DRAFT NOTE FOR GUIDANCE ON ORGANIC IMPURITIES IN
ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED
PHARMACEUTICAL PRODUCTS
(July 2016)

DRAFT FOR COMMENT

Should you have any comments on the attached text, please send these to Dr Herbert Schmidt. Medicines Quality Assurance, Technologies, Standards and Norms, World Health Organization, 1211 Geneva 27, Switzerland; email: schmidt@who.int; fax: (+41 22) 791 4730 by 16 September 2016.

In order to speed up the process for receiving draft monographs and for sending comments, please let us have your email address (to bonnyw@who.int) and we will add it to our electronic mailing list. Please specify if you wish to receive monographs.

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## SCHEDULE FOR THE ADOPTION PROCESS OF DOCUMENT QAS/15.60

### DRAFT NOTE FOR GUIDANCE ON ORGANIC IMPURITIES IN ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PHARMACEUTICAL PRODUCTS

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td><strong>First draft prepared by the Secretariat of <em>The International Pharmacopeia</em> with feedback from a group of experts</strong></td>
<td>January–March 2015</td>
</tr>
<tr>
<td><strong>Discussion at consultation on new medicines, quality control and laboratory standards</strong></td>
<td>13–15 April 2015</td>
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<tr>
<td><strong>First draft sent out for public consultation</strong></td>
<td>April 2015</td>
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<tr>
<td><strong>Review of comments received by the Secretariat of <em>The International Pharmacopeia</em> and a group of experts; possible revision of the text</strong></td>
<td>August 2015</td>
</tr>
<tr>
<td><strong>Presentation to WHO Expert Committee on Specifications for Pharmaceutical Preparations for adoption</strong></td>
<td>October 2015</td>
</tr>
<tr>
<td><strong>Preparation of the first revised draft (Rev.1) by Dr M. Brits, considering the feedback received from the members of the Subgroup and the members of the Expert Committee during the 51st meeting</strong></td>
<td>November 2015–March 2016</td>
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<td><strong>First draft sent out for comments to Working group as recommended during the 50th meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations</strong></td>
<td>April 2016</td>
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<td><strong>Discussion at consultation on quality control laboratory tools and specifications for medicines</strong></td>
<td>9–11 May 2016</td>
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<tr>
<td><strong>Preparation of second revised draft (Rev.2)</strong></td>
<td>June–July 2016</td>
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considering comments received from the working group.

<table>
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<td>Draft (Rev.2) sent out for public consultation</td>
<td>July 2016</td>
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<tr>
<td>Review of comments received</td>
<td>September 2016</td>
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<tr>
<td>Presentation to WHO Expert Committee on Specifications for Pharmaceutical Preparations for adoption</td>
<td>October 2016</td>
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<tr>
<td>Further follow-up action as required</td>
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DRAFT NOTE FOR GUIDANCE ON ORGANIC IMPURITIES IN ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PHARMACEUTICAL PRODUCTS

[Note from the Secretariat. Considering current practices in use for The International Pharmacopoeia and available guidance on how to establish limits for impurities, the following note for guidance on organic impurities in active pharmaceutical substances and finished pharmaceutical products was drafted.

It is intended to replace the text on Related substances in finished pharmaceutical product monographs in the folder Notes for guidance, Supplementary information section with the following chapter.]

1. SCOPE

Purity is a critical attribute of active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs), which potentially affect their safety and efficacy. Therefore, API and FPP monographs in The International Pharmacopoeia (Ph.Int.) shall contain specifications for purity which include requirements for the control of impurities, wherever possible.

Impurities in APIs and FPPs may include starting materials, by-products, intermediates, degradation products, reagents, ligands, residual catalysts and residual solvents. They can be classified as either organic, inorganic or biological.

This guidance note covers requirements for controlling organic process-related impurities and degradation products in APIs and FPPs, and provides guidance on how to assess compliance with Ph.Int. requirements.

Statements in this document are applicable to monographs included in the Ph.Int. after the publication of this guidance note. Compliance with monographs published before this updated guidance shall be evaluated against the previous text Related substances in dosage form monographs¹ unless required otherwise by the competent authority. A list of all monographs included in the Ph.Int. before the publication of this guidance note is presented in the document titled Monographs to be evaluated against the text Related substances in dosage form monographs which can be found in The International Pharmacopoeia under Supplementary information. [Note from the Secretariat. The mentioned list is attached at the end of this document.]

