NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

REGULATION OF DRUG AND FOOD CONTROL AGENCY

NUMBER 17 OF 2019

ABOUT

HEALTH SUPPLEMENT QUALITY REQUIREMENTS

BY THE GRACE OF GOD ALMIGHTY

HEAD OF THE FOOD AND DRUG CONTROL AGENCY,

Considering: a. that to protect the public from circulation
health supplements that don't match
quality requirements, need to be regulated regarding requirements
quality for health supplements;

b. that health supplement quality requirements
as referred to in letter a is
quality standards that must be applied in
making health supplements;

c. that based on consideration as is

referred to in letters a and b, it is necessary to stipulate Regulation of the Food and Drug Administration regarding Health Supplement Quality Requirements;

Remember : 1. Presidential Regulation Number 80 of 2017 concerning the Agency Drug and Food Control (State Gazette Republic of Indonesia of 2017 Number 180);

2. Regulation of the Food and Drug Supervisory Agency Number 26 2017 concerning Organization and Administration of Work Drug and Food Control (State Gazette of the Republic Indonesia of 2017 Number 1745);

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3. Regulation of the Food and Drug Supervisory Agency Number 12 2018 concerning Organization and Work Unit Procedures Technical Implementers within the Drug Supervisory Agency and Food (State Gazette of the Republic of Indonesia Year 2018 Number 784);
4. Regulation of the Food and Drug Supervisory Agency Number 16 2019 concerning Health Supplement Supervision (State Gazette of the Republic of Indonesia of 2019 Number 819);

DECIDING:

To stipulate: REGULATION OF DRUG AND FOOD CONTROL AGENCY ABOUT THE QUALITY REQUIREMENTS FOR HEALTH SUPPLEMENTS.

PIG

GENERAL REQUIREMENTS

article 1

In this Agency Regulation what is meant by:

1. Health supplements are products intended
to supplement nutritional needs, maintain,
improve and / or improve health function,
have nutritional value and / or physiological effects,
contains one or more ingredients in the form of vitamins,
minerals, amino acids and / or other materials not
plants that can be combined with plants.
2. Business Actor is the pharmaceutical industry, drug industry
traditional, small scale traditional medicine business, food industry,
importers and / or business entities in the marketing sector
Health Supplement owner or distribution permit holder.
3. Health supplement ingredients are active ingredients
have both benefits and additional ingredients
used in the manufacture of health supplements.
4. Material Active is component that
generate / have the intended benefits from
Health Supplements.

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5. Supplementary material is a supplement component
Health that is meant to help
formulate the active ingredients into different preparations

appropriate and proven safe and has no effect pharmacology.

6. The finished product is a product that has gone through the entire stages of the process of making Health Supplements.
7. Powder is a health supplement preparation in the form of homogeneous granules of suitable fine degree, intended for oral use .
8. Capsules are Health Supplement preparations wrapped in a shell in the form of a hard shell or soft shell.
9. Tablets or caplets are health supplement preparations compact, compact, pressed, in shape flat, cylindrical, or other shape tube, second the surface is flat or convex, with material dryer and / or suitable additives.
10. Effervescent is a health supplement solid preparation, contains sodium bicarbonate and its organic acids will react to produce carbon dioxide gas when put in the water.
11. Oral liquid is a health supplement preparation oil, solution, suspension or emulsion for oral use.
12. Chewable Tablet (*Gummy*) is a supplement preparation Health is a chewy solid that is made from gelatin and other suitable additives, purpose as a Health Supplement and not an ordinary food.
13. Maximum Limit of Good Manufacturing Method , hereinafter referred to as the CPB Maximum Limit, is the number of additives allowed is contained in Health supplements in moderation necessary to produce the desired effect.
14. Head of Agency is the Head of the Drug Control Agency and Food.

CHAPTER II

HEALTH SUPPLEMENT QUALITY REQUIREMENTS

Part One

General

Section 2

(1) Requirements for the quality of Health Supplements are requirements that have to be applied before and during Health Supplements in circulation.

(2) Business Actors are obliged to guarantee the Health Supplement made, imported, and / or distributed in the region Indonesia has met the quality requirements.

(3) Quality requirements as intended in paragraph (2) include:

a. Health Supplement Ingredients; and

b. Finished product.

(4) Health Supplement quality requirements must be appropriate with the provisions of the Indonesian Pharmacopoeia and / or Indonesian Herbal Pharmacopoeia.

(5) In the event that the Health Supplement quality requirements have not regulated in the Indonesian Pharmacopoeia and / or Pharmacopoeia Indonesian Herbal as referred to in paragraph (4) can be guided by:

a. Materia Medika Indonesia;

b. United States Pharmacopeia, British Pharmacopeia, pharmacopoeia of other countries; and / or

c. international compendium / standards, references
scientifically recognized and / or valid scientific data.

