

APPENDIX 18

LIST OF PERMITTED, PROHIBITED AND RESTRICTED SUBSTANCES

IMPORTANT NOTE:

The following lists are by no means exhaustive.

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1. LIST OF PROHIBITED AND RESTRICTED ACTIVE INGREDIENTS AND COMBINATION

1.1 List of Prohibited Active Ingredients and Combinations

a) Prohibited Active Ingredients

| NO. | PROHIBITED ACTIVE INGREDIENTS |
|-----|-------------------------------|
| 1. | 1,3-dimethylamylamine (DMAA) |
| 2. | Aristolochic Acid |
| 3. | Aminopyrine/ Amidopyrine |
| 4. | Astemizole |
| 5. | Bacillus Coagulans |
| 6. | Berberine |
| 7. | Butobarbitone |
| 8. | Chlormezanone |
| 9. | Cisapride |
| 10. | Conjugated Linoleic Acid |
| 11. | Crinis Carbonisatus |
| 12. | Danthron |
| 13. | Dipyrone |
| 14. | Enterococcus Faecalis |
| 15. | Enterococcus Faecium |
| 16. | Ethenzamide |
| 17. | Euflavine |
| 18. | Furazolidone |
| 19. | Fenfluramine/ Dexfenfluramine |
| 20. | Gadodiamide |
| 21. | Gentian Violet |

| NO. | PROHIBITED ACTIVE INGREDIENTS |
|------------|---|
| 22. | Gamma-Butyrolactone (GBL) |
| 23. | Gamma-Aminobutyric Acid (GABA) |
| 24. | Gamma-Hydroxybutyric Acid (GHB) |
| 25. | Haloquinol |
| 26. | Hexachlorophene |
| 27. | Mercurochrome |
| 28. | Nimesulide |
| 29. | Novobiocin |
| 30. | Oxyphenisatin Acetate/ Acetophenolisatin |
| 31. | Oxyphenbutazone |
| 32. | Pergolide |
| 33. | Phenacetin |
| 34. | Phenazone/ Antipyrine <ul style="list-style-type: none"> - Propylphenazone - Isopropylphenazone |
| 35. | Phenylbutazone |
| 36. | Phenylpropanolamine |
| 37. | Piperazine |
| 38. | Prenylamine |
| 39. | Quinalbarbitone |
| 40. | Salicylamide |
| 41. | Sibutramine |
| 42. | Stanozolol |
| 43. | Sulphaguanide |
| 44. | Thioridazine |
| 45. | Tegaserod |

NO. PROHIBITED ACTIVE INGREDIENTS

46. Terfenadine

b) Prohibited Combinations

NO. PROHIBITED COMBINATIONS

1. Ampicillin + Cloxacillin

2. Antibiotics + Papain/ Prolase

3. Antacid + Charcoal

4. Combinations With Any Barbiturates

5. Combinations of Two or More Analgesic with the Same Mode of Action

6. Combinations Of Vitamin (S) With Other Drugs:

a. Vitamin (S) + Appetite Suppressant

b. Vitamin (S) + Corticosteroid

NOTE:

Combination of calcipotriol (Vitamin D3 analogue) + corticosteroid for topical treatment of psoriasis may be allowed, subject to provision of data to support efficacy and safety

c. Vitamin (S) + Analgesic

d. Vitamin (S) + Laxative

e. Vitamin (S) + Slimming Agents

7. Cough, Cold and Allergy Products Containing:

a. Four or More Pharmacological Groups in One Product.

b. Two or More Drugs from the Same Pharmacological Group

c. Antypyretic - Analgesic + Expectorant

d. Anticholinergic + Bronchodilator

e. Codeine + Ephedrine/ Pseudoephedrine

f. Methapyrilene

g. Paracetamol + Mucolytic/ Expectorant

8. Combinations Containing Antacid and Surface Local Anaesthetic Agent

9. Combinations Containing Dextropropoxyphene

| NO. | PROHIBITED COMBINATIONS |
|------------|--------------------------------|
|------------|--------------------------------|

| | |
|-----|--|
| 10. | Combinations Containing Spironolactone |
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| | |
|-----|------------------------------|
| 11. | Eye Drops Containing Vitamin |
|-----|------------------------------|

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|-----|--------------------------------|
| 12. | Gripe Water Containing Alcohol |
|-----|--------------------------------|

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|-----|---------------------------|
| 13. | Propranolol + Hydralazine |
|-----|---------------------------|

| | |
|-----|------------------------------|
| 14. | Propranolol + Spironolactone |
|-----|------------------------------|

| | |
|-----|--|
| 15. | Topical Preparation Containing Combination of Antibiotic, Antifungal and Steroid |
|-----|--|