¹ Once this new guidance note is adopted by the Expert Committee on Specifications for Pharmaceutical Substances, the replaced text can be found on the homepage of The International Pharmacopoeia under Omitted texts.
Excluded from this guidance note are biological/biotechnological products, peptides, oligonucleotides, radiopharmaceuticals, herbal products and crude products of animal and plant origin.

Further excluded are the following:

- extraneous contaminants that should not occur in APIs and FPPs and are more appropriately addressed as good manufacturing practices (GMP) issues;
- crystallographic modifications (“polymorphic forms”);
- residual solvents resulting from API or FPP manufacture;
- impurities that arise from printing inks or excipients (reaction products between excipients and APIs are not excluded);
- organic impurities that are leached from container-closure systems;
- fermentation products and semisynthetic products derived therefrom;
- highly toxic (e.g. genotoxic) impurities or degradation products and residual solvents (volatile organic impurities) are addressed using separate applicable guidance.

2. DEFINING THE PURITY OF APIS AND FPPS

To control relevant organic impurities individual monographs will contain a stability-indicating test entitled Related substances. This test may be supplemented by a specific test where a given impurity is not adequately controlled by the related substances test or where there are particular reasons (for example, safety reasons a genotoxic/mutagenic or an enantiomeric impurity) requiring specific control.

Monographs of APIs shall include specification limits for all impurities (i.e. process-related impurities that result from the manufacturing process and degradation products) observed at levels above the identification threshold. Monographs on FPPs must include appropriate limits for degradation products and, if possible to be detected by the method, impurities from the manufacturing process. This approach provides, in conjunction with the monograph on the API, the means for an independent control laboratory without access to manufacturer’s data to establish whether or not an API of pharmacopoeial quality has been used to manufacture the FPP under examination.²

Instruction for control of impurities may also be included in the manufacture section of a monograph, for example, where the only analytical method appropriate for the control of a given impurity is to be performed by the manufacturer since the method is technically too complex for general use. The production process (including the purification steps) should be validated to give sufficient control so that the product, if tested, would comply with the specified limits using a suitable analytical method.

² It is recognized that limits for degradation impurities given in FPP monographs may need to be higher than the limits for the same impurities that appear in the monograph for the corresponding API to take into account any degradation which may occur during the manufacture and/or storage of the FPP. If the test for impurities in the FPP also limits impurities arising during the API synthesis, the reporting threshold as normally determined for the dosage form degradation products (not as for the API) will apply.
Under the section on Impurities in the monographs for APIs and FPPs, known impurities are listed (transparency list) that are able to be separated and detected by the described test method(s). In FPPs monographs reference may also be made to the list in the monograph of the corresponding API if the test is able to detect these known impurities. Whenever possible, the impurities are identified as degradation products and/or synthesis-related impurities.

Tests for related substances are intended to provide control of known potential or actual impurities rather than to control all possible impurities. The tests are not designed to detect any adventitious contaminants or adulteration. APIs or FPPs found to contain an impurity not detectable by means of the prescribed tests are not of pharmaceutical quality if the nature or amount of the impurity found is incompatible with GMP or applicable regulatory standards.

3. GLOSSARY

degradation product. An impurity resulting from a chemical change in the active pharmaceutical ingredient (API) brought about during manufacture and/or storage of the API or the dosage form by the effect of, for example, light, oxygen, temperature, pH, water or by reaction with an excipient or another API (in fixed-dose combination dosage form) and/or the immediate container-closure system.

extraneous contaminant. An impurity arising from any source extraneous to the manufacturing process.

identification threshold. A limit above (>) which an impurity should be identified, based on the applicable regulatory standards.

identified impurity. An impurity for which a structural characterization has been achieved.

impurity (API). Any component of an API that is not the chemical entity defined as the API.

impurity (FPP). Any component of the FPP that is not the API or an excipient in the FPP.

independent control laboratory. [Note by the Secretariat. Definition is under preparation.]

intermediate. A material produced during steps of the synthesis of an API that undergoes further chemical transformation before it becomes an active pharmaceutical ingredient.

ligand. An agent with a strong affinity to a metal ion.

polymorphic forms. Different crystalline forms of the active pharmaceutical ingredient. These can include solvation or hydration products (also known as pseudo-polymorphs) and amorphous forms.
qualification threshold. A limit above (>), which an impurity should be qualified.

