REPUBLIC OF KENYA

REGISTRATION OF FOOD/DIETARY SUPPLEMENTS AND BORDERLINE PRODUCTS IN KENYA

GUIDELINES TO SUBMISSION OF APPLICATIONS

PHARMACY AND POISONS BOARD

PREFACE

This guideline presents a common format for presentation of a well-structured application for registration of food/dietary supplements and borderline products to be submitted to Pharmacy and Poisons Board. This format of technical documentation will significantly reduce the time and resources needed to compile applications for registration of food/dietary supplements and borderline products and will in future ease the preparation of electronic submissions. Evaluation of dossiers and communication with the applicants will be facilitated by a standard document of common elements. This guideline will ensure that only good quality and safe food/dietary supplements and borderline products are available in Kenya; and to contribute towards their accessibility, cost effectiveness and appropriate use with the current state of knowledge.

DEFINITION OF TERMS

Food/Dietary/Nutritional supplement or Nutraceuticals means a product other than tobacco intended to supplement the diet and shall include all of the following characteristics

a) Contains concentrated source of one or more of the following: vitamins, minerals, amino acids, essential oils, natural substances of plants or animal origin, enzymes, substances with nutritional or physiological functions or contains any combination of these

b) Is intended to be taken orally in the form of tablet, capsule, powder, soft gel, granules or liquids

c) Is not presented for use as a conventional food or as a sole item of a meal of the diet

d) Is labeled as a food supplement and has NO medical claims on it

Borderline products.

A borderline product is one which does not fall into the medical devices category, is neither a medicinal product nor a food supplement. A product which is for use only as a toilet preparation, disinfectant or beverage is not normally regarded as a medicinal product and are generally subject to safety and labelling regulation will be considered as borderline products. However, should any of the above contain a pharmacologically active substance or make medicinal claims (claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicine).

These guidelines are intended to describe PPB policy in categorization of products. They are intended as guidelines only and should not be assumed to be a definition of the law in this area.

The PPB will offer advice on the classification of a product in cases of doubt.

SCOPE OF THE GUIDELINE

This guideline primarily addresses the organization of the information to be presented in registration applications for food/dietary supplements and borderline products . A product shall be considered as a food supplement if it contains the Recommended Dietary Allowances (RDA) as given in annex I and international standards. It is intended to provide an appropriate format for submission of data for registration. Applicants should not modify the overall organization of the document as outlined in the guideline.

SECTION A

INTRODUCTION

This guideline applies only to food/dietary supplements and borderline products. In case of other medicinal products such as conventional and herbal products, separate guidelines are available and these can be obtained from PPB offices or website (www.pharmacyboardkenya.org). This guideline provides recommendations for applicants preparing application for food/dietary supplements and borderline products for submission to the Pharmacy and Poisons Board (PPB).

This guideline prescribes the minimum information required for submission of dossiers and the evaluation of products. This guideline indicates an appropriate format and organisation of data.

Applicants are requested to carefully read this guideline, fill in application form, prepare dossiers and submit them in one (1) hard-copy as well as an **electronic copy (MS Word on a CD-ROM)** which should be cross-referenced to the dossier by clearly indicating the title and section number of all the supporting documents.

All areas are to be filled out by the applicant **EXCEPT** where indicated by **grey areas which are for PPB Official Use Only!**

LANGUAGE

All applications and supporting documents shall be in English or kiswahili and legible. Where material is not originally in English or kiswahili, a copy in the original language and a full translation should be submitted, the accuracy of which is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Kenyan Embassy or by the national drug regulatory authority of the country from where the document originates. Reports submitted only in a language other than English or kiswahili will not be accepted.

