

## Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Three categories of bulk drug substances:

- [Category 1: Bulk Drug Substances Under Evaluation](#)
- [Category 2: Bulk Drug Substances that Raise Significant Safety Risks](#)
- [Category 3: Bulk Drug Substances Nominated Without Adequate Support](#)

### Updates to Categories of Substances<sup>1</sup> Nominated for the 503B Bulk Drug Substances List

**Deletions from Category 1. These substances have been evaluated by the FDA, have not been added to the 503B Bulks List, and cannot be used in compounding:**

- Ephedrine sulfate
- Hydroxychloroquine sulfate

### Additions to Category 1:

- Edetate disodium (for ophthalmic use only)
- Indomethacin
- Sodium iodide I-131

### Addition to Category 2:

- Diethylstilbestrol will be added to Category 2 due to significant safety risks<sup>2</sup> related to potential cancer of the breast in women who were exposed while pregnant. Diethylstilbestrol is also associated with clear cell adenocarcinoma in the vagina and cervix of women who were exposed in utero. A positive association has been observed between exposure to diethylstilbestrol and cancer of the endometrium, and between in-utero exposure to diethylstilbestrol and squamous cell carcinoma of the cervix and cancer of the testis.<sup>3</sup>

### Additions to Category 3:

- Acetyl-L-Carnitine hydrochloride
- Allantoin (with aminobenzoic acid)
- Aluminum phosphate adjuvant
- Beta-nicotinamide adenine dinucleotide disodium salt, trihydrate
- Buffer Solution, pH Buffer Alkaline (pH 10.00)
- Buffer Solution, pH Buffer Neutral (pH 7.00)
- Epinephrine hydrochloride
- Liquid paraffin
- Liquid petrolatum
- Lysine aspirin
- Magnesium aluminosilicate

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<sup>1</sup> For purposes of section 503B of the FD&C Act, bulk drug substance means an active pharmaceutical ingredient as defined in 21 CFR 207.1. "Bulk drug substance" (BDS) and "active pharmaceutical ingredient" (API) may be used interchangeably with "substance" throughout this document.

<sup>2</sup> All oral and parenteral drug products containing 25 mg or more of diethylstilbestrol per unit dose are on the list of drug products withdrawn or removed from the market for reasons of safety or effectiveness (Withdrawn or Removed List) (21 CFR 216.24). The Agency is placing diethylstilbestrol products containing less than 25 mg of diethylstilbestrol per unit dose in Category 2 given the established positive association between diethylstilbestrol exposure and cancer.

<sup>3</sup> The International Agency for Research on Cancer classifies diethylstilbestrol as *carcinogenic to humans (Group 1)*. See <https://www.ncbi.nlm.nih.gov/books/NBK304340/>. Accessed June 26, 2023.

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- Mercuric sulfide, red
- Peruvian balsam oil
- Phenylephrine bitartrate (effervescent)
- Plantago seed/Psyllium seed husks
- Plantago seed/Psyllium seed, blond
- Poloxamer 188
- Poloxamer 407
- Psyllium (hemicellulose)
- Pyridoxyl-5-Phosphate
- Riboflavin
- Sodium borate monohydrate
- Sodium dihydrogen phosphate monohydrate
- Sodium perborate monohydrate
- Sodium salicylic acid phenolate
- Soybean oil, hydrogenated (powder)
- Tartrate (acid or salt)
- Theophylline mens
- Thymosin alpha-1
- Uva ursi, potassium extract

### **FDA will move the following substances from Category 3 to Category 1 because FDA received new nominations for them with sufficient supporting information:**

- Beta-nicotinamide adenine dinucleotide
- Deoxy-D-Glucose
- Levocarnitine
- Menthol
- Miconazole nitrate
- Nystatin
- Pramoxine hydrochloride
- Zinc chloride
- Zinc pyrithione

### **Revisions to Category 1:**

- FDA will modify the entry for “17-alpha-Hydroxyprogesterone” to “Hydroxyprogesterone caproate” to clarify the substance name intended for use in compounding.
- Remove “Formaldehyde” from Category 1 because placement of the substance in Category 1 was an error in the July 2023 update. On April 25, 2023, formaldehyde was recategorized to Category 3 after a 30-day notice.
- Modify the entry for “Podophyllum/Podophyllum resin” to separate the entries to “Podophyllum” and “Podophyllum resin” because these are two distinct substances.

### **Revision to Category 2:**

- FDA will modify the entry for “Edetate Disodium” to “Edetate Disodium (except for ophthalmic use)” to clarify the entry.

### **Revisions to Category 3:**

- FDA will modify the entry for “Asclepias tuberosa” to “Asclepias tuberosa” to correct a spelling error.
- FDA will modify the entry for “Betamechlomathasone” to “Betamechlomethasone” to correct a spelling error.
- FDA will modify the entry for “Gloconic acid calcium salt” to “Gluconic acid calcium salt” to correct a spelling error.
- FDA will modify the entry for “Ketoifen fumarate” to “Ketotifen fumarate” to correct a spelling error.