reporting threshold. A limit above which an impurity is to be reported.

specified impurity. An impurity that is individually listed and limited with a specific acceptance criterion in the monograph. A specified impurity can be either identified or unidentified.

starting material. A material used in the synthesis of an active pharmaceutical ingredient (API) that is incorporated as an element into the structure of an intermediate and/or of the API. Starting materials are normally commercially available and of defined chemical and physical properties and structure.

unidentified impurity. An impurity for which a structural characterization has not been achieved and that is defined solely by qualitative analytical properties (e.g. chromatographic retention time).

unspecified impurity. An impurity that is limited by a general acceptance criterion, but not individually listed with its own specific acceptance criterion (e.g. relative retention time).

4. SETTING ACCEPTANCE CRITERIA FOR ORGANIC IMPURITIES

Limits in the Ph.Int. are usually set based on:

- the evaluation of information, provided by manufacturers, concerning the nature of impurities, the reason for their presence, the concentrations that may be encountered in material produced under GMP, the manner in which the API or FPP may change during storage and when subjected to stress conditions (e.g. light, heat, moisture, acid, base or oxygen) and information on the toxicity of any organic impurity in relation to that of the substance itself;

- justified limits accepted when the marketing authorization was granted or when the product was included in the WHO list of prequalified APIs or prequalified FPPs. Such acceptance included establishing the qualification of the limits by scientific principles inter alia ICH Q3 guidelines;

- limits published by other pharmacopoeias applying good pharmacopoeial practices (GPhP);\(^3\)

- principles published in current regulatory guidance documents, such as those published by the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

\(^3\) At the time this note for guidance was drafted the draft proposal for GPhP (QAS/13.526/Rev.5) was sent out for public consultation (see [http://www.who.int/medicines/areas/quality_safety/quality_assurance/GPhP-Rev5-QAS13-526.pdf?ua=1](http://www.who.int/medicines/areas/quality_safety/quality_assurance/GPhP-Rev5-QAS13-526.pdf?ua=1)). The statement made thus refers to the future, i.e. to a time when GPhP have been implemented and put into practice by pharmacopoeias.
Safety considerations are of particular importance in establishing acceptance criteria for impurities. The historical safety record, the route of administration, the type of dosage form, the maximum daily dose, the duration of treatment, the need for and the availability of the medicine are also to be taken into consideration when setting limits for impurities. Also, comments received on the draft monographs from Member States, stakeholders and other interested parties during the public consultation phase are reviewed and considered.

5. CLAIMING COMPLIANCE WITH THE REQUIREMENTS BY A MANUFACTURER

In the event of monographs that were published prior to the publication of this guidance note which have no related substances test (or equivalent) or where the existing test does not comply with the requirements of the applicable regulatory standards the manufacturer shall nevertheless ensure that there is suitable control of organic impurities. When an API contains impurities other than those mentioned in the Impurities section (for example, because it was manufactured using an alternative method of synthesis) the manufacturer must ascertain that these impurities can be controlled by the method(s) and limits described in the monograph; otherwise a new method and specifications shall be developed and submitted to the competent authority for approval, while a revision of the monograph of The International Pharmacopoeia shall be proposed by the manufacturer.

When a chromatographic peak (at a level greater than the applicable identification threshold) cannot be assigned unambiguously to an impurity in the transparency list using the means described in the monograph (e.g. by means of retention times, relative retentions or comparison to reference substances mentioned in the monograph) the manufacturer has to apply additional measures in order to identify the impurity. These measures may include, for example, ensuring that the response is not due to the chromatographic solvent system or excipients used in the formulation and the identification of potential impurities not referred to in the monograph by the use of additional analytical techniques, e.g. so-called hyphenated analytical techniques, e.g. gas chromatography- or liquid chromatography-mass spectrometric methods. If identification by structure is initially not possible the impurity could be listed as an unidentified specified impurity until identification has been achieved.

When a related substance not listed in the transparency list is found in an API or in an FPP (at a level above the identification threshold) it is the responsibility of the manufacturer to demonstrate that it is identified and a qualified limit is set, in accordance with the applicable regulatory standards, and to communicate this to The International Pharmacopoeia.
Monographs to be evaluated against the text *Related substances in dosage form monographs*

A list of all monographs included in *The International Pharmacopoeia* before the publication of the guidance note: *Guidance on organic impurities in active pharmaceutical ingredients and finished pharmaceutical products* is presented in this document. Compliance of the monographs listed hereunder shall be evaluated against the previous text *Related substances in dosage form monographs* unless required otherwise by the competent authority.