DATA PRESENTATION

All data shall be presented on A4 and 80g/m2 paper with readily readable letters of 12 font sizes. Every page shall be numbered sequentially and state the exact location (Annex number) of any appended documents in the relevant sections of the form. Before submitting the completed form, check that you have provided all requested information. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced. Acronyms and abbreviations should be defined the first time they are used in each part. Every page should be numbered. Different sections of the dossier shall be distinctly marked and page numbered in the style: ***page x of y*** and have a table of contents indicating the sections and page numbers. All parts must be **bound** and **arranged** sequentially**.** The left-hand margin should be sufficiently large that information is not obscured by the method of binding. The dossier covers shall be made of a material which is thick and hard enough not to collapse in standing position. One or more dossier file may be used depending on the number of pages contained in each part and in this case the files shall be serially numbered in the format i.e. **FILE NO. X of Y.**

OFFICIAL REFERENCES AND TEXTS

References should be cited in accordance with the current edition of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, International Committee of Medical Journal Editors (ICMJE). When direct reference is made to specifications, quality control procedures and test methods in official compendia, text books or standard publications, reprints or authenticated copies of relevant pages shall be enclosed. References to pharmacopoeias should specify the year of issue. References should be provided for all in-house processes. There shall be no cross reference of particulars or documentation between one product and another.

SUBMISSION OF APPLICATION

The application should be submitted to the following address:

The Registrar,
Pharmacy and Poisons Board
Lenana Road,
P. O. Box 27663-00506,
NAIROBI, KENYA

For purposes of submission to PPB, an application for registration of food supplement shall include:

i. One duly filled application form and an electronic copy in MS Word on a CD-ROM including their supporting documents - see Annex I

ii. Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.

iii. Non refundable application fee for registration of food/dietary supplements and borderline products in Kenya.

iv. GMP inspection of the manufacturing site may be required incase of quality issues in the market

PAYMENT OF FEES

Every application shall be accompanied by appropriate fees at the time of application. Any application that will not be accompanied by appropriate fees will not be accepted.

Mode of Payment: Payments by crossed or bankers cheque shall be made payable to **PHARMACY AND POISONS BOARD**. Application for registration of food/dietary supplements and borderline products :

Products imported into Kenya	US$ 1000
Locally manufactured in Kenya	US$ 500
GMP inspection fee for foreign Companies	US$ 4000
GMP inspection fee for Local Companies	US$ 1000

Application for annual retention of a registered dietary/food supplement and borderline products:

Products imported into Kenya	US$ 300
Locally manufactured in Kenya	US$ 150
Penalty for late retention(after 30th January)	US$ 100

Variations: With respect to any variations to an original application, a fee of US$ 200 must be paid.

Replacement of a Certificate: A fee of KSH 500 shall be paid for a replacement copy of a Certificate, if the original is defaced, damaged or lost. The copy shall be stamped ―duplicate copy.

Appeal fee: With respect to an appeal to an original application, a fee of US$ 300 must be paid at the time of appeal. Any appeal that will not be accompanied by appropriate fees will not be accepted.

Other Charges: The Pharmacy and Poisons Board may, at its own discretion, charge an applicant such costs as it may incur for carrying out any laboratory investigations prior to the registration of a product.

Verification of compliance to current Good Manufacturing Practices (cGMP)

PPB may conduct inspection of the site or use other means to verify whether the facility complies with current Good Manufacturing Practices Regulations before a product is registered or incase of quality issues with the product in the market.

TIMELINES

The Board will implement the following timelines in processing applications for marketing authorization of food/dietary supplements and borderline products.

a) Fast-tracked registration (Locally manufactured and Priority products only), Post Approval Variation and Renewal of registration

Complete applications will be processed within 90 working days of receiving the application including evaluation of documentation and consideration by the board.

b) Evaluation of new applications

Complete new applications will be processed within 6 months of receipt of the application.

WITHDRAWAL OF AN APPLICATION

When the applicant fails to submit written responses to queries within 6 months from the date of their issuance, it will be deemed that the applicant has withdrawn the application or if the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected. The applicant will be required to apply afresh.

VALIDITY OF REGISTRATION

The registration of food/dietary supplements and borderline products shall be valid for one (1) years unless earlier suspended or revoked by PPB or withdrawn by applicant. The Board will give reasons in writing when it suspends or revokes, or amends conditions of registration. Likewise the applicant shall also give reasons for terminating registration of a food/dietary supplement and borderline products.

SECTION B

1.0 APPLICANT

1.1 Application for registration of a Dietary/Food Supplement and borderline products shall be made only by:

- the patent holder
- the manufacturer
- a distributor or Local Representative authorised by the manufacturer or patent holder

The name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided.

