**Briefing**

篮球 Nomenclature. The proposed changes to 1121 include a proposal to move the general chapter to a below 1000 general chapter. The new number for the general chapter is 8. This reflects the mandatory nature of the general chapter following USP's legal authority in creating official names. The main changes in the general chapter include:

- An updated description of USP's role in law, with amended references
- A revised Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations to clarify the definition of the active moiety. This definition applies to noncovalent chemical entities such as salts, complexes, and clathrates but excludes covalently bound esters
- General rules are applied in the naming of drug products with clear definitions such as:
  - Rules for omitting route of administration in the name
  - Rules for naming and labeling injections, where specific route (e.g., intravenous, intramuscular, etc.) is placed in the labeling rather than in the title
  - The term for is included in names to indicate that the product is a solid drug substance that must be dissolved or suspended in a suitable liquid to obtain a final dosage form
  - Provision that creams, ointments, lotions, and pastes are applied topically unless otherwise indicated in the name
  - Clarification of rules for products administered vaginally (inserts) and rectally (suppositories)
  - A system as a preparation of drug(s) in a carrier device that is applied topically or inserted into a body cavity, from which drugs are released gradually over an extended period of time, after which the carrier device is removed
  - Definitions applied for concentrates

These decisions were made by the Nomenclature Expert Committee during its July 18-19, 2011, meeting.

(NSL: A. Wilk.)

Correspondence Number—C77398

*Comment deadline:* March 31, 2012

*Change to read:*
NOMENCLATURE

The USP (or NF) titles for monograph articles are legally recognized under the Federal Food, Drug, and Cosmetic Act as the designations for use in labeling the articles to which they apply:

The value of designating each drug by one and only one nonproprietary name is important in terms of achieving simplicity and uniformity in drug nomenclature. In support of the U.S. Adopted Names program (see Mission and Preface in USP–NF), of which the U.S. Pharmacopeial Convention is a cosponsor, the USP Council of Experts gives consideration to the adoption of the U.S. Adopted Name, if any, as the official title for any compound that attains compendial recognition.

A compilation of the U.S. Adopted Names (USAN) published from the start of the USAN program in 1961, as well as other names for drugs, both current and retrospective, is provided in the USP Dictionary of USAN and International Drug Names. This publication serves as a book of names useful for identifying and distinguishing all kinds of names for drugs, whether public, proprietary, chemical, or code-designated names.

A nonproprietary name of a drug serves numerous and varied purposes; its principal function being to identify the substance to which it applies by means of a designation that may be used by the professional and lay public free from the restrictions associated with registered trademarks. Teaching in the health sciences requires a common designation, especially for a drug that is available from several sources or is incorporated into a combination drug product; nonproprietary names facilitate communication among healthcare providers; nonproprietary names must be used as the titles of the articles recognized by official drug compendia; a nonproprietary name is essential to the pharmaceutical manufacturer as a means of protecting trademark rights in the brand name for the article concerned; and, finally, the manufacturer is obligated by federal law to include the established nonproprietary name in advertising and labeling.

Under the terms of the Drug Amendments of 1962 to the Federal Food, Drug, and Cosmetic Act, which became law October 10, 1962, the Secretary of Health and Human Services is authorized to designate an official name for any drug wherever deemed “necessary or desirable in the interest of usefulness and simplicity.”

The Commissioner of Food and Drugs and the Secretary of Health and Human Services published in the Federal Register regulations effective November 26, 1984, which state, in part:

“See. 299.4 Established names of drugs.”
“(e) The Food and Drug Administration will not routinely designate official names under section 508 of the act. As a result, the established name under section 502(e) of the act will ordinarily be either the compendial name of the drug or, if there is no compendial name, the common and usual name of the drug. Interested persons, in the absence of the designation by the Food and Drug Administration of an official name, may rely on as the established name for any drug the current compendial name or the USAN adopted name listed in USAN and the USP Dictionary of Drug Names.

It will be noted that the monographs on the biologics, which are produced under licenses issued by the Secretary of the U.S. Department of Health and Human Services, represent a special case. Although efforts continue toward achieving uniformity, there may be a difference between the respective title required by federal law and the USP title. Such differences are fewer than in past revisions of the Pharmacopeia. The USP title, where different from the FDA Center for Biologics Evaluation and Research title, does not necessarily constitute a synonym for labeling purposes; the conditions of licensing the biologic concerned require that each such article be designated by the name appearing in the product license issued to the manufacturer. Where a USP title differs from the title in the federal regulations, the former has been adopted with a view to usefulness, simplicity, and conformity with the principles governing the selection of monograph titles generally.

**GENERAL NOMENCLATURE FORMS**

Some monograph titles existing in the USP–NF do not conform to the formats outlined in this general information chapter. Typically, these monograph titles were adopted before the establishment of the title formats and nomenclature policies presented in this general information chapter. Such monograph titles may be subject to subsequent revision and should not be interpreted as precedents for other monograph titles.