The second part

Quality Requirements for Health Supplement Ingredients

Article 3

(1) Health Supplement ingredients consist of:

a. Active Ingredients; and

b. Additional Material.

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(2) Health Supplement ingredients as intended
in paragraph (1) which has the potential to contain contaminants and
may pose listed health risks
in Appendix I which is part of no
separated from this Agency Regulations.

Article 4

Active ingredients as referred to in Article 3 paragraph (1)
letter a in the form of a single composition or a combination in
a formula must consider safety aspects
and rationality.

Article 5

(1) Active ingredients used in making supplements
Health can come from natural ingredients.

(2) Active ingredients derived from natural ingredients as referred to

referred to in paragraph (1) which is used in
the manufacture of Health Supplements must be in the form of isolates, fractions and extracts.

(3) In the case of natural materials used in the process
making Health Supplements not in the form of extracts
as referred to in paragraph (2), must be accompanied
with the results of studies related to manufacturing technology, dosage and benefits.

Article 6

(1) The solvent used to extract materials
nature as referred to in Article 5 paragraph (1)
can be water, alcohol, and other types of solvents.

(2) In the case of solvents used in the process
extraction is a type of solvent other than water, must be
meet the solvent residue limit.

(3) The limit of solvent residue as referred to in paragraph
(2) listed in Attachment II which is a part
inseparable from this Agency Regulations.

Article 7

(1) Additional Materials as referred to in Article 3
paragraph (1) letter b which is permitted to be used in
the process of making Health Supplements can be
preservatives, sweeteners, colorants, antioxidants, flavors

and / or other additional materials in accordance with the provisions laws and regulations .

(2) Besides having to fulfill the provisions as referred to in paragraph (1), Additional Materials used must meet boundary requirements the maximum use of Additional Materials as listed in Appendix III which is a part inseparable from this Agency Regulations.

Part Three

Quality Requirements for Finished Products

Article 8

(1) Finished Products as intended in Article 2 paragraph (3) letter b is in the form of an oral preparation.

(2) The oral preparation as intended in paragraph (1) consists of on:

a. Powder;

b. Effervescent;

c. Tablets or Caplets;

d. Capsule; and

e. Oral fluids.

(3) Tablets or Caplets as referred to in paragraph (2) letter c includes:

a. Film-Coated Tablets or Caplets;

b. Sugar Coated Tablets or Caplets;

c. Enteric Coated Tablets or Caplets;

d. Chewable Tablets or Caplets;

e. Suction Tablets or Caplets;

f. Effervescent Tablets or Caplets;

g. Slow Release Tablets or Caplets; and

h. Chewable Tablets (*gummy)* .

(4) Capsules as referred to in paragraph (2) letter d include:

a. Hard capsule; and

b. Soft capsule.

(5) Oral fluids as referred to in paragraph (2) letter e include:

a. solution;

b. emulsion;

c. syrup; and

d. suspension.

Article 9

(1) Quality requirements for Finished Products as referred to referred to in Article 8 is in the form of test parameters.

(2) The test parameters as intended in paragraph (1) consist of on:

a. organoleptic;

b. water content;

c. disintegration / disintegration time;

d. dissolution;

e. uniformity of weight;

f. microbial contamination;

g. heavy metal contamination;

h. determination of alcohol content;

i. specific gravity and pH;

j. identification of active ingredients; and

k. determination of active ingredients.

(3) The test parameters as intended in paragraph (2)

listed in Appendix IV which is a part
inseparable from this Agency Regulations.

Article 10

(1) Finished Products that state certain benefit claims
a qualitative identification test can be carried out on the material

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chemical with medicinal, psychotropic, narcotic and / or medicinal properties other addictive substances.

(2) Claims of certain benefits as referred to in paragraph
(1) listed in Appendix V which is a part
inseparable from this Agency Regulations.

Article 11

(1) Fulfillment of the finished product quality requirements as referred to
referred to in Article 9 paragraph (1) is proven by
laboratory testing.

(2) The test as referred to in paragraph (1)
implemented by:
a. an accredited laboratory; or
b. industrial laboratories that have Way certificates
Good Manufacture.

Part Four

Assessment

Article 12

(1) In the event that the Health Supplement quality requirements have not regulated in this Agency Regulation, Business Actors must apply for assessment in advance to the Head of the Agency through the Director of Standardization Traditional Medicine, Health Supplements and Cosmetics.

(2) Submission of application for assessment as referred to referred to in paragraph (1) shall be submitted in writing.

(3) A written application as referred to in paragraph (2) must be accompanied by complete data as referred to listed in Appendix VI which is a part inseparable from this Agency Regulations.