1.2 List of Restricted Active Ingredients and Combinations

| Specific Active Ingredients | Not Allowed in the Specified Preparation(s) or Condition |
|--|---|
| 1. Acetic Acid | Expectorant |
| 2. Allantoin | Eye Drop |
| 3. Allergen Extracts | Vaccines, Diagnostics |
| 4. Amphetamine | Cough Mixtures, Appetite Suppressants |
| 5. Animal Organ | All Preparations Except Natural Products |
| 6. Antihistamine | Topical Use |
| 7. Bismuth Salts Except Bismuth Subcitrate | Oral Preparations |
| 8. Boric Acid/ Borax and Related Salts | Oral, Topical (Skin), Vaginal, Nasal Dosage Form |
| 9. Buprenorphine | Single Active Ingredient Sublingual Tablet Formulation |
| 10. Caffeine | All Preparations Except for an Oral Preparation in Combination with Paracetamol/ Acetaminophen or Combination with Ergotamine |
| 11. Camphor | - Oral - External (>11%) |
| 12. Chloroform | Expectorant |
| 13. Codeine | Cough Syrup |
| 14. Cocillana Liq. Extract | Expectorant |
| 15. Cyproheptadine | Appetite Stimulant |
| 16. Dextromethorphan | Single Active Ingredient in Tablet Form, including lozenges |
| 17. Dihydrostreptomycin | Oral Antidiarrhoeals |
| 18. Diphenoxylate | Liquid Oral Dosage For Anti-Diarrhoeal |
| 19. Quinestrol, Oestrogen | Lactation Suppressant |
| 20. Ethynodiol Diacetate | Oral Contraceptives |
| 21. Euphorbia Liquid Extract | Expectorant |
| 22. Gadopentetic acid | All except Intra-articular Formulation |

| Specific Active Ingredients | Not Allowed in the Specified Preparation(s) or Condition |
|------------------------------------|---|
| 23. Gatifloxacin | All Preparations Except for Eye Drop |
| 24. Germanium | Non-Naturally Occurring |
| 25. Hydroquinone | Oral |
| 26. Lactobacillus Acidophilus | Antidiarrhoeal |
| 27. Loperamide | Liquid Oral Dosage For Anti-Diarrhoeal |
| 28. Lovastatin | In Red Yeast Rice: > 1 % w/w and > 10mg/Day |
| 29. Lynooestrenol | Oral Contraceptives |
| 30. Magnesium Ascorbryl Phosphate | Antipigmentation |
| 31. Menthol | External Preparations >16% |
| 32. Mestranol | Oral Contraceptives |
| 33. Methylene Blue | Oral Preparations |
| 34. Midazolam | All oral preparations, except 7.5mg coated tablet |
| 35. Morphine | Cough Mixtures |
| 36. Neomycin | Oral Antidiarrhoeal, Vaginal Tablets, Topical Powders, Aerosols, Nasal Preparations |
| 37. Noradrenaline | Dental Preparations |
| 38. Norgestrel | Oral Contraceptives |
| 39. Paracetamol | Liquid Oral 500mg/5ml |
| 40. Penicillin | Topical Use |
| 41. Phenazopyridine | Urinary Analgesics |
| 42. Phenolphthalein | Stimulant Purgative |
| 43. Pizotifen | Appetite Suppressant |
| 44. Podophyllum Resin | Oral Preparations |
| 45. Pseudoephedrine | All Single Active Ingredient Formulations |
| 46. Sulphonamides | Topical Use |
| 47. Sulphur | All preparations Except External Preparation |

| Specific Active Ingredients | Not Allowed in the Specified Preparation(s) or Condition |
|------------------------------------|---|
| 48. Squill | Expectorant |
| 49. Terpene Hydrate | Expectorant |

| Combinations | Not Allowed in the Specified Preparation(s) |
|---|--|
| 1. Cough, Cold And Allergy Products Containing: | |
| i) Antimony Potassium Tartrate | Expectorant |
| ii) Allylthiocyanate/ Mustard Oil | Nasal Decongestant |
| iii) Turpentine Oil | Expectorant/ Antitussive |
| 2. Vitamin(s) | Eye Drops |

2. LIST OF PROHIBITED AND RESTRICTED EXCIPIENTS

2.1 List of Prohibited Excipients

| | |
|---|--|
| 1. Colouring Agents (Including in Capsule Shells) | Amaranth (CI= 16185, FD & C Red No. 2, E123) |
| 2. Others | Chlorofluorocarbons (CFC) |