Standardized forms of nomenclature have been devised in the interest of achieving uniformity for naming compendial articles. The general nomenclature forms that follow illustrate the terminology used throughout the official compendia for consistency in establishing titles of monographs on official pharmaceutical dosage forms and preparations. Examples are shown for the more frequently encountered categories of dosage forms.

For a variety of dosage forms, titles are in the following general form: **[DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM]**.

**Examples:**

Calcium Carbonate Oral Suspension
Cetylpyridinium Chloride Topical Solution
Dexamethasone Ophthalmic Suspension
Epinephrine Bitartrate Ophthalmic Solution
Isosorbide Dinitrate Sublingual Tablets
Miconazole Nitrate Topical Powder
Triple Sulfate Vaginal Cream

The term “Vaginal Inserts”, rather than “Vaginal Tablets”, “Vaginal Capsules”, or “Vaginal Suppositories” is used in the title of this type of vaginal preparation to avoid the potential for misuse of these products if the term “Tablets” or “Capsules” or “Suppositories” were to appear in the title.
Example:

Clotrimazole Vaginal Inserts

The term for route of administration is omitted for those dosage forms for which the route of administration is understood. The general form then becomes simply [DRUG] [DOSAGE FORM]. Thus, capsules, tablets, and lozenges are administered via the oral route unless otherwise indicated by the title.
Examples:

Acetaminophen Capsules
Aminophylline Delayed-Release Tablets
Aspirin Extended-Release Tablets
Hexylresorcinol Lozenges
Meperidine Hydrochloride Tablets

Drugs that are injected may be administered via the intravenous, intramuscular, subcutaneous, etc., route, the route being specified in the labeling rather than in the name.
Examples:

Aurothioglucose Injectable Suspension
Epinephrine Injection
Fluoresuracil Injection
Hydrocortisone Acetate Injectable Suspension
Phytonadione Injectable Emulsion
Creams, ointments, lotions, and pastes are applied topically, unless otherwise indicated by the name.

Examples:

- Benzoyl Peroxide Lotion
- Betamethasone Dipropionate Cream
- Estradiol Vaginal Cream
- Nystatin Ointment
- Zinc Oxide Paste

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

Example:

- Aspirin Suppositories

The term “for” is included in names, as appropriate, of preparations for which a solid drug substance must be dissolved or suspended in a suitable liquid to obtain a dosage form, and the general form becomes [DRUG] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM].

Examples:

- Ampicillin for Oral Suspension
- Epinephrine Bitartrate for Ophthalmic Solution
- Nafcillin for Injection
- Spectinomycin for Injectable Suspension

In some instances, the drug is supplied in one dosage form for the preparation of the intended dosage form.

Examples:

- Aspirin Effervescent Tablets for Oral Solution
- Methadone Hydrochloride Tablets for Oral Suspension
- Papain Tablets for Topical Solution

Systems are preparations of drugs in carrier devices that are applied topically or inserted into body cavities, from which drugs are released gradually over extended times, after which the carrier device is removed. The general form for a system is [DRUG] [ROUTE] [SYSTEM].
Examples:

Nicotine Transdermal System
Progestosterone Intrauterine Contraceptive System

Some drugs are available as concentrated solutions that are not intended for direct administration to humans or animals, but are to be diluted with suitable liquid vehicles to obtain the intended preparation. The general form for these preparations, which are not dosage forms, is [DRUG] [CONCENTRATE].

Examples:

Isosorbide Concentrate (used to prepare Isosorbide Oral Solution)
Glutaral Concentrate (used to prepare Glutaral Disinfectant Solution)

For products intended for parenteral administration, the use of the word “Concentrate” in the monograph title is restricted to one specific monograph, Potassium Chloride for Injection Concentrate. The word “Concentrate” should not appear in the monograph title for any other parenteral product, rather, this issue is to be addressed in the product labeling.

Some drugs are supplied as preparations that may be intermediates used for convenience in formulating finished dosage forms. The general form for such preparations, which are not finished dosage forms, is [DRUG] [PREPARATION].

Examples:

Vitamin E Preparation
Cranberry Liquid Preparation

MONOGRAPH NAMING POLICY FOR SALT DRUG SUBSTANCES IN DRUG PRODUCTS AND COMPOUNDED PREPARATIONS

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, as defined below. The strength of the product or preparation also is 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 an ester, salt (including a salt with hydrogen or coordination bonds), or other nonequivalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance, without
regard to the actual charged state of the molecule in vivo.
For example, the active moiety of a hydrochloride salt of a base will be the free base and not the protonated form of the base. The active moiety of a metal acid salt will be the free acid. 

i. Example: Chelocardin Hydrochloride active moiety is Chelocardin

\[ \text{Chelocardin Hydrochloride} \]

\[ \text{H}_2\text{C} = \text{O} \quad \text{OH} \quad \text{O} \quad \text{OH} \quad \text{CH}_3 \quad \text{H} \quad \text{NH}_2 \quad \text{HCl} \]

ii. Example: Alendronate Sodium active moiety is Alendronic Acid

\[ \text{Alendronate Sodium} \]

\[ \text{HO} \quad \text{CO} \quad \text{P} = \text{O}^- \quad \text{Na}^+ \quad \text{HO} \quad \text{OH} \quad \text{H}_2\text{O} \quad \text{HO} \quad \text{OH} \quad \text{OH} \quad \text{HO} \quad \text{H}_2\text{N} \]
not intended, except where the USP Council of Experts determines that, for reasons such as safety, a nomenclature change is warranted.