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- FDA will remove the entry for “Methapyrilene Hydrochloride” because the Agency determined that the nominator intended to nominate methapyrilene hydrochloride, which appears on the Withdrawn and Removed List and is not eligible for inclusion on the 503B Bulks List.<sup>4</sup>
- FDA will modify the entry for “Methylbenzethoniim chloride” to “Methylbenzethonium chloride” to correct a spelling error.
- FDA will modify the entry for “Nonylphenoxy poly (ethyleneoxy) ethanol iodine” to “nonylphenoxy poly (ethyleneoxy) ethanol iodine” to correct a spelling error.
- FDA will modify the entry for “Nonylphenoxypoly nonoxynol 9” to “nonylphenoxy poly nonoxynol 9” to correct a spelling error.
- FDA will modify the entry for “Phenylmercuric cetate” to “phenylmercuric acetate” to correct a spelling error.
- FDA will remove the entries for “Phenylpropanolamine bitartrate,” “Phenylpropanolamine hydrochloride,” and “Phenylpropanolamine maleate” because phenylpropanolamine appears on the Withdrawn and Removed List and is not eligible for inclusion on the 503B Bulks List.<sup>5</sup>
- FDA will modify the entry for “Racephedrine hydrochloride” to “racedrine hydrochloride” to correct a spelling error.
- FDA will modify the entry for “Sodium priopionate” to “sodium propionate” to correct a spelling error.
- Remove the entry for “Sulfacetamide sodium” because it is also listed in Category 1 and FDA received at least one nomination with adequate support for sulfacetamide sodium monohydrate.
- FDA will remove the entry for “Thioctic” because the Agency determined that the nomination is for “thioctic acid.” “Thioctic” and “alpha lipoic acid” are duplicate entries because “thioctic acid” and “alpha lipoic acid” are synonyms.
- FDA will modify the entry for “Turpantine oil” to “Turpentine oil” to correct a spelling error.
- FDA will modify the entry for “Turpantine, venice” to “Turpentine, venice” to correct a spelling error.

As stated in an FDA announcement dated March 5, 2020, effective March 23, 2020, biological products that were approved under section 505 of the FD&C Act are deemed licensed under section 351 of the Public Health Service (PHS) Act. As stated in the 503B bulks interim policy, biological products subject to approval under section 351 of the PHS Act are not eligible for the 503B Bulks List because such products are not eligible for the exemptions in section 503B of the FD&C Act. FDA will remove the following substances from Category 3 because the Agency determined that they are biological products and are not eligible for inclusion on the 503B Bulks List:

- Amylase
- Aspergillus oryza enzymes
- Collagenase
- Pancreatin
- Pepsin

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<sup>4</sup> The Withdrawn or Removed List is available at 21 CFR 216.24.

<sup>5</sup> Phenylpropanolamine bitartrate, phenylpropanolamine hydrochloride, and phenylpropanolamine maleate contain the same active moiety, phenylpropanolamine, which appears on the Withdrawn and Removed List available at 21 CFR 216.24.

### 503B Category 1: Bulk Drug Substances Under Evaluation

\*\* Designates bulk drug substances that are components of FDA approved drugs<sup>6</sup>

Bulk drug substances used in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act must meet certain other requirements, including, if an applicable monograph exists under the United States Pharmacopeia (USP), National Formulary (NF), or another compendium or pharmacopeia recognized by the Secretary, the bulk drug substance complies with the monograph.

For the purposes of the bulk drug substance names in the categories, hydrates of a bulk drug substance (i.e., compounds containing water of crystallization), when described in the applicable USPNF drug substance monograph, are included in the scope of the bulk drug substance name. However, the differences in physico-chemical properties (e.g., solubility, stability) of anhydrous versus hydrated forms of the nominated bulk drug substance could have potential impact on the performance of the compounded drug product. As a result, outsourcing facilities should be mindful of any such potential differences, and when evaluating the appropriate form (anhydrous or hydrate) of the nominated BDS for compounding should assess whether such difference in physico-chemical characteristics (e.g., solubility, stability) could have any adverse impact on the performance of the compounded preparation.

- 5-Methyltetrahydrofolate Calcium
- Acetaminophen\*\*
- Acetylcysteine\*\*
- Acyclovir\*\*
- Adapalene\*\*
- Adenosine\*\*
- Allantoin
- Alpha Lipoic Acid
- Alprostadil\*\*
- Aluminum Chloride
- Aluminum potassium sulfate
- Amantadine Hydrochloride\*\*
- Aminophylline\*\*
- Amiodarone Hydrochloride\*\*
- Amitriptyline Hydrochloride\*\*
- Amphotericin B\*\*
- Anastrozole\*\*
- Arginine Hydrochloride/L-arginine
- Hydrochloride\*\*
- Ascorbic acid\*\*
- Ascorbyl Palmitate
- Aspartic Acid
- Atenolol\*\*
- Atropine sulfate\*\*
- Azelaic Acid\*\*
- Azithromycin\*\*
- Baclofen\*\*
- Benzocaine
- Benzoyl Peroxide\*\*
- Betahistine Hydrochloride
- Betamethasone Acetate\*\*
- Betamethasone Dipropionate\*\*
- Betamethasone Sodium Phosphate\*\*
- Betamethasone Valerate\*\*
- Beta-Nicotinamide Adenine Dinucleotide
- Bethanechol Chloride\*\*

<sup>6</sup> A condition of section 503B of the FD&C Act is that the compounded drug product is not essentially a copy of one or more approved drug products. For more information about the “essentially a copy” provision in section 503B, see FDA’s guidance for industry [“Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”](#) In addition, FDA does not intend to take action against an outsourcing facility for failing to compound in accordance with section 503B(a)(5) if it fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed. Bulk drug substances in Category 1 that are components of FDA-approved drugs are designated with two asterisks (\*\*) below.