1.2 Authorised representative in kenya

A body corporate (company) shall be the applicant's local representative in Kenya with legal authorisation (power of attorney) to take full responsibility for the product on behalf of the applicant, and will be answerable to PPB.

This body corporate shall be called the **Local Representative (LR)**. A copy of the legal authority given to the representative or agent shall be enclosed.

2.0 PARTICULARS OF THE DIETARY/FOOD SUPPLEMENT AND BORDERLINE PRODUCT

2.1 **Proprietary name** means the (trade or brand) name which is **unique** to a particular food/Dietary Supplement or borderline Product and by which it is generally identified.

2.1.1 All Dietary/Food Supplements or borderline products shall be notified as per their proprietary Name. The Proprietary Name should not be derived from INN name and should not have an INN stem.

2.1.2 If derived from Generic Name should not be similar to the Generic Name.

2.1.3 Each Name used should be distinctive in sound and in writing not to be confused with Names of other Products.

2.1.4 The Name should not be misleading e.g. use Protavit for product not containing implied micro or macronutrient. Names which lead to self-diagnosis in conditions requiring professional diagnosis will be considered as misleading.

2.1.5 Any Phrase that implies superiority, speed or better performance over other products shall not be allowed.

2.1.6 Meaning of abbreviations, symbols, alpha-numerals must be explained in a covering letter.

2.1.7 A proprietary name should not carry prescription information unless otherwise backed with a strong scientifically proven report that support the connotation.

2.1.8 When the Name being applied for is identical or very close to already registered Name, applicant shall be advised to change to another Name.

2.1.9 Proprietary Names shall not be reserved for applications that have not been yet received.

2.2 ***Approved / INN / generic name*** in relation to a Dietary/Food Supplement or borderline products means the internationally recognised non-proprietary name of such a product or Name of the micro or macro active or such other name as the PPB may determine.

2.3 ***Strength*** shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/mL, mg per 5mL spoonful, mg per G, etc.

2.4 ***Dosage form*** shall mean the form in which the Dietary Supplement or borderline products is presented, e.g. solution, suspension, Tablet, emulsion, Capsules, Sachet, etc.

2.5 ***Visual description of the Product*** shall mean a full visual description of the Dietary Supplement or borderline products including colour, size, shape and other relevant features, e.g. 'Orange and white gelatin capsule with marks "Provit", or 'pink film-coated tablets with word "Haemforte" embossed on one side' etc.

2.6 ***Commercial pack sizes of the product*** Pack size of the product shall mean presentation of the product to be registered ie list all pack sizes intended for marketing in Kenya.

2.7 ***Labelling:*** The applicant shall ensure that the primary (immediate) packaging of the product is labelled according to the law applicable in Kenya. The following minimum information shall be required in English or kiswahili on the label of the immediate packaging:

(i) brand name where appropriate
(ii) International non-proprietary name/generic name where it is applicable
(iii) Quantity of active ingredient per dosage unit; and incase of food/dietary supplement the % of Recommended Dietary Allowances (RDA) of each ingredient per dosage unit should be provided.
(iv) Total packed quantity in a unit pack.
(v) Date of manufacture
(vi) Date of expiry
(vii) Batch number
(viii) Storage conditions
(ix) Name and physical address of the manufacturer
(x) Directions for use.
(xi) Precautions and warnings.

Due to lack of space, the date of manufacture, address of the manufacturer and storage conditions may be omitted on the primary container if it is a blister or strip pack. The name of the manufacturer may be substituted with a trade-mark or other symbol. However these details shall appear in full on the secondary packaging.

2.8 ***Information leaflet:*** Applicants should be encouraged to include Scientific Package Inserts in Dietary Supplements Packs.
Package Inserts will ensure that food/dietary supplements are safely and effectively used under the recommended conditions of use.

Package inserts should not carry promotional statements and make comparison of its product to other products.

In case of changes in the Scientific package information leaflet after product has been registered, PPB should be notified of the variation.