**Related Issues**

**Labeling**—The labeling clearly states the specific salt form of the active moiety that is present in the product/preparation, as this information may be useful to practitioners and patients. The names and strengths of both the active moiety and specific salt form (where applicable) are provided in the labeling.

**Exceptions**—In those rare cases in which the use of the specific salt form of the active moiety in the title provides vital information from a clinical perspective, an exception to this Policy may be considered. In such cases, where the monograph title contains the specific salt form of the active moiety, the strength of the product or preparation also is expressed in terms of the specific salt form.

**POLICY FOR POSTPONEMENT SCHEDULES**

It is the practice of USP to postpone the official dates of nomenclature and labeling revisions for a reasonable time primarily to allow for product label changes to be made and to allow health practitioners and consumers time to become familiar with the new terminology. A postponement period of 18 months is usually applied when only one or a small number of products is affected. A postponement period of 30 months is usually applied when names or labeling of multisource products or multiproduct lines of a firm’s preparations are being changed. A postponement period of 60 months is usually applied for title and labeling changes that affect excipients, because such changes would require relabeling of very large numbers of prescription-only and OTC preparations.

There may be exceptions to this postponement schedule where a shorter time is needed in order to specify nomenclature and labeling changes in cases where public health and safety are a concern.

The assignment of a postponement schedule is handled by the USP Expert Committee on Nomenclature. The postponement schedules are presented below. USP’s implementation of a postponement schedule is automatic, unless an exception is sought. Exceptions to the postponement schedule are rarely made, and must have suitable justification as well as the approval of the Expert Committee on Nomenclature. Any questions or concerns regarding this postponement schedule may be addressed to the USP staff liaison assigned to the Expert Committee on Nomenclature.

**48 months**—Schedule for title and labeling changes for a drug product. One or few
companies are involved. Example: Sterile [Drug] change to [Drug] for Injection.

30 months—Schedule for title and labeling changes for prescription only and OTC products.

1. Extensive product line for a company. Examples: syrups and elixirs.
2. Several companies are involved. Examples: syrups and elixirs; lotions; sunscreens.

60 months—Schedule for title and labeling changes for excipient monographs. Ingredient names in numerous multisource products are affected.

Naming is critical for determining exactly which articles are subject to particular standards. In turn, compendial tests for identity are critical for linking compendial names (and the accompanying standards) to a particular article by confirming whether the article is indeed the one named or recognized in USP–NF. Articles in USP and NF, including drug substances, drug products, and excipients, are given their nonproprietary names or official titles by an expert committee, usually the committee charged with responsibility for nomenclature matters, often in the context of monograph development and approval but increasingly closer in time to initial marketing approval by FDA. USP is not involved in the approval or designation of proprietary or brand names. When an International Nonproprietary Name or US Adopted Names Council (USAN) name has been designated previously, the responsible USP expert committee may decide to retain the name for compendial use but is not required to do so. The designation of a compendial name is part of the setting of compendial standards (“determining and approving content of the official compendia”), which under USP bylaws is the responsibility of the USP Council of Experts and various expert committees. See generally USP Bylaws Article VII, Section 1, and General Notices Sections 2.20, 3.10, 3.10.10, and 5.40.

ROLE IN LAW OF ARTICLES RECOGNIZED IN USP–NF

Naming and nomenclature also play critical roles in FDA’s regulation of medicines, particularly in the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), which apply as well to biologics licensed under the Public Health Service Act (PHSA). Under those adulteration and misbranding provisions, if an article “purports to be or is represented as a drug the name of which is recognized in an official compendium” such as USP or NF, it must comply with compendial identity standards or be deemed adulterated, misbranded, or both [FDCA §§501(b) and 502(e)(3); see also FDA
regulations, 21 CFR §299.5(a&b)]. To avoid being deemed adulterated, such drugs also must comply with compendial standards for strength, quality, and purity unless they are labeled to show all respects in which the drug differs from the USP article [FDCA §501(b), and 21 CFR §299.5(c)].

FDA regulations reflect the agency’s longstanding practice of ordinarily relying on the official name in USP–NF or, if there is not such a compendial name, the name adopted by USAN and listed in the USP Dictionary of USAN and International Drug Names [21 CFR §299.4(e)].