- Bimatoprost\*\*
- Biotin\*\*
- Bismuth Nitrate Oxide
- Boric Acid
- Brilliant Blue G\*\*
- Brimonidine Tartrate\*\*
- Bromfenac sodium (for ophthalmic solutions only) \*\*
- Brompheniramine maleate\*\*
- Budesonide\*\*
- Bumetanide\*\*
- Bupivacaine Hydrochloride\*\*
- Caffeine\*\*
- Calcipotriene\*\*
- Calcium Chloride\*\*
- Calcium Gluconate\*\*
- Cantharidin
- Capsaicin\*\*
- Carbamazepine\*\*
- Chloramphenicol (except for oral administration)
- Chloroquine Phosphate\*\*
- Chlorpheniramine Maleate\*\*
- Chlorpromazine Hydrochloride\*\*
- Cholestyramine Resin\*\*
- Choline Chloride
- Chromic Chloride\*\*
- Chromium Chloride\*\*
- Ciclopirox Olamine\*\*
- Cimetidine\*\*
- Ciprofloxacin Hydrochloride\*\*
- Citric Acid Anhydrous\*\*
- Citrulline/L-Citrulline
- Clindamycin Hydrochloride\*\*
- Clindamycin Phosphate\*\*
- Clioquinol\*\*
- Clobetasol Propionate\*\*
- Clomipramine Hydrochloride\*\*
- Clonidine Hydrochloride\*\*
- Clotrimazole\*\*
- Coal Tar Solution
- Cocaine Hydrochloride\*\*
- Copper Gluconate
- Cromolyn Sodium\*\*
- Cupric Sulfate\*\*
- Cyanocobalamin\*\*
- Cyclobenzaprine Hydrochloride\*\*
- Cyclopentolate Hydrochloride\*\*
- Cyclosporine/Cyclosporine A\*\*
- Dapiprazole Hydrochloride\*\*
- Dapsone\*\*
- Deoxy-D-Glucose
- Desoximetasone\*\*
- Dexamethasone Acetate
- Dexamethasone Sodium Phosphate\*\*
- Dexpanthenol\*\*
- Dextromethorphan hydrobromide\*\*
- DHEA (dehydroepiandrosterone) \*\*
- D-glucose\*\*
- Dibucaine Hydrochloride\*\*
- Diclofenac Sodium\*\*
- Diiodohydroxyquinoline
- Diltiazem Hydrochloride\*\*
- Dimercapto-1-propanesulfonic acid (DMPS)\*\*
- Diphenhydramine Hydrochloride\*\*
- Disulfiram\*\*
- Dorzolamide Hydrochloride\*\*
- Doxycycline Hyclate\*\*
- Droperidol\*\*
- Dutasteride\*\*
- Dyclonine Hydrochloride\*\*
- Econazole Nitrate\*\*
- Edetate disodium (for ophthalmic use only)
- Enalapril Maleate\*\*
- Ephedrine Hydrochloride
- Epinephrine\*\*
- Epinephrine Bitartrate\*\*
- Erythromycin Ethylsuccinate\*\*
- Estradiol\*\*
- Estradiol Cypionate\*\*
- Estriol
- Estrone\*\*
- Ethanol\*\*
- Etomidate\*\*
- Famotidine\*\*
- Fentanyl Citrate\*\*
- Finasteride\*\*
- Fluconazole\*\*
- Fluocinolone Acetonide\*\*
- Fluocinonide\*\*
- Fluorouracil\*\*
- Fluoxetine HCl\*\*