(4) Against submission plea assessment as referred to in paragraph (1) which has been stated Fulfill completeness document as referred to in paragraph (3) shall be evaluated.

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Article 13

(1) The Head of the Agency submits a decision on the evaluation results as referred to in Article 12 paragraph (4) at the most 85 (eighty five) working days as of the assessment request document is received by complete.

(2) The decision as referred to in paragraph (1) shall be in the form of:

a. approval; and

b. denial.

CHAPTER III

TRANSITIONAL PROVISIONS

Article 14

Business Actors in the field of Health Supplements who have
obtain a distribution permit prior to the enactment of the Agency Regulations
this must comply with the provisions in the Regulations
This agency is no longer than 2 (two) years from the time of the Regulation
This agency is promulgated.

CHAPTER IV

CLOSING

Article 15

All Food Supplements that have been numbered
distribution permits that existed before this Agency Regulation came into effect,
should be interpreted as a Health Supplement, as long as it is not
contrary to this Agency Regulation.

Article 16

This Agency Regulation comes into force on the date
invited.

APPENDIX I
REGULATION OF DRUG AND FOOD CONTROL AGENCY
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ABOUT
HEALTH SUPPLEMENT QUALITY REQUIREMENTS

POTENTIAL HEALTH SUPPLEMENT INGREDIENTS

CONTAINS THAT RISK TO HEALTH RISKS

Source Material	Contamination	Limitation
Blue-green algae (BGA), Aphanizomenon flos-aquae	Cyanobacterial Toxins Microcystin-LR (MC-LR)	0.02 µg MC-LR / kg bb / day
Material from animals that is suspected contains hormones	Hormone	Negative
The results of the oxidation reaction on the oil material	Oil material not from sea animal	Pharmacopoeia compliant
	Peroxide value (PV)	≤ 5 mEq / kg
	AV Anisidine value (AV)	≤ 20 mEq / kg
	TOTOX Value (oil's overall oxidation state) (2X PV + AV)	≤ 26 mEq / kg
Derived product from bees and derivatives	Chloramphenicol	Negative

HEAD OF THE FOOD AND DRUG CONTROL AGENCY,

sgd.

PENNY K. LUKITO

APPENDIX II
REGULATION OF DRUG AND FOOD CONTROL AGENCY
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ABOUT
HEALTH SUPPLEMENT QUALITY REQUIREMENTS

EXTRACTION SOLUTION RESIDENCE LIMITS

Solvent	**Maximum Residual Solvent Limit in the End Product**
Ethanol	1% or 10,000 ppm
n-Hexane	0.029% or 290 ppm
Ethyl acetate	0.5% or 5,000 ppm

The use of solvents other than those mentioned above must be accompanied by a related study safety and benefits.

HEAD OF THE FOOD AND DRUG CONTROL AGENCY,

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APPENDIX III
REGULATION OF DRUG AND FOOD CONTROL AGENCY
NUMBER 17 OF 2019
ABOUT
HEALTH SUPPLEMENT QUALITY REQUIREMENTS

MAXIMUM LIMITS OF USE OF ADDITIONAL MATERIALS

Use of Additives in Health Supplements must be appropriate

provisions:

a. Products with a reconstitution process (eg effervescent products), use additives are counted towards ready-to-consume products, except ingredients preservative.

b. The use of a combination of additives follows the ratio requirements usage is less than or equal to 1 (one).

Type of Additional Material

A. Dyes

No.	Natural Dyes	INS / CAS	Synonym	Limit (mg / kg product)
1.	Caramel III - Ammonia process	150c	Ammonia caramel	20,000
2.	Caramel IV - Sulphite Ammonia process	150d	Ammonia sulfite caramel	20,000
3.	Carmines	120	- Carmine - CI (1975) No. 75470 - CI Natural Red 4 - Cochineal carmine	300
4.	Carotenes, beta	160a (ii)	- Carotenes-natural - CI Food Orange 5 - Mixed carotenes - Natural beta-carotene	600
5.	Carotenal, beta-apo-8 '	160e	CI. Food Orange 6	300
	beta-Carotenes (*Blakesela trispora*)	160a (iii)	CI. Food Orange 5	
	beta-Carotenes (synthetic)	160a (i)	CI. Food Orange 5	

