.
- Use of the term “and”:
  - Where all drug substances are active, the term “and” is used between the drug substances in the monograph title (e.g. Acetaminophen and Codeine Phosphate Tablets).
  - 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).
- Use of the term “in”:
  - 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).

### Punctuation Used in Nomenclature: Brackets and Braces

- Brackets [ ] are used in compendial nomenclature to indicate that the appropriate term(s) for the word(s) used within the brackets are required.
  - For instance, [DRUG] must display a drug name (e.g., Acyclovir), and [DOSAGE FORM] must display the appropriate dosage form (e.g. Tablets).
- Braces { } are used in compendial nomenclature to indicate that the appropriate term(s) for the word(s) enclosed in the braces are included in the name when applicable. The dosage form



information explains how the terms should be used, for example: “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} [DOSAGE FORM]– (Glutaral Disinfectant Solution).”<sup>d</sup>

#### Inserts and Suppositories

- 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 the defining term for the administration route.
- The term “Suppositories” is used in the titles of solid preparations that are intended for rectal administration.

#### Specific Administration Instructions are Not Included in Titles

- 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.

#### “Hydrous” Nomenclature

Water of hydration in drug substances is not included in the drug product name. It is no longer preferred to use the term “hydrous,” in monograph titles. Similarly, the term “anhydrous” is typically not preferred.

### **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 a formulation such as gastro-retentive technology.

#### Extended-Release:

Extended-release products are formulated in a manner that makes the drug substance available over an

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<sup>d</sup> Example taken from **Solutions** section of the *Nomenclature Guidelines*



extended period of time following administration, compared to that observed or anticipated for an immediate-release dosage form. Descriptors such as “prolonged-release,” “repeat-action,” “controlled-release,” “long-acting,” “sustained-release,” and their corresponding acronyms should not be used to describe such dosage forms. The term “extended-release” is used for compendial nomenclature.

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.

### **Compounded Preparation Titles**

- The monograph title for an official compounded preparation uses the following convention:  
[DRUG SUBSTANCE] Compounded [ROUTE OF ADMINISTRATION] [DOSAGE FORM]<sup>°</sup>  
(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**

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<sup>°</sup> The word “Compounded” was approved for use in compounded monograph titles by the Nomenclature, Safety, and Labeling Expert Committee in August 2012.





- 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 that enclose a central aqueous compartment. The general format used when naming a liposomal drug product 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/or 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.

### 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 generally 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.

- 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<sup>f</sup>

For additional guidance for implementation or exceptions to the Policy, refer to *Guidance for Implementation and Exceptions: The Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations in General Chapter <1121> Nomenclature*.

## Nomenclature Guidelines for Specific Dosage Forms

The following presents a brief description of the particular dosage forms with specific naming examples for each.

### Aerosols

Aerosols are dosage forms that are 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) (Mometasone Furoate and Formoterol Fumarate Inhalation Aerosol)

**[DRUG] Lingual Aerosol**

**[DRUG] Nasal Aerosol** (Ciclesonide Nasal Aerosol)

**[DRUG] Topical Aerosol** (Tolnaftate Topical Aerosol)

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<sup>f</sup> Excerpt taken from General Chapter <1121> *Nomenclature - MONOGRAPH NAMING POLICY FOR SALT DRUG SUBSTANCES IN DRUG PRODUCTS AND COMPOUNDED PREPARATIONS*



## **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} Capsules**

The term noted above is described below:

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

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

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

**[DRUG] Extended-Release Capsules** (Chlorpheniramine Maleate Extended-Release Capsules)

## **Caplets**

Not preferred, see **Tablets**

## **Collodions**

Not preferred, see **Solutions**

The term is reserved for Pyroxylin in Alcohol and Ether.

## **Concentrates**

Historically, “concentrate” had two meanings: one was simply reflecting a high concentration that was 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 term “concentrate” is being phased out of the nomenclature for drug products. Instead, the appropriate dosage-form terms, e.g., solution or suspension, should be used. When a drug product is to be diluted, the statement “must be diluted” is to be displayed prominently on the label. However, there are several historical exceptions. Other than those historical exceptions, use of the word “Concentrate” for drug products is restricted to one specific monograph: Potassium Chloride for Injection Concentrate.

For additional information about the use of “concentrate” pertaining to drug substances, see the **Drug Substances** section.

