

Unit 3: Nutraceuticals

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3.1 Nutraceuticals: meaning, current trends and future scope

A nutraceutical is a product derived from food sources, or presented in a food derived form, that is taken for a health benefit beyond basic nutrition: the word joins nutrition and pharmaceutical, and the category lives, as Unit 1 of the wider subject keeps showing, on the border between food and medicine. Nutraceuticals are sold as foods and supplements, not as licensed medicines, so they carry no premarket proof of efficacy of the drug kind; what regulation controls is their composition, their manufacture, their labelling and the claims they may make. Current trends, stated qualitatively as this course teaches them, run in a clear direction. Demand is driven by preventive health thinking: consumers buy products for the maintenance of health and the support of normal function rather than waiting to treat disease. The market has moved from single vitamins towards formulated products, combinations aimed at a named purpose such as joint support, gut health or healthy ageing. Botanical and traditional ingredients have moved into the mainstream supplement market worldwide. Personalised and convenience formats, gummies, drinks, bars and powders alongside the classic tablet and capsule, continue to grow, and quality marks, testing and label transparency have become selling points as regulators tighten claim and composition rules. The future scope follows from the same forces: an ageing population, rising lifestyle related ill health, and growing scientific work on the gut microbiome, on botanical standardisation and on bioavailability all point to continued growth, accompanied by continued regulatory tightening, since a larger market with health claims invites closer control. The examination point is balance: scope is real, and so is the rule that a nutraceutical may support health but may not claim to treat, cure or prevent disease without becoming a drug.

3.2 The nutraceutical categories

The syllabus lists the nutraceutical categories one by one, and they are best learned as a single map before each is taken in turn. The categories are: inorganic mineral supplements; vitamin supplements; digestive enzymes; dietary fibres; cereals and grains; health drinks of natural origin; antioxidants; polyunsaturated fatty acids; and herbs as functional foods. The map below shows them together, and the sections that follow teach each in turn.

The nutraceutical categories

Minerals Inorganic supplements	Vitamins Fat and water soluble	Digestive enzymes Amylase, protease, lipase
Dietary fibres Soluble and insoluble	Cereals and grains Whole grain value	Health drinks Natural origin liquids
Antioxidants Vitamins, polyphenols	PUFAs Omega-3 and omega-6	Herbs as foods Functional food herbs

Nine categories, one rule: composition, labelling and claims are controlled

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Figure: The nutraceutical categories of the syllabus on one map. Formulation and standardisation, regulatory aspects and the nine named products follow in this unit.

3.3 Inorganic mineral supplements

Minerals are the inorganic elements the body needs and cannot make, divided by the size of the daily need into macrominerals, needed in larger amounts, such as calcium, phosphorus, magnesium, sodium and potassium, and trace elements, needed in small amounts, such as iron, zinc, iodine, selenium, copper and manganese. As supplements they are supplied in chemical forms chosen for stability, tolerability and absorption: calcium as carbonate or citrate salts, iron as ferrous salts such as ferrous sulfate or fumarate, zinc as gluconate or sulfate, iodine commonly through iodised salt and supplements as iodides. The pharmacy points are three. First, the elemental amount is what matters, and labels state the salt and the elemental content, which differ. Second, minerals interact with each other and with medicines: calcium and iron compete in absorption, and divalent minerals can bind certain antibiotics in the gut and reduce their absorption, a food and supplement interaction of the kind Unit 5 studies formally. Third, more is not better: minerals have safe upper levels, and excess iron, selenium or vitamin A related mineral products can harm, which is why formulation and labelling discipline in this category is a safety matter and not only a quality one.

3.4 Vitamin supplements

Vitamins are organic compounds needed in small amounts for normal metabolism, grouped as fat soluble (A, D, E and K), which the body can store, and water soluble (the B complex and vitamin C), which it stores far less. Vitamin supplements supply a named vitamin, or a multivitamin combination, in a measured dose form, and their legitimate roles are the prevention and correction of deficiency and the meeting of increased needs, for example folic acid around conception and vitamin D where sunlight and diet do not supply enough. The characteristic features the student should hold are these. Chemical form matters: vitamin E is supplied as tocopherols and tocotrienols (Unit 4 returns to them as phytopharmaceuticals), and vitamin A as retinol compounds or as its provitamin beta carotene. Stability matters: vitamins degrade with heat, light, oxygen and moisture, so formulation protects them and shelf life is set by assay, not by hope. And the storage difference is a safety difference: the fat soluble vitamins can accumulate, so chronic excess of vitamins A and D is a real toxicity, while excess water soluble vitamins are largely excreted. A supplement label therefore states the amount per dose against the recommended dietary reference for the population, the framework Unit 3 returns to under regulatory aspects.