No.	Natural Dyes	INS / CAS	Synonym	Limit (mg / kg product)
	Carotenoic acid, ethyl ester, beta-apo-8'-	160f	CI. Food Orange 7 (Ethyl Ester)	
6.	Chlorophylls, Copper Complexes	141 (i)	- CI (1975) No. 75810 - CI Natural Green 3 - Copper chlorophyll - Copper phaeophytin	500
7.	Chlorophyllin copper complexes, potassium, and sodium salts	41 (ii)	- CI (1975) No. 75810 - Potassium copper chlorophyllin - Sodium copper chlorophyllin	500
8.	Grape Skin Extract	163 (ii)	- ENO - Enociania	500
9.	Riboflavin from *Bacillus subtilis*	101 (iii)	-	300
	Riboflavin 5 '- sodium phosphate	101 (ii)	- Vitamin B2 Ester Monosodium Salt	
	Riboflavin, synthetic	101 (i)	- Riboflavin 5'- phosphate ester monosodium salt - Vitamin B2 phosphate ester monosodium salt	
10.	Curcumin	CI. 75300 Curcumin		CPB
11.	Vegetable Carbon	153 CI. 77266	Plant carbon	CPB
12.	Anato extract (bixin based)	CI. No. 75120	*Annatto extracts, bixin based*	CPB
13.	Red beet (*Beet red*)			CPB
14.	Anthocyanins		*Anthocyanins*	CPB
15.	Titanium dioxide	CI. No. 77891	*Titanium dioxide*	CPB

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No.	Synthetic Dyes	INS / CAS	Synonym	Limit (mg / kg product)
1.	Allura Red AC	129	- CI (1975) No. 16035 - CI Food Red 17 - FD&C Red No. 40	300
2.	Brilliant Blue FCF	133	- CI (1975) No. 42900 - CI Food Blue 2 - FD&C Blue No. 1	300
3.	Fast Green FCF	143	- CI Food Green 3 - CI (1975) No. 42053 - FD&C Green No.3	600
4.	Indigotine (Indigo carmine)	132	- CI Food Blue 1 - CI (1975) No. 73015 - FD&C Blue No. 2 - Indigo Carmine	300
5.	Iron oxide, black	172 (i)	- CI Pigment Black 11 - CI (1975) No. 77499	7,500
	Iron oxide, red	172 (ii)	- CI Pigment Red 101 - CI Pigment Red	

		102 - CI (1975) No. 77491	
Iron oxide, yellow	172 (iii)	- CI Pigment Yellow 42 - CI Pigment Yellow 43 - CI (1975) No. 77492	
6. Ponceau 4R (Cochineal Red A)	124	- CI Food Red 7 - Cochineal Red A. - New Coccine	300

No.	Synthetic Dyes	INS / CAS	Synonym	Limit (mg / kg product)
7.	Sunset Yellow FCF	110	- CI (1975) No. 15985 - CI Food Yellow 3 - Crelborange S - FD&C Yellow No. 6	300

Examples of using dye mixes:

Dye	Maximum Limit (mg / kg)	Use on Product (mg / Kg)	Calculation
Chlorophyll CI. No. 75810	500	X	X / 500

Blue FCF diamond CI No. 42090	300	Y	Y / 300

(X / 500) + (Y / 300)

B. Sweetener

No.	Natural Sweetener	Maximum Limit (mg / kg)
1.	Cane sugar (sugar), palm sugar, sugar coconut, sugar beet, stevia leaf, saga leaf, legi wood, and other natural sweeteners	CPB
2.	Sorbitol (*Sorbitol*) Sorbitol Syrup (*Sorbitol syrup*)	CPB
3.	Manitol (*Mannitol*)	CPB
4.	Isomalt / Isomaltitol (*Isomalt / Isomaltitol*)	CPB
5.	*Steviol glycosides* (*Steviol glycosides*)	2500 steviol equivalent
6.	Maltitol (*Maltitol*) Maltitol syrup (*Maltitol syrup*)	CPB
7.	Lactitol (*Lactitol*)	CPB
8.	Silitol (*Xylitol*)	CPB
9.	Erythritol (*Erythritol*)	CPB

Steviol Equivalence Calculation Formula

$$[\ SE\ ] = \Sigma\ ([\ SG\ ] \times CF\ )$$

Information:

[SE] = Equivalent levels of steviol (*Steviol Equivalents*)

[SG] = *Steviol* glycoside levels (*Steviol Glycoside*)

CF = Steviol Glycoside *Conversion Factor* (*Conversion Factor*)

Steviol Glycoside Conversion Factor (CF)

Types of Steviol Glycosides	Conversion Factor Steviol Glycosides
Dulcoside A	0.40
Rebaudiosida A.	0.33
Rebaudiosida B	0.40
Rebaudiosida C	0.33
Rebaudiosida D	0.28
Rebaudiosida F	0.34
Rubusosida	0.50
Steviol	1.00
Steviolbiocides	0.50
Stevioside	0.40

No.	Artificial sweeteners	INS / CAS	Synonym	Limit (mg / kg product)
1.	Acesulfame Potassium	950	- Acesulfame K	2,000
2.	Aspartame	951	- APM - Aspartyl phenylalanine methyl ester	5,500
3.	Cyclamic acid	952 (i)	- Cyclohexylsulfa-mic acid	1,250 mg / kg as acid cyclamate
	Calcium cyclamate	952 (ii)	-	
	Sodium cyclamate	952 (iv)	-	

