

F.No. 1-4/Nutraceuticals/FSSAI-2003
Food Safety and Standards Authority of India
(A statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110002

Dated: The 24th November, 2016

Subject: Direction under section 16(5) of Food Safety and Standards Act, 2006 regarding operationalisation of standards of Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food.

In exercise of the powers conferred under section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), the FSSAI has framed the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

2. Gazette publication of final regulations would take some more time as the regulations are being translated in Hindi. Considering that the regulations are final, the FSSAI has made the above regulations (as enclosed) operational with immediate effect (i.e. 24th November, 2016) in order to facilitate food businesses.

3. In exercise of the power vested under Sections 16(5) of Food safety and Standards Act, 2006, the Competent Authority hereby directs Food Safety Commissioners of States/ UTs to take note of these standards. The licenses now be issued under the categories of 13.3, 13.4, 13.5 and 13.6, as applicable.

4. This issues with the approval of the Competent Authority


24/11/2016

(Kumar Anil)
Advisor (Standards)

To

1. All Food Safety Commissioners,
2. All Authorized Officers, FSSAI,
3. All Designated Officers, FSSAI.

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI

[To be published in the Gazette of India, Extraordinary, Part III, Section 4]

Government of India
Ministry of Health Welfare and Family
Food Safety and Standards Authority of India

New Delhi, the 24th November, 2016

No. 1-4/ Nutraceutical/ FSSAI-2013.- As required by sub-section(1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006) the draft Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, and Novel Food) Regulations, 2015, was published vide notification of the Food Safety and Standards Authority of India No. 1-4/ Nutraceutical/ FSSAI-2013, dated the 30th July, 2015 in the Gazette of India, Extraordinary, Part III, Section 4.

The draft regulations were made available to the public on the 11th September, 2015. Objections and suggestions were invited from the persons likely to be affected within sixty days from the above mentioned date.

And whereas objections and suggestions received from the public within the specified period on the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (v) of sub-section (2) of section 92, read with sub-section (1) of section 22 of the Food Safety and Standards Act, 2006 (34 of 2006), the Food Safety and Standards Authority of India hereby makes the following regulations, namely:-

Regulations

- 1. Short title and commencement.** - (1) These regulations may be called the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.
(2) The enforcement of these regulations shall come into force from 1st January 2018.

2. Definitions.- In these regulations, unless the context otherwise requires,-

(a) "Act" means the Food Safety and Standards Act, 2006 (34 of 2006);

(b) "Food Authority" means the Food Safety and Standards Authority of India established under section 4 of the Act;

(c) "food for special dietary use" shall have the meaning assigned to it in section 22 of the Act;

(d) "food for special medical purpose" means food intended for -

(i) particular dietary use specially processed or formulated;

(ii) the dietary management of persons and used only under medical advice;

(iii) the exclusive or partial feeding of persons with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites; or

(iv) other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by food for specific nutritional use, or a combination of them;

(e) "food with added prebiotic ingredients" means food that contains added prebiotic ingredients which are non-viable food components that confer health benefits to the consumer by modulation of gut microbiota;

(f) "food with added probiotic ingredients" means food with live micro-organisms beneficial to human health, which when ingested in adequate numbers as a single strain or as a combination of cultures, confer one or more specified or demonstrated health benefits in human beings;

(g) "functional food" shall have the meaning assigned to it in section 22 of the Act;

(h) "health supplements" shall have the meaning assigned to it in section 22 of the Act;

(i) "non-food" means an ingredient or a substance which is not a 'food' as referred to in clause (j) of section 3 of the Act;

(j) "novel food" shall have the meaning assigned to it in section 22 of the Act;

(k) "nutraceuticals" shall have the meaning assigned to it in section 22 of the Act;

- (l) "**nutritional ingredients**" means the ingredients specified in **Schedules** other than the food additives specified in **Schedule VA to Schedule VF**, packed and made available in a form not for retail-consumer use, but meant for use in formulating a product falling under various categories of these regulations or other categories specified in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011;
- (m) "**nutrient ingredients**" means vitamins, minerals, and amino acids as specified in **Schedule I and Schedule II**;
- (n) "**pre-mixes**" means a combination of two or more ingredients specified in the Schedules in a specific proportion with or without additives, packed and meant for use in formulating a product falling under any category of these regulations or under the categories specified in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011;
- (o) "**specialty food containing plant or botanical ingredients**" means food which is shown to be containing plant or botanical ingredients with a history of safe usage; and
- (p) "**Schedules**" means the Schedules to these regulations.

3. General requirements.- (1) The articles of food sold in capsule format, hard or soft or vegetarian, shall comply with the general monograph and quality requirements specified for them in Indian Pharmacopoeia:

Provided that the food business operator may use the approved colours and additives permitted in **Schedule VF**;

Provided further that the food business operator may use the natural flavors or nature identical flavours or synthetic flavors in accordance with the provisions of regulation 3.3.1 of Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

- (2) For the purposes of sub-regulation (1) the food business operator may declare the addition of flavour on labels of such products in accordance with the provisions of Food Safety and Standards (Labelling and Packaging) Regulations, 2011.
- (3) The tablets, capsules and syrups shall fulfil the general quality requirements and standards as specified in Indian Pharmacopoeia, British Pharmacopoeia or United States Pharmacopoeia.
- (4) The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical

Research and in case such standards are not specified, the standards laid down by international food standards body, namely, Codex Alimentarius Commission, shall apply.

- (5) In case of food products falling under health supplement categories, the individual nutrient content shall not be less than fifteen per cent of the recommended daily allowance where a nutrient content claim is being made:

Provided that, if claim of higher nutrient content is made, the nutrient content shall not be less than thirty per cent of the recommended daily allowance.

- (6) For the articles of food specified in these regulations, the Food Authority may permit the food business operator to add food colours subject to the level restrictions as mentioned in Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

- (7) The articles of food with standard nutrient or nutritionally complete formulation shall consist of a composition delivering the desired level of energy, protein, vitamins and minerals, and other essential nutrients required for respective age group, gender and physiological stage in accordance with the guidelines made by the Indian Council of Medical Research.

- (8) The purity criteria for the ingredients used in the categories of articles of food covered under these regulations shall be as determined and notified in the official gazette by the Food Authority from time to time.

- (9) In case such standards are not specified, the purity criteria generally accepted by pharmacopoeias, namely, Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, relevant Bureau of Indian Standards Specifications, Quality Standards of Indian Medicinal Plants, Indian Council of Medical Research, British Pharmacopoeia, United States Pharmacopoeia, Food Chemical Codex, Joint Food and Agriculture Organization or World Health Organisation Expert Committee on Food Additives or CODEX Alimentarius may be adopted by food Business operators.

- (10) The food business operator shall intimate the purity criteria adopted for ingredients to the Food Authority including any change when adopted.

- (11) The tolerance limit for variation in case of articles of food covered in these regulations during analysis of samples of finished products, shall not be more than (-) ten per cent from the declared value of the nutrients or nutritional ingredients on the label.

(12) The manufacturing of ingredients and products covered under these regulations shall be carried out in compliance with the established good manufacturing practices.

(13) For purposes of these regulations, any of the ingredients specified in **Schedule I, Schedule II, Schedule III, Schedule IV, Schedule VI, Schedule VII, and Schedule VIII** may be used in food in accordance with the provisions of these regulations, and for the said purpose, may use additives as applicable to categories specified in **Schedule VA to Schedule VF**.

Explanation 1.- For the purposes of these regulations food or ingredients referred to in Food Safety and Standards Regulations, 2011, and for which standards are provided, and the plants and botanicals specified in **Schedule IV** of these regulations offered in normal or naturally occurring forms shall not constitute a health supplement or nutraceutical, or food for special dietary use or food for special medical purpose.

Explanation 2.- Mere food forms such as vegetables, namely, bhindi, karela and other vegetables; cereals, namely, ragi, jowar, millets and other cereals; legumes, namely, rajmah and other legumes; spices, namely, pepper, jeera, turmeric and other spices; fruits, namely, amla, jamun, grapes and other fruits; and other plants or botanicals, minimally processed (cleaned, de-weeded, sorted, dried or powdered), in either as juice or cooked form, shall not constitute 'health supplement' or 'nutraceutical' or 'food for special dietary use' or 'food for special medical purpose'.

(14) The formulation of articles of food shall be based on the principles of sound medicine or nutrition and supported by validated scientific data, wherever required.

(15) No hormones or steroids or psychotropic ingredients shall be added in any of the articles of food specified in these regulations.

(16) The label on articles of food shall specify the purpose, the target consumer group and the physiological or disease conditions which they address, recommended duration of use, and the specific labelling requirements as mentioned against each type of article of food.

(17) The label, accompanying leaflet or other labelling and advertisement of each type of article of food, referred to in these regulations shall provide sufficient information on the nature and purpose of the article of food and detailed instructions and precautions for its use, and the format of information given shall be appropriate for the intended consumer.

(18) An article of food which has not been particularly modified in any way but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated as 'health supplement' or 'special dietary' or 'special dietetic'

or by any other equivalent term, and such food may bear a statement on the label that 'this food is by its nature X' ('X' refers to the essential distinguishing characteristic as demonstrated by the generally accepted scientific data), provided that the statement does not mislead the consumer.

(19) The Food Authority may suspend or restrict sale of such articles of food as have been placed in the market that are not clearly distinguishable from articles of food for normal consumption and are not suitable for their claimed nutritional purpose, or may endanger human health, in accordance with the provisions of the Act.

(20) The Food Authority may, at any time, direct a food business operator manufacturing and selling such special type of article of food, to furnish details regarding the history of use of the novel or modified ingredients added and their safety evaluation.

(21) The mere combination of vitamins and minerals formulated in tablets, capsules, syrup formats shall not be covered in any of the categories of these regulations except when vitamins and minerals are added to an article of food or in a food format.

(22) The labelling on the article of food shall be in accordance with the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, and the specific labelling requirements provided in these regulations.

(23) The articles of food shall conform to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

(24) No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import any food products referred to in these regulations unless they comply with the requirements laid down in these regulations.

(25) Whoever contravenes the provisions of these regulations shall be liable for punishment provided under Chapter IX of the Act.

4. Claims. - (1) Every food business operator may make nutritional or health claims in respect of an article of food.

(2) For the purposes of sub - regulation (1), a nutritional claim shall consist of the 'Ingredients (nutrient or nutritional) content' of an article of food which shall be subject to the nutritional supplement requirements specified in **Schedule I, Schedule II, Schedule III, Schedule IV, and Schedule VI.**

(3) For the purposes of these regulations, health claim means any representation in respect of an article of food that states, suggests or implies that a relationship

exists between the constituent of that nutrient or nutritional, health, and specific disease conditions.

- (4) The health claim in respect of an article of food consists of the following two essential components, namely:-
- (i) nutrient or nutritional ingredients; and
 - (ii) health related benefits.
- (5) The health claim in respect of an article of food may include the following types, but not limited to
- (i) ingredients (nutrient or nutritional) function claims;
 - (ii) enhanced function claims;
 - (iii) disease risk reduction claims;
 - (iv) health maintenance claims;
 - (v) immunity claims – increased resistance (excluding vaccines); and
 - (vi) anti-ageing claims.
- (6) The other claims in an article of food that are not drug claims may be allowed subject to prior approval of the Food Authority.
- (7) The health claims in respect of an article of food shall be commensurate with the adequate level of documentation and valid proof made available for review by the Food Authority when called for.
- (8) To claim ingredients, nutrient or nutritional, in respect of an article of food for enhanced function and disease risk reduction, regard shall be had to-
- (i) claims that led to ingredients (nutrient or nutritional);
 - (ii) available scientific literature including official traditional texts and post market data or consumer studies or cohort or retroactive studies based on eating pattern and health benefits, epidemiological international and national data, and other well documented data;
 - (iii) consensual, congruent and concurrent validity studies;
 - (iv) health promotive and disease risk reduction based on proof from literature and human data of efficacy and safety of the nutrient;
 - (v) not only controlled clinical trials for efficacy and safety data; but also nutraepidemiological data;
 - (vi) qualified structure function claims for specific organ or function which are comprehensible to consumer;
 - (vii) prohibition of implied claims for curing disease or claims of drug like efficacy such as '*Prevents bone fragility in post menopausal women*';

- (viii) prohibition of implied cure for disease claims by the name of the product such as cancer cure or through pictures, vignettes or symbols, namely, electrocardiogram tracing, lipid profile; and
 - (ix) for structure-function claims, a case-to-case basis consumer information for specific age or gender or vulnerable population.
- (9) (i) For the product led claims in respect of an article of food based on human studies with evidence based data, regard shall be had to-
- (a) valid data and suitable statistical design proving the benefit for disease risk reduction, that is, human intervention studies;
 - (b) ingredient, that is, nutrient or nutritional;
 - (c) the product compatibility for the proposed claim benefit and suitable qualifiers such as *heart healthy* claim on polyunsaturated fatty acids;
 - (d) the use of word "shown" as depicted in the example below when a single human intervention study shows significant benefit:

"Product <Name of the Product> is 'shown' to be helping in <keeping your heart healthy> or <heart healthy>:"
 - (e) the use of word "Proven" as depicted in the example below when more than one human intervention studies or epidemiological evidence on Indian population have been provided with concurrent validity:

"Product <Name of the Product> is 'proven' <to make you lose weight>:"
- (ii) For health claims where scientific support does not exist, or if a novel ingredient is to be introduced, there shall be a prior approval of the Authority which shall be based on adequate scientific evidence.
- (iii) If the health claims are product led, the food business operator shall notify to the Food Authority before putting the same in the market, by submitting relevant documents along with a copy of the label.

5. General principles for query or challenge.-The food business operator shall-

- (i) prepare and make available the comprehensive product information, safety and claims support data and shall periodically get it reviewed and scrutinised by a scientist or expert with relevant qualifications and experience;
- (ii) attach the scientific view of the reviewer on claims and its veracity along with the qualification and experience of the reviewer as an essential part of the document;

- (iii) clarify, in case of a technical query from the Food Authority or on a public complaint lodged with the Food Authority, and assist the Food Authority to examine or authorise an appropriate expert group to review the case; and
- (iv) alter or modify or stop claim when directed by the Food Authority which shall be based on the opinion of an expert group.

6. Health supplements.- (1) (i) Health supplements may be used to supplement the normal diet of a person above the age of five years.

(ii) the health supplements shall contain concentrated source of one or more nutrients, namely, amino acids, enzymes, minerals, proteins, vitamins, other dietary substances, plants or botanicals, prebiotics, probiotics and substances from animal origin or other similar substances with known and established nutritional or beneficial physiological effect, which are presented as such and are offered alone or in combination, but are not drugs as defined in the clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder.

(iii) the health supplements shall be marketed in single use packaging as appropriate to maintain integrity and quality of the product, or in dosage forms namely, capsules, tablets, pills, sachets; jelly or gel, semi-solids and other similar forms or any other forms of liquids and powders designed to be taken in measured unit quantities.

(iv) the health supplements shall not include any of the food products or categories of articles of food for which specific standards have been laid down in any other parts of these regulations.

- (2) (i) The health supplements shall contain any of the ingredients specified in **Schedule I** or **Schedule II** or **Schedule IV** or **Schedule VII** or **Schedule VIII** or enzymes only of **Schedule VI**.
- (ii) The ingredients specified in the Schedules referred to in clause (i) of sub-regulation (2) may be used in manufacturing of health supplements without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
- (iii) The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not specified, standards laid down by the international food standards body, namely, Codex Alimentarius Commission shall apply.

- (iv) The food business operator shall apply to the Food Authority for inclusion of any new nutrient or other substance with a nutritional or physiological function, which has no history of use in India or that without evidence, establishing that the nutrient may result in certain nutritional and physiological benefits with justification for approval.
- (v) The Food Authority may, after proper scientific evaluation, specify the nutrients approved by it from time to time.
- (3) (i) The labelling, presentation and advertisement shall not claim that the health supplement has the property of preventing, treating or curing a human disease, or refer to such properties;
- (ii) The statement by the food business operator relating to the structure or function or the general well being of the body may be allowed by the Food Authority if the statement is supported by the generally accepted scientific data;
- (iii) Every package of health supplement shall carry the following information on the label, namely:-
 - (a) the words "HEALTH SUPPLEMENT";
 - (b) the common name of the health supplement, or a description sufficient to indicate the true nature of the health supplement including the common names of the categories of nutrients or substances that characterise the product;
 - (c) a declaration as to the amount of the nutrients or substances with a nutritional or physiological effect present in the product;
 - (d) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;
 - (e) the quantity of nutrients, where applicable expressed in terms of percentage of the relevant recommended daily allowances as specified by the Indian Council of Medical Research and bear a warning, "Not to exceed the recommended daily usage";
 - (f) a statement that the health supplement is not be used as a substitute for a varied diet;
 - (g) a warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and published product or drug interactions, as applicable; and

- (h) a statement that the product is required to be stored out of reach of children.
- (4) No food business operator shall use additives for health supplement formulation except those specified in **Schedule VA** or **Schedule VE** or **Schedule VF**.
- 7. Nutraceuticals.-** (1)(i) The nutraceuticals shall provide a physiological benefit and help maintain good health.
- (ii) A food business operator may extract, isolate and purify nutraceuticals from food or non-food sources, that is preparing amino acids and their derivatives by bacterial fermentation under controlled conditions.
- (iii) A food business operator may prepare and sell the nutraceuticals in the food-format of granules, powder, tablet, capsule, liquid, jelly or gel, semi-solids and other formats and may be packed in sachet, ampoule, bottle, and in any other format as measured unit quantities except those formats that are meant for parenteral administration.
- (2) (i) The nutraceuticals shall contain any of the ingredients specified in **Schedule I** or **Schedule II** or **Schedule IV** or **Schedule VI** or **Schedule VII** or **Schedule VIII**.
- (ii) A food business operator may use ingredients specified in the Schedules referred to in clause (i) of sub-regulation (2) in manufacturing an article of food containing nutraceuticals without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product;
- (iii) The quantity of nutrients added where applicable, shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not specified, the standard laid down by international food standards body, namely Codex Alimentarius Commission shall apply;
- (iv) A nutraceutical which is not provided in these regulations but its safety has been established in India or in any other country, shall be manufactured or sold in India only on prior approval of the Food Authority;
- (v) For the purposes of clause (iv), a food business operator shall apply to the Food Authority for approval which shall be accompanied by documented history of usage of at least fifteen years in India, or thirty years in the country of origin;
- (vi) The Food Authority may from time to time specify the nutraceuticals as approved by it after undertaking proper scientific evaluation.

- (3) (i) No ingredient other than those specified in **Schedule VI** shall be used as nutraceutical with standardisation to marker compounds specified and at daily usage levels specified therein;
- (ii) The ingredient for which the standardisation of the marker compound has not been specified shall comply with manufacturer specifications or quality requirements and purity criteria as specified in regulation 3;
- (iii) For the ingredient for which the daily minimum and maximum usage levels have not been specified, the food business operator shall adopt the usage level based on relevant scientific data and retain the documentary evidence of such data;
- (iv) For the purpose of clause (iii), the food business operator shall submit the documented scientific data to the Food Authority as and when called for;
- (v) No food business operator shall use the extract of ingredient as nutraceutical other than that specified in **Schedule IV**;

Provided that the ingredient of plant or botanical origin specified in **Schedule IV** and **Schedule VI** may be used either in the given form, or their extract, subject to the extractive ratios in relation to the daily usage value.

- (4) (i) The labelling, presentation and advertisement shall not claim that the nutraceutical has the property of preventing, treating or curing a human disease, or refer to such properties;
- (ii) The statement by the food business operator relating to the structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data;
- (iii) Every package of food containing nutraceutical shall carry the following information on the label, namely:-
- (a) the word "NUTRACEUTICAL";
- (b) the common name of the nutraceutical;
- (c) a declaration as to the amount of each nutraceutical ingredient in the product that either has a nutritional or physiological effect;
- (d) where it is appropriate, the quantity of nutrient shall be expressed in terms of percentage of the relevant recommended daily allowances as specified by the Indian Council of Medical Research even when the nutrient is present along with a nutraceutical as an adjunct and shall bear an advisory warning 'not to exceed the stated recommended daily usage';

- (e) an advisory warning for 'recommended usage' ;
 - (f) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;
 - (g) an advisory warning in cases where a danger may exist with excess consumption;
 - (h) an advisory warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable;
 - (i) a statement that the product is required to be stored out of reach of children;
- (5) No food business operator shall use additives for nutraceutical formulation except those specified in **Schedule VA** or **Schedule VE** or **Schedule VF**.