2.2 List of Restricted Excipients

| Excipients | Restrictions |
|---|---|
| 1. Colouring Agents (Including in Capsule Shells) | |
| a) Tartrazine (CI= 19140, FD & C Yellow No.5, E102) | Not allowed in the following preparations: – Oral; – Rectal; – Vaginal or – Nasal Preparations |
| b) Red 2G | Not allowed in the following preparations: – Oral Preparations; and – Preparations Used for Mucosa Membrane |
| 2. Sweeteners/ Flavouring Agent | |
| a) Menthol | 0 to 4mg/kg body weight/day (dosage and use in children should be clearly stated). |
| b) Saccharin and Salts | Limited to not more than 5mg/kg/day |
| c) Cyclamates | Limited to not more than 1.5mg/kg body weight/day |
| 3. Preservatives | |
| a) Chloroform | Limited to not more than 0.5% in Pharmaceuticals for Internal Use |

| | | |
|----------------|---|--|
| b) Thiomersal* | Not allowed in ophthalmic Preparations | |
| 4. Others | | |
| a) Phthalates | Variant | Maximum Limit of Daily Exposures (mg/kg body weight/day) |
| | Dibutyl Phthalate (DBP) | 0.01mg/ kg/ day |
| | Diethyl Phthalate (DEP) | 4mg/ kg/ day |
| | Polyvinyl Acetate Phthalate (PVAP) | 2mg/ kg/ day |
| b) Cetrimide | Limited to less than 0.1% w/v (topical preparations for Natural Products) | |

* For other preparations, the warning specified in [Appendix 20: Specific Labelling Requirements](#) shall be included in the package insert and product literature of products containing thiomersal.

Additional Information

1. **Methylene Chloride/ Dichloromethane** are not allowed as solvent in film-coating for locally manufactured products.

For details on implementation, refer to *Surat Pekeliling Berhubung Larangan Penggunaan 'Methylene Chloride' atau 'Dichloromethane (DCM)' Dalam Proses Pengilangan Produk Tempatan: Bil. (2)d/m.BPFK/30/06/2 Bhgn. 2* (23 May 2013)

2. **Alcohol** is not allowed except if it is essential to the formulation and no suitable alternatives to alcohol is available. The alcohol content shall be kept to the most minimum level as possible.

3. LIST OF PERMITTED AND RESTRICTED COLOURING AGENTS

3.1 List of Permitted Colouring Agents

| NO. | COLOURING AGENTS | COLOUR INDEX NUMBER (CI) |
|-----|--|--------------------------|
| 1. | Allura Red AC/ FD & C Red No.40 | 16035 |
| 2. | Anthocyanins a. Those glycosides of 2-phenylbenzopyrylium salts which are anthocyanins b. The following anthocyanidin aglycones: i. Pelargonidin ii. Cyanidin iii. Peonidin iv. Delphinidin v. Petunidin vi. Malvidin | |
| 3. | Black PN (Brilliant Black BN) | 28440 |
| 4. | Brilliant Blue FCF | 42090 |
| 5. | Calcium Carbonate | |
| 6. | Carbo Medicinals/ Vegetalis; (Charcoal) | |
| 7. | Caramel | |
| 8. | Carmoisine (or Azorubine) | 14720 |
| 9. | Carotenoids a. Alpha, Beta, Gamma-Carotene b. Bixin, Noribixin, Roucou c. Annatto d. Capsanthin, Capsorubin, (paprika extract) e. Lycopene f. Beta-Apo-8' carotenal (C 30) g. Ethyl ester of Beta-Apo-8 Carotenoic Acid (C30) i. Chlorophyll ii. Copper complexes of Chlorophyll and Chlorophyllins | 75120 40820 75810 |
| 10. | Chocolate Brown HT | 20285 |
| 11. | Cochineal or Carminic Acid, Carmine from Cochineal | 75470 |

| NO. | COLOURING AGENTS | COLOUR INDEX NUMBER (CI) |
|-----|---|--------------------------|
| 12. | Curcumin | 75300 |
| 13. | Fast Green FCF (FD & C Green No.3) | 42053 |
| 14. | Green S (Acid Brilliant Green BS, Lissamine Green) | |
| 15. | Indigo Carmine (Indigotine) | 73015 |
| 16. | Lactoflavin, Riboflavin | |
| 17. | Patent Blue V | 42051 |
| 18. | Ponceau 4R (Cochineal Red A) | 16255 |
| 19. | Quinoline Yellow | 47005 |
| 20. | Xanthophylls a. Flavoxanthin b. Lutein c. Cryptoxanthin (Kryptoxanthin) d. Violoxanthin e. Rhodoxanthin f. Canthaxanthin | 40850 |
| 21. | The Following Colouring Matters Natural to Edible Fruits or Vegetables: a. Alkannin b. Annatto (including eye) c. Carotene (including eye) d. Chlorophyll e. Flavine f. Indigo g. Osage h. Orange i. Persian Berry j. Safflower k. Saffron l. Sandalwood m. Turmeric n. or their pure coloring principles whether isolated from such natural colors or produced synthetically | 75530 |
| 22. | Bole or Iron Oxide, Carbon Black (or Vegetable Origin), Titanium Dioxide | 77891 |