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No.	Artificial sweeteners	INS / CAS	Synonym	Limit (mg / kg product)
4.	Neotame	961	-	90
5.	Saccharin Calcium Saccharin Potassium saccharin Sodium Saccharin	954 (i) 954 (ii) 954 (iii) 954 (iv)		1,200 mg / kg as saccharin
6.	Sucralose (Trichlorogalactosu-crose)	955	- 4,1 ', 6'-trichlorogalacto-sucrose	2,400

Examples of using sweetener blends:

Sweetener	Maximum Limit (mg / kg)	Use on Product (mg / Kg)	Calculation
Aspartame	5500	X	X / 5500
Sucralose	2400	Y	Y / 2400
			(X / 5500) + (Y / 2400)

C. Preservatives

No.	Common Name	INS / CAS	Synonym	Limit (mg / kg product)
1.	Methyl paraben	218 / 99-76-3	- E218 - 4-hydroxybenzoic acid methyl ester - methyl p-hydroxy-benzoate - Nipagin M	- Oral preparations: 2,000 - Soft capsules: 2,000 counted as a product so

			- Uniphen P-23	
2. Ethyl paraben			- ethyl p-hydroxy-benzoate	- Oral preparations: 2000 - Soft capsules: 2000 counted as a product so
3. Benzoic acid		210	-	2,000 counted as acid benzoate
Sodium benzoate		211	-	
Potassium benzoate		212	-	
Calcium benzoate		213	-	

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No.	Common Name	INS / CAS	Synonym	Limit (mg / kg product)
4. Bronopol		52-51-7	- 2-Bromo-2-nitro-1,3-propanediol - β-Bromo β-nitrotrimethylene-glycol - Myacide	1,000 (w / v)
5. Propionic acid, Propionic Na, Propionic Potassium, Propionic Calcium		79-09-4	- E280 - Carboxyethane - Ethanecarboxylic AC ID - Ethylformic acid - Metacetonic acid - Methylacetic acid - Propanoic acid - Pseudoacetic acid	10000 counted as acid propionate
6. Sorbic Acid		200	-	2000 counted

Sodium sorbate	201	-	as acid
Potassium sorbate	202	-	sorbat
Calcium sorbate	203	-	

Examples of using preservative mixes:

Preservative	Maximum Limit Use (mg / kg)	Use on the Product (mg / kg)	Calculation
Benzoic acid	2,000	X	X / 2,000
Sorbic acid	2,000	Y	Y / 2,000
			(X / 2,000) + (Y / 2,000)

D. Antioxidants

No.	Antioxidants	INS / CAS	Synonym	Maximum Limit
1.	α-Tocopherol	59-02-9	- Vitamin E - D-α-Tocopherol - Phytogermine - (2R, 4'R, 8'R) -α-Tocopherol	500 mg / kg of product (used on formula based fat; v / v)

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No.	Antioxidants	INS / CAS	Synonym	Maximum Limit
2.	Ascorbic acid	50-81-7	- L-Ascorbic acid - L-Theroascorbic AC ID	1,000 mg / kg of product (used on water based formula; w / v)

		- Vitamin C	
3. - Ascorbil palmitate *(Ascorbyl palmitate)* - Ascorbil stearate *(Ascorbyl stearate)*	137-66-6	- L-Ascorbyl 6-palmitate - 6-O-palmitoyl ascorbate	500 mg / kg of product (as Ascorbil stearate)
4. *Butylated hydroxyanisole* (BHA)	10605-09-1	- 6- (Stearoyloxy) - L-ascorbic acid - 6 -O-Stearoyl-L-ascorbic Acid - 2 - (3,4-dihydroxy-5-oxo-2,5-dihydrofuran-2-yl) -2-hydroxyethyl octadecanoate	400 mg / kg of product (for formulas fat-based or oil), single or can combined with BHT and / or propyl error.
5. *Butylated hydroxytoluene* (BHT)	128-37-0	- 2, 6-Di-tert-butyl-4-methylphenol - Butylated hydroxytoluene - Topanol	400 mg / kg of product (for formulas fat-based or oil), single or can combined with the BHA and / or propyl errors
6. Butyl hydroquinone tertiary / TBHQ (*Tertiary butylhydroquinone)*	-	-	400 mg / kg of product (for formulas fat-based or oil), single or can combined with the BHA and / or BHT