FDA's policy of relying on USP and not routinely designating official names is founded on the adulteration and misbranding provisions of FDCA (§§501, 502, and 508) to which all drugs, including biologics, are subject whether they are legally marketed under FDCA or PHSA. In the absence of a §508 nonproprietary name, secondary priority next goes, in the case of "an article recognized" in USP, to “the official title” in USP [FDCA §502(e)(3)(B)].

Third in priority, after an FDA §508 name or USP compendial name, is “the common or usual name, if any, of such drug or such ingredient…” [FDCA §502(e)(3)(C)]. Nonproprietary names derived by USAN apply to this third category unless a USP expert committee subsequently acts to include them in USP (see below).

Last in priority is a name given by FDA (interim official name) in the course of licensing a drug or biologic under FDCA (which requires a New Drug Application (NDA)) or PHSA (which requires a Biologic License Application (BLA)). These interim official names are not specifically provided for in the adulteration and misbranding provisions of FDCA, but the courts have upheld FDA's authority to use what the agency has termed “interim official names” in the absence of either a §508 rulemaking name or a USP compendial name. Unless FDA establishes the “official” name of a drug or biologic by means of §508 rulemaking, then the USP-specified name prevails even if USP assigns the name after FDA has already licensed a drug or biologic. In such cases, a manufacturer may be required to change the nonproprietary name to conform to USP or risk being deemed adulterated or misbranded. The USP Nomenclature, Safety and Labeling Expert Committee acts under its own schedule, so that its designation of a name qualifying under §502(e)(3)(B) need not coincide with FDA's approval of the drug.

USAN has been engaged in the assignment of nonproprietary names for drug substances (most drugs and biologics, but not drug products, mixtures, combinations, and excipients) since 1964. Firms planning to market in the United States a therapeutic substance of a type named by USAN can request designation of a USAN nonproprietary name and can engage in negotiations to reach consensus on a name for balloting by the USAN Council. In many cases a USAN name may be designated before USP undertakes development of a compendial standard. In such cases, and in the absence of FDA designating an official name under FDCA Section 508 (or USP's later designating a different nonproprietary name), FDA
would consider the USAN name to be the official nonproprietary name. Biologics are a subset of drugs, and all of the drug regulatory authority of FDCA—other than what type of license FDA may issue, a BLA or NDA—applies to biologics approved under any provision of the PHSA. In particular, this includes the adulteration and misbranding provisions of FDCA, which contain the authority for USP's role in naming and nomenclature, as well as for compendial identity and quality standards. Since FDA assumed responsibility for the regulation of biological products in 1972, biologics have been subject to the regulatory and compliance provisions of FDCA, including the adulteration and misbranding provisions. This understanding was confirmed by Congress in 1997 with enactment of PHSA §351(j), which specifically provides that PHSA biological products are subject to regulation under FDCA. This provision was unaffected by the passage of the biosimilars approval pathway legislation [Biologics Price Competition and Innovation Act of 2009, which added §§351(k) and (l) to PHSA].

**MONOGRAPH NAMING POLICY FOR SALT DRUG SUBSTANCES IN DRUG PRODUCTS AND COMPOUNDED PREPARATIONS**

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, as defined below. The strength of the product or preparation also is 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. The active moiety is responsible for the physiological or pharmacological action of the drug substance, without regard to the actual charged state of the molecule in vivo. For example, the active moiety of a hydrochloride salt of a base is the free base and not the protonated form of the base. The active moiety of a metal salt of an acid is the free acid. 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. This policy is followed by USP in naming drug products and compounded preparations that are newly recognized in *USP*. USP does not intend to revise existing monographs to conform to this policy unless the USP Council of Experts determines that, for reasons such as safety, a nomenclature change is warranted.

**Labeling:** The labeling clearly states the specific salt form of the active moiety that is present
in the product or preparation because this information may be useful to practitioners and patients. The names and strengths of both the active moiety and specific salt form (when applicable) are provided in the labeling.

**Exceptions:** In rare cases in which the use of the specific salt form of the active moiety in the title provides vital information from a clinical perspective, an exception to this policy may be considered. In such cases, when the monograph title contains the specific salt form of the active moiety, the strength of the product or preparation also is expressed in terms of the specific salt form.

### GENERAL NOMENCLATURE FORMS

Some monograph titles in *USP–NF* do not conform to the formats outlined in this general information chapter. Typically, these monograph titles were adopted before the establishment of the title formats and nomenclature policies presented in this general information chapter. Such monograph titles may be subject to revision and should not be interpreted as precedents for other monograph titles.

Standardized forms of nomenclature have been devised in the interest of achieving uniformity for naming compendial articles. The general nomenclature forms that follow illustrate the terminology used throughout the official compendia for consistency in establishing titles of monographs for official pharmaceutical dosage forms and preparations.