The information leaflet shall include the following minimum information:
i) Proprietary Name
ii) Approved INN/Generic Name if it's applicable
iii) Identification: Brief description of the physical appearance of the product.
iv) Presentation: Dosage form, and total quantity presented per unit pack e.g. milligrams, grams, Number of Tablets e.t.c.
v) Composition of product's active ingredients, stating name of each active ingredient and content in a unit dose.
vi) Name of the preservative and unit quantity per dose added into the product.
vii) Name of Anti-oxidants and unit quantity per dose added into the product.
viii) Quantity of total alcohol contained in Dietary Supplement products for human consumption.

ix) Warning in block letters of ingredients that are likely to cause harm to humans eg "CONTAINS TARTRAZINE" if tartrazine was added to preparations for human consumption.

x) Approved Name of any other inactive ingredients contained in the formulation.

xi) Nutritional benefit of the dietary supplement. The stated nutritional claims must be to educate the users and must not be for promotional purposes. Food supplements must not be labelled for any specific medicinal purposes ie treatment or prevention, implied or otherwise of any disease or disorder including its related disorders.

xii) Dosage and directions for use:
   a) Indicate dosages and dosage intervals
   b) Contraindications
   c) Precautions in pregnancy, lactation, renal and hepatic failure etc
   d) Side effects and Special precautions
   e) Symptoms and treatment of over dosage
   f) Storage instructions
   g) Shelf-life
   h) Name and address of the manufacturer

xiii) Trade Marks and logos*:* Infringements on Trade marks or logos are the concern of the applicant and not PPB. Disputes regarding trademarks infringements not identified by PPB during the time of registration or amendments shall be the responsibility of the applicants. If however, valid safety concerns are identified, the new applicants shall be advised to make appropriate amendments.

2.9 Applicant should provide a registration certificate or authorization to market the product as Food/Dietary supplement and borderline products in the country of manufacture. (If a food/dietary supplement and borderline products is not registered in country of manufacture, a valid explanation must be given) A copy of the manufacturing licence of the manufacturer shall be provided.

2.10 Proposed shelf life and storage conditions. The proposed shelf life means the specified length of time prior to use for which the product is inherently subject to deterioration and is deemed to be made fit for use under prescribed storage conditions

2.11 Particulars of the manufacturer(s) and activity

The name, physical address, telephone number, fax number, and e-mail address of the manufacturer shall be provided.

Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated as in the examples below.

	Name	Physical Address	Activity
1.	XYz Ltd	Plot 8, Hobe Rd, Nairobi PO Box 4456, Nairobi, kenya Tel: (020)892546	Granulation
2.	A.M.T Pharmaceuticals	Plot 25, lavington, Industrial area, Nairobi PO Box 502, Nairobi, Kenya	Compression Coating

		Tel: 222218	
3.	D.M.K and Sons Ltd	Mukinduri plaza, London, UK Tel: 235 898 491	Packing

A copy of a valid manufacturing licence shall be provided for each site.

3.0 TECHNICAL INFORMATION

3.1 COMPOSITION OF THE PRODUCT

State the approved / INN /generic name(s) of the active and inactive ingredients in the food/dietary supplement and borderline products. Trade names shall not be used.

State quantities of each ingredient per unit dose e.g. mg/tablet, mg/mL, etc.

Where applicable state the Reference text or Reference to official specifications for each ingredient e.g. USP,BP,JP.

State reason for inclusion of each inactive ingredient in the dietary supplement.

3.2 SUITABILITY OF THE PRODUCT AS A DIETARY SUPPLEMENT

For a product to qualify as a nutritional or dietary supplement, it should conform to the definition of dietary supplement stated in this guideline and in addition should meet the following requirements;

i. There should not be any medicinal or therapeutic claims in relation to use of the product for treatment or averting of a disease condition.
ii. The product should not contain any drug substances that are listed one of the Schedules in Cap 244.
iii. The product should not contain any substance of known pharmacological activity.
iv. The recommended overall intake in a day for each micro or macro nutrient content should not be above 200% of each nutrient's RDA's or above acceptable upper tolerable daily intake levels.

3.3 RAW MATERIAL SPECIFICATIONS

Raw material specifications and certificates of analysis shall be given.

Copies of the supplier's or manufacturer's Certificates of Analysis shall be supplied for each raw material as proof of conformance to all declared specifications.