- Flurbiprofen\*\*
- Fluticasone Propionate\*\*
- Furosemide\*\*
- Gabapentin\*\*
- Gamma-Aminobutyric Acid
- Gatifloxacin (for ophthalmic solutions only)\*\*
- Gentamicin Sulfate\*\*
- Glucosamine Sulfate Potassium Chloride
- Glucosamine Sulfate Sodium Chloride
- Glutamic acid\*\*
- Glutamine\*\*
- Glutathione
- Glycerin\*\*
- Guaifenesin\*\*
- Haloperidol\*\*
- Heparin sodium\*\*
- Hyaluronic acid sodium salt
- Hydralazine Hydrochloride\*\*
- Hydrochloric Acid
- Hydrocortisone\*\*
- Hydromorphone Hydrochloride\*\*
- Hydroquinone\*\*
- Hydroxocobalamin\*\*
- Hydroxocobalamin Hydrochloride
- Hydroxyprogesterone caproate\*\*
- Hydroxyzine Pamoate\*\*
- Ibuprofen\*\*
- Imipramine Hydrochloride\*\*
- Imiquimod\*\*
- Indomethacin\*\*
- Inositol
- Iodoform
- Isoproterenol Hydrochloride\*\*
- Isotretinoin\*\*
- Itraconazole\*\*
- Ivermectin\*\*
- Ketamine Hydrochloride\*\*
- Ketoconazole\*\*
- Ketoprofen\*\*
- Ketorolac Tromethamine\*\*
- Labetalol Hydrochloride\*\*
- Lactic Acid\*\*
- Lansoprazole\*\*
- Latanoprost\*\*
- Levocarnitine\*\*
- Levocetirizine Dihydrochloride\*\*
- Lidocaine\*\*
- Lidocaine Hydrochloride\*\*
- Lincomycin Hydrochloride\*\*
- L-Lysine
- L-lysine Hydrochloride/Lysine Hydrochloride
- Lorazepam\*\*
- Loteprednol etabonate\*\*
- L-Ornithine Hydrochloride
- L-Proline
- Magnesium Chloride \*\*
- Magnesium Sulfate \*\*
- Malic Acid
- Manganese Chloride\*\*
- Manganese Sulfate \*\*
- Medroxyprogesterone Acetate\*\*
- Menthol\*\*
- Meperidine Hydrochloride (a.k.a. Pethidine Hydrochloride)\*\*
- Methadone Hydrochloride\*\*
- Methionine/ Methionine (L)
- Methylcobalamin/Methyl B12
- Methylprednisolone Acetate\*\*
- Methylsulfonylmethane (MSM)
- Metronidazole\*\*
- Miconazole nitrate\*\*
- Midazolam Hydrochloride\*\*
- Mineral Oil\*\*
- Minocycline Hydrochloride\*\*
- Minoxidil\*\*
- Mitomycin\*\*
- Mometasone Furoate\*\*
- Monosodium Glutamate
- Morphine Sulfate \*\*
- Moxifloxacin hydrochloride\*\*
- Mupirocin\*\*
- Naloxone Hydrochloride\*\*
- Naltrexone\*\*
- Naltrexone Hydrochloride\*\*
- Nandrolone Decanoate\*\*
- Neostigmine Methylsulfate\*\*
- Nepafenac\*\*
- Niacin\*\*
- Niacinamide\*\*
- Nicotinamide riboside chloride
- Nifedipine\*\*
- Norepinephrine Bitartrate\*\*

- Nystatin\*\*
- Ondansetron Hydrochloride\*\*
- Oxymetazoline Hydrochloride\*\*
- Oxytocin\*\*
- Papaverine Hydrochloride
- Pentoxifylline\*\*
- Phenol
- Phenoxybenzamine Hydrochloride\*\*
- Phentolamine Mesylate\*\*
- Phenylephrine Hydrochloride\*\*
- Phosphatidylcholine
- Phytonadione\*\*
- Podophyllum
- Podophyllum Resin
- Polidocanol\*\*
- Polymyxin B Sulfate\*\*
- Potassium chloride\*\*
- Potassium Phosphate Monobasic [KH<sub>2</sub>PO<sub>4</sub>]\*\*
- Potassium Phosphate Dibasic [K<sub>2</sub>HPO<sub>4</sub>]/ Potassium Phosphate Dibasic Anhydrous\*\*
- Pramoxine hydrochloride\*\*
- Precipitated Sulfur
- Prednisolone\*\*
- Prednisolone Acetate\*\*
- Prednisolone Sodium Phosphate\*\*
- Prilocaine\*\*
- Procaine Hydrochloride\*\*
- Progesterone\*\*
- Promethazine Hydrochloride\*\*
- Proparacaine Hydrochloride\*\*
- Propranolol hydrochloride\*\*
- Prostaglandin E1\*\*
- Pyridoxal 5-Phosphate Monohydrate
- Pyridoxine Hydrochloride\*\*
- Remifentanyl Hydrochloride\*\*
- Riboflavin Sodium Phosphate\*\*
- Rocuronium Bromide\*\*
- Ropivacaine Hydrochloride\*\*
- Salicylic Acid
- Scopolamine hydrobromide
- Sermorelin Acetate\*\*
- Sildenafil Citrate\*\*
- Sincalide\*\*
- Sodium Acetate Anhydrous\*\*
- Sodium Ascorbate\*\*
- Sodium Benzoate\*\*
- Sodium Chloride\*\*
- Sodium Citrate\*\*
- Sodium Iodide I-131\*\*
- Sodium L-Aspartate Monohydrate
- Sodium Molybdate
- Sodium phosphate/Sodium Phosphate Monobasic\*\*
- Sodium Selenite Pentahydrate
- Sodium Tetradecyl Sulfate\*\*
- Sodium thiosulfate (for topical administration only)\*\*
- Spironolactone\*\*
- Succinylcholine Chloride\*\*
- Sufentanil Citrate\*\*
- Sulfacetamide Sodium\*\*
- Sulfamethoxazole\*\*
- Sulfan Blue
- Tacrolimus\*\*
- Tadalafil\*\*
- Taurine
- Tazarotene\*\*
- Terbinafine Hydrochloride\*\*
- Testosterone\*\*
- Testosterone Cypionate\*\*
- Testosterone Enanthate\*\*
- Testosterone Propionate\*\*
- Tetracaine\*\*
- Tetracaine Hydrochloride\*\*
- Tetracycline Hydrochloride\*\*
- Theophylline\*\*
- Thiamine Hydrochloride (vitamin B1)\*\*
- Thymol iodide
- Timolol Maleate\*\*
- Tofacitinib Citrate\*\*
- Tolnaftate\*\*
- Tramadol Hydrochloride\*\*
- Tranexamic Acid\*\*
- Tretinoin\*\*
- Triamcinolone
- Triamcinolone Acetonide\*\*
- Triamcinolone diacetate\*\*
- Trimethoprim\*\*
- Tromethamine\*\*
- Tropicamide\*\*
- Trypan Blue\*\*
- Ubidecarenone (Coenzyme Q10)