8. Food for special dietary use, other than infants, and those products intended to be taken under medical advice. - (1) No food business operator shall manufacture, formulate or process an article of food for special dietary use unless-

- (i) specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain physiological or specific health conditions, namely:-
 - (a) low weight, obesity, diabetes, high blood pressure;
 - (b) pregnant and lactating women; and
 - (c) geriatric population and celiac disease and other health conditions.
- (ii) The food business operator shall clearly indicate on the label whether or not the food for special dietary use is to be taken under medical advice;
- (iii) A food business operator may manufacture or sell an article of food for special dietary use in single use packaging or in dosage form, namely, granules, capsules, tablets, pills, jelly, semi-solid and other similar forms, sachets of powder, or any other similar forms of liquids and powders designed to be taken in measured unit quantities with a nutritional or physiological effect;
- (iv) A food business operator may formulate an article of food for special dietary use in formats meant for oral feeding through enteral tubes but shall not be used for parenteral use;
- (v) An article of food for special dietary use shall not include the normal food which is merely enriched or modified with nutrients and meant for mass consumption, intended for improvement of general health for day to day use and do not claim to be targeted to consumers with specific disease conditions and also not include

the article of food intended to replace complete diet covered under food for special medical purpose specified in regulation 9.

- (2) (i) The articles of food for special dietary use shall contain any of the ingredients specified in **Schedules I** or **Schedule II** or **Schedule III** or **Schedule IV** or **Schedule VI** or **Schedule VII** or **Schedule VIII**.
- (ii) A food business operator may use the ingredients specified in the Schedules referred to in clause (i) of sub-regulation (2) in manufacturing food for special dietary use without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
- (iii) For any new nutrient, which has no history of use in India or that without a proof establishing that the nutrient may result in certain nutritional and physiological benefits, the food business operator shall apply to the Food Authority with justification for approval, and the Food Authority may, from time to time specify the nutrients approved by it after proper scientific evaluation.
- (iv) A food business operator may add the quantity of the nutrients at a level higher than the recommended daily allowance, but not exceeding the limits of vitamins and minerals specified in **Schedule III**.
- (v) (i) The articles of food used as a formula food presented as a replacement for all meals of the daily diet for slimming, weight management and weight control purposes shall comply with the following, namely:-
- (a) provide energy not less than 800 kcal (3,350 kJ) and not more than 1,200 kcal (5,020 kJ);
 - (b) the individual portions or servings contained in the formula food shall provide approximately one-third or one-fourth of the total energy of the food in the pack depending on whether the recommended number of portions or servings per day is three or four, as the case may be, respectively.
- (ii) A formula food presented as a replacement for one or more meals of the daily diet shall comply with the following, namely:-
- (a) provide energy not less than 200 kcal (835 kJ) and not more than 400 kcal (1,670 kJ) per meal;
 - (b) when such products are presented as a replacement for the major part of the diet, the total energy intake shall not exceed 1,200 kcal (5,020 kJ).
- (iii) Not less than twenty five per cent and not more than fifty per cent of the energy available from the food, when ready-to-serve, shall be derived from its protein content and the total amount of protein shall not exceed 125 g per day.

- (iv) The quality of protein shall have-
 - (a) the protein digestibility corrected amino acid score of 1.0 known as, the reference protein;
 - (b) the protein digestibility corrected amino acid score where less than 1.0, the minimum level shall be increased to compensate for the lower protein quality;
 - (c) the protein with a protein digestibility corrected amino acid score of 0.8 or more shall be used in a formula food for use in a weight control diet; and
- (v) For improving the protein quality, the food business operator shall add only L-forms of essential amino acids except for methionine where DL form is allowed.
- (vi) Not more than thirty per cent of the energy available from fat and not less than three per cent of the energy from linoleic acid in the form of a glyceride.
- (vii) A formula food represented as a replacement for all meals per day, shall not have less than a hundred per cent of the recommended daily allowance of vitamins and minerals in the daily intake.
- (viii) The formula food for special dietary use shall have adequate dietary fiber.
- (3) (i) No statement or claim shall be made on the label implying prevention, cure or treatment of any specific disease or its diagnosis or otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, unless otherwise approved by the Food Authority;
- (ii) The statement by the food business operator relating to the structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data;
- (iii) Every package containing food for special dietary use shall carry the following information on the label, namely:-
 - (a) the words "FOOD FOR SPECIAL DIETARY USE" followed by "Food for....." (mentioning the particular physiological or health condition)";
 - (b) a statement "For weight control and management" in close proximity to the name of the articles of food specially prepared for weight management and control;
 - (c) a statement that the product is not to be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically advised;

- (d) a statement on the target consumer group, rationale for use of the product and a description of the properties or characteristics that make it useful;
 - (e) if the product has been formulated for a specific age group, a prominent statement to that effect;
 - (f) a statement specifying the nutrient which is reduced, deleted, increased or otherwise modified, relating to normal requirement, and the rationale for the reduction, deletion, increase or other modification;
 - (g) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;
 - (h) a warning in cases where a danger may exist with excess consumption;
 - (i) a warning that the product is not for parenteral use;
 - (j) a warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable;
 - (k) the quantity of nutrients expressed in terms of percentage of the recommended daily allowance where it is appropriate;
 - (l) information on osmolality or osmolarity or on acid-base balance where appropriate; and
 - (m) a statement that the product shall be stored out of reach of children.
- (4) No food business operator shall use additives for food for special dietary uses, except those specified in **Schedule VB** or **Schedule VE** or **Schedule VF**.

9. Food for special medical purpose.- (1) (i) Food for special medical purpose shall include food specially prepared for weight reduction and intended as total replacement of normal diet.

(ii) A food business operator may formulate food for special medical purpose in format meant for oral feeding through enteral tubes.

(iii) The articles of food for special medical purpose shall not be used for parenteral use.

(iv) The articles of food for special medical purpose, other than those intended for infants, may either be nutritionally complete food which, when used in accordance with the manufacturer's instructions, shall constitute the sole source of nourishment for the persons for whom they are intended or nutritionally

incomplete food with formulation specific for a disease, disorder or medical condition, but are not suitable to be used as the sole source of nourishment.

- (v) For the purposes of these regulations, the food for special medical purpose may be classified in to following three categories, namely:-
- (a) 'nutritionally complete food with a standard nutrient formulation', which when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;
 - (b) 'nutritionally complete food with a nutrient-adopted formulation specific for a disease, disorder or medical condition', which when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended; and
 - (c) 'nutritionally incomplete food with a standard formulation or a nutrient-adopted formulation specific for a disease, disorder or medical condition', which is not suitable to be used as the sole source of nourishment.

Note.- the food specified in sub-clauses (b) and (c) of clause (v) may be used as a partial replacement or as a supplement to the person's diet.

- (2) (i) Food for special medical purpose shall contain any of the ingredients specified in **Schedule I** or **Schedule II** or **Schedule III** or **Schedule IV** or **Schedule VII** or **Schedule VIII** or enzymes only of **Schedule VI**.
- (ii) A food business operator shall use only the ingredients specified in the Schedules referred to in clause (i) of sub-regulation (2) in manufacturing food for special medical purpose without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
- (iii) A food business operator may apply to the Food Authority for any new nutrient, which has no history of use in India or those without proof establishing that the nutrient may result in certain nutritional and physiological benefits with justification for approval and the Food Authority may from time to time specify the nutrients approved by it after proper scientific evaluation.
- (iv) The articles of food specially prepared for weight reduction and intended as total replacement of complete diet shall, apart from complying with **Schedule III**, shall also ensure the following, namely:-
- (a) that a formula food for very low energy diet is prepared according to instructions, with a daily energy intake of 450-800 kcal as the only source of energy;
 - (b) that not less than 50 g protein with a protein digestibility corrected amino acid score of 1 is present in the recommended daily intake of energy, and

essential amino acids may be added to improve protein quality only in amounts necessary for this purpose;

- (c) for the purposes of clause (b) the food business operator shall add only L-forms of essential amino acids except for methionine where DL form is allowed.
 - (d) very low energy diet provides not less than-
 - (I) 3 g of linoleic acid; and
 - (II) 0.5 g α -linolenic acid in the recommended daily intake with the α -linoleic acid and linolenic acid ratio between 1:5 and 1:15;
 - (e) very low energy diet provides not less than 50 g of available carbohydrates in the recommended daily intake of energy;
 - (f) that the formula food for special medical purpose have adequate dietary fiber.
- (v) In food for special medical purpose, nutrients may be added at levels higher than the recommended daily allowance, but not exceeding the limits of vitamins and minerals as specified in **Schedule III**.
- (3) Every package of food for special medical purpose shall carry the following information on the label, namely:-
- (a) the words 'FOOD FOR SPECIAL MEDICAL PURPOSE' printed in the immediate proximity of the name or brand name of the product;
 - (b) an advisory warning "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY" appearing on the label in bold letters in an area separated from other written, printed or graphic information;
 - (c) the statement "For the dietary management of _____" (*with the blank to be filled in with the specific disease, disorder or medical condition for which the product is intended, and for which it has been shown to be effective*) supported by appropriate scientific, and clinical or epidemiological data, and subject to its approval by the Food Authority;
 - (d) a statement 'NUTRITIONALLY COMPLETE' if the food is intended to be used as a nutritionally complete food;
 - (e) a statement on the rationale for use of the product by the target consumer group and a description of the properties or characteristics that make it useful;
 - (f) a statement if the product has been formulated for a specific age group;
 - (g) a statement specifying the nutrient which have been reduced, deleted, increased or otherwise modified, relating to normal requirements, and the rationale for the reduction, deletion, increase or other modification;

- (h) the quantity of nutrients expressed in terms of percentages of the recommended daily allowances, where it is appropriate;
 - (i) information on osmolality or osmolarity, Renal Solute Load, Potential Renal Solute Load or acid-base balance, wherever applicable;
 - (j) instructions for appropriate preparation, feeding, use and storage of the product after the opening of the container;
 - (k) a warning that the product is not for parenteral use; and
 - (l) a statement that the product required to be stored out of reach of children.
- (4) No food business operator shall use additives for food for special medical purpose except those specified in **Schedule VC** or **Schedule VD** or **Schedule VE** or **Schedule VF**.
- (5) No food business operator shall advertise the food for special medical purpose for use by general public.

10. Food with added probiotic ingredients. – (1) (i) No food business operator shall use probiotic ingredients in food except the probiotic culture of the microorganisms specified in **Schedule VII** or those probiotic microorganisms approved by the Food Authority from time to time. Probiotic preparations may contain added prebiotics permitted under these regulations.

- (ii) The viable number of organisms in food with added probiotic ingredients shall be $\geq 10^8$ CFU/g:

Provided that a lower viable number may be specified with proven studies on health benefits with those numbers subject to the prior approval of the Food Authority.

- (iii) The Food Authority may, from time to time, specify the probiotic microorganisms approved by it after proper scientific evaluation:

Provided that the presence of the commonly used starter cultures of lactic acid producing bacteria such as *Lactococcus spp.*, earlier known as *Streptococcus spp.*, *Lactobacillus spp.* and other such microorganisms used in the preparation of fermented milk (dahi) and related products shall not be considered as probiotics, if the probiotic properties have not been substantiated.

Note.- The guidelines issued by the Indian Council of Medical Research and Department of Biotechnology with respect to probiotics provide additional information on their use.

- (2) (i) The labelling, presentation and advertisement shall not claim that the probiotic food has the property of preventing, treating or curing a human disease, or refer to such properties.
- (ii) The statement by the food business operator relating to structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data.
- (iii) Every package of probiotic food shall carry the following information on the label, namely:-
- (a) the words "PROBIOTIC FOOD";
 - (b) genus and species including strain designation or culture collection number, where applicable, in brackets where probiotics are mentioned in the list of ingredients;
 - (c) viable numbers at the end of the shelf-life of probiotic strain corresponding to the level at which the efficacy is claimed;
 - (d) the recommended serving size which shall deliver the effective viable dose of probiotics related to health claims and recommended duration of use, proper storage temperature conditions, and time limit for 'Best Use' after opening the container;
 - (e) an advisory warning 'NOT FOR MEDICINAL USE' prominently written; and
 - (f) a warning or any other precaution to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable.
- (3) No food business operator shall use additives in probiotic preparations except those specified in **Schedule VA** to **Schedule VF**.

11. Food with added prebiotic ingredients.- (1) (i) No food business operator shall use prebiotics in manufacturing food containing prebiotics except those specified in **Schedule VIII** or those prebiotics approved by the Food Authority from time to time.

- (ii) The prebiotic component, not an organism, to which the claim of being made, shall be characterised for a given product by providing the source, origin, purity, chemical composition and structure, vehicle, concentration and amount in which it is to be delivered to the host.
- (2) (i) The labelling, presentation and advertising shall not claim that the prebiotic has the property of preventing, treating or curing a human disease, or refer to such properties.

- (ii) The statement by the food business operator relating to structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data.
- (iii) Every package of food containing prebiotics shall carry the following information on the label, namely:-
 - (a) the words "PREBIOTIC FOOD";
 - (b) name of prebiotic;
 - (c) the suggested or recommended serving size which shall deliver the effective dose of prebiotic related to the health claim;
 - (d) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;
 - (e) a warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable.
- (3) No food business operator shall use additives in prebiotic preparations except those specified in **Schedule VA to Schedule VF**.

12. Specialty food containing plant or botanical ingredients with safe history of usage.- (1) (i) A food business operator shall use only plant or botanical ingredients specified in **Schedule IV** for the preparation of specialty food containing plant or botanical ingredients.

- (ii) The plant or botanical ingredient which is not specified in these regulations but its safety has been established in India or in any other country, may be manufactured or sold in India only after taking prior approval of the Food Authority.
 - (iii) The application for approval to the Food Authority shall be accompanied by documented history of usage of at least fifteen years in India, or thirty years in the country of origin.
- (2) The health supplement or nutraceutical or food for special dietary use or food for special medical purpose may contain the ingredient as specified in **Schedule IV**, formulated either alone or in combination of ingredients or botanicals or their extracts either in unprocessed or in approved processed forms, formulated in a regular or conventional food format such as liquid or syrup, suspension or powder, granule, tablet or capsule or any other format approved by the Food Authority.

(3) (i) Every manufacturer or importer shall prepare and maintain a product information file, which shall contain information on the ingredients from **Schedule IV** used, finished product quality confirmation, and the test methods to demonstrate the presence of the active ingredient in the food.

(ii) The usage level of the specialty food containing plant or botanical ingredients shall not exceed those levels specified in **Schedule IV**:

Provided that the usage level may be distributed or provided, or formulated for delivery in one portion daily, or distributed in more than one portion to be taken in a day.

(iii) To use any other plant or botanical ingredient, which is not specified in **Schedule IV**, the food business operator shall seek prior approval of the Food Authority by submitting-

(a) a product information file containing information on the material used;

(b) quality confirmation, test methods to demonstrate the presence of the ingredient in the food;

(c) relevant published literature providing scientific and technical information of the material or product related to safety and health benefits; and

(d) any human intervention study published or conducted, and other relevant information.

(iv) The product information file shall be produced for inspection and review by the Food Authority as and when called for.

(v) The product information file shall primarily consist of technical and scientific information covering the following, namely:-

(a) information on quality of all raw ingredients with official scientific or botanical name;

(b) details of formulation or block diagram and brief description of the processing methods or steps adopted;

(c) shelf life study data;

(d) quality specifications and test methods for analysis of the finished product;

(e) safety and pharmacological information, literature base, and additional study, if any conducted;

- (f) information on human studies, if any;
 - (g) regulatory status in other countries, if any; and
 - (h) any other relevant product information.
- (4) No food business operator shall use additives for preparation of specialty food containing plant or botanical ingredients except those specified in **Schedule VE** or **Schedule VF**.

13. Novel food.- (1)(i) For the purposes of these regulations novel food is a food that-

- (a) may not have a history of human consumption; or
 - (b) may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or
 - (c) a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.
- (ii) No novel food shall be manufactured or imported for commercial purpose without the prior approval of the Food Authority by filing an application along with all relevant documents and details as specified by the Food Authority from time to time.

(2) The labelling of novel food shall be-

- (i) in accordance with the specific labelling requirements, if any; or
- (ii) specific to claims relating to the novel product; or
- (iii) as per the category notified by the Food Authority in the specific regulations.

Schedule - I

[See regulations 3.(13), 4.(2), 6.(2)(i), 7.(2)(i), 8.(2)(i) and 9.(2)(i)]

List of vitamins and minerals and their components

S.No.	Vitamins and Minerals		Components
A.	Vitamins-		
1.	Vitamin A	(i)	Retinol – all trans retinol
		(ii)	Retinyl acetate
		(iii)	Retinyl palmitate
2.	Provitamin A	(i)	Beta-Carotene
3.	Vitamin B₁	(i)	Thiamine chloride hydrochloride
		(ii)	Thiamine mononitrate
3.	Vitamin B₂	(i)	Riboflavin
		(ii)	Riboflavin 5'- phosphate, sodium
4.	Vitamin B₆	(i)	Pyridoxine hydrochloride
		(ii)	Pyridoxal 5'-phosphate
5.	Vitamin B₁₂	(i)	Cyanocobalamin
		(ii)	Hydroxocobalamin
6.	Vitamin C	(i)	L-ascorbic acid
		(ii)	Sodium-L-ascorbate
		(iii)	Calcium-L-ascorbate
		(iv)	Potassium-L-ascorbate
		(v)	6-palmitoyl-L-ascorbic acid
		(vi)	Ascorbyl palmitate
7.	Vitamin D	(i)	Vitamin D ₃ (cholecalciferol) – Animal source
		(ii)	Vitamin D ₂ (ergocalciferol) – Plant source
8.	Vitamin E	(i)	D-alpha-tocopherol
		(ii)	DL-alpha-tocopherol
		(iii)	D-alpha-tocopheryl acetate
		(iv)	DL-alpha-tocopheryl acetate
		(v)	D-alpha-tocopheryl acid succinate
		(vi)	DL-alpha-tocopheryl acid succinate
		(vii)	DL-alpha-tocopheryl polyethylene glesol succinate
9.	Vitamin K₁	(i)	Phylloquinone
		(ii)	Phytomenadione (2-methyl 3-phytyl-1)
		(iii)	1,4-napthoquinone

S.No.	Vitamins and Minerals		Components
		(iv)	Phytonamidione
9.	Vitamin K ₂ (MK-7)	(i)	Menaquinone
10.	Vitamin K ₂ (MK-4)	(i)	Menatetrenone
12.	Biotin	(i)	D-biotin
13.	Folic Acid	(i)	n-pteroyl-l-glutamic acid
14.	Niacin	(i)	Nicotinic acid
		(ii)	Nicotinamide
		(iii)	Nicotinic acid amide
15.	Pantothenic acid	(i)	D-pantothenate, calcium
		(ii)	D-pantothenate, sodium
		(iii)	D-panthenol
		(iv)	DL- pantholnol
		(v)	Sodium-D-pantothenate

Note.- Addition of appropriate overages to ensure adequate availability of vitamins in the products shall be permitted based on scientific rationale. However, the maximum proportion of overages shall not exceed as given in the Table 'C', below, unless scientifically justified. Labels of such products shall make a declaration of the same as "appropriate overages added" in the composition declaration Panel.