#### General Rules and Policies for Drug Product Nomenclature

- The term “Vaginal Inserts,” rather than “Vaginal Tablets,” “Vaginal Capsules,” or “Vaginal Suppositories” is used in the title of this type of vaginal preparation to avoid the potential for misuse of these products if the term “Tablets” or “Capsules” or “Suppositories” were to appear in the title.
- The term for route of administration is omitted for those dosage forms for which the route of administration is understood. The general form then becomes simply [DRUG] [DOSAGE FORM]. Thus, capsules, tablets, and lozenges are administered via the oral route unless otherwise indicated by the title.
- Drugs that are injected may be administered via the intravenous, intramuscular, subcutaneous, etc., route. The route is specified in the labeling rather than in the name.
- Creams, ointments, lotions, and pastes are applied topically, unless otherwise indicated by the name.
- The term “Suppositories” is used in the titles of preparations that are intended for
rectal administration.

- The term “for” is included in names, as appropriate, of preparations for which a solid drug substance must be dissolved or suspended in a suitable liquid to obtain a dosage form, and the general form becomes [DRUG] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM].
- In some instances, the drug is supplied in one dosage form for the preparation of the intended dosage form, e.g., Aspirin Effervescent Tablets for Oral Solution.
- Systems are preparations of drugs in carrier devices that are applied topically or inserted into body cavities, from which drugs are released gradually over extended times, after which the carrier device is removed. The general form for a system is [DRUG] [ROUTE] [SYSTEM].
- Some drugs are available as concentrated solutions that are not intended for direct administration to humans or animals but are to be diluted with suitable liquid vehicles to obtain the intended preparation. The general form for these preparations, which are not dosage forms, is [DRUG] [CONCENTRATE]. For products intended for parenteral administration, the use of the word “Concentrate” in the monograph title is restricted to one specific monograph, Potassium Chloride for Injection Concentrate. The word “Concentrate” should not appear in the monograph title for any other parenteral product. Rather, this issue should be addressed in the product labeling.
- Some drugs are supplied as preparations that may be intermediates used for convenience in formulating finished dosage forms. The general form for such preparations, which are not finished dosage forms, is [DRUG] [PREPARATION].

Nomenclature for Dosage Forms

The titles for drug product monographs shall appear in the following format: [DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM]

Drug product categories are listed below alphabetically:

Aerosols

[DRUG] Inhalation Aerosol
[DRUG] Lingual Aerosol, e.g., Nitroglycerin Lingual Aerosol
[DRUG] Nasal Aerosol
[DRUG] Topical Aerosol e.g. Benzocaine Topical Aerosol, Tolnaftate Topical Aerosol

Capsules

[DRUG] Capsules e.g. Tamsulosin Capsules, Rifampin and Isoniazid Capsules
[DRUG] Delayed-release Capsules e.g. Aspirin Delayed-release Capsules, Erythromycin Delayed-release Capsules, Omeprazole Delayed-release Capsules

[DRUG] Extended-release Capsules e.g. Chlorpheniramine Maleate Extended-release Capsules, Propranolol Hydrochloride and Hydrochlorothiazide Extended-release Capsules, Theophylline Extended-release Capsules

Concentrates
For products intended for parenteral administration, the use of the word “Concentrate” in the monograph title is restricted to one specific monograph: Potassium Chloride for Injection Concentrate

Creams

[DRUG] [ROUTE OF ADMINISTRATION] Cream e.g. Betamethasone Dipropionate Cream, Clotrimazole Cream, Estradiol Vaginal Cream, Nystatin and Triamcinolone, Acetonide Cream

Emulsions

[DRUG] [ROUTE OF ADMINISTRATION] Emulsion e.g. Cyclosporine Ophthalmic Emulsion, Hexachlorophene Cleansing Emulsion

Films

[DRUG] [ROUTE OF ADMINISTRATION] FILM e.g. Fentanyl Buccal Film

[DRUG] ORALLY DISINTEGRATING FILM

Foams

[DRUG] [ROUTE OF ADMINISTRATION] FOAM

Gels

[DRUG] [ROUTE OF ADMINISTRATION] Gel

[DRUG] Nasal Gel

[DRUG] Ophthalmic Gel e.g. Ganciclovir Ophthalmic Gel

[DRUG] Oral Gel

[DRUG] Vaginal Gel e.g. Metronidazole Vaginal Gel

[DRUG] Topical Gel e.g. Erythromycin Topical Gel, Erythromycin and Benzoyl, Peroxide Topical Gel, Metronidazole Gel
Granules

[DRUG] [ROUTE OF ADMINISTRATION] Granules e.g. Montelukast Oral Granules

Gums

[DRUG] Gum e.g. Nicotine Polacrilex Gum

Implants

[DRUG] [ROUTE OF ADMINISTRATION] Implant e.g. Dexamethasone Intravitreal Implant, Etonogestrel Implant

Injections

There are seven categories of injections recognized in the nomenclature:

[DRUG] Injection—Liquid preparations that are drug substances or solutions thereof
[DRUG] for Injection—Dry solids that, upon the addition of suitable vehicles, yield solutions conforming in all respects to the requirements for Injections
[DRUG] Injectable Emulsion—Liquid preparations of drug substances dissolved or dispersed in a suitable emulsion medium
[DRUG] Injectable Suspension—Liquid preparations of solids suspended in a suitable liquid medium
[DRUG] for Injectable Suspension—Dry solids that, upon the addition of suitable vehicles, yield preparations conforming in all respects to the requirements for Injectable Suspensions
[DRUG] Extended-release Injectable Suspension—Liquid preparations of solids suspended in a suitable liquid medium and formulated in a manner that allows the drug substance to be available over an extended period of time
[DRUG] for Extended-release Injectable Suspension—Dry solids that, upon the addition of suitable vehicles, yield preparations conforming in all respects to the requirements for Extended-release Injectable Suspensions

Examples of Vehicle formats that currently appear in USP monograph titles are:

[DRUG] in Dextrose Injection
[DRUG] in Dextrose and Sodium Chloride Injection
[DRUG] in Lactated Ringer's and Dextrose Injection
[DRUG] in Sodium Chloride Injection
[DRUG] Injection e.g. Epinephrine Injection, Fluorouracil Injection
[DRUG] for Injection e.g. Nafcillin for Injection, Theophylline in Dextrose Injection
[DRUG] Injectable Emulsion e.g. Propofol Injectable Emulsion
[DRUG] Injectable Suspension e.g. Meroxyprogesterone Acetate Injectable Suspension, Triamcinolone Acetonide Injectable Suspension
[DRUG] for Injectable Suspension e.g. Spectinomycin for Injectable Suspension
[DRUG] Extended-release Injectable Suspension e.g. Paliperidone Palmitate Extended-release Injectable Suspension
[DRUG] for Extended-release Injectable Suspension e.g. Naltrexone for Extended-release Injectable Suspension

Inserts

[DRUG][ROUTE OF ADMINISTRATION] Inserts e.g. Clindamycin Phosphate Vaginal Inserts, Estradiol Vaginal Inserts
[DRUG][ROUTE OF ADMINISTRATION] Extended-release Inserts e.g. Dinoprostone Vaginal Extended-release Inserts

Irrigations

[DRUG] [ROUTE OF ADMINISTRATION] Irrigation e.g. Dimethyl Sulfoxide Irrigation, Glycine Irrigation, Acetic Acid Irrigation, Sodium Chloride Irrigation, Intraocular Irrigation

Lipid Complexes

[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

[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.
Lotions

[DRUG] Lotion e.g. Betamethasone Valerate Lotion, Triamcinolone Acetonide Lotion

Lozenges

[DRUG] Lozenge e.g. Clotrimazole Lozenges, Fentanyl Lozenges

Ointments

[DRUG] [ROUTE OF ADMINISTRATION] Ointment
[DRUG] Ointment e.g. Bacitracin Ointment, Fluocinolone Acetonide Ointment
[DRUG] Nasal Ointment e.g. Mupirocin Nasal Ointment
[DRUG] Ophthalmic Ointment e.g. Neomycin and Polymyxin B Sulfates and Bacitracin Ophthalmic Ointment, Vidarabine Ophthalmic Ointment

Pastes

[DRUG] [ROUTE OF ADMINISTRATION] Paste e.g. Zinc Oxide Paste Powders

Powders

[DRUG] [ROUTE OF ADMINISTRATION] Powder e.g. Cromolyn Sodium Inhalation Powder, Sodium Bicarbonate Oral Powder, Nystatin Topical Powder

Radiopharmaceuticals

[DRUG] [ISOTOPE] {ROUTE OF ADMINISTRATION} [DOSAGE FORM] e.g. Urea C 14 Capsules, Fludeoxyglucose F 18 Injection
[DRUG] [ISOTOPE] [LIGAND] {ROUTE OF ADMINISTRATION} [DOSAGE FORM] e.g. Indium In 111 Pentetate Injection, Technetium Tc 99m Sestamibi Injection

Rinses

[DRUG] Oral Rinse e.g. Chlorhexidine Gluconate Oral Rinse

Shampoos (Medicated)