3.5 Digestive enzymes

Digestive enzyme products supply enzymes that assist the breakdown of food: amylases act on starch, proteases such as pepsin, trypsin and papain (from papaya) and bromelain (from pineapple) act on proteins, lipases act on fats, and lactase acts on lactose. Two settings must not be confused. As medicines, high strength pancreatic enzyme preparations are licensed drugs for pancreatic insufficiency. As nutraceuticals, lower strength products, often of plant or fungal origin, are sold as digestive support supplements. The pharmacognosy interest is the natural origin of enzymes such as papain and bromelain, and the formulation interest is protection: enzymes are proteins, sensitive to heat, moisture and gastric acid, so products are formulated and stored to preserve measured enzyme activity, the quantity a standardised product declares.

3.6 Dietary fibres

Dietary fibres are the carbohydrate polymers of plant foods that human digestive enzymes do not break down, passing to the large intestine where they act by their physical properties and as material for the gut microbiota. The working classification is by solubility and behaviour. Soluble fibres, such as the mucilage of ispaghula (psyllium husk), oat beta glucans and pectins, dissolve and form gels; they slow gastric emptying and nutrient absorption and are fermented by gut bacteria to short chain fatty acids. Insoluble fibres, such as wheat bran cellulose, add bulk and speed transit. As nutraceuticals, fibres are supplied as husk, powder, granules and formulated products, and their health associations in teaching are bowel regularity, support of normal cholesterol and glucose handling as part of the diet, and satiety. The formulation cautions are standard: fibre products must be taken with adequate fluid, they can bind medicines and reduce or delay their absorption if taken at the same time, and dose is increased gradually to limit gas and bloating. Ispaghula is the classic pharmacognosy example, a traditional crude drug that is also a modern fibre supplement.

3.7 Cereals and grains

Cereals and grains enter the nutraceutical unit as the staple foods whose whole grain forms carry fibre, B vitamins, minerals and phytochemicals, and whose fractions supply supplement ingredients. The teaching points are the contrast between refined grains, milled down to the starchy endosperm, and whole grains, which keep the bran and germ and therefore the fibre, vitamin E compounds, minerals and oils; named fractions such as oat beta glucan fibre, rice bran and its oryzanol fraction, and wheat germ; and the use of cereal materials as the base of formulated health foods and drinks. Cereals are the clearest example of the functional food idea: the health value is delivered by the food itself, in ordinary amounts, not by a concentrated dose form.

3.8 Health drinks of natural origin

Health drinks of natural origin are liquid products built on natural ingredients and marketed for refreshment with an added health association: herbal and botanical drinks, aloe and amla based drinks, fruit and vegetable drinks, fermented drinks and tea based drinks. Green tea is one of the nine named products of this unit, studied in detail below. The quality points for the category are the identity and strength of the natural ingredient in a matrix that is mostly water, control of added sugars, which can contradict the health positioning, the preservation and microbiological control any liquid food needs, and honest labelling of contents per serving.

3.9 Antioxidants

Antioxidants, in nutraceutical teaching, are substances that protect cells and food components against oxidative damage by free radicals, whether made in the body, eaten in foods or taken as supplements. The named teaching examples span the chemistry of this whole subject: vitamins C and E, the carotenoids including beta carotene and lycopene, the flavonoids and other polyphenols of tea, turmeric and coloured vegetables, selenium as a component of antioxidant enzymes, and compounds such as coenzyme Q10. The disciplined teaching position, and the one an examination answer should take, is that oxidative processes are genuinely involved in ageing and disease, antioxidant nutrients are genuinely required by the body, and deficiency is harmful; and at the same time high dose antioxidant supplementation is not thereby proved to prevent disease, some high dose supplements have disappointed or harmed in trials, and the products are regulated and labelled as supplements supporting normal function, not as disease prevention medicines.