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- Urea\*\*
- Valacyclovir Hydrochloride\*\*
- Vancomycin Hydrochloride\*\*
- Vecuronium Bromide\*\*
- Vitamin A acetate
- Vitamin D3\*\*
- Ziconotide\*\*
- Zinc chloride\*\*
- Zinc Oxide\*\*
- Zinc pyrithione\*\*
- Zinc Sulfate\*\*



### **503B Category 2: Bulk Drug Substances that Raise Significant Safety Risks**

- Chloral Hydrate
- Diethylstilbestrol<sup>7</sup>
- Edetate Disodium (except for ophthalmic use)
- Germanium Sesquioxide
- Ibutamoren Mesylate
- Neomycin sulfate (all parenteral drug products containing neomycin sulfate except when used for ophthalmic or otic use or in combination with polymyxin B sulfate for irrigation of the intact bladder)
- Quinacrine Hydrochloride for intrauterine administration

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<sup>7</sup> All oral and parenteral drug products containing 25 mg or more of diethylstilbestrol per unit dose are on the list of drug products withdrawn or removed from the market for reasons of safety or effectiveness (Withdrawn or Removed List) (21 CFR 216.24). The Agency is placing diethylstilbestrol products containing less than 25 mg of diethylstilbestrol per unit dose in Category 2 given the established positive association between diethylstilbestrol exposure and cancer.

### 503B Category 3: Bulk Drug Substances Nominated Without Adequate Support

- 4-Aminopyridine
- 7-Keto Dehydroepiandrosterone, Micronized
- Acacia Gum, Spray-Dried Powder
- Acacia Syrup
- Acesulfame Potassium
- Acetanilide
- Acetic acid
- Acetone
- Acetone Sodium Bisulfite
- Acetyl Hexapeptide-3
- Acetyl-L-Carnitine hydrochloride
- Acidophilus Lactobacillus
- Adenosine-5-triphosphate disodium salt
- Agar
- Alcloxa
- Aldioxa
- Aldosterone
- Alfalfa
- Alfalfa leaves
- Alginic acid
- Aliphatic Polyesters
- Allantoin (with aminobenzoic acid)
- Almadrate sulfate
- Aloe ingredients (aloe, aloe extract, aloe flower extract, aloe vera, aloe vera gel extract)
- Aloin
- Alpha Ketoglutaric acid
- Alumina Powder, hydrated
- Aluminum acetate
- Aluminum phosphate adjuvant
- Aluminum phosphate
- Aluminum sulfate
- Aminacrine Hydrochloride
- Aminoacetic acid
- Ammonia solution, strong
- Ammonium Alginate
- Ammonium bromide
- Ammonium chloride
- Ammonium hydroxide
- Anise oil
- Anise seed
- Argentyn
- Arginine
- Aromatic powder
- Asafetida
- Asclepias tuberosa
- Asefetida Tincture
- Asparagus
- Aspartame
- Attapulgit
- Barosma
- Basic Fuchsin
- Beachwood creosote
- Bean
- Benzalkonium Chloride
- Betamechlomethasone
- Beta-nicotinamide adenine dinucleotide disodium salt, trihydrate
- Bethanechol
- Bichloroacetic Acid
- Bipeptide Biocosmetic
- Bronopol
- Buffer Solution, pH Buffer Acid
- Buffer Solution, pH Buffer Alkaline (pH 10.00)
- Buffer Solution, pH Buffer Neutral (pH 7.00)
- Butylated Hydroxytoluene
- Butylene Glycol
- Calcium Alginate
- Calcium Folate
- Calcium glycinate
- Capsules, Empty Gelatin Vegetable
- Carbamide
- Carbazochrome
- Carbimazole
- Carbolic Acid
- Carbomer 940 /Carbomer gel (aqueous)/Carbomer gel (hydroalcoholic)
- Caustic Potash
- Caustic Soda (sodium hydroxide)
- Cedarwood Essential Oil
- Ceratonia
- Ceresin
- Cetrimide
- Chloramphenicol Palmitate (for topical and otic administration)
- Chlorhexidine Diacetate Hydrate
- Choline Bitartrate