B.	Minerals (Chemical sources)		
1.	Calcium	(i)	Calcium carbonate
		(ii)	Calcium chloride
		(iii)	Calcium salts of citric acid
		(iv)	Calcium gluconate
		(v)	Calcium glycerophosphate
		(vi)	Calcium orthophosphate
		(vii)	Calcium hydroxide
		(viii)	Calcium oxide
		(ix)	Calcium phosphate, monobasic
		(x)	Calcium phosphate, dibasic
		(xi)	Calcium phosphate, tribasic
		(xii)	Calcium sulphate
		(xiii)	Calcium from algal source (<i>Algae calcarius</i>)
		(xiv)	Calcium lactate
2.	Chloride	(i)	Calcium chloride
		(ii)	Choline chloride
		(iii)	Magnesium chloride
		(iv)	Manganese chloride

S.No.	Vitamins and Minerals		Components
		(v)	Potassium chloride
		(vi)	Sodium chloride
3.	Chromium	(i)	Chromium (III) chloride
		(ii)	Chromium (III) sulphate
4.	Copper	(i)	Cupric carbonate
		(ii)	Cupric citrate
		(iii)	Cupric gluconate
		(iv)	Cupric sulphate
		(v)	Copper lysine complex
5.	Iodine	(i)	Sodium iodide
		(ii)	Sodium iodate
		(iii)	Potassium iodide
		(iv)	Potassium iodate
6.	Iron	(i)	Ferrous succinate
		(ii)	Ferrous citrate
		(iii)	Ferric ammonium citrate
		(iv)	Ferrous gluconate
		(v)	Ferrous fumarate
		(vi)	Ferric sodium di-phosphate
		(vii)	Ferrous lactate
		(viii)	Ferrous sulphate
		(ix)	Ferric di-phosphate
		(x)	Ferric saccharate
		(xi)	Ferrous bis glycinate
		(xii)	Hydrogen reduced iron
		(xiii)	Sodium iron EDTA
		(xiv)	Carbonyl iron
		(xv)	Ferrous orthophosphate
		(xvi)	Ferrous sodium pyrophosphate
		(xvii)	Elemental iron
		(xviii)	Electrolytic iron
7.	Magnesium	(i)	Magnesium aspartate
		(ii)	Magnesium carbonate
		(iii)	Magnesium chloride
		(iv)	Magnesium gluconate
		(v)	Magnesium phosphate dibasic (Magnesium

S.No.	Vitamins and Minerals		Components
			hydrogen phosphate)
		(vi)	Magnesium phosphate tribasic (Trimagnesium phosphate)
		(vii)	Magnesium oxide
		(viii)	Magnesium sulphate
8.	Manganese	(i)	Manganese carbonate
		(ii)	Manganese chloride
		(iii)	Manganese citrate
		(iv)	Magnanese sulphate
		(v)	Magnanese gluconate
		(vi)	As amino acid chelate
9.	Molybdenum	(i)	Ammonium molybdate (Molybdenum (VI))
		(ii)	Sodium molybdate (Molybdenum (VI))
		(iii)	As amino acid chelate
10.	Phosphorous	(i)	Potassium glycerophosphate
		(ii)	Potassium phosphate, monobasic
		(iii)	Potassium phosphate, dibasic
11.	Potassium	(i)	Potassium bicarbonate
		(ii)	Potassium carbonate
		(iii)	Potassium chloride
		(iv)	Potassium citrate
		(v)	Potassium gluconate
		(vi)	Potassium glycerophosphate
		(vii)	Potassium lactate
		(viii)	Potassium monobasic phosphate
		(ix)	Potassium dibasic phosphate
12.	Selenium	(i)	Sodium selenate
		(ii)	Sodium selenite
		(iii)	Sodium hydrogen selenite
		(iv)	Selenomethionine
13.	Sodium	(i)	Sodium bicarbonate
		(ii)	Sodium carbonate
		(iii)	Sodium chloride
		(iv)	Sodium citrate (Trisodium citrate)
		(v)	Sodium gluconate
		(vi)	Sodium lactate

S.No.	Vitamins and Minerals		Components
		(vii)	Sodium phosphate monobasic (Sodium dihydrogen phosphate)
		(viii)	Sodium phosphate dibasic (disodium hydrogen phosphate)
		(ix)	Sodium sulphate
14.	Zinc	(i)	Zinc acetate
		(ii)	Zinc chloride
		(iii)	Zinc citrate
		(iv)	Zinc gluconate
		(v)	Zinc lactate
		(vi)	Zinc oxide
		(vii)	Zinc carbonate
		(viii)	Zinc sulphate
15	Boron	(i)	Boron proteonate

Note- Suitable esters and salts of vitamins and salts and chelates of minerals may be used

Table C. Permissible overages*		
S.No.	Micronutrient	Overage (per cent)
1.	Vitamin A	30
2.	Vitamin C	20
3.	Vitamin D	30
4.	Vitamin E	10
5.	Thiamine (vitamin B ₁)	25
6.	Riboflavin (vitamin B ₂)	25
7.	Niacin (vitamin B ₃)	10
8.	Vitamin B ₆	25
9.	Vitamin B ₁₂	25
10.	Folic acid	25
11.	Pantothenic acid	10
12.	Vitamin K ₁	30
13.	Minerals	10
14.	Iodine	20

* Overage means the amount of excess nutrients added above label claim during manufacture as a means of maintaining at least the claimed amount of the ingredient(s) for the normal shelf life of the product to compensate for the expected manufacturing / storage loss and to allow for variation in assay performance. Where overages are more than those listed in **Schedule I, Table C**, the same shall be scientifically substantiated.

Schedule – II

[See regulations 3.(13), 4.(2), 6.(2)(i), 7.(2)(i), 8.(2)(i) and 9.(2)(i)]

List of amino acids and other nutrients

A. Essential Amino Acids			
(i)	L-Histidine	(xii)	L-Aspartic acid
(ii)	L-Histidine hydrochloride	(xiii)	L-Argine L-aspartate
(iii)	L-Isoleucine	(xiv)	L-Threonine
(iv)	L-Isoleucine hydrochloride	(xv)	L- Alanine
(v)	L-Leucine	(xvi)	L-Phenylalanine
(vi)	L-Leucine hydrochloride	(xvii)	L-Cyststeine hydrochloride
(vii)	L-Lysine	(xviii)	L-Tyrosine
(viii)	L-Lysine hydrochloride	(xix)	L-Arginine
(ix)	DL-Methionine	(xx)	L-Tryptophan
(x)	L-Cysteine	(xxi)	L-Valine
(xi)	L-Cysteine hydrochloride	(xxii)	L-Arginine hydrochloride
B. Non- Essential Amino Acids			
(i)	L-Carnitine	(xv)	L- Proline
(ii)	L-Carnitine hydrochloride	(xvi)	L-Lycine-L-glutamate dihydrate
(iii)	Carnitine, acetyl-L	(xvii)	Megnesium L- aspartate
(iv)	L-Glutamic acid	(xviii)	Calcium L- glutamate
(v)	L-Glutamine	(xix)	Potassium – L- glutamate
(vi)	Glycine	(xx)	Carnitine tartrate
(vii)	L-Hydroxylysine	(xxi)	Taurine
(viii)	L-Hydroxyproline	(xxii)	Choline
(ix)	L-Lycine acetate	(xxiii)	Choline chloride
(x)	N-acetyl-L-cysteine	(xxiv)	Choline citrate
(xi)	L- Ornithine	(xxv)	L-Serine
(xii)	L-Ornithine mono hydrochloride	(xxvi)	Tyrosine, acetyl-L
(xiii)	L-Lycine –L- aspartate	(xxvii)	Choline hydrogen tartrate
(xiv)	L-Citruline	(xxviii)	Myo-inositol
C. Nucleotides			
(i)	Adenosine 5-monophosphate (AMP)	(v)	Disodium uridine 5-monophosphate
(ii)	Cystidine 5-mono phosphate (CMP)	(vi)	Disodium guanosine 5-mono phosphate
(iii)	Guanosine 5-mono phosphate (GMP)	(vii)	Disodium ionosine 5-mono phosphate
(iv)	Inosine 5-mono phosphate (IMP)		

Note.- Suitable esters and salts of amino acids may be used.

Schedule – III

[See regulations 3.(13), 4.(2), 8.(2)(i), 8.(2)(iv), 9.(2)(i), 9.(2)(iv) and 9.(2)(v)]

Values for vitamins, minerals and trace elements allowed to be used in food for special dietary use and food for special medical purpose (other than those intended for use in infant formula)

1. Vitamins

Vitamins	RDA for Vitamins			
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum*	Minimum	Maximum*
Vitamin A (µg RE)	8.4	43	35	180
Vitamin D (µg)	0.12	0.65 (0.75) ¹	0.5	2.5 (3) ¹
Vitamin K (µg)	0.85	5	3.5	20
Vitamin C (mg)	0.54	5.25	2.25	22
Thiamin (mg)	0.015	0.12	0.06	0.5
Riboflavin (mg)	0.02	0.12	0.08	0.5
Vitamin B ₆ (mg)	0.02	0.12	0.08	0.5
Niacin (mg NE)	0.22	0.75	0.9	3
Folic acid (µg)	2.5	12.5	10	50
Vitamin B ₁₂ (µg)	0.017	0.17	0.07	0.7
Pantothenic acid (mg)	0.035	0.35	0.15	1.5
Biotin (µg)	0.18	1.8	0.75	7.5
Vitamin E (mg α-TE)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	0.75	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kcal	3

(¹): For products intended for children of 1 to 10 years of age; NE – Niacin equivalent; TE – Tocopherol equivalent.

* When no upper safe level (maximum permissible level higher than 1 (100 percent) RDA) has been specified for a particular vitamins and minerals, the content of such nutrient shall not exceed NOAEL (No observed adverse effect level) or one tenth of LOAEL (Lowest observed adverse effect level)

2. Minerals

Minerals	RDA for Minerals			
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum*	Minimum	Maximum*
Sodium (mg)	7.2	42	30	175
Chloride (mg)	7.2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8.4 (12) ¹	42 (60) ¹	35 (50) ¹	175 (250) ¹
Phosphorus (mg)	7.2	19	30	80
Magnesium (mg)	1.8	6	7.5	25
Iron (mg)	0.12	0.5	0.5	2.0
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (µg)	15	125	60	500
Iodine (µg)	1.55	8.4	6.5	35
Selenium (µg)	0.6	2.5	2.5	10
Manganese (mg)	0.012	0.12	0.05	0.5
Chromium (µg)	0.3	3.6	1.25	15
Molybdenum (µg)	0.72	4.3	3.5	18

(1): For products intended for children of 1 to 10 years of age;
 *When no upper safe level (maximum permissible level higher than 1 (100 per cent) RDA) has been specified for a particular nutrient the content of such nutrient shall not exceed NOAEL (No observed adverse effect level) or one tenth of LOAEL (Lowest observed adverse effect level)

Schedule – IV

[See regulations 3.(13), 4.(2), 6.(2)(i), 7.(2)(i), 7.(3)(v), 8.(2)(i), 9.(2)(i), 12.(1)(i), 12.(2), 12.(3)(i), 12.(3)(ii) and 12.(3)(iii)]

List of plant or botanical ingredients

S. No.	Botanical name and part used	Common name	Permitted range of usage for adults per day (given in terms of raw herb/material)
1.	<i>Abelmoschus esculentus</i> (L.) Moench.		
	Fruit/Root	Bhindi	5-10 g (as powder)
2.	<i>Abies spectabilis</i> (D.Don) / <i>A. pindrow</i> Royle		
	Leaves	Talis patra / Talis bhed	2-4 g (as powder)
3.	<i>Asculus indica colebs.</i> / <i>A. hippocastanum</i>		
	Fruit /kernel	Indian Horse Chestnut/ kanar	10-20 g
4.	<i>Abelmoschus moschatus</i>		
	Seed	<i>Lata kasturi</i>	3-5 g
5.	<i>Abutilon indicum</i> (L.) Sweet ssp. <i>Indicum</i> / <i>A. fruticosum</i>		
	Seed/Root	Atibala	5-10 g (as powder)
6.	<i>Acacia arabica</i> Willd. (Now known as <i>Acacia nilotica</i> (L.) Willd. ex Del. ssp. <i>indica</i> (Benth.) Brenan)		
	Gum	Babbula	5-10 g
	Stem bark	Babbula	5-10 g
7.	<i>Acacia catechu</i>		
	Extract	Katha/khair	1-3 g
8.	<i>Achyranthes aspera</i> (L.) / <i>A. bidentata</i>		
	Seed/Plant	Chirchida	3-5 g (as powder)
9.	<i>Adhatoda zeylanica</i> / <i>A. vasaka</i>		
	Leaf/Root/Flower	Adusa/Vasa	5-10 g
10.	<i>Aegle marmelos</i> (L.) Corr.		
	Unripe fruit pulp	Bael	5-10 g
	Ripe fruit	Bael	50-100 g (as pulp)
	Leaves/Bark	Bael Pather/Bael chhal	5-10 g (as pulp)
11.	<i>Ajuga bracteosa</i> wall		
	Plant	Neel Kanthi	2-3 g
12.	<i>Alangium salvifolium</i> (L.f.) Wang. ssp. <i>salvifolium</i>		
	Fruit	Ankota	10-20 g (as powder)
13.	<i>Albizia lebbbeck</i> (L.) Benth/A. <i>Procera</i> /A. <i>odoratissima</i>		
	Flower	Siris	3-6 g (as powder)
	Seed	Siris	1-3 g (as powder)
	Stem bark	Siris	3-6 g
	Leaf	Siris	3-6 g (as powder)

14.	<i>Alpinia galanga</i>		
	Rhizome	Kulanjan	2-4 g
15.	<i>Allium cepa</i> L.		
	Bulb	Pyaja	10-20 ml (as juice)
	Seed	Pyaja	1-3 g (as powder)
	Leaf	Pyaja	20-40 g (as vegetable)
16.	<i>Allium sativum</i> L.		
	Bulb	Lahsuna	3-6 g (Not recommended during pregnancy)
	Leaf	Lahsuna	20-40 g (as vegetable)
17.	<i>Allium stracheyi</i> Bakerno		
	Whole plant	Farana	2-3 g
18.	<i>Alocasia indica</i> Spach (Now known as <i>Alocasia macrorhiza</i> (L.) G. Don)		
	Tuber	Mankanda	5-10 g
19.	<i>Aloe barbadensis</i> Mill. / <i>A. Ferox</i> / <i>A. vera</i>		
	Leaf	Ghikvar	5-10 g
	Dry leaf juice	Elua - Mussabar	0.5 -1 g
20.	<i>Althaea officinalis</i> Linn		
	Flower/Root	Resh-Khatmi	5-10 g (as powder)
21.	<i>Alternanthera sessilis</i> (L.) R. Br. ex DC.		
	Whole plant	Gudarisaga	3-5 g (as powder)
22.	<i>Amaranthus gangeticus</i> L. (Now known as <i>Amaranthus tricolor</i> L.) / <i>Amaranthus blitum</i> L.		
	Aerial part	Lal marsa - Sag marsa	10-20 g (as leafy vegetable)
23.	<i>Amaranthus spinosus</i> L. / <i>A. paniculatus</i> L. (<i>A. hybridus</i> L.)		
	Whole plant	Chaulai Kateli / Jal Chaulai	20-30 g (as leafy vegetable)
24.	<i>Amomum aromaticum</i> Roxb. / <i>A. aromaticum</i>		
	Seed	Bangiya Ela	2-4 g (as powder)
25.	<i>Amomum subulatum</i> Roxb./ <i>A. aromaticum</i>		
	Fruit	Badi Elaichi	1-3 g (as powder)
	Seed	Badi Elaichi	1-2 g (as powder)
26.	<i>Amorphophallus campanulatus</i> (Roxb.) Blume ex Decne		
	Corm	Jimikanda	20-50 g (as vegetables)
27.	<i>Anacardium occidentale</i> L.		
	Fruit Kernel	Kaju	10-20 g
28.	<i>Anacyclus pyrethum</i> DC.		
	Root	Akarkara	100 - 250 mg (as powder) (Not recommended for children below 5 years)
	Seed	Akarkara	100 - 250 mg (as powder) (Not recommended for children below 5 years)
29.	<i>Ananas comosus</i> (L.) Merr.		
		Pineapple	50-100 g (as fruit) 50-100 ml (as juice) (Not recommended during pregnancy)
30.	<i>Anethum sowa</i> Roxb. ex Flem. (Now known as <i>Anethum graveolens</i> L.)		
	Fruit	Sowa	3-6 g (as powder (fruit))
	Leaf	Sowa	10-20 g (as powder (leaf))

31.	<i>Angelica glauca</i> Edgew./ <i>Angelica archangelica</i> L.		
	Root and Root stock	Chora	1-3 g (as powder)
32.	<i>Annona squamosa</i> L./ <i>A. reticulata</i> / <i>A. muricata</i> / <i>A. Cherimola</i>		
	Fruit pulp	Shareefa / Shareefa bhed	20-30 g (as fruit pulp)
	Leaf	Shareefa	3-5 g (as powder) (Not recommended for children below 16 years)
33.	<i>Apium leptophyllum</i> (Pers.) Muell. / <i>A. Graveolens</i> Linn.		
	Fruit	Ajamod / Ajmoda bhed	1-3 g (as powder)
34.	<i>Arachis hypogaea</i> L.		
	Seeds	Chinia Badam / Mungphali	10-20 g
	Seed oil	Mungaphali tail	5-10 ml
35.	<i>Areca catechu</i> L.		
	Seed	Supari	1-2 g (as powder) (only to be used after shodhana (purification)) (Not recommended for children below 5 years)
36.	<i>Artemisia absinthium</i> Linn /		
	Whole plant	Afsantin / Astimisia / Chauhar /	3-6 g
37.	<i>Artocarpus heterophyllum</i> Lam.		
	Ripe / unripe fruit	Katahal	20-50 g
	Seeds	Katahal	5-10 g
38.	<i>Artocarpus lakoocha</i> Roxb.		
	Ripe Fruit / unripe fruit	Badhal	20-30 g
	Seed	Badhal	5-10 g
39.	<i>Arnebia nobilis</i> / <i>A. benthamii</i>		
	Root	Ratanjot	2-4 g
40.	<i>Asparagus adscendens</i> Roxb.		
	Tuberous root	Safed musali	3-6 g (as powder)
41.	<i>Asparagus officinalis</i> L.		
	Root	Shatavar bhed	3-6 g (as powder)
	Tender Shoots	Shatavar bhed	20-50 g
42.	<i>Asparagus racemosus</i> Willd.		
	Tuberous root	Sitawar	3-6 g (as powder)
	Tender Shoots	Sitawar	20-50 g
43.	<i>Asparagus sarmentosus</i> Linn.		
	Tuberous root	Badi Shataver	3-6 g (as powder)
44.	<i>Avena sativa</i> L.		
	Seed	Oat	10-30 g (as powder)
45.	<i>Averrhoa carambola</i> L.		
	Fruit	Kamarakh	10-20 g
46.	<i>Azadirachta indica</i> A. Juss.		
	Leaf	Neem	1-3 g (as powder) (Not recommended for males and females planning to

	Fruit	Neem	conceive) 1-2 g (as pulp) (Not recommended for males and females planning to conceive) (Not recommended for children below 5 years)
	Flower	Neem	2-4 g (as powder)
	Root bark	Neem	3-6 g (as powder)
47.	<i>Bambusa arundinacea</i> (Retz.) Willd.		
	Tender shoots (Young leaf)	Bansh	20-30 g (as vegetable)
	Seed	Bansh chaval	20-30 g (as powder)
	Crystals	Bansalochan	0.5-2g (as powder)
48.	<i>Bacopa monnieri</i>		
	Whole plant	Brahmi	5-10 g (as powder)
	Extract	<i>Brahmigha</i>	1-2 g
49.	<i>Basella alba</i> L.		
	Leaf	Poyi Saag	20-30 g (as vegetable)
50.	<i>Bauhinia variegata</i> L. / <i>Bauhinia purpurea</i> L. / <i>B. tomentosa</i> . Linn		
	Stem bark	Kachnar / Sona	3-6 g
	Flower / Buds	Kachnar / Sona	10-20 g (as juice)
51.	<i>Benincasa hispida</i> (Thunb.) Cogn.		
	Fruit	Petha, Bhatua	30-50 g (as vegetable)
52.	<i>Berberis aristata</i> DC. / <i>B. asiatica</i> / <i>B. lycium</i> / <i>B. vulgaris</i>		
	Fruit	Daruhaldi	5-10 g (as fruit)
	Stem extract	Rasaunt	0.5-1 g
53.	<i>Beta vulgaris</i> L.		
	Tuber	Chukandar	10-20 ml (as juice)
54.	<i>Boerhaavia diffusa</i> L. (Now known as <i>Boerhaavia repens</i> L. var. <i>diffusa</i> (L.) Hook.f.) / <i>B. verticillata</i>		
	Aerial part	Saag itsit	20-30 g (as aerial parts)
	Root	Vishkhaprs	10-15 g (as root)
55.	<i>Bombax ceiba</i> L.		
	Stem bark	Semal	5-10 g
	Flower	Semal	10-20 ml (as juice)
	Gum	Semal	1-3 g (as powder)
	Root	Semal Musali	5-10 g (as powder)
56.	<i>Bombax malabarica</i> / <i>Salmalia malabarica</i>		
	Fruit/Flower/Root	Semal/Semar	10-20 g
57.	<i>Boswellia serrata</i> Roxb.		
	Oleoresin	Salai guggal	2-4 g
58.	<i>Borassus flabellifer</i> L.		
	Dried inflorescence	Tarkul/Taad	1-3 g (as powder)
	Seed pulp of unripe fruit	Tarkul/Taad	10-30 g
	Exudate of stem / sap	Tarkul/Taad	100-200 ml (as juice)
59.	<i>B. verticillata</i>		
	Root		10-15 g
60.	<i>Brassica campestris</i> L. (Now known as <i>Brassica rapa</i> L. sp. <i>campestris</i> (L.) Clapham)		
	Seed	Sarson	10-20 g (as paste)
	Seed oil	Sarson	10-20 ml
	Leaf	Sarson	10-30 g (as leafy vegetable)

