

Unit 2: International and Global Aspects

Free notes at pharmacolearn.fyi

2.1 WHO guidelines on nutrition: the global reference point

The **World Health Organization** is the specialised agency of the United Nations for health, and its nutrition work is the global reference layer beneath every national system in this course. WHO does not license products and does not write binding food law for any country. What it issues is **guidelines**: systematically developed, evidence based recommendations, prepared through its guideline development process with expert review, on the intake of nutrients and on dietary patterns for populations and for specific groups. Their subject matter is the classical territory of nutrition science: the role of sugars, fats, sodium and potassium in the diet, fruit and vegetable intake, diet and the prevention of chronic disease, and the feeding of infants, children and other defined groups. For the regulatory student, three functions matter. First, WHO guidance is the **scientific anchor** national authorities cite when they set nutrient reference values, fortification policy and dietary guidance of their own, so the RDA sections of Units 3 to 5 all stand downstream of this layer. Second, WHO works jointly with the Food and Agriculture Organization in the **Codex Alimentarius**, the international food standards body whose standards on food labelling, food additives, contaminants and foods for special dietary uses are the reference texts national regulators adopt or align with, and the natural bridge between global guidance and enforceable national rules. Third, WHO's framing is **public health, not product approval**: it speaks of diets and populations, leaving products, factories and labels to national authorities, a division of labour the whole unit illustrates, since its second actor, NSF, is also not a government and also governs without a statute.

2.2 Reading WHO nutrition guidance as a regulatory document

A WHO guideline is read differently from a regulation, and the skill is worth a section. Its recommendations carry **strength gradings**, strong or conditional, which tell the adopting authority how firmly the evidence supports the recommendation and how much room local adaptation has. Its values are expressed for **populations and life stage groups**, not for products: a guideline on nutrient intake does not itself set the level a manufacturer may put in a capsule, which is the national authority's task, taken up for India by the Indian Council of Medical Research and its National Institute of Nutrition, for the United States by the National Academies' Food and Nutrition Board, and for Europe by EFSA, the three RDA authorities of this course. And its recommendations are **revised on evidence cycles**, which is why this subject teaches the architecture and the responsible bodies rather than memorised values: the values in force at any examination date are those of the current revision, in the current national table. The examination use of WHO material is therefore institutional: what WHO is, what a guideline is, how Codex relates to it, and how national systems convert its science into binding product rules.

2.3 NSF International: its role in the industry

NSF International, founded in the United States as the National Sanitation Foundation and now an independent, not for profit, non governmental organisation, is a standards developer, testing laboratory and certification body for public health products and for the food and supplement industries. Its role in the dietary supplement and nutraceutical industries rests on a gap in the statutory systems, and understanding the gap is understanding NSF. Under the American settlement of Unit 4, supplements reach the market **without premarket approval**: the FDA acts largely after marketing, against unsafe or misbranded

products. Retailers, sports bodies and careful consumers therefore demanded an independent signal that a product contains what its label claims, in the amount claimed, without harmful contaminants, and was made under good manufacturing practice. NSF supplies that signal as **third party certification**: a private, voluntary attestation, by an accredited body independent of the manufacturer, that the product and its facility meet a published standard. Its wider supplement industry roles follow from the same position: developing the consensus standards the industry is certified against, auditing manufacturing facilities to GMP, testing finished products, certifying products for sport against prohibited substance concerns, and registering facilities. None of this is law, and all of it is commercially powerful, because a certification mark answers the trust question that a no premarket approval system deliberately leaves open.

```
How global guidance becomes a marketable product rule
WHO guideline: evidence based recommendation for populations
|
Codex Alimentarius: international standard text
(WHO and FAO jointly)
|
National authority: FSSAI, FDA, European Commission
with EFSA advice: binding rule, list, label or claim
|
Manufacturer: formulation, GMP, label built to the rule
|
Voluntary layer: NSF certification attests the product
and the factory against a published standard
```

2.4 NSF certification

NSF certification of a dietary supplement is a staged attestation, and the stages are the syllabus topic in their own right. The process, in its standard shape, runs as follows. The manufacturer applies and submits the product formulation and label for **review**: the ingredients are checked against the standard's requirements and the label against the certified claims. The product is **tested** in NSF's laboratories: the contents are verified against the label declaration, and the product is screened for contaminants, including heavy metals, microbial contamination, pesticides and, for sport certified products, prohibited substances. The manufacturing facility undergoes a **GMP audit** against the applicable GMP standard, because certification of a product made in an uncontrolled factory would certify nothing durable. Only when formulation, testing and audit all pass is certification granted, the product entered in NSF's listings and the **certification mark licensed for use on the label**. Certification is then **maintained, not merely won**: facilities are reaudited, products are subject to ongoing and unannounced testing and surveillance, and certification can be suspended or withdrawn when a product or facility falls out of conformity. Read the logic as an examiner does: certification transfers trust from a maker's promise to an independent body's continuing surveillance, which is why the mark, not the maker's own test report, is what retailers and sports authorities accept.

NSF certification: the five stages



© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The NSF certification sequence of section 2.4: formulation and label review, laboratory testing for contents and contaminants, the facility GMP audit, grant of certification and the licensed mark, then continuing surveillance with retesting and reaudit (Unit 2, section 2.4).