### **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**

Emulsions are dosage forms consisting of a two-phase system composed of at least two immiscible liquids, one of 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] Ophthalmic Emulsion** (Cyclosporine Ophthalmic 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** (Buprenorphine and Naloxone Buccal Film)

**[DRUG] Oral Film** (Ondansetron Oral Film)

**[DRUG] Sublingual Film** (Buprenorphine and Naloxone Sublingual Film)

#### **Foams**

Foams are dispersions of gas in a liquid or solid continuous phase, wherein the liquid or solid contains the drug substance and suitable excipients. A foam may contain one or more drug substances, surfactants, and aqueous or nonaqueous liquids, and is produced with or without the aid of propellants. A foam can be formulated to quickly break down into a liquid or to remain as a foam to ensure prolonged contact.

#### Foams Nomenclature

**[DRUG] [ROUTE OF ADMINISTRATION] Foam**

**[DRUG] Topical Foam** (Calcipotriene Topical Foam, Tazarotene Topical Foam)

**[DRUG] Rectal Foam** (Budesonide Rectal Foam)



## **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 (e.g., Topical, Vaginal, Periodontal, etc.).

Although the term “Jelly” has been used historically, 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. The 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.

### Gel and Gels Nomenclature

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

[DRUG] [ROUTE OF ADMINISTRATION] Gel



**[DRUG] Dental Gel**

**[DRUG] Nasal Gel** (Testosterone Nasal Gel)

**[DRUG] Ophthalmic Gel** (Lidocaine Hydrochloride Ophthalmic Gel)

**[DRUG] Oral Gel**

**[DRUG] Periodontal Gel**

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

**[DRUG] Vaginal Gel** (Metronidazole 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 agents are intended to enhance consumer acceptance and mask the taste of the delivered labeled drug substance or dietary supplement. 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

The term “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 swallowed or granules can be sprinkled on soft food or dissolved in liquid 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.





For granules that may be formulated in modified-release dosage forms, the appropriate nomenclature would include the release characteristics (the term Delayed-Release or Extended-Release is to be substituted for Release Characteristics in the example below).

#### Granules Nomenclature

**[DRUG] {RELEASE CHARACTERISTICS} [ROUTE OF ADMINISTRATION] Granules**

**[DRUG] Oral Granules** (Ivacaftor Oral Granules)

**[DRUG] Delayed-Release Oral Granules** (Rabeprazole Sodium Delayed-Release 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 procedure or by a suitable special injector (e.g., trocar). Implants are available in a variety of shapes, sizes, and materials including pellets, resorbable microparticles, polymer implants (biodegradable or non-biodegradable), and metal or metal/plastic implants (osmotic pumps and stents). An implant can have a 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 titling the product.

#### Implants Nomenclature



## **[DRUG] [ROUTE OF ADMINISTRATION] Implants**

**[DRUG] Implants** (Testosterone Implant, Buprenorphine Implants)

**[DRUG] Intravitreal Implants** (Ganciclovir Intravitreal Implant)

**[DRUG] Sinus Implants**

## **Infusions**

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

## **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 are in agreement 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–NF* 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 liquid, 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 consisting of solids suspended in a liquid.
5. **[DRUG] for Injectable Suspension** — Dry solids that, upon the addition of a suitable liquid, yield preparations conforming in all respects to the requirements for Injectable Suspensions.
6. **[DRUG] Extended-Release Injectable Suspension** — Liquid preparations consisting of solids suspended in a suitable liquid formulated to allow the 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 liquid, 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 the **Drug Substance** and **Drug Product** sections.

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 that currently appear in USP monograph 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** (Paliperidone Palmitate Extended-Release Injectable Suspension)

**[DRUG] for Extended-Release Injectable Suspension** (Olanzapine 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 the 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** (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, with the exception of animal drugs for use in medicated articles and medicated feeds (see **Nomenclature for Animal Drugs for Use in Animal Feeds**).

## **Lotions**

Lotions are emulsified liquids (see **Emulsions** for additional information) 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 applied more easily to large surfaces of the skin than can 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 that usually contain 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**

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

## **Pastes**

Pastes are semisolid dosage forms that contain a high percentage (e.g., 20%–50%) of finely dispersed solids, have a stiff consistency, are usually intended for topical application, and serve as a protective coating over body areas to which they are applied. Orally administered pastes may be indicated for adhesion to the teeth or mucous membranes for a local effect. 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)



## **[DRUG] Oral Paste**

### **Patch**

Not preferred, see **Systems**

### **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 **Systems**

### **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–NF*, 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** (Fluticasone Propionate 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 of these products are named inhalation powders.

**[DRUG] Nasal Powder**

**[DRUG] Oral Powder** (Atazanavir Oral Powder)

**[DRUG] Topical Powder** (Nystatin Topical Powder)

Powders that are Reconstituted

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. The format to be used with powders that are reconstituted is as follows:

**[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 animal drug 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, Ophthalmic, Oral, 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. For animal drugs, particularly for products intended for aquaculture, solutions may be administered by immersion (i.e., partial or complete submersion of the animal in the solution).