3.4 DETAILS OF THE PROCEDURES INVOLVED IN THE VARIOUS STAGES OF MANUFACTURE. The details should include in process controls, control of critical steps, packaging, a flow diagram and a copy of complete Batch Manufacturing record (BMR).

3.5 SUMMARISED SPECIFICATIONS OF THE FINAL PRODUCT shall be given, i.e. the acceptable limits of the physical, chemical, biological and (where applicable)

microbiological parameters. A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above shall be given.
The Finished product specification should include but not limited to the following tests;

1) **Tests for all food/dietary supplement and borderline products**
   a) Description
   b) Identity - test method should be specific for active ingredient(s)
   c) Assay - test method should be specific and stability indicating for active ingredient(s)
   d) Impurity limits - to determine the level of degradation products of active ingredients, and active ingredient-excipient interaction impurities.

2) **Additional tests for Hard Gelatin capsules and tablets**
   a) Dissolution (for relatively water insoluble active ingredients)
   b) Disintegration (for readily soluble active ingredients)
   c) Hardness & friability
   d) Uniformity of weight / uniformity of content
   e) Water content
   f) Microbial limits

3) **Additional tests for oral liquids**
   a) pH
   b) Microbial limits
   c) Antimicrobial preservative content/ preservative efficacy test
   d) Antioxidant preservative content
   e) Extractables from primary container
   f) Alcohol content
   g) Dissolution of suspensions
   h) Particle size distribution
   i) Re-dispersibility
   j) Specific gravity
   k) Water content

All tests should be performed unless development pharmaceutics studies or process validation prove that they are unnecessary. Such proof should be provided in the application dossier.

3.6 SPECIFICATIONS OF THE PACKAGING MATERIAL

The following information shall be provided:
a) A general description of the container and closure system including primary (inner) and secondary (outer) packaging materials used.
b) Specifications for primary (immediate) packaging components such as: glass containers, plastic containers, rubber closures.
c) Evidence of suitability of the container and closure system for the finished product and proof of compatibility of primary packaging components with finished product.

3.7 STABILITY DATA OF THE PRODUCT. All applications must include stability data for the proposed shelf life of the finished product. The stability data must be sufficient to demonstrate, or indicate with a high probability that the product intended for market will remain safe, of consistent quality and efficacious throughout the product's shelf life. The stability data will form the basis for setting a shelf life and recommended storage conditions for the product.
While applicants may choose the format for the presentation of stability data, the following headings are recommended: study design; test methods; commentary on the results obtained in the studies for individual parameters (including any trends); conclusions and summary of claims.

3.8 SAFETY REQUIREMENTS FOR BORDERLINE PRODUCTS
Provide referenced literature on safety of the product.

4.0 POST MARKET SURVEILLANCE OF FOOD/DIETARY SUPPLEMENTS AND BORDERLINE PRODUCTS

4.1 Each consignment of food/dietary supplements and borderline products that is imported into KENYA shall be inspected at the port of entry by PPB Inspectors for physical attributes and only registered food/dietary supplements and borderline products shall be accepted.

4.2 Each batch of every consignment shall be accompanied by an authenticated certificate of analysis that states;

i). Name of the food/dietary Supplement and borderline products
ii). Batch Number
iii). Manufacturing date
iv). Packaging Date if different from Manufacturing date
v). Expiry date
vi). Identification for each micronutrient
vii). Assay for each micronutrient
viii). Impurity tests
ix). Specific tests for applicable dosage form e.g. DT, Uniformity of weight, Friability tests for tablets and pH, viscosity, wt/ml for oral liquid dosage forms.
x). Tests for microbial limits
xi). Certification that all Excipients used are food grade.

4.3 The inspector at the port of entry shall ensure that Dietary supplements are properly labelled with the following minimum labelling requirements.

- Name of the Supplement.
- quantity per pack.
- date of manufacture
- date of expiry
- batch number
- storage conditions
- name and address of manufacturer
- Direction for usage
- Name of added nutrients, quantities added per serving dose and % of the added quantity of each nutrient to their RDA values.