- Choline magnesium trisalicylate
- Chondroitin Sulfate
- Chromium glycinate
- Chrysin
- Cidofovir
- Cocoa butter
- Coconut Oil Edible
- Coenzyme Q50
- Colophony
- Copper
- Copper Bisglycinate
- Copper Hydrosol
- Corn Oil
- Corn Starch
- Corn Starch and Pregelatinized Starch
- Cottonseed Oil
- Creatine, Monohydrate
- Cucumber Melon Fragrance
- Cyclopentolate
- Decyl Oleate
- Decylmethylsulfoxide
- Desonide
- Diaminopyridine (3,4-)
- Dichloroacetic Acid
- Difluoroethane
- Diindolymethane
- Dimercaptosuccinic acid
- Dimethyl Ether (aka Methoxymethane)
- Dimethyl Ketone
- Dimethyl Phthalate
- Dimethylacetamide
- Dimethylaminoethanol Bitartrate
- Dimethylaminoethanol Complex
- Dimethylglycine Hydrochloride
- Dinitrochlorobenzene
- Diphenhydramine
- Dipropylene Glycol
- Disodium Hydrogen Phosphate
- Disodium Phosphate
- Disodium Salt Trihydrate
- DL-Phenylalanine
- Docosanol
- Dodecyl Gallate
- Domperidone
- Edetate tetrasodium tetrahydrate
- Epinephrine hydrochloride
- Ergoloid Mesylates
- Ergotamine Tartrate
- Ethanolamine
- Ethyl Lactate
- Ethylene Vinyl Acetate
- Ferric subsulfate
- Ferric sulfate hydrate
- Ferric sulfate solution
- Folinic acid calcium salt
- Formaldehyde
- Formoterol Fumarate Dihydrate
- Fructose and Pregelatinized Starch
- GHRP-2
- GHRP-6
- Ginger root powder
- Ginko Biloba Standardized Extract
- Gluconic acid calcium salt
- Glutaraldehyde solution
- Glycerol Formal
- Glyceryl Monostearate
- Glyceryl Palmitostearate
- Glycofurol
- Glydiazinamide
- Grape seed oil
- Gum Arabic
- Hectorite
- Heptafluoropropane
- Hexetidine
- Hydrazine sulfate
- Hydrogen Peroxide
- Hydroxyethylpiperazine Ethane Sulfonic Acid
- Hydroxymethylmethyl Cellulose
- Ichthammol
- ICU Bottom Paste (Maalox)
- Indigo Carmine
- Indole-3-carbinol
- Inositol Hexanicotinate
- Iodochlorhydroxyquin
- Iopanoic Acid
- Iron Glycinate Chelate
- Isopropyl Isostearate
- Kaolin, Colloidal Powder
- Karaya Gum

- Ketotifen Fumarate
- Kojic Acid
- Lactose Monohydrate
- Lactose, Monohydrate and Corn Starch
- Lactose, Monohydrate and Microcrystalline Cellulose
- Lactose, Monohydrate and Powdered Cellulose Lactose, Spray-Dried
- Lanolin, Hydrous
- L-Aspartic Acid Sodium Salt
- Lavender Oil
- L-Carnosine
- L-Cysteine
- Lecithin Soya Granular
- Lecithin Organogel
- Levomenthol
- Levulose
- L-Histidine Monohydrochloride, Monohydrate
- Linoleic Acid
- Liquid paraffin
- Liquid petrolatum
- Loxasperse
- L-Triiodothyronine Sodium
- Lysine
- Lysine aspirin
- Magaldrate
- Magnesium
- Magnesium aluminum silicate
- Magnesium aluminosilicate
- Magnesium ascorbate
- Magnesium bisglycinate
- Magnesium carbonate
- Magnesium citrate
- Magnesium glycinate
- Magnesium hydroxide
- Magnesium oxide
- Magnesium salicylate
- Magnesium stearate
- Magnesium trisilicate
- Malt
- Malt soup extract
- Maltodextrin
- Manganese Bisglycinate
- Manganese citrate
- Mannitol and sorbitol
- MBK
- m-cresol
- Meclizine Hydrochloride
- Medium Cream
- Menfegol
- Menthol/peppermint oil
- Meradimate (menthyl anthranilate)
- Meralein sodium
- Merbromin
- Mercufenol chloride
- Mercuric chloride
- Mercuric oxide
- Mercuric salicylate
- Mercuric sulfide
- Mercuric sulfide, red
- Mercury
- Mercury oleate
- Mercury sulfide
- Mercury, ammoniated
- Metaproterenol sulfate
- Methenamine
- Methoxyphenamine Hydrochloride
- Methoxypolyoxyethyleneglycol 550 laurate
- Methyl nicotinate
- Methyl salicylate
- Methylbenzethonium chloride
- Methylcellulose
- Methylparaben
- Microcrystalline Cellulose
- Milk and molasses
- Milk of sulfur
- Milk solids, dried
- Mineral oil and Lanolin Alcohols
- Minerals
- Molasses
- Molybdenum Glycinate
- Mono- and di-glycerides
- Monosodium L-Aspartate
- Monosodium Phosphate
- Mullein
- Mustard oil (allilthiocyanate)
- Mycozyme
- Myrrh
- Myrrh (fluid extract)