No.	Antioxidants	INS / CAS	Synonym	Maximum Limit
7.	Propyl error *(Propyl gallate)*	121-79-9	- Propyl 3,4,5-trihydroxyben-zoate - N-Propyl gallate - Benzoic acid, 3,4,5-trihydroxy-, propyl ester - 3,4,5-Trihydroxyben-zene-1-propylcarboxylate - 3,4,5-Trihydroxybenzo-ic acid propyl-ester	400 mg / kg of product (for formulas fat-based or oil), single or can combined with the BHA and / or BHT.
8.	- Calcium disodium ethylene diamine tetraacetate (*Calcium disodium ethylenedia Minetetra acetate*)	62-33-9	- Edetate calcium disodium - Edta, disodium calcium salt trihydrate - Dipotassium 2-[9-(carboxylatomethyl) -4,11-dioxo-1,3-dioxa-6,9-diaza-2-calcacycloundecan-6-yl] acetate	150 mg / kg of product (as Calcium ethylene disodium diamine tetraacetate)
	- Disodium ethylene diamine tetraacetate *(Disodium ethylenedia Minetetra acetate)*	6381-92-6	- EDTA disodium salt - EDTA-Na2 - Sequestrene Na2	

Examples of using antioxidant blends:

Antioxidants	Maximum Limit (mg / kg)	Use on Product (mg / Kg)	Calculation
BHA	400	X	X / 400
BHT	400	Y	Y / 400
			(X / 400) + (Y / 400)

E. Taste

Refer to the prevailing laws and regulations.

F. Other Additives (Anti-stick, Emulsifier, Coating, Stabilizer, Solvent and others)

No.	Other Additional Materials	Maximum Limit
1.	Castor oil (*Ricinus oil*)	1,000 mg / kg of product
2.	Cetyl alcohol *(Cetyl alcohol)*	100,000 mg / kg of product (as coating, emulsifier)

3.	Diacetyl tartaric (*Diacetyltartaric*) and esters fatty acids than glycerol	5,000 mg / kg of product
4.	Magnesium stearate	50,000 mg / kg of product (as lubricant)
5.	Phosphate	2,200 mg / kg product (as phosphorus).
6.	Polidimethylsiloxane	50 mg / kg of product
7.	Polyethylene glycol	70,000 mg / kg of product
8.	- Polyoxyethylene (20) sorbitan monolaurate (Polysorbate 20) - Polyoxyethylene (20) sorbitan monooleate (Polysorbate 80) - Polyoxyethylene (20) sorbitan monopalmitate (Polysorbate 40) - Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60) - Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65)	25,000 mg / kg of product

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No.	Other Additional Materials	Maximum Limit
9.	Polyvinyl alcohol *(Polyvinyl alcohol)*	45,000 mg / kg of product (as coating and stabilizer)
10.	Potassium citrate *(potassium citrate)*	20,000 mg / kg of product (as an *alkalizing agent*,

	buffering agent, and sequestering agent)
12. Sucroglycerides (*Sucroglycerides*)	2,500 mg / kg of product
13.Titanium dioxide (TiO_2)	qs as a dye
14. Dextrin	qs as a filler
15. Avicel	qs as a filler
16. Amylum	qs as a filler

Additional materials that have not been regulated in this regulation can be referred to to the prevailing laws and regulations.

HEAD OF THE FOOD AND DRUG CONTROL AGENCY,

sgd.

PENNY K. LUKITO

ANNEX IV
REGULATION OF DRUG AND FOOD CONTROL AGENCY
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ABOUT
HEALTH SUPPLEMENT QUALITY REQUIREMENTS

PRODUCT QUALITY REQUIREMENTS

➢ Quality requirements for Health Supplement Finished Products as appropriate listed in the Indonesian Pharmacopoeia monograph or pharmacopoeia other international.

➢ If not listed in the monograph, the quality requirements of the finished product refer to the following table:

Shape Preparations	**ptik ole na rgO**	**ir dar aK**	**A. si rag te in Dis**	**ur) cn aH tu ka (W**	**si * olu Dis**	**n ma ag sera eK**	**bot * Bo**	**a nra ma Ce**	**ikrob M**	**ma og L n pa ma Ce**	**tightly B**	**n t ra Be**	**pH Type**	**na tu ne da P**	**ol oh dar aK**	**si a spe n e Al Id**	**tif k A pific ah a B**	**pan ta e n e P**	**dar a a K**
Tablet, caplet, capsule	V	V	V		V	V		V		V						V		V	
Capsule soft	V		V			V		V		V						V		V	
Powder	V	V						V		V						V		V	
Powder Effervescent	V	V						V		V						V		V	
Tablet Effervescent	V	V						V		V						V		V	
Gummy	V	V						V		V						V		V	
Fluid Oral (Solution, Emulsion, Syrup,	V							V		V		V		V		V		V	

Suspension)

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Explanation:

1. Organoleptic

Observations were made on shape, taste, smell and color.