4.4 The manufacturer shall be liable to ensure the quality and safety of their products in the Kenyan market

5.0 REFERENCE

References to literature shall be precise, quoting the year of publication and the relevant page(s). Photocopies of relevant literature may be attached.

DECLARATION

The signatory shall be a qualified personnel working for and/or authorised by the manufacturer / applicant. The designation and qualification of the qualified personnel shall be stated. The declaration must be signed, dated and authenticated by an official stamp.

REFERENCES AND RESOURCE LIST:

1. *Guidelines for the registration of food/dietary supplements for Uganda.*
2. A Food Labeling Guide; Reference Values for Nutrition Labeling. (www.cfsan.fda.gov/~dms/flg-7a.html).
3. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. http://books.nap.edu/execsumm_pdf/6015.pdf.
4. Overview of Dietary Supplements. *http://www.cfsan.fda.gov/~dms/ds-oview.htm* .
5. Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Vitamins. *http://www.iom.edu/Object.File/Master/21/372/DRI%20Tables%20after%20electrolytes%20plus%20micro-macroEAR_2.pdf*.
6. *Institute of Medicine of the National Academics in USA; The Food and Nutrition Board. http:www.iom.edu*

ANNEX I

The table below lists some of the most common dietary ingredients with their recommended dietary allowance (RDA) values and acceptable maximum daily intake limits as a dietary supplement.

Name of Nutrient	**RDA**	**Acceptable maximum daily intake**	**Targeted Nutritional benefit**
ACETYL CYSTEINE	250 mg	500 mg	Powerful anti-oxidant and cell detoxification co-factor, NAC works to eliminate your body of free radicals and heavy metals.
BETA CAROTENE (PROVITAMIN A)	*	50,000 IU	Converted to Vitamin A. Acts as tissue anti-oxidant, helping to maintain healthy cells.
BIOTIN	3µg	50-200 µg	Functions as a Co-enzyme in the metabolism of carbohydrates, fats and proteins.
BORON	*	3 mg	Influences cell membrane structure and function
CALCIUM	1000 mg. 1200 mg for pregnancy & lactation; & for adolescents between 11-24 yrs	1500mg	Maintenance of healthy bones and teeth. Essential for enzyme activation, nerve impulse transmission and muscle contraction
CHLORIDE	3400 mg	6800 mg	Essential for maintenance of acid/base balance of body fluids. Also influential in the conservation of potassium, which is inefficiently resorbed by the body
CHOLESTEROL	300mg	300mg	Required in small quantities for production of many hormones, vitamin D and bile acids that help to digest fat.
CHROMIUM	200 µg	600 µg of Glucose Tolerance Form (GTF)	Enhances insulin function as glucose tolerance factor
COPPER	2 mg	3 mg taken with Zinc at a 10:1 or 15:1 ratio (Zinc:Copper)	For proper use of iron & haemoglobin in the body. Required for connective tissue formation & oxidation

Name of Nutrient	RDA	Acceptable maximum daily intake	Targeted Nutritional benefit
DIETARY FIBRE	25g	50g	Prevents and relieves bowel problems such as constipation, haemorrhoids, diverticular disease, and irritable bowel syndrome; improve cholesterol levels in the blood; reduces risk of heart disease and risk of diabetes
FLUORIDE	4 mg	8 mg	Component of VitB12. Promotes development of red blood cells.
FOLATE (AS FOLIC ACID) - Vitamin B9	200 µg for men; 180 µg for women & 400 µg for pregnant women	800 µg	Required for metabolic reactions during cell division and for regeneration of blood & cells
IODINE	150 µg	300 µg	Essential component of Thyroid hormone.
IRON	Men-10mg, women-18mg, menopause women-10mg. As a dietary supplement, inorganic iron (ferrous sulphate) which destroys Vitamin E should not be used. Organic iron (ferrous fumarate, ferrous citrate or ferrous gluconate) should be used.	36 mg	Required for maintenance of healthy red blood cells for transport of oxygen.
MANGANESE	2 mg	10 mg	Required for enzymes involved in energy metabolism, bone formation, fat synthesis
MAGNESIUM	Men-350 mg, women-280mg, pregnant & lactating	800 mg (Recommended with twice as much calcium)	Required for protein synthesis, glucose metabolism and for smooth muscle contraction