61.	<i>Brassica juncea</i> (L.) Czern.		
	Seed	Rai	1-2 g
	Leaf	Rai	10-20 g (as leafy vegetable)
62.	<i>Brassica nigra</i> (L.) Koch.		
	Seeds	Banarasi rai	0.5-1 g
63.	<i>Brassica rapa</i> L.		
	Tuber	Shalgam	20-40 g
	Leaf	Shalgam	20-30 g (as vegetable)
64.	<i>Buchanania lanzan</i> Spreng.		
	Seed	Cherounjee	5-10 g (as powder)
65.	<i>Butea monosperma</i>		
	Seed/Gum/Root/Bark	Dhark	3-6 g
66.	<i>Bixa orellana</i>	Annato Plant	1-3 g
67.	<i>Caesalpinia bonducella</i> (L.) Flem. (Now known as <i>Caesalpinia bonduc</i> (L.) Roxb.)		
	Leaf	Karanjuva	2-3 g
	Seed	Karanjuva	2-3 g
68.	<i>Cajanus cajan</i> (Linn.) Millsp.		
	Seed	Arahar / Tuvar	30-50 g
69.	<i>Camellia sinensis</i>		
	Tea leaf / extract	Chaya / Tea extract	1-2 g
	Tea catechins	Green tea catechins	0.5-1 g
70.	<i>Canavalia ensiformis</i> sensu Baker (Now known as <i>Canavalia gladiata</i> (Jacq.) DC.)		
	Seed	Sema	5-10 g
71.	<i>Canscora decussata</i> (Roxb.) J.F. and J.H. Schult.		
	Leaf	Bangiya Sankhapuspi	2-4 g (as powder)
72.	<i>Capparis decidua</i> (Forssk.) Edgew.		
	Fruit	Kareer / Dela	10-20 g
73.	<i>Capsicum annum</i> L. var. <i>annum</i>		
	Unripe fruit	Hari Mircha	1-2 g (Not recommended for children below 5 years)
	Ripe fruit	Lal Mircha	0.5-1.0 g (as powder) (Not recommended for children below 5 years)
74.	<i>Capsicum frutescens</i> L.		
	Fruit	Simla Mirch	30-50 g (as vegetable)
75.	<i>Carica papaya</i> L.		
	Ripe fruit	Papita	50-100 g (as ripe fruit)
	Unripe fruit	Papita	30-50 g (as unripe fruit)
76.	<i>Carissa carandas</i> L.		
	Fruit	Karounda	5-10 g
77.	<i>Carissa spinarum</i> L.		
	Fruit	Karawan	5-10 g
78.	<i>Carthamus tinctorius</i> L.		
	Flower Head	Barre	2-4 g (as powder)
	Seed	Barre	2-4 g (as powder)
	Seed oil	Barre -tail	5-10 ml
79.	<i>Carum carvi</i> L.		
	Fruit	Syaha jeera	1-3 g (as powder)

80.	<i>Cassia absus</i> L.		
	Seed	Chaksu	2-5 g
81.	<i>Cassia occidentalis</i> L.		
	Leaf	Kasoundi	5-10 g
	Seed	Kasoundi	1-3 g
82.	<i>Cassia tora</i> L.		
	Leaf	Chakvad / Chakarmard	10-20 g
	Seed	Chakwad	3-5 g (as powder)
83.	<i>Cassia fistula</i>		
	Fruit pulp	Amaltas	10-20 g (as pulp)
	Seed	Amaltas	2-5 g (as seed)
84.	<i>Cassia angustifolia</i> / <i>C. acutifolia</i>		
	Seed/leaves	Sanay / Senna	3-6 g
85.	<i>Cedrus deodar</i> Roxb.		
	Seed/Wood/Oil	Devdar	5-10 g / 2-4 ml
86.	<i>Celosia argentea</i> L. var. <i>argentea</i>		
	Seed	Surwali / Safed murga	3-6 g
87.	<i>Celastrus paniculatus</i>		
	Seed/Oil	Malkanguni	5-10 g, (as powder (seed)) 2-4 ml (as oil)
88.	<i>Centella asiatica</i> (L.) Urban		
	Leaf/Whole Plant	Brahmi (Galpatri)	20-30 g (as vegetable)
	Extract	Brahmi (Galpatri)	1-3 g
89.	<i>Centratherum anthelminticum</i>		
	Fruit/Seed	Kali-jirii / Van- jirii	3-6 g
90.	<i>Chenopodium album</i> L.		
	Whole plant/leaves	Bathua	20-30 g (as leafy vegetable)
	Seed	Bathua	2-5 g
91.	<i>Chlorophytum borivillianum</i> / <i>C. arundinaceum</i> / <i>C. tuberosum</i>		
		Musali	5- 10 g
92.	<i>Cicca acida</i> (L.) Merrill		
	Fruit	Harfa rewadi	10-20 g
93.	<i>Cicer arietinum</i> L.		
	Tender leaf	Chana / Kalachana	30-50 g (as leafy vegetable)
	Seed	Chana / Kalachana	20-30 g
94.	<i>Cichorium endivia</i>		
	Seed	kasani	5-10g
95.	<i>Cinnamomum tamala</i> Nees and Eberm. / <i>C. wightii</i>		
	Leaf	Tejapatra	2-3 g
96.	<i>Cinnamomum zeylanicum</i> Blume (Now known as <i>Cinnamomum verum</i> J. S. Presl.)		
	Stem bark	Dalchini (Ceyloni)	1-2 g (Not recommended during pregnancy)
97.	<i>Cissampelos pareria</i> L. var. <i>hirsuta</i> (Buch.-Ham. ex DC.) Forman.		

	Leaf / Plant	Padhi	10-20 g (as powder)
98.	<i>Cissus quadrangularis</i> L.		
	Aerial part	Hadjod	10-20 g (as wet chutney (paste))
	Stem	Hadjod	3-6 g
99.	<i>Citrullus colocynthis</i> (L.) Schard.		
	Fruit	Indarun / Indrayan	0.25-0.5 g (as powder) (Not recommended during pregnancy)
100.	<i>Citrullus vulgaris</i> Schrad. ex Eckl. and Zeyh. var. <i>fistulosus</i> (Stocks) Stewart		
	Fruit	Tinda	20-40 g (as vegetable)
101.	<i>Citrullus lanatus</i> (Thunb.) Matsura and Nakai		
	Fruit pulp	Tarbuji	50-100 g
	Seed	Tarbuji	3-6 g
	Seed oil	Tarbuji	1-3 ml
102.	<i>Citrus aurantifolia</i> (Christm. and Panz.) Swingle		
	Fruit	Nimbu	3-5 ml (as juice)
103.	<i>Citrus limon</i> (Linn.) Burm.f.		
	Fruit	Jameerinibu	5-10 ml (as juice)
104.	<i>Citrus maxima</i> (Burm.) Merr.		
	Fruit	Chakotara	5-10 ml (as juice) 30-50 g (as fruit)
105.	<i>Citrus medica</i> L. var. <i>medica</i>		
	Fruit	Bijoura	5-10 ml (as juice)
106.	<i>Citrus reticulata</i> Blanc.		
	Fruit	Narangi	30-50 ml (as juice)
107.	<i>Citrus sinensis</i> (L.) Osbeck		
	Fruit	Mousami	50-100 ml (as juice)
108.	<i>Clerodendrum phlomidis</i>		
	Whole plant	Arani	10-20 g
109.	<i>Clerodendrum serratum</i>		
	Whole plant	Bharangi	10-20 g
110.	<i>Coccinia grandis</i> (L.) Voigt. / <i>C. indica</i>		
	Leaf	Kundru phal / Kuntru shak	5-10 g (Not recommended for children below 5 years)
	Stem	Kundru	3-6 g (as powder)
	Whole plant	Kundru	3-6 g (as powder) 5-10 ml (as juice)
	Fruit	Kundru	20-50 g (as vegetable)
111.	<i>Cocos nucifera</i> L.		
	Endosperm	Nariyal	10-20 g
	Water	Nariyal jala	100-200 ml
	Flower	Nariyal	5-10 g
112.	<i>Cocculus hirsutus</i> (L.) Theob.		
	Leaf	Jalajamani	10-20 g
113.	<i>Coix lacryma-jobi</i> L.		
	Seed	Gargri	10-20 g
114.	<i>Coffea arabica</i>		
	Seed/Dry/Green	Coffea	3-5 g (Not recommended for children below 5 years)
115.	<i>Coleus forskohlii</i> / <i>C. aromaticus</i>	Pathachoor, Parn-yavani	5-10 g (Not recommended for children below 5 years)

116.	<i>Colocasia antiquorum</i> Schott. (Now known as <i>Colocasia esculenta</i> (L.) Schott.)		
	Rhizome	Arui	20-30 g (as vegetable) (Not recommended for children below 16 years)
117.	<i>Commelina bengalensis</i> L.		
	Whole plant	Kausar	3-6 g
118.	<i>Commiphora wightii</i>		
	Oleoresin	Guggal	2-4 g (Not recommended for children below 5 years)
119.	<i>Commiphora myrrha</i>		
	Oleoresin	Hirabol	2-4 g (Not recommended for children below 5 years)
120.	<i>Convolvulus pluricaulis</i>		
	Whole plant	Shankh-pushpi	10-20 g
121.	<i>Corchorus acutangulus</i> Lam. (Now known as <i>Corchorus aestuans</i> L.)		
	Aerial part	Chench	10-20 ml
122.	<i>Corchorus capsularis</i> L.		
	Aerial part	Narcha	10-20 ml (as juice)
123.	<i>Corchorus olitorius</i> L.		
	Aerial part	Palva Saag	10-20 ml (as juice)
124.	<i>Cordia dichotoma</i> Forst. f. (<i>Cordia wallichii</i> G. Don)		
	Fruit	Lisora	10-20 g
125.	<i>Cordia rotthii</i> Roem. and Schult. (Now known as <i>Cordia gharaf</i> (Forssk.) Ehrenb and Asch.)		
	Fruit	Chhota Lisora	10-20 g
126.	<i>Coriandrum sativum</i> L.		
	Fruit	Dhaniya	1-3 g (as powder)
	Aerial part	Dhaniya	10-20 ml (as juice)
127.	<i>Costus speciosus</i>		
		Kemuk	2-4 g (as powder) (Not recommended for children below 5 years)
128.	<i>Crataeva nurvala</i>		
	Fruit/Bark/leaf	Varana	10-20 g
129.	<i>Crocus sativus</i> L.		
	Style and Stigma	Kumkum (Kesar)	25-50 mg (Not recommended for children below 16 years)

130.	<i>Cucumis melo</i> L.		
	Fruit	Kharbooja	50-100 g
	Seed	Kharbooja	1-3 g (as powder)
131.	<i>Cucumis melo</i> L. var. <i>momordica</i> Duthie and Fuller		
	Fruit	Phoot	40-50 g (as vegetable)
132.	<i>Cucumis melo</i> L. var. <i>utilissimus</i> (Roxb.) Duthie and Fuller		
	Seed	Kakri	3-6 g
	Fruit	Kakri	50-100 g (as vegetable)
133.	<i>Cucumis sativus</i> L.		
	Seed	Khira	3-6 g (as powder)
	Fruit	Khira	50-100 g (as vegetable)
134.	<i>Cucurbita maxima</i> Duch. ex Lam.		
	Seed	Kashiphal	5-10 g

	Fruit	Kashiphal	50-100 g (as vegetable)
135.	<i>Cucurbita pepo</i> L.		
	Fruit	Safed Kaddu / safed petha	50-100 g (as vegetable)
	Seed	Safed petha	5-10 g (as powder)
136.	<i>Cuminum cyminum</i> L.		
	Fruit	Jeera	1-3 g (as powder)
137.	<i>Curculigo orchioides</i> Gaertn.		
	Tuber	Kalimushli	3-5 g
138.	<i>Curcuma amada</i> Roxb.		
	Rhizome	Amahaldi	5-10 g (as fresh) 2-4 g (as powder)
139.	<i>Curcuma angustifolia</i>		
	Root	Tavkshir	2-5 g
140.	<i>Curcuma longa</i> L.		
	Rhizome	Haldi	2-5 g (as powder)
	Fresh Rhizome	Haldi	5-10 ml (as juice)
141.	<i>Curcuma zedoaria</i> Roxb. (Now known as <i>Curcuma aromatica</i> Salisb.)		
	Rhizome	Kachur	2-5 g (as powder)
142.	<i>Cyamopsis tetragonoloba</i>		
	Pod/Seed/Gum	Guar, Guar gum	20-30 g (as powder: pod/seed) 5-10 g (as powder: gum)
143.	<i>Cymbopogon citratus</i> (DC.) Stapf		
	Whole plant	Harichaya	1-3 g
144.	<i>Cymbopogon coloratus</i> Stapf		
	Aerial part	Manjan pullu	1-3g
145.	<i>Cymbopogon jwarankusa</i> (Jones) Schult.		
	Root	Lamajjaka	1-3 g
146.	<i>Cymbopogon martini</i> (Roxb.) Wats.		
	Whole plant	Rosha ghas	1-3 g
147.	<i>Cynodon dactylon</i> (L.) Pers.		
	Leaf	Duba	3-5 g
148.	<i>Cyperus rotundus</i> L.		
	Rhizome	Nagarmotha	2-5 g
149.	<i>Daucus carota</i> L.		
	Tuberous root	Gajar	50-100 g (as vegetable) 50-100 ml (as juice)
	Seed	Gajar	1-2 g (as powder) (Not recommended during pregnancy)
150.	<i>Desmodium gangeticum</i> / <i>D. latifolium</i>		
	Whole plant	Sarvan	5-10 g
151.	<i>Dillenia indica</i> L.		
	Fleshy fresh sepals (Fruit)	Chalta	40-50 g (as vegetable)
152.	<i>Dioscorea alata</i> L. / <i>D. deltoidea</i>		
	Tuber/Corm	Kathalu	10-20 g
153.	<i>Dioscorea bulbifera</i> L.		
	Tuber	Genthi / Taradi	20-30 g (as vegetable) 5-10 g (as powder)
	Extract	Genthi / Taradi	1-2 g (as extract)
154.	<i>Dioscorea esculenta</i> (Lour.) Burkill		

	Tuber	Suthani	5-10 g
155.	<i>Dioscorea pentaphylla</i> L.		
	Tuber	Kantalu	5-10 g
156.	<i>Diplezia maxima</i>		
	Tender shoots	Lungru	30-50 g
157.	<i>Diospyros peregrina</i> Gurke (Now known as <i>Diospyros malabarica</i> (Desr.) Kostel)		
	Ripe fruit	Gab	50-100 g
	Unripe fruit	Gab	4-8 g (as powder)
158.	<i>Dolichos biflorus</i> L. (Now known as <i>Vigna unguiculata</i> (L.) Walp.)		
	Seed	Kulathi	30-50 g
159.	<i>Dolichos lablab</i> L. (Now known as <i>Lablab purpureus</i> (L.) Sweet)		
	Seed	Sem	20-40 g (as seed)
	Tender Pod	Sem	30-40 g (as vegetable)
160.	<i>Echinochloa frumentacea</i> Link		
	Fruit	Sanwa	50-100 g
161.	<i>Eclipta prostrata</i> L.		
	Whole plant	Bhangra	3-6 g (as powder)
162.	<i>Elettaria cardamomum</i> (L.) Maton		
	Seed	Choti elaichi	250-500 mg (as powder)
163.	<i>Eleusine coracana</i> (L.) Gaertn. ssp. <i>coracana</i>		
	Caryopsis	Madua	20-50 g
164.	<i>Emblica officinalis</i> Gaertn. (Now known as <i>Phyllanthus emblica</i> L.)		
	Fruit	Anwala / Amla	20-30 g (as fresh fruit)
			3-6 g (as powder)
			5-10 ml (as juice)
Extract		2-4 g (as extract)	
165.	<i>Embelia ribes</i> Burm. f.		
	Fruit	Bhabhiranga	1-2 g (Not recommended for females planning to conceive)
166.	<i>Encostemma littorale</i> Blume	Mamejwa	2-3 g
167.	<i>Ephedra Gerardiana</i> Wall.		
	Leaves/Whole plant	Somlata	2-5g
168.	<i>Euphorbia neriifolia</i> / <i>E. pilosa</i>		
	Stem (tender) after boiling / Leaf	Thuhar	10-20 g (as stem) 3-5 g (as leaf) (Not recommended for children below 5 years)
169.	<i>Euryale ferox</i> Salisb.		
	Seed	Makhana	20-30 g (as seed) 3-5 g (as powder)
170.	<i>Evolvulus alsinoides</i>		
	Plant	Vishnukranta	10-20 g
171.	<i>Fagopyrum esculentum</i> Moench.		
	Seed	Kottu	50-100 g
172.	<i>Ferula asafoetida</i> L.		
	Oleo-gum resin	Hing	125 mg, Max (as powder)
173.	<i>Ficus benghalensis</i> L.		
	Fruit / Shoots	Baragad	40-50 g (as fruit)/ 5-10 g (as shoots)
174.	<i>Ficus carica</i> L. / <i>F. palmata</i> / <i>F. lacor</i>		
	Fruit / Leaf	Anjeer	20-30 g
175.	<i>Ficus glomerata</i> Roxb. (Now known as <i>Ficus racemosa</i> L.)		
	Fruit / Leaf	Gular	20-30 g (as vegetable)

176.	<i>Ficus hispida</i> L.f.		
	Fruit	Kathgulara (Kakodumba)	10-20 g
	Tender leaf	Kathgulara	20-40 ml (as juice)
177.	<i>Ficus religiosa</i> L.		
	Fruit	Pipal	5-10 g
	Tender Leaf	Pipal	5-10 g
178.	<i>Flacourtia jangomas</i> (Lour.)Raeusch syn. <i>F. cataphracta</i> Roxb. ex Willd.		
	Fruit	Paniyala	10-20 g
179.	<i>Flacourtia ramontchi</i> L'Herit (Now known as <i>Flacourtia indica</i> (Burm.f.) Merr.)		
	Fruit	Katai / Kanghu	5-10 g
180.	<i>Foeniculum vulgare</i> Mill.		
	Fruit	Sounf	5-10 g (as powder)
181.	<i>Fumaria vaillantii</i> (Lois.) Hook. f. and Thoms. var. <i>indica</i> Haussk. (Now known as <i>Fumaria indica</i> (Haussk.) Pugsley)		
	Leaves	Pittapapda	5-10 g
182.	<i>Garcinia indica</i> (Thour.) Choisy / <i>G. cambogia</i>		
	Mature fruit / Butter/ Oil	Kokam	10-20 ml (as juice) 5-10 g (as powder)
183.	<i>Garcinia pedunculata</i> Roxb. ex Buch.-Ham.		
	Fruit rind	Amalbeda	5-10 ml/g (as juice/Powder)
184.	<i>Gardenia turgida</i> Roxb. (Now known as <i>Ceriscoides turgida</i> (Roxb.) Tirveng.)		
	Gum	Kharahar	1-3 g (as powder)
185.	<i>Gisekia pharnaceoides</i> L.		
	Leaf	Baluka Saga	5-10 g
186.	<i>Glycine max</i> (L.) Merr.		
	Seed	Soyabean	20-40 g
187.	<i>Glycyrrhiza glabra</i> L.		
	Root and Stolon	Mulethi	5-10 g (as powder)
188.	<i>Gmelina arborea</i> Roxb.		
	Fruit	Gamhari	20-30 g
189.	<i>Gmelina asiatica</i> L.		
	Fruit	Badhara	20-30 g
190.	<i>Gossypium herbaceum</i>		
	Seed/Root	Kapas	10-20g
191.	<i>Grewia hirsuta</i> Vahl		
	Root	Gulsakari	5-10 g
192.	<i>Grewia populifolia</i> Vahl (Now known as <i>Grewia tenax</i> (Forssk.) Fiori)		
	Stem bark / Fruit	Gangeran	5-10 g (as powder)
193.	<i>Grewia tiliaefolia</i> Vahl / <i>G.sclerophylla</i>		
	Fruit	Dhamin	20-30 g
194.	<i>Gymnema sylvestre</i>		
	Plant	Gudmar	5-10 g
	Extract	Gudmar	1-2 g
195.	<i>Gynandropsis gynandra</i> (L.) Briq. (Now known as <i>Cleome gynandra</i> L.)		
	Seed	Hurhur	1-3 g (as powder)
	Whole plant	Hurhur	10-20 ml (as juice)
196.	<i>Habenaria intermedia</i>		
	Root tuber, Rhizome	Ridhi	3-5 g
197.	<i>Hedychium spicatum</i> Ham ex Smith		
	Rhizome	Kapur-	3-5 g