2. Water Content

a. The limit of water content for non-liquid preparations is 10%.

b. Checking the water content is necessary if the material is classified as hygroscopic.

c. Inspection of water content is greatly influenced by the nature of the active ingredient especially materials containing crystalline water.

d. Checking the moisture content is not necessary if:

(1) the finished product is in the form of deep effervescent tablets / tablets the manufacturing process when the *critical point* has been carried out examination; and / or

(2) the dosage form is a soft shell capsule.

e. Check moisture content for certain materials such as ingredients contains crystalline water or essential oil, is carried out the examination using the toluene (azeotropic) or Karl Fisher distillation method (titrimetric).

f. If quality assurance does not measure moisture content then it is necessary ensuring the potential and stability of the product by doing

examination for microbial contamination.

3. Disintegration (Breaking Time)

a. Capsule : ≤ 30 minutes

b. Soft capsule : ≤ 60 minutes

c. Uncoated tablet / caplet: ≤ 30 minutes

d. Sugar coated tablet : ≤ 60 minutes

e. Film coated tablet : ≤ 60 minutes

f. Enteric coated tablets : not destroyed within 120 minutes
in acid solution and so on
crushed ≤ 60 minutes in a buffer solution
phosphate

g. Effervescent tablets : ≤ 5 minutes

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4. Dissolution

a. This test is to measure the release of the active substance (usually the active ingredient single) on the claiming solid dosage form (tablet / capsule)
controlled release of active substances.

b. Checking the levels of active substances is carried out at one point (*Single-point measurements*) when the preparation is the same dosage form
claiming to dissolve quickly.

c. The level at some points (*multiple-point measurements*)
if the preparation is a dosage form with the release of the active substance
under control (*time release, extended release*).

For example :

Time release health supplements containing water soluble vitamins or which is combined with water soluble vitamins, then the test is done to:

a. representatives of water soluble vitamins; and / or

b. if it contains folic acid, the priority for testing is folic acid.

5. Uniformity of Weight

Required for *sustained release* tablets or capsules .

6. Microbial Contamination

The test is carried out in accordance with the Pharmacopeia or Monograph.

Unless otherwise stated requirements refer to the following table:

		Allowable Criteria and Limits		
No.	**Type of preparation**	**ALT (CFU / g or CFU / ml)**	**AKK (CFU / g or CFU / ml)**	**Specific microorganisms**
Health supplements contain herbs				
	A. Aqueous preparations B. Non Aqueous preparations	≤ 2 x 10^4	≤ 2 x 10^2	a. Eschericia coli: negative / g b. Salmonella spp: negative / 10 g c. Staphylococcus aureus: negative / g
Health supplements do not contain herbs				
A.	Aqueous preparations	≤ 2 x10^2	≤ 2 x10	*Escherichia coli* : negative / g
B.	Non Aqueous preparations	≤ 2 x10^3	≤ 2 x10^2	*Escherichia coli* : negative / g

7. Heavy Metal Contamination

Heavy Metal Types	Limit
Health supplements contain herbs	
Arsenic (As)	≤5 mg / kg or mg / L or ppm
Cadmium (Cd)	≤ 0.3 mg / kg or mg / L or ppm
Lead (Pb)	10 mg / kg or mg / L or ppm
Mercury (Hg)	≤ 0.5 mg / kg or mg / L or ppm
Health supplements do not contain herbs	

The test is carried out in accordance with the Pharmacopeia or Monograph

8. Determination of Alcohol Levels

a. Maximum limit of ethyl alcohol permitted in health supplements with a content not greater than 1% (one percent) in the form oral liquid preparations.

b. Determination of alcohol content by distillation or gas chromatography.

9. Identification of Active Ingredients

Health supplements containing herbs can be identified to the active ingredients by:

a. using marker compounds; or

b. use a *finger print* or a picture of the chromatographic pattern if not already marker compound is available.

10. Determination of Active Material Content

The concentration of the active ingredients is carried out on the materials used in the formula and composition according to the marking.

a. The determination of the active ingredient content is carried out by considering:

(1) active ingredient components that support the claim; and / or

(2) the most unstable active ingredient components.

b. Assignment of active ingredients in finished health supplement products carried out in accordance with point 10.a with the standard method or the results of the development of the method itself that has been validated.

c. Health supplement products contain multivitamin combinations
conducted determination of levels with priority on vitamins
has the fastest degradation rate, namely:

(1) Vitamin A or vitamin K, representing fat soluble vitamins; and / or

(2) Vitamin C or pyridoxine, represents water soluble vitamins.

d. Other active ingredients in health supplement products that are not tested
according to point 10.a, point 10.b and point 10.c, verification can be done
levels without testing *(quantified by input).* Verification
levels by means of *quantified by input*, which is a way of ascertaining levels
active ingredients when the test analysis method cannot go through
verification, the active ingredients that are included in the manufacturing process

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(batch record processing *records*) in accordance with the amount
listed on the marking.