In some cases, drug products are dispensed as soluble solids or soluble mixtures of solids in the form of 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 names of such products shall be in the format [DRUG] [DOSAGE FORM] for [ROUTE OF ADMINISTRATION] Solution (e.g., Aspirin and Caffeine Effervescent Tablets for Oral Solution).

The drug substance and excipients must all go into solution for the final product to be called a solution. If the drug substance 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** (Potassium Bicarbonate Effervescent Tablets for Oral Solution)

**[DRUG] Immersion Solution**

**[DRUG] Inhalation Solution** (Ipratropium Bromide 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, 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, 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 (for example, 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, and 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 following monographs: Camphor Spirit, Aromatic Ammonia Spirit, Peppermint Spirit, and Compound Orange Spirit.



## **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** (Ipratropium Bromide and Albuterol Inhalation Spray)

**[DRUG] Lingual Spray** (Nitroglycerin Lingual Spray)

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

**[DRUG] Oral Spray** (Zolpidem Tartrate Oral Spray)

**[DRUG] Topical Spray** (Clobetasol Propionate Topical Spray)

## **Strips**

A strip is a dosage form or device in the shape of a long, narrow, thin, absorbent, solid material such as filter paper. Typically, it is sterile and it may be impregnated with a compound or be gauged to allow measurements for diagnostic purposes, such as in measuring tear production. The term “strip” should not be used when another term such as “film” is more appropriate. Strip is only used for diagnostic products. Otherwise, it is not preferred; See **Film**.

### Strips Nomenclature

**[DRUG] [ROUTE OF ADMINISTRATION] Strips** (Fluorescein Sodium Ophthalmic Strips)

## **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 may 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, or topical. Some animal drug products that are suspensions are approved for the intramammary route of administration. 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] Inhalation Suspension** (Budesonide Inhalation Suspension)

**[DRUG] Intramammary Suspension** (Ceftiofur Intramammary 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** (Loteprednol Etabonate Ophthalmic Suspension)

**[DRUG] for Ophthalmic Suspension**

**[DRUG] Oral Suspension** (Posaconazole Oral Suspension)

**[DRUG] Delayed-Release Oral Suspension**

**[DRUG] Extended-Release Oral Suspension** (Carbinoxamine Maleate Extended-Release Oral Suspension)



**[DRUG] for Oral Suspension** (Aprepitant for Oral Suspension)

**[DRUG] for Delayed-Release Oral Suspension** (Esomeprazole Magnesium for Delayed-Release Oral Suspension)

**[DRUG] for Extended-Release Oral Suspension**

**[DRUG] Otic Suspension** (Ciprofloxacin and Hydrocortisone Otic Suspension)

**[DRUG] for Otic Suspension**

**[DRUG] Rectal Suspension** (Mesalamine Rectal Suspension)

**[DRUG] Topical Suspension** (Spinosad 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 Suspension or Rectal Suspension.

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

## **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 notation of strength is defined in terms of either the amount of the drug substance released from the system over a specific period of time, or the drug concentration within the formulation (e.g., the percentage of the drug). 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 it is not preferred for use in drug product monograph nomenclature when referring to a system.

### Systems Nomenclature

**[DRUG] {SITE OF APPLICATION} System**

**[DRUG] Buccal System** (Testosterone Buccal System)

**[DRUG] Intrauterine System** (Levonorgestrel Intrauterine System)

**[DRUG] Ocular System** (Hydroxypropyl Cellulose Ocular System)

**[DRUG] Oral Mucosal System** (Amlexanox Oral Mucosal System)

**[DRUG] Periodontal System** (Minocycline Periodontal System)

**[DRUG] Topical System**

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

**[DRUG] Vaginal System** (Etonogestrel and Ethinyl Estradiol Vaginal 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 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 items 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 their 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** (Miconazole Buccal Tablets)

**[DRUG] Chewable Tablets** (Loratadine Chewable Tablets)

**[DRUG] Delayed-Release Tablets** (Risedronate Sodium Delayed-Release Tablets)

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

**[DRUG] Orally Disintegrating Tablets** (Clonazepam Orally Disintegrating Tablets)

**[DRUG] Delayed-Release Orally Disintegrating Tablets** (Lansoprazole Delayed-Release Orally Disintegrating Tablets)

**[DRUG] Sublingual Tablets** (Nitroglycerin Sublingual Tablets)

**[DRUG] Tablets for Oral Solution**

**[DRUG] Effervescent Tablets for Oral Solution** (Alendronate Sodium Effervescent Tablets for Oral Solution)

**[DRUG] Tablets for Topical Solution**

**[DRUG] Tablets for Oral Suspension** (Everolimus Tablets for Oral Suspension)

### **Tape**

Not preferred, see **Systems**

### **Tinctures**

Not preferred, see **Solutions**

### **Troche**

Not preferred, see **Lozenges**

## **Nomenclature for Animal Drugs for Use in Animal Feeds**

Some animal drugs are approved for manufacture into medicated articles and feeds that are used to deliver the drugs via the feed given to animals. Animal drugs in feeds are regulated as Type A medicated articles and Type B or Type C medicated feeds.