2.5 NSF standards for food and dietary supplements

The standards are the documents that make certification possible, because a body can only certify against published, testable criteria. NSF's system works through **joint and consensus standards** developed with the American national standards process: the best known for this subject is the NSF/ANSI standard for dietary supplements, which sets the requirements for the identity, strength and composition of supplement contents, the limits for contaminants, and the basis on which label claims are verified. Beside the product standard sit the **GMP standards and audit criteria** for supplement and food facilities, against which the facility audits of section 2.4 are conducted, and NSF's food equipment and food safety standards family, which belongs to its older food industry work. Two distinctions carry the marks. A **standard** states the criteria; **certification** is the attestation that a named product or facility meets them, issued after testing and audit and kept under surveillance. And a private standard, however rigorous, **does not replace the law**: a certified product must still comply with the labelling, ingredient and claim rules of every market it is sold in, and certification is evidence of quality discipline, not a licence or an approval. The Indian and European systems of Units 3 and 5 make the converse arrangement, reaching much of the same assurance through statutory licensing and positive lists instead of voluntary certification, and the comparison is a favourite synthesis question.

2.6 Good Manufacturing Practices for nutraceuticals

Good Manufacturing Practice for nutraceuticals is the application to food supplement manufacture of the quality discipline this branch met for drugs in MRA101T, adjusted for products that are foods in law and medicines in presentation. Its elements are constant across the systems that impose it, the United States in its dietary supplement current GMP rule, India in the hygiene and manufacturing requirements of its food regulations, and the NSF audit criteria of this unit. Premises and equipment must be designed and maintained for hygienic manufacture, with contamination and cross contamination controlled.

Specifications must exist for every component, for in process stages and for the finished product, covering identity, purity, strength and composition. Identity testing of incoming dietary ingredients is the characteristic nutraceutical duty: the manufacturer must verify that a botanical or nutrient raw material is what it claims to be, because the whole market failure pattern of this industry begins with substituted or diluted ingredients. Production and process controls, batch records, laboratory controls, packaging and labelling controls

(including the reconciliation of labels, the classic source of supplement misbranding), holding and distribution controls, and a system for handling returned products and complaints complete the standard shape. Two ideas carry the examination weight. GMP is the **substitute assurance** of a no premarket approval system: where the state does not examine the product before sale, it examines and enforces the system that makes the product, which is why GMP violations are the commonest enforcement ground in this field. And GMP is **documentary**: a control that is not recorded is treated in audit as a control that did not happen, the same lesson MRA102T taught for drug documentation.

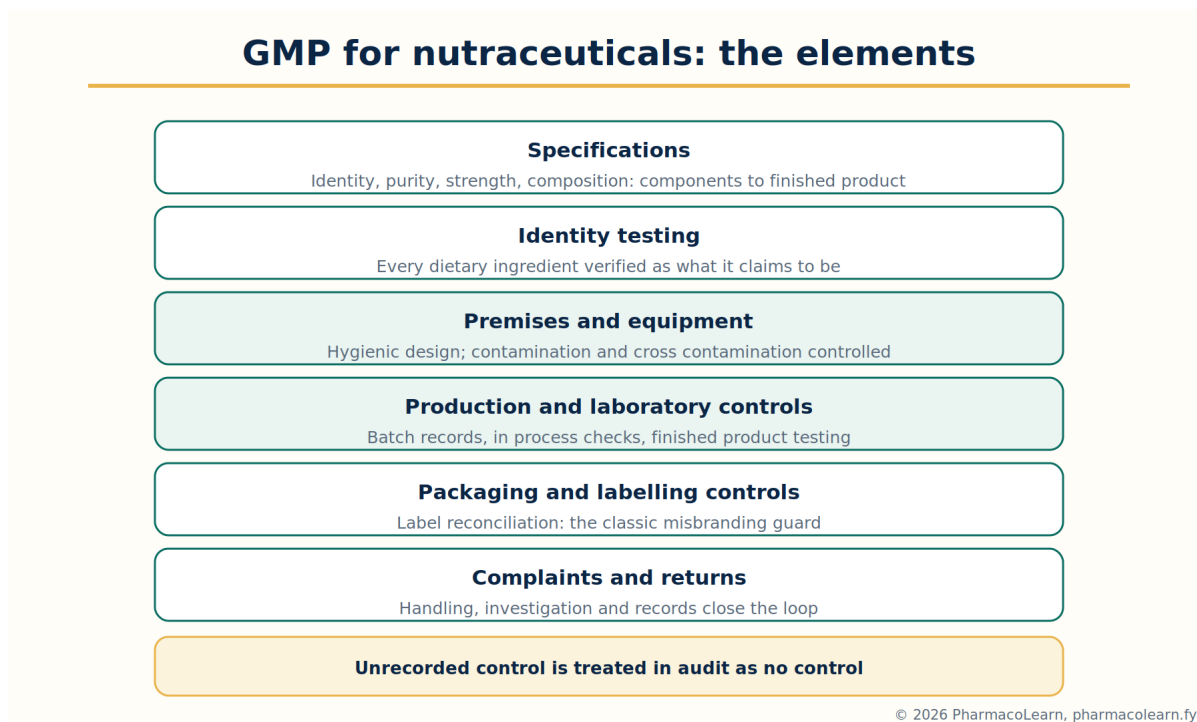


Figure: The GMP elements of section 2.6 in one view: specifications and identity testing of ingredients at the gate, premises, equipment and hygienic manufacture, production and laboratory controls with batch records, packaging and labelling controls, and complaint and return handling closing the loop (Unit 2, section 2.6).

More free M.Pharm notes and unit wise PDFs at pharmacolearn.fyi
Free video lectures on the PharmacoLearn YouTube channel