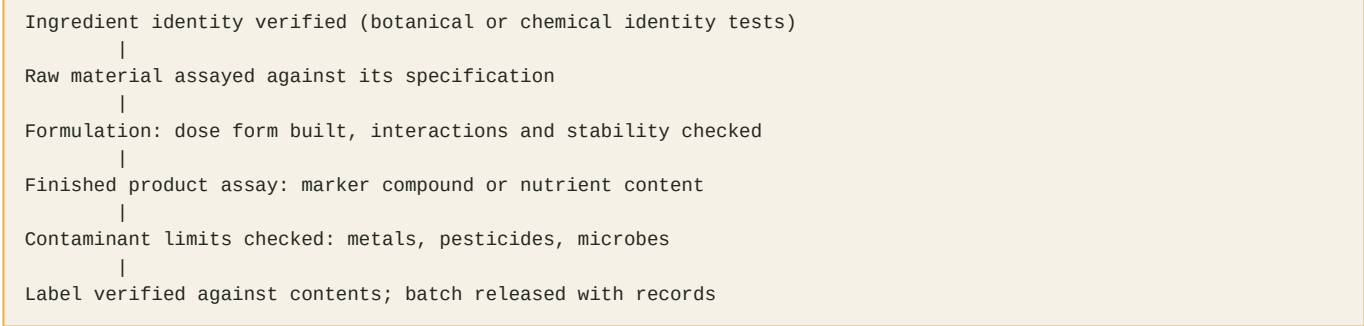
3.10 Polyunsaturated fatty acids

Polyunsaturated fatty acids (PUFAs) are long chain fatty acids with more than one double bond, and the two families that matter in nutrition are the omega-3 family, whose parent is alpha linolenic acid from plant sources such as flax seed, and whose long chain members EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) come chiefly from oily fish and fish oils and from algae, and the omega-6 family, whose parent is linoleic acid from seed oils. Neither parent fatty acid can be made by the body, so both are essential in the diet. As nutraceuticals, fish oil capsules and algal oil products are among the most established products in the whole category, used in teaching for the support of normal heart and brain function and as a source of EPA and DHA for people who eat little oily fish. The quality points are characteristic: the oils oxidise readily, so products are protected with antioxidants and encapsulation and are controlled for oxidation values, and the label states the EPA and DHA content per capsule, since it is those two compounds, not the gross oil weight, that carry the purpose.

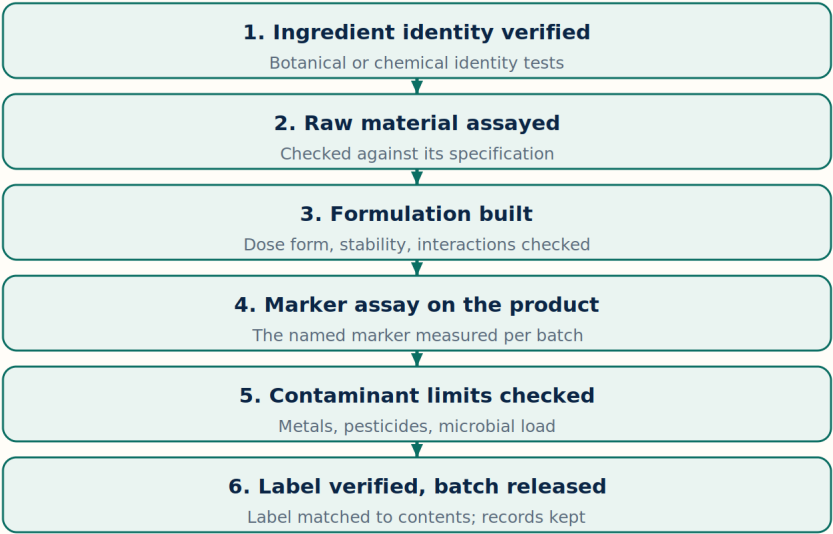
3.11 Herbs as functional foods, formulation and standardisation of nutraceuticals

A functional food is an ordinary food, or a food like product, that delivers a health benefit beyond its basic nutrition, and herbs as functional foods are the botanical case: culinary and medicinal herbs and spices eaten in food amounts for their phytochemistry as well as their flavour, with turmeric in food, garlic in food and green tea as a drink as the unit's own examples. The line between a herb as a functional food and the same herb as a concentrated supplement or a herbal medicine is dose, presentation and claim, and the student should be able to place one plant in all three positions.