- Myrrh gum tincture
- Myrrh tincture
- N-Acetyl-D-Glucosamine
- Naphazoline Hydrochloride
- Natural estrogenic hormone
- Neohesperidine Dihydrochalcone
- Nettle
- Nickel-pectin
- Nicotinamide
- Nicotinic Acid
- Nitromersol
- Non-Fat Dry Milk
- Nonylphenoxypoly (ethyleneoxy) ethanol iodine
- Nonylphenoxypoly nonoxynol 9
- Noscapine
- Noscapine Hydrochloride
- Nutmeg oil
- Nux vomica extract
- Obtundia
- Octinoxate
- Octisalate
- Octocrylene
- Octoxynol 9
- Octyl Gallate
- Octyl triazone
- Oil of erigeron
- Opium powder
- Opium tincture
- Organic vegetables
- Orthophosphoric acid
- Ox bile
- Ox bile extract
- Oxitriptan
- Oxybenzone
- Oxyquinoline
- Oxytetracycline Hydrochloride
- Padimate a
- Padimate o
- Pambron
- Panthenol
- Pantothenic acid
- Papain
- Papaverine
- Papaya enzymes
- Papaya, natural
- Para-chloromercuriphenol
- Paraffin
- Paregoric
- Parethoxycaine Hydrochloride
- Parsley
- Passion flower extract
- Patchouli Essential Oil
- Pectin
- Pennyroyal Oil
- Pentylene-tetrazole
- Peppermint
- Peppermint Oil
- Peppermint Spirit
- Peruvian Balsam
- Peruvian balsam oil
- Petrolatum
- Phenacaine Hydrochloride
- Phenindamine Tartrate
- Pheniramine Maleate
- Phenobarbital
- Phenolate sodium
- Phenolphthalein
- Phenoxyacetic acid
- Phenyl salicylate
- Phenylalanine
- Phenylephrine bitartrate
- Phenylephrine bitartrate (effervescent)
- Phenylmercuric Borate
- Phenylmercuric acetate
- Phenylmercuric nitrate
- Phenyltoloxamine citrate
- Phenyltoloxamine dihydrogen citrate
- Phenyltoloxamine Hydrochloride
- Phosphate fluoride
- Phosphorated carbohydrate
- Phosphoric acid
- Phosphorus
- Phytolacca
- Picrotoxin
- Pilocarpine Nitrate
- Pimobendan
- Pine tar
- Piperazine citrate
- Piperocaine Hydrochloride

- Piperonyl butoxide
- Pipsissewa
- Piracetam
- Piracetam dihydrogen citrate
- Piscidia erythrina
- Pitcher Plant
- Plantago ovata husks
- Plantago seed
- Plantago seed/Psyllium seed, blond
- Plantago seed/Psyllium seed husks
- Poloxamer 188
- Poloxamer 407
- Poloxamer
- Poloxamer-iodine complex
- Poly (DL-Lactic Acid)
- Poly(methyl vinyl ether/maleic anhydride)
- Polycarbophil
- Polydimethylsiloxane and poloxamer
- Polyethylene Glycol 1450
- Polyethylene Glycol 300
- Polyethylene Glycol 400
- Polyethylene Glycol 6000
- Polyols, liquid
- Polyoxeythylene laurate
- Polysorbate 20
- Polysorbate 80
- Polyvinyl alcohol
- Potash Lye
- Potassium bicarbonate
- Potassium bitartrate
- Potassium bromide
- Potassium carbonate
- Potassium chlorate
- Potassium citrate
- Potassium ferrocyanide
- Potassium guaiacolsulfonate
- Potassium hydroxide
- Potassium iodide
- Potassium nitrate
- Potassium Phosphate Tribasic [K<sub>3</sub>PO<sub>4</sub>]
- Potassium salicylate
- Povidone
- Povidone-iodine
- Povidone-vinylacetate copolymers
- Powdered Cellulose
- Pracasil Plus
- Pregnenolone micronized
- Prolase
- Propionic acid
- Propylene glycol
- Propylhexedrine
- Propylparaben
- Protease
- Protein hydrolysate
- Protirelin
- Prune concentrate dehydrate
- Prune powder
- Pseudoephedrine Hydrochloride
- Pseudoephedrine Sulfate
- Psyllium
- Psyllium (hemicellulose)
- Psyllium hydrophilic mucilloid
- Psyllium seed
- P-T-butyl-m-cresol
- Pyrantel pamoate
- Pyrethrum extract
- Pyridoxine
- Pyridoxyl-5-Phosphate
- Pylamine maleate
- Pyrithione zinc
- Pyrrolidone
- Pyruvic Aldehyde 40% Aqueous Solution
- Quinine
- Racemethionine
- Racephedrine hydrochloride
- Racepinephrine hydrochloride
- Raffinose
- Red petrolatum
- Reosote (Creosote?)
- Resorcinol
- Resorcinol monoacetate
- Resveratrol
- Retinoic Acid-All Trans
- Rhubarb fluid extract
- Rhubarb, Chinese
- Riboflavin
- Rice polishings
- Romohydrate
- Sabadilla, alkaloids
- Saccharin