		Kachari	
198.	<i>Hemidesmus indicus</i>		
	Root / Stem	Anantmula	3-6 g
199.	<i>Hibiscus rosa-sinensis</i> L.		
	Flower	Gudahal	1-3 g (as powder) (Not recommended during pregnancy)
200.	<i>Hibiscus sabdariffa</i> L.		
	Leaf	Patawa	5-10 g (as powder)
	Seed	Patawa	1-3 g (as powder)
	Ripe calyx	Patawa	5-10 g (as powder)
201.	<i>Hippophae rhamnoides</i> L. / <i>H. salicifolia</i>		
	Fruit / Leaf	Amlavetasa	10-20 g
	Extract	Amalvets	1-3 g
202.	<i>Hordeum vulgare</i> L.		
	Fruit	Jaou	100-200 g (as powder)
	Whole plant	Jaou	10-20 g
203.	<i>Hygrophila spinosa</i>	Makhana / Tal makhana	20-30 g
204.	<i>Hypericum perforatum</i>		
	Leaf	Basant	3-6 g
	Plant extract	Basant	1-1.5 g (as extract)
205.	<i>Illicium verum</i> Hook. f.		
	Fruit	Badiyan Khatai	250 - 500 mg As powder -
206.	<i>Inula racemosa</i> . Hook		
	Root	Pushkar mool	3- 6 g (as powder)
207.	<i>Ipomoea aquatica</i> Forssk.		
	Leaf	Kalamisaag	20-30 g
208.	<i>Ipomoea batatas</i> (L.) Lam.		
	Tuber	Shakarkand	20-30 g
209.	<i>Ipomoea digitata</i> auct. non L. (Now known as <i>Ipomoea mauritiana</i> Jacq.)		
	Root/Tuber	Bilaikand	3-6 g
210.	<i>Juglans regia</i> Linn.		
	Fruit/Leaf/Bark	Akhrot	10-20 g
211.	<i>Juniperus communis</i>		
	Flower/Leaf	Hauber	5-10 g
212.	<i>Lagenaria vulgaris</i> Ser. (Now known as <i>Lagenaria siceraria</i> (Mol.) Standl.)		
	Fresh fruit	Alabu	100 -150 g (as vegetable)
	Seed	Alabu	1-3 g (as powder)
213.	<i>Lagerstroemia indica</i>		
	Leaf	Jarul	6 - 12 g (as powder)
	Fruit extarct	Frash	1-2 g (as extract)
214.	<i>Lagerstroemia parviflora</i>		
	Leaf	Sidh	6-12 g (as powder)
	Fruit extract	Sidh	1-2 g (as extract)
215.	<i>Lens culinaris</i> Medik.		
	Seed	Masura	20-40 g (as seed)
216.	<i>Lepidium sativum</i> L.		
	Seed	Chansur	3-6 g (as powder) (Not recommended during pregnancy)
	Aerial part	Chansur	50-100 g (as vegetable)

217.	<i>Leptadenia reticulata</i> (Retz.)W. and A.		
	Leaf	Dodisaka	20-30 g (as vegetable)
218.	<i>Leucas cephalotus</i> (Koenig ex Roth) Spreng.		
	Leaf	Guma	20-30 g
219.	<i>Limonia acidissima</i> L.		
	Fruit	Kaith	20- 40 g (as fruit)
220.	<i>Linum usitatissimum</i> L.		
	Seed	Atasi	10-20 g
	Seed Oil	Atasi	10-20 ml
221.	<i>Litchi chinensis</i> Sonner		
	Fruit	Litchi	50-100 g
222.	<i>Luffa acutangula</i> (L.)Roxb.		
	Whole plant	Torai	5 -10 g (as powder)
	Fruit	Torai	30-50 g (as vegetable)
	Seed	Torai	1-3 g (as powder)
223.	<i>Luffa cylindrica</i> (L.)M. Roem.		
	Fruit	Nenua	20-40 g (as vegetable)
	Seed	Nenua	1-3 g (as powder)
224.	<i>Lycopersicon esculentum</i> Mill. (Now known as <i>Lycopersicon lycopersicum</i> (L.) Karsten.)		
	Fruit	Tamatar	20-40 g (as vegetable)
225.	<i>Madhuca indica</i> Gmel.(Now known as <i>Madhuca longifolia</i> (Koen.) Macbride var. <i>latifolia</i>)		
	Flower	Mahua	10-15 g (as flower)
	Fruit	Mahua	10-15 g
	Seed oil	Koyna ka tel	2-5 ml
226.	<i>Madhuca longifolia</i> (Koenig) Macbride var. <i>longifolia</i>		
	Flower/Fruit	Jal mahua	10-15 g
227.	<i>Malva sylvestris</i> L.		
	Fruit	Gulkhair	5-7 g (as powder)
	Leaf	Gulkhair	3-6 g (as powder)
228.	<i>Mangifera indica</i> L.		
	Ripe fruit	Aam	50-150 g
	Unripe fruit pulp	Aam	10-30 g
	Seed Kernel	Aam Beej / Majja	1-2 g (as powder)
	Leaf	Aam	3-5 g
	Extract	<i>Amara (ghan)</i>	0.5-1 g
229.	<i>Maranta arundinacea</i> L.		
	Rhizome	Ararota	10-30 g (as powder)
230.	<i>Marsilea minuta</i> L.		
	Leaf	Chowpatia	20-30 g (as vegetable) 2-4 g (as powder)
	Extract	Chowpatia	1-2 g (as extract)
231.	<i>Mentha spicata</i> L. <i>Mentha arvensis</i> L. / <i>M. aquatica</i> Linn.		
	Aerial part	Pudina	5-10 g
232.	<i>Mentha piperata</i> L./ <i>Mentha species</i>	Peppermint/ Sat pudina	10-30 mg
233.	<i>Mesua ferrea</i> Linn.		
	Stemen/Flower	Nagkesar	2-5 g
234.	<i>Microstylis musifera</i> Ridley		
	Tuber	Jivaka	5-10 g

235.	<i>Microstylis wallichii</i> Lindl. (Now known as <i>Malaxis acuminata</i> D. Don)		
	Tuber	Rishabhka	5-10 g
236.	<i>Mimosa pudica</i>		
	Whole plant/Seed	Lajwanti	3-6 g
237.	<i>Mimusops elengi</i> L.		
	Pericarp	Maulsiri	20-40 g
	Flower	Maulsiri	5-10 g
	Stem bark	Maulsiri	3-5 g
238.	<i>Mimusops hexandra</i> Roxb. (Now known as <i>Manilkara hexandra</i> (Roxb.) Dub.)		
	Pericarp	Khirni	20-40 g
239.	<i>Momordica charantia</i> L.		
	Fresh fruit / Seed	Karela	30-50 g (as vegetable) 3-5 g (as seed) (Not recommended for females planning to conceive) (Not recommended for children below 5 years)
240.	<i>Momordica dioica</i> Roxb. ex Willd.		
	Root	Khekhassa	3-6 g (as powder)
	Fruit	Khekhassa	30-50 g
241.	<i>Monochoria vaginalis</i> (Burm.f.) Presl.		
	Rhizome	Indivara	3-6 g
242.	<i>Moringa oleifera</i> Lam. / <i>M. concanensis</i> Nimmo		
	Leaf	Sahijan / Muringya / Lal sehanjan	10-20 g (as vegetable or paste)
	Seed	Sahijan / Muringya	2-6 g (as vegetable)
	Pod	Sahijan / Muringya	40-80 g
	Flower	Sahijan / Muringya	10-20 g
	Stem bark	Sahijan / Muringya	10-20 g 2-5 g (as powder)
243.	<i>Morus alba</i> L. / <i>M. Indica</i> / <i>M. nigra</i>		
	Fruit / Leaves / Bark / Flower	Shahtoot	20-30 g (as fruit) 3-5 g (as leaf)
244.	<i>Moschella esculenta</i> / <i>M. elata</i>		
	Plant	Guchhi	10-30 g
245.	<i>Mucuna pruriens</i> (L.) DC.		
	Root	Kawach	10-20 g
	Pod	Kawach	20-30 g (as vegetable)
	Seed	Kawach	5-10 g
246.	<i>Murraya koenigii</i> (L.) Spreng. / <i>M. exotica</i> Linn (kamini)		
	Leaf / Fruit	Kadhipatta	5-10 g
247.	<i>Musa paradisiaca</i> L.		
	Flower	Kela	20-30 g
	Fresh shoot	Kela	20-50 g 10-20 ml (as juice)
	Ripe Fruit	Kela	100-200 g
	Unripe Fruit	Kela	50-100 g
248.	<i>Myrica esculenta</i> Buch. Ham. / <i>M. nagi</i> Hook		
	Fruit	Kaiphall	5-10 g
	Stem bark	Kaiphall	2-3 g

249.	<i>Myristica fragrans</i> Houtt.		
	Seed	Jaiphala	0.25- 1.0 g (Caution: excessive use may cause giddiness)
250.	<i>Myristica malabarica</i> Lam.		
	Aril	Javitri	0.25 -1 g (as powder)
251.	<i>Nardostachys jatamansi</i>		
	Seed	Jangali Jayaphala	0.5 -2 g
252.	<i>Nardostachys jatamansi</i>		
	Aril	Jangali javitri	0.25 -1 g
253.	<i>Nasturtium officinale/ N. aquaticum</i>		
	Seed	Jatamansi	2-5 g
253.	<i>Nelumbo nucifera</i> Gaertn.		
	Water-cress	Water-cress	20-40 g
	Flower	Kamal	3-6 g (as powder)
	Rhizome	Bhen	30-50 g
254.	<i>Nymphaea alba</i> Linn/ <i>N. rubra</i> / <i>N. stellate</i>		
	Stalk	Murar	30-50 g (as powder)
255.	<i>Nymphaea alba</i> Linn/ <i>N. rubra</i> / <i>N. stellate</i>		
	Seed	Kamalgatta	3-6 g (as powder)
256.	<i>Nigella sativa</i> L.		
	Rhizome/ Seed/ Flower	Kamlini	10-20 g 3-6 g (as flower)
257.	<i>Nigella sativa</i> L.		
	Seed	Kalaunji	5-10 g (Not recommended during pregnancy)
258.	<i>Nyctanthes arbortristis</i> L.		
	Flower	Harshringara	1-2 g
259.	<i>Nyctanthes arbortristis</i> L.		
	Leaf	Harshringara	1-3 g
260.	<i>Nymphaea rubra</i> Roxb. ex Salisb		
	Flower	Lal Kumud	3-6 g (as powder)
261.	<i>Nymphaea stellata</i> Willd.		
	Flower	Neelofer	3-6 g (as powder)
262.	<i>Ocimum basilicum</i> L.		
	Leaf	(Bhavari Tulsi) Niajboo	3-6 ml (as juice) 1-3 g (as powder)
	Seed	Tulasi (Jangali)	125-250 mg
263.	<i>Ocimum gratissimum</i> L.		
	Leaf	Ram Tulasi (Mumbai)	2-4 g (as powder)
264.	<i>Ocimum sanctum</i> L. (Now known as <i>Ocimum tenuiflorum</i> L.)		
	Leaf	Tulasi	2-5 g
265.	<i>Olea europaea</i>		
	Seed	Tulasi	1-2 g
266.	<i>Olea europaea</i>		
	Seed/Oil	Jaitun/Tail	10-20 g/ml
267.	<i>Onosma bracteatum</i>		
	Whole plant/Leaf	Gaujvan	5-10 g
268.	<i>Onosma hispidum</i>		
	Root	Ratanjol	3-5 g
269.	<i>Operculina turpethum</i>		
	Root/seed	Nishoth	3-5 g (Not recommended for children below 5 years)
270.	<i>Opuntia vulgaris / O. dillenii</i>		
	Fruits	Nagphani	10-20 g
271.	<i>Orchis latifolia</i> L. (Now known as <i>Dactylorhiza hategeria</i> (D. Don) Soo)		

	Tuber	Salampanja	5-10 g (as powder)
268.	<i>Origanum majorana</i> L.		
	Leaf	Marubaka	5-10 drops (as juice)
269.	<i>Oroxylum indicum</i>		
	Bark/Seed	Shyonok	5-10 g
270.	<i>Oryza sativa</i> L.		
	Seed	Chawal - shali	100-200 g (as powder)
271.	<i>Oxalis corniculata</i> L.		
	Leaf	Tinpatia	5-10 ml (as juice)
272.	<i>Pandanus odoratissimus</i> L.f.		
	Oil / Flower	Kewada	2-5 drops /2-5 g
273.	<i>Panicum miliaceum</i> L.		
	Seed	Cheen	50-100 g
274.	<i>Papaver somniferum</i> L.		
	Seed	Postadana	2-5 g (as powder)
275.	<i>Parmelia perlata</i>		
	Whole plant	Chharila	3-5 g
276.	<i>Paspalum scrobiculatum</i> L.		
	Seed/Caryopsis	Kodo	50-100 g
277.	<i>Paspalum scrobiculatum</i>		
	Fruit/Seed	Kodon	30-500 g
278.	<i>Pedalium murex</i>	Bada gokharu	5-10 g
279.	<i>Pennisetum typhoideum</i> L. C. Rich. (Now known as <i>Pennisetum americanum</i> (L.) K. Schum.)		
	Seed	Bajra	20-40 g
280.	<i>Peucedanum graveolens</i> (L.) Benth. and Hook.f		
	Seed	Shepu	1-3 g
281.	<i>Phaseolus aconitifolius</i> Jacq. (Now known as <i>Vigna aconitifolia</i> (Jacq.) Marechal)		
	Seed	Moth	20-50 g
282.	<i>Phaseolus aureus</i> Roxb. (Now known as <i>Vigna radiata</i> (L.) Wilczek var. <i>radiata</i>)		
	Seed	Jangali moong	20-50 g
283.	<i>Phaseolus lunatus</i> L.		
	Pod	Sem	25-50 g (as pulse)
284.	<i>Phaseolus mungo</i> L. (Now known as <i>Vigna mungo</i> (L.) Hepper)		
	Seed	Urad	- 20-50 g (as pulse)
285.	<i>Phaseolus radiatus</i> L. / <i>P. trilobus</i> sensu		
	Seed	Moong	50-100 g (as pulse)
286.	<i>Phaseolus vulgaris</i> L.		
	Pod	Lobia	10-20 g (as pulse)
287.	<i>Phoenix dactylifera</i> L.		
	Fruit	Chuhara / Khajur	20-50 g
288.	<i>Phoenix sylvestris</i> (L.) Roxb. / <i>P. acaulis</i>		
	Fruit	Khajoor	20-50 g
	Nira (Sap)	Khajoor	30-50 ml (as fresh juice)
289.	<i>Phyllanthus amarus</i> / <i>P. urinaria</i>		
	Plant	Tamlaki	5-10 g (as plant)
	Extract	Tamlaki	1-2 g (as extract)
290.	<i>Physalis alkekengi</i> L.		
	Fruit	Kaknaj	5-10 g
291.	<i>Physalis minima</i> L.		

	Fruit	Papoto	10-20 g
292.	<i>Physalis peruviana</i> L.		
	Fruit	Rasbhari	10-20 g
293.	<i>Pimpinella anisum</i> L.		
	Fruit	Anisoon	1-3 g
294.	<i>Pinus excelsa</i>		
	Fruit /Oil	Kail	5-10 g/1-2 ml (Not recommended for children below 5 years)
295.	<i>Pinus gerardiana</i> Wall.		
	Endosperm	Chilgoja	5-10 g
296.	<i>Pinus roxburghii</i>		
	Fruit /Oil	Chiia	5-10 g / 1-2 ml (Not recommended for children below 5 years)
297.	<i>Piper betle</i> L.		
	Leaf	Pana	2-5 g (Not recommended below the age of 5 years)
298.	<i>Piper chaba</i> Hunter (non Blume) (Now known as <i>Piper retrofractum</i> Vahl)		
	Leaf	Chabh	1-3 g (as powder)
299.	<i>Piper cubeba</i> L.f.		
	Fruit	Kabab chini	1-3 g (as powder)
300.	<i>Piper longum</i> L.		
	Fruit	Pipar	0.5-2 g (as powder) (Not recommended for prolonged use)
301.	<i>Piper nigrum</i> L.		
	Fruit	Kali Maricha	0.5-2 g
302.	<i>Pistacia integerrima</i> Stewart (Now known as <i>Pistacia chinensis</i> Bunge ssp. <i>Integerrima</i> (Stewart) Rech.f.)		
	Gall	Kakadasingi	1-2 g
303.	<i>Pistacia vera</i> L.		
	Seed	Pista	5-10 g
304.	<i>Pisum sativum</i> L.		
	Seed	Matar	50-150 g (as vegetable)
305.	<i>Plantago ovata</i> Forssk.		
	Seed / Husk	Isabgol	5-10 g (as vegetable)
306.	<i>Polygonatum cirrhifolium</i> (Wall.) Royle		
	Rhizome	Meda	5-10 g
307.	<i>Polygonatum verticillatum</i> (L.) All.		
	Rhizome	Mahameda	5-10 g
308.	<i>Portulaca oleracea</i> L.		
	Aerial part	Kulpha - sag	20-30 g (as vegetable)
309.	<i>Portulaca quadrifida</i> L.		
	Aerial part	Nonia - sag	20-30 g
310.	<i>Premna integrifolia</i> / <i>P. latifolia</i>		
	Whole plant / Bark	Agnimanth	5-10g
311.	<i>Prunus amygdalus</i> Baill. var. <i>dulchin</i>		
	Kernel	Badama	10-20 g
	Seed oil	Badama ka tel	3-5 ml
312.	<i>Prunus armeniaca</i> L.		
	Pericarp	Khumani	10-20 g
	Kernel	Khumani	3-5 g

	Seed oil	Khumani	3-5 ml
313.	<i>Prunus cerasoides</i>		
	Wood/Flower	Padamkasht / Pajja	5-10 g
314.	<i>Prunus persica</i> (L.) Batsch.		
	Pericarp	Adu	10-20 g
315.	<i>Psidium guajava</i> L.		
	Fruit	Amruda	20-50 g (as fresh fruit)
	Leaf	Amruda	3-5 g
316.	<i>Pterocarpus marsupium</i>		
	Ht. Wood	Vijaysar	5-10 g
317.	<i>Pterocarpus santalinus</i>		
	Ht Wood	Lal chandan	5-10 g
318.	<i>Pueraria tuberosa</i> (Roxb. ex Willd.) DC.		
	Tuber	Patal Kohda	10-20 g
319.	<i>Punica granatum</i> L.		
	Seed	Anar	20-50 g (as seed)
	Fruit rind	Anar	5-10 g (as fruit rind)
320.	<i>Putranjiva roxburghii</i>		
	Fruit	Jiya-pota	3-6 g (Not recommended for children below 5 years)
321.	<i>Pyrus communis</i> L.		
	Fruit	Nashpaati	50-100 g
322.	<i>Pyrus malus</i> L. (Now known as <i>Malus pumila</i> Mill.)		
	Fruit	Seb	100-200 g 20-40 ml (as juice)
323.	<i>Raphanus sativus</i> L.		
	Root	Muli	20-50 g
	Leaf	Muli	20-50 g
	Seed	Muli	125-250 mg
324.	<i>Reinwardtia indica</i>		
	Whole plant/leaf/ extract	Basanti	5-10 g (as powder) 0.5-1 g (as extract)
325.	<i>Rhododendron arboreum</i> Sm. / <i>R. companulatum</i> / <i>R. lepidotum</i> Wall		
	Flower	Buransa	20-30 g (as flower)
	Extract	Buransa	2-3 g (as extract)
326.	<i>Rheum emodi</i> Wall. ex Meissn. / <i>R. officinale</i>		
	Leaf	Revand chini	0.5-1 g
327.	<i>Rhus parviflora</i> Roxb. ex DC.		
	Fruit	Samakdana	30-75 g
328.	<i>Ricinus communis</i>		
	Seed/Root/Leaf	Erand	5-10 g (Not recommended for children below 5 years)
329.	<i>Rosa alba</i> L.		
	Flower	Safed gulab	10-20 g
330.	<i>Rosa centifolia</i> L.		
	Flower	Gulab	10-20 g (as flower)
	Oil	Gulab	2-5 drop (as oil)
331.	<i>Rosa damascena</i> Mill.		
	Flower/oil	Gulab Fasali	10-20 g / 2-5 drops
332.	<i>Roscoea procera</i> Wall.		
	Root tuber	Kandamula	5-10 g (as powder)