HEAD OF DRUG AND FOOD CONTROL AGENCY

sgd.

PENNY K. LUKITO

APPENDIX V
REGULATION OF DRUG AND FOOD CONTROL AGENCY
NUMBER 17 OF 2019

ABOUT
HEALTH SUPPLEMENT QUALITY REQUIREMENTS

EXAMPLES OF SPECIFIC HEALTH SUPPLEMENT CLAIMS THAT CAN BE TESTED QUALITATIVE IDENTIFICATION OF MEDICINAL EFFECTS, PSYCHOTROPICS, NARCOTICS AND / OR OTHER ADDICTIVES

No.	Benefit claims	Qualitative Identification of
1.	Male / healthy male stamina	a) Sildenafil citrate, tadalafil, vardenafil HCl, thiodimetilsildenafil, hydroxyhomosildenafil, hydroxithiohomosildenafil. b) Yohimbine HCl
2.	Slimming / lowering fat content / diet	Sibutramin HCl, bisacodil, furosemide, hydrochlorothiazide, phenolphthalene
3.	Gym / fitness	a) Dexamethasone b) Liotironin

HEAD OF THE FOOD AND DRUG CONTROL AGENCY,

sgd.

PENNY K. LUKITO

APPENDIX VI
REGULATION OF DRUG AND FOOD CONTROL AGENCY
NUMBER 17 OF 2019
ABOUT
HEALTH SUPPLEMENT QUALITY REQUIREMENTS

ASSESSMENT APPLICATION FORM

FORM A (1 of 2)

APPLICATION LETTER

Number :

Subject :

Attachments:

Dear.

Head of the Food and Drug Administration

Cq. Director of Standardization of Traditional Medicines, Health Supplements and

Cosmetics

In accordance with the provisions of Article 12 of the Regulation of the Drug and Supervisory Agency

Food Number 17 of 2019 concerning Supplement Quality Requirements

Health, we hereby the undersigned:

Applicant's name :

Company name :

Company's address :

Contact Person :
Tel / Fax / E-mail :

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FORM A (2 of 2)

APPLICATION LETTER

apply as follows:

SK category : DOMESTIC DECREE / IMPORT SKILL / LICENSE *

Applications submitted **):

Thus we submit this letter, enclosed with forms and documents

supporter.

Thank you for your attention and cooperation.

Jakarta, ...
Applicant

(.....)
(Name, Signature & Stamp
Company)

*) cross the unnecessary ones

**) examples of applications submitted:

1. Composition Rationality
2. New Active Ingredients
3. New Additives
4. Certain Simplicia powders
5. Claims
6. etc.

FORM B (1 of 3)

A. GENERAL INFORMATION

1. Product / Material Name :

2. Product Data
    a. Dosage Form :
    b. Packaging :
    c. Distribution Permit Number :
    d. Composition :
    e. Usability proposed :
    f. Rules of Use proposed :
3. Registrant
    a. Registrant's name :
    b. Registrant Address :
4. Manufacturers
    a. Name of Manufacturer :
    b. Address of the Manufacturer :
5. If the license
    a. Name of Licensor :
    b. Address of Licensor

B. SPECIAL INFORMATION

1. History of use as a health supplement
2. Monograph of the standard compendial
3. Regulatory status in various countries
4. Data to support the safety of materials / products (toxicity test results, status international security, eg: JECFA, GRAS)
5. Data to support the benefits of materials / products (research results that have been published)
6. Other supporting documents, if needed.

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FORM B (2 of 3)

ADDITIONAL FORM OF FOOD SUPPLEMENT ACTIVE INGREDIENTS

INN *

Language
Indonesia *

Number
CAS *

Synonym *

Function *

Molecular Weight *

Dose
Common *

Limit
Maximum*

Bibliography *

AKG / ALG

General	Infants 0-6 Month	Child 7-11 Month	Children 1-3 Years	Pregnant Mothers	Breastfeeding
(2150 kcal)	(550 kcal)	(725 kcal)	(1125 kcal)	(2510 kcal)	(2615 kcal)

	SECURITY	
ADI	**NOAEL**	**LD50**

**) Data marked with an asterisk (*) is mandatory*

FORM B (3 of 3)

ADDITIONAL MATERIALS FORM

INN *

General Name *

INS Number *

CAS number *

Synonym *

Function *

Preparations *

Bibliography *

	MAXIMUM LIMITS	
Dosage form	**% b / b**	**% b / v% v / v% v / b**

	SECURITY	
ADI	**NOAEL**	**LD50**

**) Data marked with an asterisk (*) is mandatory*

HEAD OF THE FOOD AND DRUG CONTROL AGENCY,

sgd.

PENNY K. LUKITO