APPENDIX 18

LIST OF PERMITTED, PROHIBITED AND RESTRICTED SUBSTANCES

IMPORTANT NOTE:

The following lists are by no means exhaustive.

Contents:

1. List of Prohibited and Restricted Active Ingredients and Combination

1.1 List of Prohibited Active Ingredients and Combinations

a) Specific Active Ingredients

b) Combinations

1.2 List of Restricted Active Ingredients and Combinations

a) Specific Active Ingredients

b) Combinations

2. List of Prohibited and Restricted Excipients

2.1 List of Prohibited Excipients

2.2 List of Restricted Excipients

3. List of Permitted and Restricted Colouring Agents

3.1 List of Permitted Colouring Agents

3.2 List of Restricted Colouring Agents

4. List of High-Risk Ingredients in Oral Liquid Dosage Forms That Require Diethylene Glycol (DEG) And Ethylene Glycol (EG) Testing

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.	17-Hydroxyprogesterone Caproate (17-OHPC)
3.	Aristolochic Acid
4.	Aminopyrine/ Amidopyrine
5.	Astemizole
6.	Bacillus Coagulans
7.	Berberine
8.	Butobarbitone
9.	Chlormezanone
10.	Cisapride
11.	Conjugated Linoleic Acid
12.	Crinis Carbonisatus
13.	Danthron
14.	Dipyrone
15.	Enterococcus Faecalis
16.	Enterococcus Faecium
17.	Ethenzamide
18.	Euflavine
19.	Furazolidone
20.	Fenfluramine/ Dexfenfluramine
21.	Gadodiamide

NO.	PROHIBITED ACTIVE INGREDIENTS
22.	Gentian Violet
23.	Gamma-Butyrolactone (GBL)
24.	Gamma-Aminobutyric Acid (GABA)
25.	Gamma-Hydroxybutyric Acid (GHB)
26.	Haloquinol
27.	Hexachlorophene
28.	Mercurochrome
29.	Nimesulide
30.	Novobiocin
31.	Oxyphenisatin Acetate/ Acetophenolisatin
32.	Oxyphenbutazone
33.	Pergolide
34.	Phenacetin
35.	Phenazone/ Antipyrine - Propylphenazone - Isopropylphenazone
36.	Phenylbutazone
37.	Phenylpropanolamine
38.	Pholcodine
39.	Piperazine
40.	Prenylamine
41.	Quinalbarbitone
42.	Salicylamide
43.	Sibutramine
44.	Stanozolol
45.	Sulphaguanide

NO.	PROHIBITED ACTIVE INGREDIENTS
46.	Thioridazine
47.	Tegaserod
48.	Terfenadine

b) <u>Prohibited Combinations</u>

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

NO.	PROHIBITED COMBINATIONS
8.	Combinations Containing Antacid and Surface Local Anaesthetic Agent
9.	Combinations Containing Dextropropoxyphene
10.	Combinations Containing Spironolactone
11.	Eye Drops Containing Vitamin
12.	Gripe Water Containing Alcohol
13.	Propanolol + Hydralazine
14.	Propanolol + 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: i) Oral Preparation in Combination with Paracetamol/ Acetaminophen or Combination with Ergotamine; and ii) Caffeine citrate preparations (solution for infusion and oral solution) indicated for the treatment of primary apnoea of premature newborns under the supervision of a physician experienced in neonatal intensive care.
11. Camphor	- Oral - External (>11%)
12. Codeine	Cough Syrup
13. Cocillana Liq. Extract	Expectorant
14. Cyproheptadine	Appetite Stimulant
15. Dextromethorphan	Single Active Ingredient in Tablet Form, including lozenges
16. Dihydrostreptomycin	Oral Antidiarrhoeals
17. Diphenoxylate	Liquid Oral Dosage For Anti-Diarrhoeal

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

Specific Active Ingredients	Not Allowed in the Specified Preparation(s) or Condition
45. Sulphonamides	Topical Use
46. Sulphur	All preparations Except External Preparation
47. Squill	Expectorant
48. Terpene Hydrate	Expectorant

Combinations	Not Allowed in the Specified Preparation(s)
1. Cough, Cold And Allergy Products Containing:	
i) Antimony Potassium Tartrate	Expectorant
ii) Allylisothiocyanate/ 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)	Limited to not more than 7.5mg/kg body weight/day
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) 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)	
c) Chloroform	Not allowed to be used as preservative or other function(s) except solvent.	

** 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)dlm.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 Oxychloride (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) • 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 (Limited to not more than 7.5mg/kg body weight/day)	19140

4. LIST OF HIGH-RISK INGREDIENTS IN ORAL LIQUID DOSAGE FORMS THAT REQUIRE DIETHYLENE GLYCOL (DEG) AND ETHYLENE GLYCOL (EG) TESTING

4.1	List of High-Risk Ingredients	Requirement
a)	Glycerin	Products in oral liquid dosage form that contain high-risk ingredients must be tested for Diethylene Glycol (DEG) and Ethylene Glycol (EG).
b)	Propylene Glycol (PG)	
c)	Polyethylene Glycol (PEG)	
d)	Sorbitol and Sorbitol Solution	
e)	Maltitol and Maltitol Solution	Limit: Not more than 0.1% (1000 ppm).
f)	Hydrogenated starch hydrolysate	
g)	Other sugar polyols synthesized via catalytic hydrogenation	The PRH/manufacturer may choose to conduct testing on either the ingredient or the finished product.

Note: The following lists above are by no means exhaustive.

For details on implementation, refer to **Directive No. 8, 2026**. *NPRA/600-1/9/13(2) Jld. 2 Direktif Keperluan Pengujian Kandungan Diethylene Glycol (DEG) dan Ethylene Glycol (EG) Dalam Bahan Aktif, Excipient dan / atau Produk Siap Berbentuk Dos Cecair Untuk Kegunaan Dalaman (Oral) Dengan Bahan Aktif / Excipient Berisiko* (10 February 2026).