333.	<i>Rubia cordifolia</i>		
	Root/Stem	Manjeeth	3-6 g
334.	<i>Rumex vesicarius</i> L.		
	Leaf	Ambat chukka	10-20 g
335.	<i>Rumex nepalensis</i> / <i>R.maritimus</i> / <i>R.acetosella</i>	Shak/Fafru	20-40 g (Not recommended for children below 5 years)
336.	<i>Saccharum officinarum</i> L.		
	Stem / Juice / Root / Decoction	Ganna	100-200 ml (as juice) (Not recommended for diabetics)
	Sugar	Chini / Shakkar	50-100 g (Not recommended for diabetics)
	Jaggery	Gud	50-100 g (Not recommended for diabetics)
337.	<i>Salacia chinensis</i> L. / <i>Salacia oblonga</i> Wall. ex Wight and Arn / <i>Salacia reticulata</i> Wight / <i>S. roxburghii</i> / <i>S. macrosperma</i>		
	Root	Saptrangi	5-10 g
	Stem extract	Saptrangi	0.5-1 g
338.	<i>Salvadora persica</i> / <i>S. oleoides</i>		
	Fruit/Leaf	Peelu / Bada pelu	5-10 g
339.	<i>Santalum album</i> L.		
	Oil	Chandan ka tel	3-5 drops (as oil)
	Hard wood		1-2 g (as hard wood)
340.	<i>Saraca asoca</i>		
	Bark/Leaf	Ashok	5-10 g (Not recommended for children below 5 years)
341.	<i>Saussurea lappa</i>		
	Root/Rhizome	Kuth	3-5 g (Not recommended for children below 5 years)
342.	<i>Scindapsus officinalis</i>		
	Stem	Gaj pippali	3-5 g
343.	<i>Scirpus kysoor</i> Roxb. (Now known as <i>Scirpus grossus</i> (L.f.) Palla)		
	Rhizome	Kasheru	20-50 g (as vegetable)
344.	<i>Selinum tenuifolium</i> / <i>S.vaginatam</i>		
	Rhizome / Root	Bhootkesi	3-5 g
345.	<i>Sesamum indicum</i> L. (Now known as <i>Sesamum orientale</i> L.)		
	Seed	Tila	10-20 g
	Oil	Tila	5-10 ml
346.	<i>Sesbania grandiflora</i> (L.) Poir.		
	Flower	Agathi	10-20 g (as vegetable)
	Leaf	Agathi	10-20 g
347.	<i>Setaria italica</i> (L.) P. Beauv.		
	Seed	Kangu	10-50 g
348.	<i>Sida cordifolia</i> L. / <i>S. rhombifolis</i> Linn / <i>S. acuta</i>		
	Whole plant / Extract	Bariyara	10-30 g
	Seed	Bariyara	3-5 g
349.	<i>Solanum indicum</i> / <i>S.surattense</i> / <i>S.torvum</i>		
	Whole plant	Kantkari	5-10 g
	Fruit extract	Kateli	1-2 g (as extract)

350.	<i>Solanum melongena</i> L.		
	Fruit	Baigan	50-100 g
351.	<i>Solanum nigrum</i> L.		
	Leaf / Plant	Choti Makoy	30-60 g
352.	<i>Sorghum vulgare</i> Pers.		
	Seed	Jwara	50-100 g
353.	<i>Sphaeranthus indicus</i>		
	Flower	Gorakmundi	5-10 g
354.	<i>Spinacia oleracea</i> L.		
	Leaf	Palak	50-100 g
355.	<i>Spondias mangifera</i> Willd. (Now known as <i>Spondias pinnata</i> (L.f.) Kurz.)		
	Fruit / Leaf	Ambada	20-50 g 1-3 g (as powder)
356.	<i>Strychnos potatorum</i> L.		
	Seed	Nirmali	5-10 g (as powder)
357.	<i>Swertia chirayita</i> / <i>S.ciliata</i> / <i>S.angustifolia</i>		
	Whole plant	Chiraita	3-5 g (as whole plant)
	Extract	Chiraita	0.5-1 g (as extract)
358.	<i>Symplocos racemosa</i>		
	Bark/Leaf	Lodhar	3-5 g
359.	<i>Syzygium aromaticum</i> (L.) Merr. and L.Perry		
	Flower bud	Laung	0.5-1 g
360.	<i>Syzygium cuminii</i> (L.) Skeels		
	Pericarp and mesocarp	Jamun	10-50 g
	Seed	Jamun	5-10 g
361.	<i>Tacca aspera</i> Roxb.		
	Tuber	Bhevara ke kand	20-50 g
362.	<i>Tamarindus indica</i> L.		
	Fruit pulp	Imali	5-10 g (Not recommended during skin ailments)
	Seed	Imali	5-10 g
363.	<i>Tephrosia purpurea</i>		
	Whole plant	Sarponkha	5-10 g
364.	<i>Teramnus labialis</i> (L.f.) Spreng.		
	Whole plant	Mashaparni	20-50 g
365.	<i>Terminalia arjuna</i>		
	Bark/Leaf/Fruit	Arjun	5-10 g
	Extract	Arjun	0.5 -1 g (as extract)
366.	<i>Terminalia belerica</i> (Gaertn.) Roxb.		
	Fruit pericarp	Bahera	3-5 g (as fruit pericarp)
	Extract	Bahera	0.5-1 g (as extract)
367.	<i>Terminalia catappa</i> L.		
	Kernel	Desi badama	10-20 g
368.	<i>Terminalia chebula</i> Retz.		
	Fruit pericarp	Harad	3-5 g (as powder)
	Extract	Harar	0.5-1 g (as extract)
369.	<i>Terminalia tomentosa</i>		
	Stem/Bark/Leaf	Jarandrum / Asan	5-10 g
370.	<i>Thymus serpyllum</i> auct. non L. (Now known as <i>Thymus linearis</i> Benth.)		
	Leaf	Ban ajwain	1-3 g (as powder)

371.	<i>Trachyspermum ammi</i> (L.) Sprague		
	Seed	Ajwain	1-3 g (as powder)
	Leaf	Ajwain	10-20 g
372.	<i>Trapa bispinosa</i> Roxb. (Now known as <i>Trapa natans</i> L. var. <i>bispinosa</i> (Roxb.) Makino)		
	Endosperm / Fruit	Singhada	30-60 g
373.	<i>Trianthema portulacastrum</i> L.		
	Whole plant	Swet punarnava	10-20 g
374.	<i>Tribulus terrestris</i>		
	Fruit/Whole plant	Gokhru	5-10 g
375.	<i>Tricholepis glaberrima</i>		
	Plant	Brahm dandi	3-6 g
376.	<i>Trichosanthes anguina</i> L.		
	Fruit	Chichinda	30-60 g
377.	<i>Trichosanthes dioica</i> Roxb.		
	Fruit/ Leaf	Parawal	30-60 g
378.	<i>Trigonella foenum-graceum</i> L.		
	Seed	Methi	5-10 g
	Leaf	Methi	50-100 g
379.	<i>Triticum aestivum</i> L.		
	Seed	Gehun	50-100 g
	Tender shoot/spout	Ankurita Gehu	10-50 g
380.	<i>Typhonium trilobatum</i> (L.) Schott.		
	Tuber	Konchu	20-50 g
381.	<i>Tinospora cardifolia</i> Miers. (<i>menispermaceae</i>) Syn. <i>T. glabra</i> (n. Burm)		
	Roots/stem		5-10 g (as powder) 10-20 ml (as decoction) 400 mg, Max (as sattva)
	Extract		1-2 g
382.	<i>Urtica parviflora</i> / <i>U. dioica</i>		
	Tender Leaf	Bicchubuti	10-20 g
383.	<i>Uraria picta</i>		
	Whole plant	Pithvin	5-10 g
384.	<i>Valeriana jatamansi</i> Jones / <i>V. wallichii</i>		
	Rhizome	Tagar	1-3 g (as powder)
385.	<i>Vetiveria zizanioides</i>		
	Whole plant	Khas	10-20 g
386.	<i>Vigna trilobata</i> (L.) Verdc.		
	Whole plant	Mugvan	20-50 g
387.	<i>Viola odorata</i> / <i>V. pilosa</i> / <i>V. sylvestris</i>		
	Whole plant/Flower	Vanksha	3-5 g (Not recommended for children below 5 years)
388.	<i>Vitex agnus-castus</i> Linn.		
	Seed / Leaf	Renuka beej / Sage	3-6 g (Not recommended for children below 5 years)
389.	<i>Vitex negundo</i> / <i>V. trifolia</i>		
	Fruit/Seed/Leaves	Nirgundi	3-5 g
390.	<i>Vitis vinifera</i> L.		
	Fruit	Munakka	10-30 g
	Seed / Fruit skin	Munakka	1-3 g

391.	<i>Wedelia calendulacea</i> (L.) Less. (Now known as <i>Wedelia chinensis</i> (Osbeck) Mer.)		
	Leaf	Pila bhagra	5-10 g (as powder)
392.	<i>Withania coagulans</i> (Stocks) Dunal		
	Fruit	Paneer Doda	5-10 g
393.	<i>Withania somnifera</i> (L.) Dunal.		
	Root	Asgandh	3-6 g (as powder)
	Extract	Asgandh	0.5-1 g (as extract)
394.	<i>Woodfordia fruticosa</i>		
	Flower	Dhay ke phool	5-10g
395.	<i>Wrightia tinctoria</i> / <i>W.tomentosa</i>		
	Bark/Leaf/Seed	Meetha kutaj	5-10 g
396.	<i>Zanthoxylum alatum</i> Roxb. (Now known as <i>Zanthoxylum armatum</i> DC.)		
	Seed / Stem bark	Timura	1-3 g
397.	<i>Zea mays</i> L.		
	Seed	Makka	20-100 g
	Anthers	Makka	5-10 g
398.	<i>Zingiber officinale</i> Rosc.		
	Rhizome	Adrakh	5-10 g (Not recommended during hypertension and bleeding disorders)
399.	<i>Zizyphus jujuba</i> Lam.		
	Pericarp	Ber	10-50 g
400.	<i>Zizyphus nummularia</i> (Burm.f.)W. and A.		
	Pericarp	Jangali Ber / Jhar ber	15-30 g

Note 1.- Ingredients listed in the above Schedule shall be used after due processing or in their extract forms subject to permissible usage range given in the last column of the Table. Offering these ingredients, either alone or in combinations as such or minimally processed (cleaned, de-weeded, sorted, dried or powdered) is/are not permitted.

Note 2.- The ingredients listed above shall comply with Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

Note 3.- Permitted range of usage for children between 5-16 years is ½ of the permitted range of usage for adults.

Note 4.- Permitted range of usage for children between 1-5 years is ¼ of the permitted range of usage for adults.

Schedule – VA

[See regulations 3.(13), 6.(4), 7.(5), 10.(3) and 11.(3)]

List of food additives for health supplements, nutraceuticals and food with added probiotics and prebiotics

S. No.	INS No.	Food Additive or Group	Maximum permitted level
1.	950	Acesulfame potassium	2,000 mg/kg
2.	304, 305	Ascorbyl Esters	500 mg/kg
3.	951	Aspartame	5,500 mg/kg
4.	962	Aspartame-Acesulfame salt	2,000 mg/kg
5.	901	Beeswax	GMP
6.	210, 211, 212, 213	Benzoates	2,000 mg/kg
7.	133	Brilliant blue FCF	300 mg/kg
8.	320	Butylated hydroxyanisole (BHA)	400 mg/kg
9.	321	Butylated hydroxytoluene (BHT)	400 mg/kg
10.	902	Candelilla wax	GMP
11.	150c	Caramel III – Ammonia caramel	20,000 mg/kg
12.	150d	Caramel IV – Sulfite ammonia caramel	20,000 mg/kg
13.	903	Carnauba wax	5,000 mg/kg
14.	160a(ii)	beta-Carotenes (vegetable)	600 mg/kg
15.	160a(i), (iii), 160e, 160f	Carotenoids	300 mg/kg
16.	1503	Castor oil	1,000 mg/kg
17.	141(i),(ii)	Chlorophylls and Chlorophyllins, Copper Complexes	500 mg/kg
18.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
19.	385, 386	Ethylene diamine tetra acetates	150 mg/kg
20.	143	Fast green FCF	600 mg/kg
21.	163(ii)	Grape skin extract	500 mg/kg
22.	132	Indigotine (Indigo carmine)	300 mg/kg
23.	961	Neotame	90 mg/kg
24.	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i),(ii), 343(i)-(iii), 450(i)-(iii),(v)-(vii), 451(i),(ii), 452(i)-(v), 542	Phosphates	2,200 mg/kg
25.	1203	Polyvinyl alcohol	45,000 mg/kg

S. No.	INS No.	Food Additive or Group	Maximum permitted level
26.	900a	Polydimethylsiloxane	50 mg/kg
27.	1521	Polyethylene Glycol	70,000 mg/kg
28.	432-436	Polysorbates	25,000 mg/kg
29.	1201	Polyvinylpyrrolidone	GMP
30.	124	Ponceau 4R (Cochineal red A)	300 mg/kg
31.	310	Propyl gallate	400 mg/kg
32.	101(i)-(iii)	Riboflavins	300 mg/kg
33.	954(i)-(iv)	Saccharins	1,200 mg/kg
34.	904	Shellac, Bleached	GMP
35.	200-203	Sorbates	2,000 mg/kg
36.	960	Steviol Glycosides	2,500 mg/kg
37.	955	Sucralose (Trichlorogalactosucrose)	2,400 mg/kg
38.	474	Sucroglycerides	2,500 mg/kg
39.	110	Sunset yellow FCF	300 mg/kg

Schedule – VB

[See regulations 3.(13), 8.(4), 10.(3) and 11.(3)]

List of food additives for foods for special dietary use and food with added probiotics and prebiotics

S. No.	INS No.	Food Additive or Group	Maximum permitted Level
1.	950	Acesulfame potassium	450 mg/kg
2.	956	Alitame	300 mg/kg
3.	304, 305	Ascorbyl Esters	500 mg/kg
4.	951	Aspartame	1,000 mg/kg
5.	962	Aspartame-acesulfame salt	450 mg/kg
6.	210, 211, 212, 213	Benzoates	2,000 mg/kg
7.	133	Brilliant blue FCF	300 mg/kg
8.	150c	Caramel III - Ammonia caramel	20,000 mg/kg
9.	150d	Caramel IV - Sulfite ammonia caramel	20,000 mg/kg
10.	160a(ii)	Beta-Carotenes (vegetable)	600 mg/kg
11.	160a(i), (iii), 160e, 160f	Carotenoids	300 mg/kg
12.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
13.	163(ii)	Grape skin extract	250 mg/kg
14.	132	Indigotine (Indigo carmine)	300 mg/kg
15.	961	Neotame	65 mg/kg
16.	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i),(ii), 343(i)-(iii), 450(i)-(iii),(v)-(vii), 451(i),(ii),452(i)-(v), 542	Phosphates	2,200 mg/kg
17.	900a	Polydimethylsiloxane	50 mg/kg
18.	124	Ponceau 4R (Cochineal red A)	300 mg/kg
19.	101(i)-(iii)	Riboflavins	300 mg/kg
20.	954(i)-(iv)	Saccharins	200 mg/kg
21.	200-203	Sorbates	1,500 mg/kg
22.	960	Steviol glycosides	660 mg/kg
23.	955	Sucralose (Trichlorogalactosucrose)	400 mg/kg
24.	110	Sunset yellow FCF	300 mg/kg

Schedule - VC

[See regulations 3.(13), 9.(4), 10.(3) and 11.(3)]

List of food Additives for foods for special medical purpose (other than those products intended for foods for infants) and food with added probiotics and prebiotics

S. No.	INS No.	Food Additive or Group	Maximum Permitted Level
1.	950	Acesulfame potassium	500 mg/kg
2.	951	Aspartame	1,000 mg/kg
3.	962	Aspartame-acesulfame salt	500 mg/kg
4.	210 - 213	Benzoates	1,500 mg/kg
5.	133	Brilliant blue FCF	50 mg/kg
6.	150c	Caramel III - Ammonia caramel	20,000 mg/kg
7.	150d	Caramel IV - Sulfite Ammonia caramel	20,000 mg/kg
8.	160a(ii)	beta-Carotenes (vegetable)	600 mg/kg
9.	160a(i), (iii), 160e, 160f	Carotenoids	50 mg/kg
10.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
11.	163(ii)	Grape skin extract	250 mg/kg
12.	132	Indigotine (Indigo carmine)	50 mg/kg
13.	961	Neotame	33 mg/kg
14.	338, 339(i)-(iii), 340 (i)-(iii), 341(i)-(iii), 342 (i),(ii), 343(i), (iii), 450 (i)-(iii), (v)-(vii), 451(i), (ii), 452(i)-(v), 542	Phosphates	2,200 mg/kg
15.	900a	Polydimethylsiloxane	50 mg/kg
16.	432 - 436	Polysorbates	1,000 mg/kg
17.	124	Ponceau 4R (Cochineal red A)	50 mg/kg
18.	477	Propylene glycol esters of fatty acids	5,000 mg/kg
19.	101(i)-iii)	Riboflavins	300 mg/kg
20.	954 (i)-(iv)	Saccharins	200 mg/kg
21.	200-203	Sorbates	1,500 mg/kg
22.	960	Steviol glycosides	350 mg/kg
23.	955	Sucralose (Trichlorogalactosucrose)	400 mg/kg
24.	474	Sucroglycerides	5,000 mg/kg
25.	110	Sunset yellow FCF	50 mg/kg

Schedule – VD

[See regulations 3.(13), 9.(4), 10.(3) and 11.(3)]

List of food additives for foods for special medical purpose (other than those intended for infant foods); formula for slimming purpose and weight reduction and food with added probiotics and prebiotics

S. No.	INS No.	Food Additive or Group	Maximum permitted Level
1.	950	Acesulfame potassium	450 mg/kg
2.	304, 305	Ascorbyl Esters	500 mg/kg
3.	951	Aspartame	800 mg/kg
4.	962	Aspartame-acesulfame salt	450 mg/kg
5.	210 - 213	Benzoates	1,500 mg/kg
6.	133	Brilliant blue FCF	50 mg/kg
7.	150c	Caramel III – Ammonia caramel	20,000 mg/kg
8.	150d	Caramel IV - Sulfite Ammonia caramel	20,000 mg/kg
9.	160a(ii)	Beta-Carotenes (vegetable)	600 mg/kg
10.	160a(i), (iii), 160e, 160f	Carotenoids	50 mg/kg
11.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
12.	163(ii)	Grape skin extract	250 mg/kg
13.	132	Indigotine (Indigo carmine)	50 mg/kg
14.	961	Neotame	33 mg/kg
15.	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i),(ii), 343(i)-(iii), 450 (i)-(iii),(v)-(vii), 451(i),(ii), 452(i)-(v), 542	Phosphates	2,200 mg/kg
16.	900a	Polydimethylsiloxane	50 mg/kg
17.	432 - 436	Polysorbates	1,000 mg/kg
18.	124	Ponceau 4R (Cochineal red A)	50 mg/kg
19.	477	Propylene glycol esters of fatty acids	5,000 mg/kg
20.	101(i)-iii)	Riboflavins	300 mg/kg
21.	954 (i)-(iv)	Saccharins	300 mg/kg
22.	200-203	Sorbates	1,500 mg/kg
23.	960	Steviol Glycosides	270 mg/kg
24.	955	Sucralose (Trichlorogalactosucrose)	320 mg/kg
25.	474	Sucroglycerides	5,000 mg/kg
26.	110	Sunset yellow FCF	50 mg/kg

Schedule - VE

[See regulations 3.(13), 6.(4), 7.(5), 8.(4), 9.(4), 10.(3), 11.(3) and 12.(4)]

List of food additives to be used (at GMP levels) for-

- (I) Nutraceuticals,
- (II) Foods for special dietary use other than foods for infants,
- (III) Foods for special medical purpose,
- (IV) Foods with added probiotic ingredients and prebiotic ingredients,
- (V) Specialty foods containing plant or botanical ingredients, and
- (VI) Health supplements