In the event that a revision of any of the specified text is to be published in *The International Pharmacopoeia*, the revised text will be removed from this list and compliance of the revised text will be evaluated against the *Guidance on organic impurities in active pharmaceutical ingredients and finished pharmaceutical products* guidance note.

**Pharmaceutical substances monographs**

- Abacavir sulfate
- Acacia
- Acetazolamide
- Acetic acid
- Acetylsalicylic acid
- Aciclovir
- Albendazole
- Alcoholic
- Alcuronium chloride
- Alginic acid
- Allopurinol
- Aluminium hydroxide
- Aluminium magnesium silicate
- Aluminium sulfate
- Amidotrizoic acid
- Amikacin sulfate
- Amikacin
- Amiloride hydrochloride
- Aminophylline
- Amitriptyline hydrochloride
- Amodiaquine
- Amodiaquine hydrochloride
- Amoxicillin trihydrate
- Amphotericin B
- Ampicillin
- Ampicillin sodium
- Anaesthetic Ether

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4 Once the new guidance note *Guidance on organic impurities in active pharmaceutical ingredients and finished pharmaceutical products* is adopted by the Expert Committee on Specifications for Pharmaceutical Substances, the replaced text can be found in *The International Pharmacopoeia* under Omitted texts.
<table>
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<tr>
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<th>Name of Chemical Substance</th>
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<td>253</td>
<td>Antimony sodium tartrate</td>
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<tr>
<td>254</td>
<td>Arachis oil</td>
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<tr>
<td>255</td>
<td>Artemether</td>
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<tr>
<td>256</td>
<td>Artemisinin</td>
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<tr>
<td>257</td>
<td>Artemotil</td>
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<tr>
<td>258</td>
<td>Artenimol</td>
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<tr>
<td>259</td>
<td>Artesunate</td>
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<tr>
<td>260</td>
<td>Ascorbic acid</td>
</tr>
<tr>
<td>261</td>
<td>Atazanavir sulfate</td>
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<td>262</td>
<td>Atenolol</td>
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<td>263</td>
<td>Atropine sulfate</td>
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<tr>
<td>264</td>
<td>Azathioprine</td>
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<tr>
<td>265</td>
<td>Bacitracin</td>
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<td>Bacitracin zinc</td>
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<td>267</td>
<td>Barium sulfate</td>
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<tr>
<td>268</td>
<td>Beclometasone dipropionate</td>
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<td>269</td>
<td>Bentonite</td>
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<td>270</td>
<td>Benzalkonium chloride</td>
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<td>Benzathine benzylpenicillin</td>
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<td>272</td>
<td>Benznidazole</td>
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<td>273</td>
<td>Benzocaine</td>
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<td>274</td>
<td>Benzoic acid</td>
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<td>277</td>
<td>Benzyl hydroxybenzoate</td>
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<td>278</td>
<td>Benzylpenicillin potassium</td>
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<td>Benzylpenicillin sodium</td>
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<td>Bephenium hydroxynaphthoate</td>
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<td>Bleomycin hydrochloride</td>
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<td>287</td>
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<td>288</td>
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<td>Butylated hydroxyanisole</td>
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<td>Calcium sulfate</td>
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Capreomycin sulfate
Captopril
Carbamazepine
Carbidopa
Carbomer
Carmellose sodium
Carnauba wax
Cellacefate
Cetomacrogol 1000
Cetostearyl alcohol
Cetrimide
Cetyl alcohol
Cetyl esters wax
Charcoal, activated
Chlormethine hydrochloride
Cimeticidine
Cimetidine
Ciprofloxacin
Ciprofloxacin hydrochloride
Cisplatin
Citric acid
Clindamycin phosphate
Clofazimine
Clomifene citrate
Cloxacillin sodium
Coal tar
Codeine monohydrate
Codeine phosphate
Colchicine
Colecalciferol
Cyanocobalamin
Cyclophosphamide
Cycloserine
Cytarabine
Dacarbazine
Dactinomycin
Dapsone
Deferoxamine mesilate
Dehydroemetine dihydrochloride
Dexamethasone
Dexamethasone acetate