Formulation of nutraceuticals uses the dosage form skills of pharmaceuticals on food grade materials: tablets, capsules, powders, granules, liquids, gummies and bars, with excipients permitted for foods and supplements. The formulation problems are practical ones: bulky actives that make large tablets, unpleasant tastes and odours (fish oils, garlic, botanicals), unstable actives (vitamins, oils, enzymes, probiotics), and combinations in which the ingredients must not react with each other. Standardisation is the quality answer, and it works by markers. A standardised nutraceutical is controlled by identity testing of each ingredient, assay of a named marker compound or nutrient content, limits for contaminants (heavy metals, pesticide residues, microbial load, and adulterants), stability testing to support the shelf life, and manufacture under good manufacturing practice with batch records. The marker idea is the bridge to the next section: for each named product the syllabus asks for the marker compound by name and chemical nature, because the marker is what the laboratory measures to say that this batch is the product it claims to be.



Standardising a nutraceutical



The marker assay converts a recipe into a reproducible product

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Figure: The standardisation chain for a nutraceutical. The marker assay is the step that converts a recipe into a reproducible product.

3.12 Regulatory aspects and FSSAI guidelines

In India, nutraceuticals are regulated as foods, under the Food Safety and Standards Act, 2006, administered by the Food Safety and Standards Authority of India (FSSAI). The FSSAI system licenses food businesses in tiers (registration for the smallest, state licences, and central licences for the largest and for reserved categories, nutraceutical manufacture among them), sets product standards and composition rules, controls labelling and advertising claims, and governs imports. For nutraceuticals specifically, the dedicated FSSAI regulations for health supplements, nutraceuticals and related special categories (first made in 2016 and issued in consolidated form in 2022) set which ingredients may be used, in which forms and within which ranges, tied to recommended dietary allowances, and which claims may be made. The regulatory character to teach is premarket control by composition and licence rather than by drug style marketing authorisation: a compliant product made of permitted ingredients, in a licensed premises, labelled within the claim rules, may be sold; a product with a non permitted ingredient, an out of range dose or a disease cure claim may not, whatever its quality. Products that cross into disease treatment claims or drug composition leave the food system and fall under drugs law. That border, and the FSSAI guidelines that police it, are the regulatory content of this unit.

3.13 The nine named nutraceuticals

The syllabus closes Unit 3 with nine named products, each to be known by source, marker compound and its chemical nature, medicinal uses and health benefits. The table states the markers and chemical nature;

the paragraphs after it give the source, uses and benefits for each. No percentages or doses are stated, because the syllabus asks for the marker's name and nature, and standardisation values vary by product and pharmacopoeia.

Product	Source	Marker compound(s)	Chemical nature of marker
Spirulina	Blue green alga <i>Arthrospira</i> (<i>Spirulina</i>) <i>platensis</i> , cultivated in open ponds or tanks	Phycocyanin; also valued for its protein content	Phycocyanin is a blue phycobiliprotein pigment protein
Soya bean	Seeds of <i>Glycine max</i>	Genistein and daidzein	Isoflavone flavonoids (isoflavonoids)
Ginseng	Roots of <i>Panax ginseng</i> (Asian ginseng) and <i>Panax quinquefolius</i> (American ginseng)	Ginsenosides	Triterpenoid saponin glycosides
Garlic	Bulbs of <i>Allium sativum</i>	Allicin, formed from alliin on crushing	Allicin is an organosulfur thiosulfinate compound
Broccoli	Florets of <i>Brassica oleracea</i> (broccoli)	Glucoraphanin, converted to sulforaphane	Glucoraphanin is a glucosinolate; sulforaphane is an isothiocyanate
Green and herbal tea	Leaves of <i>Camellia sinensis</i> for tea; various botanicals for herbal teas	Epigallocatechin gallate (EGCG) and other catechins	Catechins are flavan-3-ol flavonoids (polyphenols)
Flax seeds	Seeds of <i>Linum usitatissimum</i>	Alpha linolenic acid; lignans such as secoisolariciresinol diglucoside (SDG)	Alpha linolenic acid is an omega-3 polyunsaturated fatty acid; SDG is a lignan
Black cohosh	Roots and rhizomes of <i>Actaea racemosa</i> (syn. <i>Cimicifuga racemosa</i>)	Triterpene glycosides such as actein	Triterpene glycosides
Turmeric	Rhizomes of <i>Curcuma longa</i>	Curcumin, with demethoxycurcumin and bisdemethoxycurcumin	Curcuminoids are diarylheptanoid phenolic compounds

Spirulina. A blue green alga grown commercially in alkaline ponds and sold dried as powder, tablets and capsules. It is valued as a concentrated food source, rich in protein and containing the pigment protein phycocyanin, carotenoids and B vitamins; its health positioning is nutritional support and antioxidant content. Quality control watches the identity of the alga and contamination, including other algae and heavy metals from the growing water.