- Sage Oil
- Salicyl alcohol
- Salicylamide
- Salsalate
- Sanguinaria extract
- Saponite
- Saw palmetto
- Scopolamine aminoxide hydrobromide
- Sea mineral
- Secretin, human 99%
- Selenium
- Selenium sulfide
- Senecio aureus
- Senna
- Senna fluid extract
- Senna pod concentrate
- Senna syrup
- Sennosides a and b
- Serotonin Hydrochloride
- Sesame Oil
- Sesame Seed
- Shark liver oil
- Shea Butter, Organic
- Short Chain Fatty Acid
- Silver Bulk Drug Substance
- Silver nitrate
- Silver protein mild
- Silver, colloidal
- Silver[1] (Canadian\_License\_Sovereign\_)
- Simethicone
- Simplgel 30
- Skin protectant
- Sodium
- Sodium 3, 4-dimethylphenyl-glyoxylate
- Sodium acetylsalicylate
- Sodium aluminum chlorohydroxy lactate
- Sodium aspartate
- Sodium biphosphate
- Sodium bisulfate
- Sodium borate
- Sodium borate monohydrate
- Sodium bromide
- Sodium caprylate
- Sodium carbonate
- Sodium carboxymethylcellulose
- Sodium caseinate
- Sodium diacetate
- Sodium dichromate
- Sodium dihydrogen phosphate
- Sodium dihydrogen phosphate monohydrate
- Sodium fluoride
- Sodium Hexachloroplatinate (IV) Hexahydrate
- Sodium monofluoro phosphate
- Sodium nitrate
- Sodium octanoate
- Sodium oleate
- Sodium para-amino benzoate
- Sodium perborate
- Sodium perborate monohydrate
- Sodium phosphate dibasic
- Sodium potassium tartrate
- Sodium propionate
- Sodium salicylate
- Sodium salicylic acid phenolate
- Sodium sulfide
- Soft Paraffin
- Sols, secondary
- Sorbitol
- Soy meal
- Soybean oil
- Soybean oil, hydrogenated (powder)
- Soybean protein
- Splenda
- Squill preparations
- Stannous fluoride
- Stannous pyrophosphate
- Stearyl alcohol
- Stevia Powder Extract
- Strawberry
- Strontium chloride
- Strychnine
- Sublimed sulfur
- Sucrose
- Sugars
- Sulferated oils of turpentine
- Sulfobutylether B-Cyclodextrin
- Sulfur
- Sulisobenzone

- Supposibase-F
- T3 Sodium Dilution
- Talc
- Tannic acid
- Tannic acid glycerite
- Taraxacum officinale
- Tartaric acid
- Tartrate
- Tartrate (acid or salt)
- Tea Tree Oil
- Teaberry Oil
- Terpin hydrate preparations
- Tetrafluoroethane
- Tetrahydrochloride
- Thaumatin
- Thenyldiamine Hydrochloride
- Theobromine Sodium Salicylate
- Theophylline calcium salicylate
- Theophylline sodium glycinate
- Theophylline, anhydrous
- Theophylline compound with ethylenediamine
- Theophylline mens
- Thiamine mononitrate (vitamin B1)
- Thimerosal
- Thiocynoacetate
- Thonzylamine Hydrochloride
- Threonine
- Thylene blue
- Thymol
- Thymosin alpha-1
- Titanium dioxide
- Tolindate
- Toltrazuril
- Tolu balsam
- Tommy gel
- Topical starch
- Tranilast
- Triacetin
- Tricalcium phosphate
- Tricaprylin
- Triclocarban
- Triclosan
- Triethanolamine
- Triglycerides
- Trillium
- Trilostane
- Triolein
- Tripelennamine Hydrochloride
- Triple dye
- Triprolidine Hydrochloride
- Triticum
- Trolamine salicylate (triethanolamine salicylate)
- Tryptophan
- Turpentine oil
- Turpentine, venice
- Tyrosine
- Uinolinium bromide
- Ulose
- Undecoylium chlorideiodine complex
- Undecylenic acid
- Uva ursi, extract of
- Uva ursi, potassium extract
- Valic acid
- Valine
- Vegetable (green)
- Verapamil
- Vitamin A
- Vitamin A palmitate
- Vitamin E
- Vitromersol
- Water and additives
- Water, purified
- Wax, Anionic Emulsifying
- Wax, white
- Wax, yellow
- Wheat germ
- White ointment
- White petrolatum
- Witch hazel (hamamelis water)
- Witch hazel skin
- Woodruff
- Xanthan gum
- Xylometazoline Hydrochloride
- Yeast
- Yeast cell derivative
- Yellow mercuric oxide
- Zinc
- Zinc acetate



**Updated August 21, 2023**

- Zinc caprylate
- Zinc carbonate
- Zinc citrate
- Zinc phenol sulfonate
- Zinc picolinate
- Zinc propionate
- Zinc stearate
- Zinc sulfide
- Zinc undecylenate
- Zirconium oxide
- Zyloxin