Dexamethasone sodium phosphate
Dextromethorphan hydrobromide
Diazepam
Diazoxide
Dicloxacillin sodium
Dicoumarol
Didanosine
Diethylcarbamazine dihydrogen citrate
Diethyltoluamide
Digitoxin
Digoxin
Diloxanide furoate
Dilute hydrochloric acid
Dilated Isosorbide dinitrate
Dimercaprol
Dinitrogen oxide
Diphenoxylate hydrochloride
Disodium edetate
Dithranol
Dopamine hydrochloride
Doxorubicin hydrochloride
Doxycycline hyclate
Edrophonium chloride
Efavirenz
Emetine hydrochloride
Emtricitabine
Epibatidine
Ephedrine
Ephedrine hydrochloride
Ephedrine sulfate
Epinephrine
Epinephrine hydrogen tartrate
Ergocalciferol
Ergometrine hydrogen maleate
Ergotamine tartrate
Erythromycin
Erythromycin ethylsuccinate
Erythromycin lactobionate
Erythromycin stearate
Ethambutol hydrochloride
Ethanol
Ethinylestradiol
Ethionamide
Ethosuximide
Ethyl hydroxybenzoate
Ethylcellulose
Etoposide
Ferrous fumarate
Ferrous sulfate
Fluconazole
Flucytosine
Fludrocortisone acetate
Fluorescein sodium
Fluorouracil
Fluphenazine decanoate
Fluphenazine enantate
Fluphenazine hydrochloride
Folic acid
Furosemide
Gallamine triethiodide
Gelatin
Gentamicin sulfate
Glibenclamide
Glucose
Glycerol
Glycerol 85% m/m
Glyceryl monostearate
Griseofulvin
Haloperidol
Halothane
Hard fat
Hard paraffin
Heparin calcium
Heparin sodium
Homatropine hydrobromide
Homatropine methylbromide
Hydralazine hydrochloride
Hydrochloric acid
Hydrochlorothiazide
Hydrocortisone
Hydrocortisone acetate
Hydrocortisone sodium succinate
Hydrous Benzoyl peroxide
Hydroxocobalamin
Hydroxocobalamin chloride - Hydroxocobalamin sulfate - Hydroxocobalamin sulfas
Hydroxyethylcellulose
Hydroxypropylcellulose
Hypermellose
Ibuprofen
Idoxuridine
Imipramine hydrochloride
Indinavir sulfate
Indometacin
Insulin
Iodine
Iohexol
Iopanoic acid
Iotroxic acid
Ipecacuanha root
Isoniazid
Isoprenaline hydrochloride
Isoprenaline sulfate
Kanamycin acid sulfate
Kanamycin monosulfate
Kaolin
Ketamine hydrochloride
Ketoconazole
Lactic acid
Lactose
Lamivudine
Levamisole hydrochloride
Levodopa
Levonorgestrel
Levothyroxine sodium
Lidocaine
Lidocaine hydrochloride
Lindane
Lithium carbonate
Loperamide hydrochloride
Lopinavir
Lumefantrine
Magnesium hydroxide
Magnesium oxide
Magnesium stearate
Magnesium sulfate heptahydrate
Mannitol
Mebendazole
Medroxyprogesterone acetate
Mefloquine hydrochloride
Meglumine
Mercaptopurine
Mercuric oxycyanide
DL-Methionine
Methotrexate
Methyl hydroxybenzoate
Methylcellulose
Methyldopa
Methylrosanilinium chloride
Methyltestosterone
Methylthioninium chloride
Metoclopramide hydrochloride
Metrifonate
Metronidazole
Metronidazole benzoate
Miconazole nitrate
Microcrystalline cellulose
Morphine hydrochloride
Morphine sulfate
Naloxone hydrochloride
Nelfinavir mesilate
Neomycin sulfate
Neostigmine bromide
Neostigmine metilsulfate
Nevirapine
Niclosamide
Nicotinamide
Nicotinic acid
Nifedipine
Nifurtimox
Niridazole
Nitrazepam
Nitrofurantoin
Nonoxinol 9
Norethisterone acetate
Norethisterone
Norethisterone enantate
Noscapine
Noscapine hydrochloride
Nystatin
Oseltamivir phosphate
Oxamniquine
Oxygen
Oxytetracycline dihydrate
Oxytetracycline hydrochloride
Oxytocin
Papaverine hydrochloride
Paracetamol
Paromomycin sulfate
Penicillamine
Pentamidine isethionate
Pentamidine mesilate
Pethidine hydrochloride
Phenobarbital
Phenobarbital sodium
Phenoxybenzylpenicillin
Phenoxybenzylpenicillin calcium
Phenoxybenzylpenicillin potassium
Phenylmercuric nitrate
Phenytoin
Phenytoin sodium
Phystostigmine salicylate
Phytomenadione
Pilocarpine hydrochloride
Pilocarpine nitrate
Piperazine adipate
Piperazine citrate
Podophyllum resin
Polysorbates 20, 60, 80
Potassium chloride
Potassium citrate
Potassium iodide
Povidone
Praziquantel
Prednisolone
Prednisolone acetate
Prednisolone sodium phosphate
Primamidine diphasate
Probenecid
Procainamide hydrochloride
Procaine benzylpenicillin
Procaine hydrochloride
Procarbazine hydrochloride
Progestosterone
Proguanil hydrochloride
Promethazine hydrochloride
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Streptomycin sulfate
Sulfacetamide
Sulfacetamide sodium
Sulfadiazine silver
Sulfadimidine
Sulfadimidine sodium
Sulfadoxine
Sulfamethoxazole
Sulfamethoxypyridazine
Sulfasalazine
Suramin sodium
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Tamoxifen citrate
Tenofovir disoproxil fumarate
Testosterone enantate
Testosterone propionate
Tetracaine hydrochloride
Tetracycline hydrochloride
Thiamine hydrobromide
Thiamine hydrochloride
Thiamine mononitrate
Thioacetazone
Thiopental sodium
Tiabendazole
Timolol maleate
Tolbutamide
Trihexyphenidyl hydrochloride
Trimethadione
Trimethoprim
Tropicamide
Tubocurarine chloride
Verapamil hydrochloride
Vinblastine sulfate
Vincristine sulfate
Warfarin sodium
Water for injections
White, soft paraffin; Yellow soft paraffin
Wool fat
Zidovudine
Zinc acetate
Zinc gluconate
Zinc oxide
Zinc sulfate
671 **Dosage form monographs**