S. No.	INS No.	Additive	Functional Class
1.	260	Acetic acid, glacial	Acidity regulator, Preservative
2.	472a	Acetic and fatty acid esters of glycerol	Emulsifier, Sequestrant, Stabilizer
3.	1422	Acetylated distarch adipate	Emulsifier, Stabilizer, Thickener
4.	1417	Acetylated distarch phosphate	Emulsifier, Stabilizer, Thickener
5.	1451	Acetylated oxidized starch	Emulsifier, Stabilizer, Thickener
6.	1401	Acid treated starch	Emulsifier, Stabilizer, Thickener
7.	406	Agar	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
8.	400	Alginic acid	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener
9.	1402	Alkaline treated starch	Emulsifier, Stabilizer, Thickener
10.	1100 (i)	alpha-Amylase from <i>Aspergillus oryzae</i>	Flour treatment agent
11.	1100 (vi)	Carbohydrase from <i>Bacillus licheniformis</i>	Flour treatment agent
12.	1100 (iv)	alpha-Amylase from <i>Bacillus megaterium</i> expressed in <i>Bacillus subtilis</i>	Flour treatment agent
13.	1100 (ii)	alpha-Amylase from <i>Bacillus stearothermophilus</i>	Flour treatment agent
14.	1100 (v)	alpha-Amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus subtilis</i>	Flour treatment agent
15.	1100 (iii)	alpha-Amylase from <i>Bacillus subtilis</i>	Flour treatment agent
16.	264	Ammonium acetate	Acidity regulator
17.	403	Ammonium alginate	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener

S. No.	INS No.	Additive	Functional Class
18.	503(i)	Ammonium carbonate	Acidity regulator, Raising agent
19.	510	Ammonium chloride	Flour treatment agent
20.	503(ii)	Ammonium hydrogen carbonate	Acidity regulator, Raising agent
21.	527	Ammonium hydroxide	Acidity regulator
22.	328	Ammonium lactate	Acidity regulator, Flour treatment agent
23.	300	Ascorbic acid, L.	Acidity regulator, Anti-oxidant, Flour treatment agent
24.	162	Beet red	Colour
25.	1403	Bleached starch	Emulsifier, Stabilizer, Thickener
26.	1101(iii)	Bromelain	Flavour enhancer, Flour treatment agent, Stabilizer
27.	629	Calcium 5'-guanylate	Flavour enhancer
28.	633	Calcium 5'-inosinate	Flavour enhancer
29.	634	Calcium 5'-ribonucleotides	Flavour enhancer
30.	263	Calcium acetate	Acidity regulator, Preservative, Stabilizer
31.	404	Calcium alginate	Anti-foaming agent, Bulking agent, Carrier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer
32.	302	Calcium ascorbate	Anti-oxidant
33.	170(i)	Calcium carbonate	Acidity regulator, Anti-caking agent, Carrier, Firming agent, Flour treatment agent, Stabilizer
34.	509	Calcium chloride	Firming agent, Stabilizer, Thickener
35.	623	Calcium di-L-glutamate	Flavour enhancer
36.	578	Calcium gluconate	Acidity regulator, Firming agent, Sequestrant
37.	526	Calcium hydroxide	Acidity regulator, Firming agent
38.	327	Calcium lactate	Acidity regulator, Flour treatment agent
39.	352(ii)	Calcium malate, DL-	Acidity regulator
40.	529	Calcium oxide	Acidity regulator, Flour treatment agent
41.	282	Calcium propionate	Preservative
42.	552	Calcium silicate	Stabilizer
43.	516	Calcium sulfate	Firming agent, Flour treatment agent, Sequestrant, Stabilizer
44.	150a	Caramel I - plain caramel	Colour
45.	290	Carbon dioxide	Carbonating agent, Packaging gas, Preservative, Propellant

S. No.	INS No.	Additive	Functional Class
46.	410	Carob bean gum	Emulsifier, Stabilizer, Thickener
47.	407	Carrageenan	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
48.	427	Cassia gum	Emulsifier, Gelling agent, Stabilizer, Thickener
49.	140	Chlorophylls	Colour
50.	1001	Choline salts and esters	Emulsifier
51.	330	Citric acid	Acidity regulator, Anti-oxidant, Sequestrant
52.	472c	Citric and fatty acid esters of glycerol	Anti-oxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer
53.	466	Cross carmellose sodium	Binder, Thickening agent, Disintegrant
54.	468	Cross-linked sodium carboxymethyl cellulose (Crosslinked- cellulose gum)	Stabilizer, Thickener
55.	424	Curdlan	Firming agent, Gelling agent, Stabilizer, Thickener
56.	457	Cyclodextrin, alpha-	Stabilizer, Thickener
57.	458	Cyclodextrin, gamma-	Stabilizer, Thickener
58.	1504 (i)	Cyclotetraglucose	Carrier, Glazing agent
59.	1504 (ii)	Cyclotetraglucose syrup	Carrier
60.	1400	Dextrins, roasted starch	Emulsifier, Stabilizer, Thickener
61.	628	Dipotassium 5'-guanylate	Flavour enhancer
62.	627	Disodium 5'-guanylate	Flavour enhancer
63.	631	Disodium 5'-inosinate	Flavour enhancer
64.	635	Disodium 5'-ribonucleotides	Flavour enhancer
65.	1412	Distarch phosphate	Emulsifier, Stabilizer, Thickener
66.	315	Erythorbic Acid (Isoascorbic acid)	Anti-oxidant
67.	968	Erythritol	Flavour enhancer, Humectant, Sweetener
68.	462	Ethyl cellulose	Bulking agent, Carrier, Glazing agent, Thickener
69.	467	Ethyl hydroxyethyl cellulose	Emulsifier, Stabilizer, Thickener
70.	297	Fumaric acid	Acidity regulator
71.	418	Gellan gum	Stabilizer, Thickener
72.	575	Glucono delta-lactone	Acidity regulator, Raising agent, Stabilizer
73.	1102	Glucose oxidase	Anti-oxidant
74.	620	Glutamic acid, L(+)-	Flavour enhancer
75.	422	Glycerol	Humectant, Thickener

S. No.	INS No.	Additive	Functional Class
76.	626	Guanylic acid, 5'-	Flavour enhancer
77.	412	Guar gum	Emulsifier, Stabilizer, Thickener
78.	414	Gum arabic (Acacia gum)	Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer, Thickener
79.	507	Hydrochloric acid	Acidity regulator
80.	463	Hydroxypropyl cellulose	Bulking agent, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener
81.	1442	Hydroxypropyl distarch phosphate	Emulsifier, Stabilizer, Thickener
82.	464	Hydroxypropyl methyl cellulose	Emulsifier, Glazing agent, Stabilizer, Thickener
83.	1440	Hydroxypropyl starch	Emulsifier, Stabilizer, Thickener
84.	630	Inosinic acid, 5'	Flavour enhancer
85.	953	Isomalt (Hydrogenated isomaltulose)	Anti-caking agent, Bulking agent, Glazing agent, Sweetener
86.	416	Karaya gum	Emulsifier, Stabilizer, Thickener
87.	425	Konjac flour	Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
88.	270	Lactic acid, L-, D- and DL-	Acidity regulator
89.	472b	Lactic and fatty acid esters of glycerol	Emulsifier, Sequestrant, Stabilizer
90.	966	Lactitol	Emulsifier, Sequestrant, Stabilizer
91.	322(i)	Lecithin (and its salts and esters from soya or other sources)	Anti-oxidant, Emulsifier
92.	1104	Lipases	Stabilizer
93.	160d(iii)	Lycopene, Blakeslea trispora	Colour
94.	160d(i)	Lycopene, synthetic	Colour
95.	160d (ii)	Lycopene, tomato	Colour
96.	504(i)	Magnesium carbonate	Acidity regulator, Anti-caking agent, Colour retention agent
97.	511	Magnesium chloride	Colour retention agent, Firming agent, Preservative
98.	625	Magnesium di-L-glutamate	Flavour enhancer
99.	580	Magnesium gluconate	Acidity regulator, Firming agent, Flavour enhancer
100.	528	Magnesium hydroxide	Acidity regulator, Colour retention agent
101.	504(ii)	Magnesium hydroxide carbonate	Acidity regulator, Anti-caking agent, Carrier, Colour retention agent
102.	329	Magnesium lactate, DL-	Acidity regulator, Flour treatment

S. No.	INS No.	Additive	Functional Class
			agent
103.	530	Magnesium oxide	Anti-caking agent
104.	553(i)	Magnesium silicate, synthetic	Anti-caking agent
105.	518	Magnesium sulfate	Firming agent, Flavour enhancer
106.	296	Malic acid, DL-	Acidity regulator
107.	965(i)	Maltitol	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener
108.	965(ii)	Maltitol syrup	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener
109.	421	Mannitol	Anti-caking agent, Bulking agent, Humectant, Stabilizer, Sweetener
110.	461	Methyl cellulose	Bulking agent, Glazing agent, Humectant, Stabilizer, Thickener
111.	465	Methyl ethyl cellulose	Emulsifier, Gelling agent, Stabilizer, Thickener
112.	460(i)	Microcrystalline cellulose (Cellulose gel)	Anti-caking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener
113.	471	Mono and di-glycerides of fatty acids	Anti-foaming agent, Emulsifier, Stabilizer
114.	624	Monoammonium L-glutamate	Flavour enhancer
115.	622	Monopotassium L-glutamate	Flavour enhancer
116.	621	Monosodium L-glutamate	Flavour enhancer
117.	1410	Monostarch phosphate	Emulsifier, Stabilizer, Thickener
118.	941	Nitrogen	Packaging gas, Propellant
119.	942	Nitrous oxide	Anti-oxidant, Foaming agent, Packaging gas, Propellant
120.	1404	Oxidized starch	Emulsifier, Stabilizer, Thickener
121.	1101(ii)	Papain	Flavour enhancer
122.	440	Pectins	Emulsifier, Gelling agent, Stabilizer, Thickener
123.	1413	Phosphated distarch phosphate	Emulsifier, Stabilizer, Thickener
124.	1200	Polydextroses	Bulking agent, Glazing agent, Humectant, Stabilizer, Thickener
125.	964	Polyglycitol syrup	Sweetener
126.	1202	Poly vinyl pyrrolidone, insoluble, including cross povidone	Colour retention agent, Stabilizer
127.	632	Potassium 5'-inosinate	Flavour enhancer
128.	261	Potassium acetates	Acidity regulator, Stabilizer
129.	402	Potassium alginate	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant,

S. No.	INS No.	Additive	Functional Class
			Stabilizer, Thickener
130.	303	Potassium ascorbate	Anti-oxidant
131.	501(i)	Potassium carbonate	Acidity regulator, Stabilizer
132.	508	Potassium chloride	Flavour enhancer, Gelling agent, Stabilizer, Thickener
133.	332(i)	Potassium dihydrogen citrate	Acidity regulator, Sequestrant, Stabilizer
134.	577	Potassium gluconate	Acidity regulator, Stabilizer
135.	501(ii)	Potassium hydrogen carbonate	Acidity regulator, Raising agent, Stabilizer
136.	351(i)	Potassium hydrogen malate	Acidity regulator
137.	515 (ii)	Potassium hydrogen sulfate	Acidity regulator
138.	525	Potassium hydroxide	Acidity regulator
139.	326	Potassium lactate	Acidity regulator, Anti-oxidant
140.	351(ii)	Potassium malate	Acidity regulator
141.	283	Potassium propionate	Preservative
142.	515(i)	Potassium sulfate	Acidity regulator
143.	460(ii)	Powdered cellulose	Anti-caking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener
144.	407a	Processed eucheuma seaweed	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
145.	944	Propane	Propellant
146.	280	Propionic acid	Preservative
147.	1101(i)	Protease	Flavour enhancer, Flour treatment agent, 1999 Glazing agent, Stabilizer
148.	1204	Pullulan	Glazing agent, Thickener
149.	470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	Anti-caking agent, Emulsifier, Stabilizer
150.	470(ii)	Salts of oleic acid with calcium, potassium and sodium	Anti-caking agent, Emulsifier, Stabilizer
151.	551	Silicon dioxide, amorphous	Anti-caking agent, Anti-foaming agent, Carrier
152.	262(i)	Sodium acetate	Acidity regulator, Preservative, Sequestrant
153.	401	Sodium alginate	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener
154.	301	Sodium ascorbate	Anti-oxidant

S. No.	INS No.	Additive	Functional Class
155.	500(i)	Sodium carbonate	Acidity regulator, Anticaking agent, Raising agent
156.	466	Sodium carboxymethyl cellulose (Cellulose gum)	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
157.	469	Sodium carboxymethyl cellulose, enzymatically hydrolysed (Cellulose gum, enzymatically hydrolyzed)	Stabilizer, Thickener
158.	331(i)	Sodium dihydrogen citrate	Acidity regulator, Emulsifier, Sequestrant, Thickener
159.	350(ii)	Sodium DL-malate	Acidity regulator, Humectant
160.	316	Sodium erythorbate (Sodium isoascorbate)	Anti-oxidant
161.	365	Sodium fumarates	Acidity regulator
162.	576	Sodium gluconate	Sequestrant, Stabilizer, Thickener
163.	500(ii)	Sodium hydrogen carbonate	Acidity regulator, Anti-caking agent, Raising agent
164.	350(i)	Sodium hydrogen DL-malate	Acidity regulator, Humectant
165.	514(ii)	Sodium hydrogen sulfate	Acidity regulator
166.	524	Sodium hydroxide	Acidity regulator
167.	325	Sodium lactate	Acidity regulator, Anti-oxidant, Bulking agent, Humectant, Thickener
168.	281	Sodium propionate	Preservative
169.	500(iii)	Sodium sesquicarbonate	Acidity regulator, Anti-caking agent, Raising agent
170.	-	Sodium starch glycolate	Binder, Thickening agent, Disintegrant
171.	514(i)	Sodium sulfate	Acidity regulator
172.	420(i)	Sorbitol	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener
173.	420(ii)	Sorbitol syrup	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener
174.	1420	Starch acetate	Emulsifier, Stabilizer, Thickener
175.	1450	Starch sodium octenyl succinate	Emulsifier, Stabilizer, Thickener
176.	1405	Starches, enzyme treated	Emulsifier, Stabilizer, Thickener
177.	473a	Sucrose Oligoesters, Type I and Type II	Emulsifier, Stabilizer
178.	553(iii)	Talc	Anti-caking agent, Glazing agent, Thickener
179.	417	Tara gum	Gelling agent, Stabilizer, Thickener
180.	957	Thaumatococcus	Flavour enhancer, Sweetener
181.	171	Titanium dioxide	Colour
182.	413	Tragacanth gum	Emulsifier, Stabilizer, Thickener

S. No.	INS No.	Additive	Functional Class
183.	1518	Triacetin	Carrier, Emulsifier, Humectant
184.	380	Triammonium citrate	Acidity regulator
185.	333(iii)	Tricalcium citrate	Acidity regulator, Firming agent, Sequestrant, Stabilizer
186.	332(ii)	Tripotassium citrate	Acidity regulator, Sequestrant, Stabilizer
187.	331(iii)	Trisodium citrate	Acidity regulator, Emulsifier, Sequestrant, Stabilizer
188.	415	Xanthan gum	Emulsifier, Gelling agent, Stabilizer, Thickener
189.	967	Xylitol	Emulsifier, Humectant, Stabilizer, Thickener

Schedule VF

[See regulations 3.(1), 3.(13), 6.(4), 7.(5), 8.(4), 9.(4), 10.(3), 11.(3) and 12.(4)]

List of food additives to be used in formats such as tablets, capsules and syrups

- (I) Nutraceuticals,
 (II) Foods for special dietary uses other than foods for infants,
 (III) Foods for special medical purpose,
 (IV) Foods with added probiotic ingredients and prebiotic ingredients,
 (V) Speciality foods containing plant or botanical ingredients, and
 (VI) Health supplements

S.No.	Additive (Pharmaceutical Aid)	Functionality	Maximum Permitted Level
1.	Acacia gum	Binding agent	GMP
2.	Acetone	Solvent for coating	GMP (does not remain in the tablet and residual levels to be as per IP)
3.	Ascorbic acid and its esters and salts	Antioxidant	0.5%
4.	Benzoic acid and its salts	Preservative	0.5%
5.	BHA	Antioxidant	0.5%
6.	BHT	Antioxidant	0.5%
7.	Bronopol	Preservative	0.5%
8.	Calcium carbonate	Diluent, Dissintegrant	GMP
9.	Calcium stearate	Lubricant	1%
10.	Carboxymethylcellulose Calcium	Binding agent	5-15%
11.	Carrageenan gum	Binding agent	2%
12.	Cellulose acetate phthalate	Coating agent	2%
13.	Citric acid	Disintegrant	2%
14.	Citric and fatty acid esters of glycerol	Stabilizer	2%
15.	Copovidone	Binding agent	2-5%
16.	Corn oil	Vehicle	GMP
17.	Corn starch	Diluent, Binding agent, Dissintegrant	GMP
18.	Cross carmellose sodium	Disintegrant	2%
19.	Cyclodextrin	Diluent	GMP
20.	Dextrose	Diluent	GMP
21.	Dicalcium phosphate	Diluent	GMP
22.	Ethyl acetate	Solvent for coating	GMP (does not remain in the tablet and residual levels to be as per IP)
23.	Ethyl alcohol	Solvent for coating	GMP (does not remain in the tablet and residual levels to be as per IP)

24.	Ethyl cellulose	Coating agent, Ingredient of capsule shells	GMP
25.	Fructose	Diluent	GMP
26.	Gelatin	Binding agent, Ingredient of capsule shells	GMP
27.	Glycerin	Vehicle, Humectant for capsule shells	GMP
28.	Guar gum	Binding agent	GMP
29.	Hydrogenated castor oil	Lubricant	2%
30.	Hydrogenated vegetable oil	Lubricant	1%
31.	Hydroxy propyl methylcellulose	Coating agent, Ingredient of capsule shells	GMP
32.	Isomalt	Soluble fiber	15%
33.	Kaolin	Diluent	GMP
34.	Lactitol	Diluent	200 mgper capsule
35.	Lactose	Diluent	GMP
36.	Lecithin and its salts/esters from soya or other sources	Emulsifier, Stabilizer	GMP
37.	Light magnesium carbonate	Anticaking agent	0.5%
38.	Light magnesium oxide	Anticaking agent	0.5%
39.	Liquid glucose	Binding agent	GMP
40.	Magnesium carbonate	Adsorbant	0.3%
41.	Magnesium stearate	Antisticking agent, Glidant	2%
42.	Maize Starch	Diluent, Binding agent, Dissintegrant	GMP
43.	Maltitol	Sweetener, Diluent	GMP
44.	Maltodextrin	Diluent	GMP
45.	Maltose	Diluent	GMP
46.	Manitol	Diluent, Sweetner	GMP
47.	Methyl paraben and its salts	Preservative	0.2%
48.	Microcrystalline cellulose	Diluent	GMP
49.	Natural and synthetic colors as per FSSR	Coloring agents	Limits as per FSSR
50.	Peanut oil	Vehicle	GMP
51.	Pectin	Binding agent	GMP
52.	PEG 4000	Diluent for direct compression tablets	GMP
53.	Colors permitted under Rule 127 of Drugs & Cosmetics Rules including lake colours	Coloring agents	GMP
54.	Poly ethylene glycol (PEG)	Vehicle, Humectant for capsule shells	GMP
55.	Povidone	Binding agent	5%
56.	Propyl paraben and its salts	Preservative	0.02%

57.	Propylene glycol	Vehicle, Humectant for capsule shells	GMP
58.	Purified Talc	Glidant, Dusting powder for coating	2%
59.	Saff flower oil	Vehicle	GMP
60.	Sodium alginate	Binding agent	5%
61.	Sodium starch glycolate	Disintegrant, Binder, Thickening agent	2%
62.	Sorbitan crystalline	Diluent	15%
63.	Sorbitan oleate esters (Tweens)	Solubalizers	0.5%
64.	Sorbitol liquid	Vehicle, Humectant for capsule shells	GMP
65.	Starch, pregelatinized	Disintegrant	1%
66.	Stearic acid	Antisticking agent, Glidant	2%
67.	Sucrose	Diluent, Coating agent	GMP
68.	Sunflower oil	Vehicle	GMP
69.	TBHQ	Antioxidant	0.5%
70.	Tocopherol and its esters	Antioxidant	0.5%
71.	Tragacanth gum	Binding agent	GMP
72.	Tribasic calcium phosphate	Diluent, anticaking agent	GMP
73.	Tricalcium phosphate	Diluent	GMP
74.	Vegetable oils	Vehicle	GMP
75.	Xanthan gum	Binding agent	GMP
76.	Xylitol	Diluent, Sweetner	GMP
77.	Zinc stearate	Lubricant	0.5-1.5%