Soya bean. The seed of *Glycine max*, eaten as a food worldwide and used as a nutraceutical for its protein and its isoflavones, genistein and daidzein. The isoflavones are phytoestrogens, plant compounds with a structure resembling oestrogen and weak activity at oestrogen receptors, which is the basis of soya's positioning for menopausal symptoms and bone health support, and also the reason soya products are discussed with care in hormone sensitive conditions.

Ginseng. The root of *Panax* species, a classic tonic drug of East Asian medicine, standardised on its ginsenosides, triterpenoid saponins. Its traditional and marketed uses are support against fatigue and for general vitality and cognitive support. Ginseng is also a Unit 5 citizen: it is one of the herbs reported to interact with medicines, including anticoagulants, which is why a complete answer on ginseng mentions both the marker and the interaction caution.

Garlic. The bulb of *Allium sativum*, a food and a traditional medicine. Its chemistry is sulfur chemistry: the intact bulb holds alliin, and crushing brings the enzyme allinase into contact with it to form allicin, the pungent compound on which garlic products are standardised, directly or as allicin potential. Garlic is positioned for cardiovascular support, including support of normal blood pressure and cholesterol as part of the diet. Its antiplatelet activity is the reason garlic supplements are a standard interaction example with

anticoagulant and antiplatelet medicines.

Broccoli. A cruciferous vegetable whose marker glucoraphanin is converted, by the plant enzyme myrosinase and by gut bacteria, to sulforaphane, an isothiocyanate studied for its effects on the body's own protective enzyme systems. As a nutraceutical, broccoli and broccoli sprout extracts are standardised on glucoraphanin or sulforaphane potential and positioned for antioxidant and cellular health support.

Green and herbal tea. Green tea is the unfermented leaf of *Camellia sinensis*, standardised on its catechins, chiefly EGCG. It is taken as a drink and as concentrated extracts, positioned for antioxidant content and metabolic support. Concentrated green tea extracts carry a safety note that plain tea drinking does not: high intakes of catechin extracts have been associated with liver injury in susceptible people, a standard teaching example that form and dose change the safety of a familiar food. Herbal teas are infusions of other botanicals, such as chamomile or peppermint, valued as caffeine free drinks with their own traditional uses.

Flax seeds. The seed of *Linum usitatissimum*, a combined source of alpha linolenic acid, the plant omega-3, of lignans, and of mucilage fibre. Flax therefore sits in three of this unit's categories at once: a PUFA source, a fibre, and a functional food. Products are the whole or ground seed and flaxseed oil, and the teaching points are the protection of the oil from oxidation and the fibre cautions of Section 3.6.

Black cohosh. The root and rhizome of *Actaea racemosa*, a North American botanical standardised on its triterpene glycosides and used chiefly for menopausal symptoms such as hot flushes. It is included in examinations for its marker class and its use, and in safety teaching because rare reports of liver injury associated with black cohosh products have made it a pharmacovigilance example as well as a nutraceutical one.

Turmeric. The rhizome of *Curcuma longa*, the golden spice of Indian food and Ayurvedic medicine, standardised on the curcuminoids, chiefly curcumin. Turmeric and curcumin products are positioned for joint comfort and antioxidant and anti-inflammatory support, and curcumin's poor oral bioavailability is the standard formulation problem of the group, answered in products by combination and formulation strategies. Turmeric closes the named list where the course began, in an Indian cultivated rhizome, now standardised by its marker like every other product in this unit.

3.14 Unit 3 in one view

Nutraceuticals are food derived products taken for health benefit beyond basic nutrition, regulated as foods: in India by FSSAI under the Food Safety and Standards Act, 2006, with dedicated regulations controlling ingredients, ranges, licensing and claims. The categories run from minerals, vitamins and enzymes through fibres, cereals, health drinks, antioxidants and PUFAs to herbs as functional foods. Formulation builds the dose form; standardisation, by named markers with contaminant limits and GMP, makes the product reproducible; and the nine named products are each known by source, marker and chemical nature, uses and health benefits.

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