672 Abacavir oral solution
673 Abacavir tablets
674 Acetylsalicylic acid tablets
675 Aciclovir for injection
676 Aciclovir tablets
677 Albendazole chewable tablets
678 Allopurinol tablets
679 Amikacin for injection
680 Amodiaquine tablets
681 Amoxicillin oral suspension
682 Amphotericin B for injection
683 Ampicillin capsules
684 Ampicillin sodium for injection
685 Artemether and lumefantrine oral suspension
686 Artemether and lumefantrine tablets
687 Artemether capsules
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689 Artemether tablets
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693 Artesunate tablets
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695 Atropine sulfate tablets
696 Benzylpenicillin potassium for injection
697 Capreomycin for injection
698 Carbamazepine tablets
699 Chewable mebendazole tablets
700 Chloroquine phosphate tablets
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702 Chloroquine sulfate tablets
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704 Cloxacillin sodium capsules
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706 Codeine phosphate tablets
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710 Dexamethasone phosphate injection
711 Dexamethasone tablets
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713 Didanosine tablets
714 Diethylcarbamazine dihydrogen citrate tablets
715 Diloxanide furoate tablets
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Doxycycline tablets
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Efavirenz, emtricitabine and tenofovir tablets
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Ergometrine hydrogen maleate tablets
Ergometrine injection
Erythromycin ethylsuccinate tablets
Erythromycin stearate tablets
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Glyceryl trinitrate tablets
Griseofulvin tablets
Ibuprofen tablets
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Isoniazid tablets
Kanamycin for injection
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Lamivudine tablets
Levamisole tablets
Levonorgestrel and ethinylestradiol tablets
Levonorgestrel tablets
Lopinavir and ritonavir tablets
Magnesium sulfate injection
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Mefloquine tablets
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Nelfinavir mesilate tablets
Nevirapine oral suspension
Nevirapine tablets
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Nitrofurantoin tablets
Nystatin tablets
Oral rehydration salts
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Oxytocin injection
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Tenofovir tablets
Zidovudine and lamivudine tablets
Zidovudine capsules
Zidovudine intravenous infusion
Zidovudine, lamivudine and abacavir tablets
Zidovudine, lamivudine and nevirapine tablets
Zidovudine oral solution

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