| NO. | COLOURING AGENTS | COLOUR INDEX NUMBER (CI) |
|-----|---|--------------------------|
| 23. | The Aluminium Salts (Lakes) of Any of the Scheduled Synthetic Dyes Approved for Use, (a) Alumina (Dried Aluminium Hydroxide) | |
| 24. | Talc | |
| 25. | Indigo Carmine/ FD & C Blue No. 2 | 73015 |
| 26. | Brilliant Blue FCF Ammonium Salt/ D & C Blue No. 4 | 42090 |
| 27. | Alizarin Cyanine Green F/ D & C Green No. 5 | 61570 |
| 28. | Toney Red/ D & C Red No. 17 | 26100 |
| 29. | Eosin YS Acid Form/ D & C Red No. 21 | 45380:2 |
| 30. | Eosinys Sodium Salt/ D & C Red No. 22 | 45380 |
| 31. | Phloxine B Acid Form/ D & C Red No. 27 | 45410:1 |
| 32. | Phloxine B Sodium Salt/ D & C Red No. 28 | 45410 |
| 33. | Helindone Pink CN/ D & C Red No. 30 | 73360 |
| 34. | Erythrosine/FD & C Red No. 3 | 45430 |
| 35. | Yellow 2G (Food Yellow) | |
| 36. | Orange Yellow S Sunset Yellow FCF (FD & C Yellow No. 6, E110) | 15985 |

3.2 List of Restricted Colouring Agents

The following colouring agents are **ALLOWED** in preparations as stated in the parentheses:

| NO. | COLOURING AGENTS | COLOUR INDEX NUMBER (CI) |
|-----|---|--------------------------|
| 1. | Dihydroxyacetone (external use with specific drugs only) | |
| 2. | Bismuth Oxochloride (external use only, including eye) | 77163 |
| 3. | Ferric Ammonium Ferrocyanide (external use only, including eye) | |
| 4. | Ferric Ferrocyanide (external eye only) | |
| 5. | Chromium Hydroxide Green (external use only) | 77289 |
| 6. | Chromium Oxide Green (external use only, including eye) | |
| 7. | Guanine (external use only) | 75170 |
| 8. | Prophyllite (external use only) | |
| 9. | Mica (external use only, including eye) | 77019 |
| 10. | Mica coated with titanium dioxide and/or iron oxide (internal use only) <ul style="list-style-type: none"> for solid dosage form, not more than 3% of the preparation (in the case where the preparation was made using iron oxides, the preparation shall not contain more than 55% iron oxides) | |
| 11. | Bronze (external use only, including eye) | |
| 12. | Copper (external use only, including eye) | |
| 13. | Zinc Oxide (external use only, including eye) | 77947 |
| 14. | Quinizarine Green SS/ D & C Green No. 6 (external use only) | 61565 |

| NO. | COLOURING AGENTS | COLOUR INDEX NUMBER (CI) |
|-----|---|--------------------------|
| 15. | Pyranine Concentrated/ D & C Green No. 8 (external use only) | 59040 |
| 16. | Orange II/ D & C Orange No. 4 (external use only) | 15510 |
| 17. | Dibromofluorescein/ D & C Orange No. 5 (mouth wash, dentifrices, external use only) | 45370 |
| 18. | Diiodofluorescein/ D & C Orange No. 10 (external use only) | 45425 |
| 19. | D & C Orange No. 11 (external use only) | |
| 20. | Ponceau SX/ FD & C Red No. 4 (external use only) | 14700 |
| 21. | Lithol Rubin B/ D & C Red No. 6 (may be use in combination; total not more than 5mg/day) | 15850 |
| 22. | Lithol Rubin B CA/ D & C Red No. 7 (may be used in combination; total not more than 5mg/day) | 15850:1 |
| 23. | D & C Red No. 31 (external use only) | |
| 24. | Deep Maroon/ D & C Red No. 34 (external use only) | 15880:1 |
| 25. | D & C Red No. 39 (external use only, not more than 0.1%) | |
| 26. | Uranine Acid Form/ D & C Yellow No. 7 (external use only) | 45350:1 |
| 27. | EXT. D & C Yellow No. 7 (external use only) | |
| 28. | Uranine Sodium Salt/ D & C Yellow No. 8 (external use only) | 45350 |
| 29. | Tartrazine/ FD & C Yellow No. 5/MA Yellow A-2/ Aluminic Lake (external use only) | 19140 |