[DRUG] Shampoo e.g. Lindane Shampoo

Soaps (Medicated)
[DRUG] Soap

Solutions

[DRUG] {FOR} [ROUTE OF ADMINISTRATION] Solution
[DRUG] for Effervescent Oral Solution
[DRUG] Effervescent Tablets for Oral Solution
[DRUG] Inhalation Solution e.g. Isoproterenol Sulfate Inhalation Solution
[DRUG] for Inhalation Solution e.g. Ribavirin for Inhalation Solution
[DRUG] Solution for Inhalation
[DRUG] Intraocular Solution e.g. Carbachol Intraocular Solution
[DRUG] Intravesical Solution e.g. Valrubcin Intravesical Solution
[DRUG] Nasal Solution e.g. Cromolyn Sodium Nasal Solution
[DRUG] Metered Nasal Solution
[DRUG] Ophthalmic Solution e.g. Fluorescein Sodium and Benoxinate Hydrochloride
     Ophthalmic Solution, Methylcellulose Ophthalmic Solution, Tobramycin Ophthalmic Solution
[DRUG] for Ophthalmic Solution e.g. Echothiope Iodide for Ophthalmic Solution
[DRUG] Oral Solution e.g. Guaifenesin Oral Solution, Oxycodone Hydrochloride Oral
     Solution, Potassium Chloride Oral Solution
[DRUG] for Oral Solution e.g. Penicillin V Potassium for Oral Solution. Vancomycin
     Hydrochloride for Oral Solution
[DRUG] Otic Solution e.g. Acetic Acid Otic Solution, Carbamide Peroxide Otic Solution,
     Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution
[DRUG] for Otic Solution
[DRUG] Rectal Solution
[DRUG] Topical Solution e.g. Clotrimazole Topical Solution, Coal Tar Topical Solution,
     Hydrogen Peroxide Topical Solution, Lidocaine Hydrochloride Topical Solution
[DRUG] for Topical Solution e.g. Mafenide Acetate for Topical Solution
[DRUG] {QUALIFIER} Solution e.g. Povidone–Iodine Cleansing Solution, Glutaral
     Disinfectant Solution, Indium In 111 Chloride Solution, Lactulose Solution

Sprays

[DRUG] [ROUTE OF ADMINISTRATION] Spray
[DRUG] Inhalation Spray
[DRUG] Lingual Spray e.g. Nitroglycerin Lingual Spray
[DRUG] Nasal Spray e.g. Fluticasone Propionate Nasal Spray, Sumatriptan Nasal Spray
[DRUG] Oral Spray
[DRUG] Topical Spray
[DRUG] Metered Topical Spray

Suppositories

[DRUG] Suppositories e.g. Acetaminophen Suppositories, Glycerin Suppositories, Prochlorperazine Suppositories

Suspensions

[DRUG] Inhalation Suspension
[DRUG] for Inhalation Suspension
[DRUG] Suspension for Inhalation
[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

Systems

[DRUG] {ORGAN} {ROUTE OF ADMINISTRATION} System
Route of administration for the systems can include: intrauterine, ocular, oral mucosal, periodontal, transdermal and iontophoretic transdermal. e.g. Clonidine Transdermal System, Minocycline Periodontal System, Estradiol Transdermal System, Hydroxypropyl Cellulose Ocular System, Progesterone Intrauterine Contraceptive System

Tablets

[DRUG] {RELEASE CHARACTERISTICS} {UNIQUE DESCRIPTOR} {SITE OF DELIVERY} Tablets
[DRUG] Tablets e.g. Hydrochlorothiazide Tablets
[DRUG] Buccal Tablets e.g. Nitroglycerin Buccal Tablets
[DRUG] Chewable Tablets e.g. Acetaminophen Chewable Tablets
[DRUG] Delayed-release Tablets e.g.
[DRUG] Extended-release Tablets e.g. Zolpidem Tartrate Extended-release Tablets
[DRUG] Orally Disintegrating Tablets e.g. Hyoscyamine Sulfate Orally Disintegrating Tablets
[DRUG] Sublingual Tablets e.g. Nitroglycerin Sublingual Tablets
[DRUG] Tablets for Oral Solution e.g.
[DRUG] Effervescent Tablets for Oral Solution e.g. Aspirin Effervescent Tablets for Oral Solution
[DRUG] Tablets for Oral Suspension e.g., Pantoprazole Sodium Delayed-release Tablets

VETERINARY PREPARATIONS

Boluses

[DRUG] Boluses e.g. Amoxicillin Boluses, Ampicillin Boluses

Concentrates

[DRUG] Oral Concentrate Solution e.g. Tiamulin Oral Concentrate Solution
[DRUG] Concentrate for Dip e.g. Amitraz Concentrate for Dip

Granules

[DRUG] {ROUTE OF ADMINISTRATION} Granules e.g. Flunixin Meglumine Granules

Infusions

[DRUG] [ROUTE OF ADMINISTRATION] Infusion e.g. Amoxicillin Intramammary Infusion, Erythromycin Intramammary Infusion, Gentamicin Uterine Infusion

Pastes

[DRUG] [ROUTE OF ADMINISTRATION] Paste e.g. Ivermectin Paste

Compounded Veterinary Articles

Compounded drugs that have no equivalent for human use are distinguished by the word “veterinary” in the name, placed after a coma.
[DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM], Veterinary e.g. Potassium Bromide Oral Solution, Veterinary; Sodium Bromide Injection, Veterinary; Sodium Bromide Oral Solution, Veterinary; Pergolide Oral Suspension, Veterinary; Methylene Blue Injection, Veterinary