Schedule -VI

[See regulations 3.(13), 4.(2), 6.(2)(i), 7.(2)(i), 7.(3)(i), 7.(3)(v), 8.(2)(i) and 9.(2)(i)]

List of ingredients as nutraceuticals

PART A				
S. No.	Nutraceutical ingredients	Common name	Purity Criteria	Permitted Range
1.	Astaxanthin (from <i>Haematococcus pluvalis</i>), powder or oleoresin	-	Astaxanthin content	4 mg/day, Max
2.	Boswellia serrate - gum resin extract	Salai guggul / Kundru	Total boswellic acids or 11-keto-beta boswellic acids content	250 - 1,500 mg extract/day
3.	Caffiene	Caffiene	Per cent caffiene	Within levels specified in FSS Regulations
4.	Chromium picolinate/ nicotinate	-	Chromium picolinate/ nicotinate content	200 - 400 mcg / day
5.	<i>Cimicifuga racemosa</i> (or <i>Actaea racemosa</i>). Extracted from rhizomes and roots	<i>Black cohosh</i>	Total triterpene glycosides (minimum 0.4%), calculated as 23-epi-26-deoxyactein).	40 - 200 mg /day, Max
6.	<i>Citrus Bioflavonoids</i> (<i>Citrus x paradisi</i> , <i>Citrus reticulata x maxima</i> , <i>C. x sinensis</i> and <i>Citrus limon</i>)	Citrus	<i>Bioflavonoids and total polyphenol content</i>	150 - 600 mg / day, Max
7.	CoQ10 from non GM source	Co enzyme Q10	<i>Ubiquinone and ubiquinol content</i>	100-1,000 mg / day, Max
8.	<i>Echinacea</i> (<i>E. angustifolia</i> , <i>E. purpurea</i> , and <i>E. pallida</i>) Liquid/powder extract	Echinacea	Alkamides (0.25 mg/ml) and cichoric acid (2.5 mg/ml), if the extract used is in liquid form. In case of Hydroethanolic Echinacea extract is in a powdered form computation may be done proportionately to the weight/weight dry powder extract based on liquid extract used to obtain a dry powder format.	900 mg / day, Max
9.	<i>Ginkgo biloba</i> extract obtained from dried leaves of <i>Ginkgo</i> (<i>Ginkgo biloba</i> L.).	Ginkgo biloba extract	Ginkgo flavone glycosides and Ginkgolides (diterpene lactones). Total flavonoids content (20.2 to 27% calculated as flavanol glycosides and tested for total terpene lactones (5.4% to 12.0%). Presence of Ginkgolides A, B, C needs to be tested qualitatively.	120-240 mg/ day, Max
10.	Glucosamine hydrochloride	Glucosamine	Glucosamine content	1,500-3,000 mg/day, Max
11.	Glucosamine sulphate	Glucosamine	Glucosamine content	2,500-5,000 mg/day, Max

PART A				
S. No.	Nutraceutical ingredients	Common name	Purity Criteria	Permitted Range
12.	<i>Gymnema sylvestre</i> extract powder	Gudmar extract	Gymnemic acid content	500-1,500mg / day, Max
13.	Lactase (β -galactosidase)*	-	Enzyme activity	3,000 – 9,000 IU (or FCC units) / day, Max
14.	<i>Panax ginseng</i> (Syn;Korean Ginseng) extract - (obtained from 0.6 to 2.0 gm of Ginseng root, (<i>Panaxginseng</i> .C A. Meyer, Araliaceae)	Ginseng extract	Ginsenoside content ranging from 0.7 to 3%.	90 - 400 mg /day, Max
15.	<i>Phycococyanin from Spirulina plantesis (Aethrospira plantesis) Dried powder</i>	Spirulina	Protein: 50-70 %; Carbohydrates: 20-40%; Minerals (Ash): 5.0 – 15%; Moisture: 3.0 – 6.0 %	50 – 250 mg /day, Max
16.	<i>Piper nigrum / Piper longum extract</i>	Peeper / Pippali	Piperine content	15 mg/day of piperine, Max(Duration of use: maximum 30 days)
17.	Quercetin obtained from extracts of citrus fruits and other vegetables	-	<i>Quercetin content</i>	100 mg / day, Max
18.	<i>Schizandra</i> berry extract	Five-flavor berry	Schizandrin berries containing 2.5-3.0% schizandrin	1 – 3 g / day, Max
19.	<i>Scutellaria bicalensis</i>	Skullcap	Aq. Extract of <i>Scutellaria bicalensis</i> standardized to bicallin content (NLT 50%)	250 – 1,000 mg/ day, Max
20.	Selenium Yeast	-	<i>Selenium content and number of yeast counts (Cfu/g)</i>	2 mg/day of selenium, Max
21.	Siberian ginseng- obtained from 0.6 to 2.0 gm of Ginseng root (<i>Acanthopanax senticosus</i> , belonging to panax type, C A. Meyer, Araliaceae)	Ginseng extract	Releutherosides content	100 – 450 mg / day, Max
22.	<i>Silybum marianum</i> extract (silymarin extract)	Milk Thistle	<i>Standardized extract – silymarin content</i>	250 - 1,000 mg/ day
23.	Spirulina (algae) from <i>Spirulina platensis</i> (<i>Arthrospira platensis</i>)	Spirulina	(Protein (min.) - 55%, carbohydrates (max.)-30%, fats (lipid) – not more than 10%, minerals (ash)-5-10%, moisture-3-6% (also fatty acid profile to be mentioned on the package)	500 - 3,000 mg / day
24.	<i>Vaccinium myrstillus</i> extract	Bilberry extract	Anthocyanin content	50 - 600 mg / day, Max

Part B		
S.No.	Nutraceuticals / Ingredients	Common name.
1.	(+) Hydroxycitric acid	
2.	<i>Allium sativum</i> – bulbs dried powder / extract powder standardized	Garlic
3.	<i>Aloe vera</i> – juice /concentrate /powder of sap /gel	Indian aloe, Ghrit kumari
4.	Alpha amylase*	-
5.	Alpha mangostin	-
6.	Alpha-galactosidase*	-
7.	Alpha-lipoic acid	-
8.	<i>Amaranthus tricolor</i> – leaf powder / extract	-
9.	Amylase*	-
10.	Amyloglucosidase*	-
11.	<i>Anethum graveolens</i> L. - seeds and oil	Dill
12.	Anthocyanin	-
13.	Arabinogalactan	-
14.	Arachidonic acid	-
15.	<i>Asparagus densiflorus</i> - extract	Asparagus
16.	<i>Bacopa monnieri</i> - leaf extract	Brahmi
17.	Barley seed powder	Barley
18.	<i>Berberis vulgaris</i> – stem/root extract	Berberberry
19.	Beta carotene – standardized soft concentrate / emulsified concentrate / powder	-
20.	Beta ecdysterone	-
21.	Beta glucans	-
22.	<i>Beta vulgaris</i> – root extract	Beet
23.	Beta sitosterol	-
24.	<i>Betula platyphylla</i> - bark extract	Birch
25.	<i>Biota orientalis</i> - seed powder	Biota
26.	Black /green tea extract, standardized powder	-
27.	<i>Borago officinalis</i> - oil	Borage
28.	Campestanol	-
29.	Campesterol	-
30.	<i>Capsicum annum</i> - extract / standardized to capsaicin content	Cayenne pepper
31.	<i>Caricus papaya</i> – leaf extract	Papaya
32.	Carotenoids (natural mixed, including from algal sources)	-
33.	Casein and caseinates	
34.	<i>Caulophyllum thalictroides</i> - root extract	Blue cohosh
35.	Cellulase*	-
36.	<i>Centella asiatica</i> – leaf/aerial parts standardized extract	Mandukparni / Gotu Kola
37.	<i>Matricaria chamomilla (Matricaria recutita)</i> – aerial parts extract	Chamomile

Part B		
S.No.	Nutraceuticals / Ingredients	Common name.
38.	Chlorella platensis - dried powder	Green algae
39.	Chlorogenic acids and caffeic acid	-
40.	Chondroitin sulphate	Chondroitin
41.	<i>Cichorium intybus</i> - roasted root powder	Chicory
42.	<i>Cinnamomum verum</i> - bark powder / extract	Cinnamon
43.	Citrulline	-
44.	<i>Citrus aurantium</i> - peel extract / bioflavonoids standardized	Bitter orange
45.	Citrus naringenin	-
46.	Citrus naringinine	-
47.	Clove powder	Lavang
48.	<i>Cnicus benedictus</i> - aerial parts extract / root extract	Blessed thistle
49.	Cocoa (chocolate) bean - extract	-
50.	<i>Coccinia grandis</i> (L.) Voigt - extract	Ivy gourd
51.	Collagen hydrolysed	-
52.	Conjugated linoleic acid concentrate	-
53.	Crustacean shells	-
54.	<i>Cuminum cyminum</i> L - oil / extract	Cumin
55.	<i>Curcuma longa</i> - rhizome powder / extract standardized	Turmeric
56.	Curcuminoids - soft extract / powder and curcumin complex	-
57.	<i>Cyperus rotandus</i> - extract	Nirgundi
58.	Dehydroepiandrosterone (DHEA) and 7-Keto DHEA	
59.	Diastase*	-
60.	D-Pinitol	-
61.	Edible legumes (seed powder), legume proteins (protein isolates/ concentrates/ hydrolysates)	-
62.	Ellagic acid	-
63.	<i>Emblica officinalis</i> - dried fruit extract / spray dried pulp powder	Indian gooseberry/ amla
64.	Eriocitrin (from citrus fruit)	-
65.	Evening primrose oil	-
66.	<i>Fagopyrum esculentum</i> - seed	Buckwheat
67.	Fish oil	-
68.	<i>Foeniculum vulgare</i> - fruit - oil / extract	Fennel
69.	Freeze-dried banana powder	-
70.	Galactomannan	-
71.	Gallic acid	-
72.	Gamma-linoleic acid (GLA)	-
73.	Gamma-oryzanol	-
74.	<i>Garcinia gummi-gatti</i> and <i>Garcinia cambogia</i> - fruit rind extract standardized to hydroxyl citric acid, powder)	Kokum / Brindall Berry / Malabar tamarind
75.	<i>Garcinia mangostana</i> - seed extract standardized	Mangosteen
76.	Glucoamylase*	-

Part B		
S.No.	Nutraceuticals / Ingredients	Common name.
77.	Glucomannan	-
78.	<i>Glycyrrhiza glabra</i> - extract	Licorice
79.	Grape seed extract	-
80.	Green coffee seed extract standardized, including decaffeinated coffee bean powder/extract	-
81.	<i>Grifola frondosa</i> - standardized extract	Maitake mushroom
82.	Guar gum and gum arabic and its derivatives as a source of fibers; and fibers from other food sources	
83.	Hemicellulase*	-
84.	Hesperidin	-
85.	High oleic sun flower oil and other vegetable oils with high oleic content	-
86.	<i>Hippophaerh amnoides</i> - fruit dried powder / extract / juice	Sea buckthorn
87.	<i>Humulus lupulus</i> L - powder / extract	Hops
88.	Hydrolysed whey peptide	Whey
89.	<i>Hypericum perforatum</i> - aerial parts standardized extract	St. Johns Wort
90.	<i>Inula racemosa</i> - root extract	Pushkarmoola
91.	Invertase*	-
92.	Isoflavones (genistein, daidzein)	-
93.	Kelp (brown algae)	-
94.	Krill oil - standardized for DHA / EPA	-
95.	Lactalbumin	-
96.	Lactoferrin	-
97.	Lactoperoxidase*	-
98.	<i>Lagerstroemia speciosa</i> L (leaf extract)	Banaba
99.	Lecithins	-
100.	Lignans	-
101.	<i>Linum usitatissimum</i> - seed powder and oil	Flaxseed
102.	Lipase*	-
103.	Lutein	-
104.	Lutein/zeaxanthin complex	-
105.	Lycopene	-
106.	<i>Lycium eleagnus</i> - fruit - dried powder / concentrate standardized	Goji berry (wolfberry)
107.	Maltase*	-
108.	<i>Medicago sativa</i> extract	Alfalfa
109.	Medium chain triglycerides	-
110.	<i>Menyanth estrifoliata</i> - Leaf powder	Buckbean / bogbean
111.	Millets and their powder	-
112.	<i>Momordica charantia</i> - fruit / seed extract	Bitter melon (bitter gourd)
113.	<i>Monodora myristica</i> (Gaertn.) Dunal - oil / extract	Nutmeg
114.	<i>Morinda citrifolia</i> extract	Noni

Part B		
S.No.	Nutraceuticals / Ingredients	Common name.
115.	<i>Moringa oleifera</i> leaf / pods / seed extract powder	Moringa / drum stick
116.	Mulberry tea – leaf / fruit extract	Mulberry
117.	<i>Myrica cerifera</i> – bark extract	Bayberry
118.	<i>Myristica fragrans</i>	Mace
119.	N-Acetyl D-glucosamine	-
120.	<i>Nasturtium officinale</i> - extract	Watercress
121.	Nattokinase enzyme (as Soy Bean Fibrinase)	-
122.	<i>Ocimum tenuiflorum /Ocimum sanctum</i> – aerial parts / seed extract	Basil /tulasi
123.	Omega-3 fatty acids (docosaehaenoic acid - eicosapentaenoic acid - alpha - linolenic acid)	-
124.	Omega-6-fatty acids (linoleic acid, arachidonic acid and conjugated linoleic acid)	-
125.	Oyster shell powder	-
126.	Pancreatin*	-
127.	Pancrelipase*	-
128.	Papain*	-
129.	<i>Passiflora foetida</i> - extract	Passion flower
130.	<i>Arachis hypogaea</i> - (roasted) powder	Pea nut
131.	Pectin	-
132.	Pepsin*	-
133.	<i>Phellodendron amurense</i> leaf oil	Phellodendron
134.	Phosphatides /Phospholipids	-
135.	<i>Phyllanthus amarus</i> - extract	Bhuiamalaki
136.	Phytase*	-
137.	<i>Picrorhiza (Picrorhiza kurroa)</i> - extract	Kurchi
138.	<i>Pimento officinalis</i> L. - extract/powder	Allspice
139.	<i>Pinus gerardiana</i> - bark extract	Pine nut
140.	<i>Piper longum</i> - extract	Long pepper (pippali)
141.	<i>Piper nigrum</i> - green extract	Green pepper
142.	<i>Piper nigrum</i> – powder / standardized extract	Black pepper
143.	Policosanol	-
144.	Protease*	-
145.	<i>Prunus serotina</i> - extract	Black cherry
146.	Psyllium (Ispaghula) - seed husk	Isaphgul
147.	Pumpkin seed oil /meal	-
148.	<i>Punica granatum</i> – fruit /seed /skin extract /powder	Pomegranate / dadima
149.	<i>Raphanus sativus var. niger</i> - root powder/ extract	Black radish
150.	Red wine - extract /concentrate	-
151.	Red yeast rice	-
152.	Resveratrol	-

Part B		
S.No.	Nutraceuticals / Ingredients	Common name.
153.	<i>Rhododendron arboretum</i> - juice/extract	Rhododendron
154.	Rice bran	-
155.	Rice bran arabinoxylan compound	-
156.	Rose hips	-
157.	<i>Rosmarinus officinalis</i> - leaves/ needles extract /oil	Rosemary
158.	Royal Jelly	-
159.	Rutin from fruit peels	-
160.	<i>Salvia officinalis</i> - leaf extract	Sage
161.	<i>Sambucus nigra</i> - extract	Elderberry/ Black elderberry
162.	Shark cartilage /squalene oil	-
163.	Shiitake mushroom - extract	-
164.	<i>Solanum lycopersicum</i> - fruit powder/ extract	Tomato
165.	Soy sprouts - dried powder	-
166.	Soya protein isolate/ edible legume seed protein isolate	-
167.	Spearmint - leaf and distillate	-
168.	Stanols and sterols including cholesterol	-
169.	<i>Tagetes sp.</i> - petals oleo resin / extract	Marigold
170.	Tea catechins (epigallo catechin gallate, epicatechin, catechin gallates)	-
171.	<i>Terminalia arjuna</i> - bark /leaf extract (standardized extract)	Arjuna
172.	<i>Terminalia bellerica</i> - fruit extract	Myrobalan / Baheda
173.	<i>Terminalia chebulia</i> - fruit extract	Myrobalan / Harad
174.	Theaflavin	-
175.	Theanine	-
176.	Theobromine	--
177.	Tocopherols	-
178.	<i>Trigonella-foenum-graecum</i> - seeds extract	Fenugreek
179.	<i>Triticum sativum</i> - bran	Wheat
180.	Trypsin*	-
181.	<i>Vaccinium corymbosum</i> - fruit - dried powder / concentrate standardized	Blueberry
182.	<i>Vaccinium oxycoccos</i> - fruit - dried powder / concentrate standardized	Cranberry
183.	<i>Vitis alba and Vitis vinifera</i> - fruit - dried powder / concentrate standardized	Blue grapes
184.	Wheat germ	-
185.	Zeaxanthin (max. 4 mg/day)	-
186.	<i>Zingiber officinale</i> - rhizome standardized extracts	Ginger
187.	α -galactosidase*	-

Note.- *Enzymes- The enzymes listed in this schedule are primarily used as processing aids, but also may be used in nutraceutical products.

Schedule -VII

[See regulations 3.(13), 6.(2)(i), 7.(2)(i), 8.(2)(i), 9.(2)(i) and 10.(1)(i)]

List of strains as probiotics (live micro-organisms)

S. No.	Name of the Microorganism
1.	<i>Lactobacillus acidophilus</i>
2.	<i>Lactobacillus plantarum</i>
3.	<i>Lactobacillus reuteri</i>
4.	<i>Lactobacillus rhamnosus</i>
5.	<i>Lactobacillus salivarius</i>
6.	<i>Lactobacillus casei</i>
7.	<i>Lactobasillus brevis</i>
8.	<i>Lactobacillus johnsonii</i>
9.	<i>Lactobacillus delbrueckii</i> sub- sp. <i>bulgaricus</i>
10.	<i>Bacillus coagulans</i>
11.	<i>Lactobacillus fermentum</i>
12.	<i>Lactobacillus caucasicus</i>
13.	<i>Lactobacillus helveticus</i>
14.	<i>Lactobacillus lactis</i>
15.	<i>Lactobacillus amylovorus</i>
16.	<i>Lactobacillus gallinarum</i>
17.	<i>Lactobacillus delbrueckii</i>
18.	<i>Bifidobacterium bifidum</i>
19.	<i>Bifidobacterium lactis</i>
20.	<i>Bifidobacterium breve</i>
21.	<i>Bifidobacterium longum</i>
22.	<i>Bifidbacterium animalis</i>
23.	<i>Bifidobacterium infantis</i>
24.	<i>Streptococcus thermophilus</i>
25.	<i>Saccharomyces boulardii</i>
26.	<i>Saccharomyces cerevisiae</i>
27.	<i>Lactobacillus paracasei</i>
28.	<i>Lactobacillus gasseri</i>

- Note.- (1) These organisms may be used either singly or in combination but shall be declared on the label with full information and has to be Non-GMO.
- (2) The Food Authority may add any new strain of microorganism, possessing probiotic properties, after proper scientific evaluation, and include in this Schedule.

Schedule - VIII

[See regulations 3.(13), 6.(2)(i), 7.(2)(i), 8.(2)(i), 9.(2)(i) and 11.(1)(i)]

List of prebiotic compounds

S. No.	Prebiotic Compounds
1.	Polydextrose
2.	Soybean oligosaccharides
3.	Isomalto-oligosaccharides
4.	Fructo-oligosaccharides
5.	Gluco-oligosaccharides
6.	Xylo-oligosaccharides
7.	Inulin
8.	Isomaltulose
9.	Gentio-oligosaccharides
10.	Lactulose
11.	Lactoferrin
12.	Sugar alcohols such as lactitol, sorbitol, maltitol, inositol, isomalt
13.	Galacto-oligosaccharides

Note.- The Food Authority may add any new specific prebiotic after proper scientific evaluation and include in this Schedule.