Name of Nutrient	RDA	Acceptable maximum daily intake	Targeted Nutritional benefit
	women-430mg		
MOLYBDENUM	75 µg	200 µg	Works with riboflavin in enzymes involved in carbohydrate & fat metabolism.
PANTOTHENIC ACID	10 mg	200 mg in a B-complex supplement or up to 1000 mg in divided doses	Involved in metabolism of fats, proteins & glucose into energy. Helps to maintain healthy skin & mucous membranes.
PHOSPHORUS	1000 mg	2000 mg	Helps to maintain healthy bones. Required for energy metabolic reactions in cells.
POTASSIUM	2500 mg	4000 mg. Athletes require up to 6000 mg because of heavy perspiration.	Involved in muscle contraction, cell development, nerve stimulation, food metabolism, critical for normal functioning of the heart & kidneys
PROTEIN (TOTAL PROTEIN)	56 g	112 g	For building and repair of body tissues.
SATURATED FATTY ACIDS	20g	40g	Involved in cell wall formation and tissue repair.
SELENIUM	70 µg	400 µg	Cofactor of glutathione peroxidase and antioxidant enzyme. Works with vitamin E as an antioxidant
SODIUM	600 mg	4800 mg	Required to regulate blood pressure & blood volume. Also critical for functioning of muscles & nerves
TOTAL CARBOHYDRATES	300g	600g	Metabolised to provide energy. Excess is converted to fat & stored in fat deposits
TOTAL FAT	65g	130g	Used in synthesis of nerve cells & hormones. Excess is stored as an energy reserve (Adipose tissue).
VITAMIN A (RETINOL)	5000 IU. Pregnant women should not take over 10,000IU of Vitamin A	10000-25000 IU	Maintains epithelial tissue in skin and mucous membranes. Required for maintenance of good vision, healthy skin, nails and hair.
VITAMIN B12 (CYANOCOBALAMIN)	6 µg	500-2000 µg	Required for the production of red blood cells. Helps to

Name of Nutrient	RDA	Acceptable maximum daily intake	Targeted Nutritional benefit
			maintain proper function of nervous system.
VITAMIN B2 (RIBOFLAVIN)	1.6 mg	25-100 mg	Helps to maintain healthy skin. Involved in energy production from protein, fat & carbohydrates.
VITAMIN B3 (NIACIN/ NICOTINAMIDE)	20 mg	50-100 mg	Involved in protein metabolism and for converting of fats & carbohydrates into energy.
VITAMIN B6 (PYRIDOXINE HCL)	2.0 mg	25-100 mg	Helps to maintain healthy skin. Involved in energy production from protein, fat & carbohydrates.
VITAMIN BI (THIAMINE HCL)	1.5 mg. For pregnant & lactating women 1.9 mg should be taken	25-100 mg	Required for release of energy from glucose & transforming of carbohydrates into fat. Required for maintenance of healthy nerve functions.
VITAMIN C (ASCORBIC ACID)	60 mg	1000-6000 mg	Forms collagen, required for maintenance of healthy gums, skin & connective tissue. Enhances absorption of Iron from food. Acts as a tissue anti-oxidant, hence helping in maintaining healthy cells.
VITAMIN D3 (CHOLECALCIFEROL)	400 IU; (10.0 µg)	800 IU; (20.00 µg)	Required for maintenance of healthy bones & teeth, controls the utilization of calcium in the body.
VITAMIN E (α-TOCOPHERYL ACETATE)	30 IU	400-1200 IU	Tissue anti-oxidant, protects Vitamin A & un-saturated fatty acids against oxidation in the body.
VITAMIN K3 (MENADIONE)	80 µg for men, 65 µg for women	160 µg	For production of blood clotting factors
ZINC	15 mg	30-50 mg (taken with a Zinc:Copper ratio of 10:1	Cofactor of many enzymes involved in energy metabolism, protein synthesis, immune functions, sexual maturation, sensation of taste & smell.

* RDA value for this item has not been defined

It should be noted that the acceptable maximum daily allowance RDA shown above is not exhaustive and is bound to change from time to time according to international guidelines.