BIOLOGICS

Proteins and Polysaccharides

[DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM] e.g. Oxytocin Injection, Gonadorelin for Injection, Lypressin Nasal Solution, Heparin Sodium Injection

Vaccines

[DISEASE] Vaccine [TYPE] e.g. Anthrax Vaccine Adsorbed, Mumps Virus Vaccine Live, Poliovirus Vaccine Inactivated, Rabies Vaccine

Antivenins

Antivenin (LATIN BINOMIAL OR GENUS) [TYPE] e.g. Antivenin (Crotalidae) Polyvalent, Antivenin (Latrodectus mactans), Antivenin (Micrurus fulvius)

Cell, Gene, and Tissue Therapies

[PRIMARY CHARACTERISTIC] [SPECIES] [ORIGIN] [OTHER CHARACTERISTICS] [OTHER MODIFIERS] e.g. Construct Human Fibroblasts in Polyglatin Scaffold, Construct Human Fibroblasts in Bilayer Synthetic Scaffold, Construct Human Keratinocytes and Fibroblasts in Bovine Collagen Scaffold, Scaffold Porcine Small Intestinal Submucosa, Scaffold Human Dermis, Scaffold Bovine Tendon Collagen Cylindrical

EXCIPIENTS

Synthetic or Semisynthetic Substances

[CHEMICAL OR COMMON NAME] e.g. Xylitol, Cellulose Acetate, Diethyl Phthalate

Substances from Natural Sources

[SOURCE] {FORM} e.g. Carnauba Wax, Palm Oil, Cocoa Butter, Potato Starch

Modified Natural Substances
Manufactured Mixtures

e.g. Microcrystalline Wax, Hydrogenated Coconut Oil, Purified Siliceous Earth, Pregelatinized Starch, Activated Charcoal

Synthetic Polymers

e.g. Microcrystalline Cellulose and Carboxymethylcellulose Sodium

Historical Compounding Aids

e.g. Stronger Rose Water, Hydrophilic Ointment, Hydrophilic Petrolatum, White Ointment, White Petrolatum, Yellow Ointment, Cherry Juice, Chocolate Syrup, Sweet Orange Peel Tincture, Aromatic Elixir

Modern Compounding Aids

e.g. Vehicle for Oral Suspension; Vehicle for Oral Solution; Vehicle for Oral Solution, Sugar Free; Polyethylene Glycol Ointment; Suspension Structured Vehicle; Sugar-free Suspension Structured Vehicle

DIETARY SUPPLEMENTS

Raw Materials

The compendial name of a botanical material usually is based on the Standard Common Name (SCN) in English ([1 CFR 101.4(h)]. SCNs are published in Herbs of Commerce by the American Herbal Products Association. If the SCN is not available, the Latin binomial name is used.

e.g. Horse Chestnut, Echinacea Purpurea Aerial Parts, Echinacea Purpurea Root

Dietary Ingredients

e.g. Powdered Goldenseal, Powdered Asian Ginseng Extract, Powdered Ashwagandha Root

In-process Materials
[PROCESS] {SCN} {LATIN BINOMIAL} {PLANT PART} [FORM] e.g. Powdered Turmeric Extract, Powdered Soy Isoflavones Extract, Powdered Decaffeinated Green Tea Extract, Native Guggul Extract, Purified Guggul Extract, Powdered Echinacea pallida Extract, Tomato Extract Containing Lycopene, Grape Seeds Oligomeric Proanthocyanidins, Capsicum Oleoresin

**Dietary Supplements**

[DIETARY INGREDIENT] [FORM] e.g. Glucosamine, Chondroitin Sulfate Sodium, and Methylsulfonylmethane Tablets, Garlic Delayed-Release Tablets, Vitamin A Oral Liquid Preparation, Milk Thistle Capsules, Fish Oil Containing Omega-3 Acids Capsules, Oil- and Water-Soluble Vitamins with Minerals Oral Solution, Cod Liver Oil Capsules

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1 The term “generic” has been widely used in place of the more accurate and descriptive term “nonproprietary” with reference to drug nomenclature.

2 *USP Dictionary of USAN and International Drug Names* is obtainable on order from U.S. Pharmacopeia, Customer Service Department, 12601 Twinbrook Parkway, Rockville, MD 20852.

3 F.D.&C. Act, Sec. 508 [358].


5 The name of the Expert Committee has been changed over the years. Previous names have included: Nomenclature Expert Committee, Nomenclature and Labeling Expert Committee. It is presently the Nomenclature, Safety, and Labeling Expert Committee.

7 When curly brackets are used, it indicates that the term may not be applicable. For example, in the case of emulsions, if no route of administration is given, emulsions are topical by default. All other routes of administration shall be specified.

8 Ibid., sometimes route of administration may not be applicable for certain dosage forms; for example all capsules are oral. For other products the route of administration shall be specified.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.