A full discussion of medicated articles and feeds is provided in General Chapter <1152> *Animal Drugs for Use in Animal Feeds*. Briefly, Type A medicated articles [21 CFR 558.3(b)(2)] are concentrated forms of animal drugs intended solely for further manufacture into other approved Type A medicated articles or Type B or Type C medicated feeds. Type A medicated articles consist of one or more animal drugs with or without a carrier and/or other inactive ingredients. They cannot be fed directly to animals, but must be further diluted by mixing into feed. Type B medicated feeds [21 CFR 558.3(b)(3)] are manufactured from either Type A medicated articles or other Type B medicated feeds by dilution with non-medicated feed ingredients. Type B medicated feeds are “intermediate” medicated feeds intended only for further dilution by mixing into feed and cannot be fed directly to animals. Type C medicated feeds [21 CFR 558.3(b)(4)] are intended to be fed directly to animals. They are manufactured from Type A medicated articles, Type B medicated feeds, or other Type C medicated feeds diluted with non-medicated feed ingredients.

Medicated articles and medicated feeds may be in either dry or liquid form. Furthermore, Type C medicated feeds may be approved for specific administration modes. These forms and administration modes are captured in nomenclature that is available for medicated articles and feeds. The term “premix” is no longer used for nomenclature purposes for animal drugs for use in animal feeds.

#### Medicated Article and Medicated Feed Nomenclature

**[DRUG] Type A Medicated Article (Monensin Type A Medicated Article)**

**[DRUG] Type A Liquid Medicated Article**

**[DRUG] Type B Medicated Feed**

**[DRUG] Type B Liquid Medicated Feed**

**[DRUG] Type C Medicated Feed**

**[DRUG] Type C Liquid Medicated Feed**

**[DRUG] Type C Free-Choice Medicated Feed**

**[DRUG] Type C Liquid Free-Choice Medicated Feed**

**[DRUG] Type C Top-Dress Medicated Feed**



## References

1. *USP 42–NF 37. General Chapter <1121> Nomenclature*, U.S. Pharmacopeial Convention, Rockville, MD, 2019.
2. *USP 42–NF 37. General Chapter <1151> Pharmaceutical Dosage Forms*, U.S. Pharmacopeial Convention, Rockville, MD, 2019.
3. *AHFS Drug Information, 2019*. American Society of Health-System Pharmacists, Bethesda, MD, Accessed 12 August 2019.
4. *USP 42–NF 37. General Chapter <1152> Animal Drugs for Use in Animal Feeds*, U.S. Pharmacopeial Convention, Rockville, MD, 2019.

This *Guideline* supersedes any previous guideline issued by USP on nomenclature and labeling.

### SUMMARY OF CHANGES FOR THIS REVISION:

SUMMARY OF CHANGES	RATIONALE FOR CHANGE
<b>G01.11-03</b>	
Section: Introduction – Dietary Supplements -Removed “names” after “Latin binomials”	Binomial is synonymous with the word “name”. Binomial was changed to singular.
Section: General Nomenclature Practices -Addition of reference to animal drug products	Route of administration for animal drug products that are applied topically and have systemic effect.
Reference added to <i>Guidance for Implementation and Exceptions: The Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations in General Chapter &lt;1121&gt; Nomenclature</i>	Provides further guidance for the salt naming policy found in General Chapter <1121> <i>Nomenclature</i>
Section: Concentrates -Modification of paragraph	Provide more clarity and align with language in General Chapter <1151> <i>Pharmaceutical Dosage Forms</i>



Removal of reference to medicated foams	Medicated foams dosage form text in General Chapter <1151> <i>Pharmaceutical Dosage Forms</i> is still under review by USP.
Drug product example removed	Drug product no longer on the market
Section: Powders -Subheading modified	Updated for clarification: “ <u>Powders that are Reconstituted</u> ”
Referrals to “Systems” -Removed “(Transdermal)”	There are not defined sections within “Systems”, therefore detailed cross-references were not necessary.
Formatting changes	Changes made to improve document appearance.