NOTESKARTS | PREMIUM STUDY NOTES

BP812ET — DIETARY SUPPLEMENTS & NUTRACEUTICALS

UNIT — V | Processing, Regulatory Aspects, HACCP, GMP, Adulteration & Pharmacopeial Specifications

B.Pharm 8th Semester · PCI / AKTU Syllabus · Premium Notes

UNIT-V | LEARNING OBJECTIVES

After completing this unit, the student will be able to:

- LO-1: Explain the effect of various processing methods (thermal, drying, fermentation, extraction) and storage conditions (temperature, light, O_2, humidity) on the stability and bioavailability of nutraceuticals.
- LO-2: Describe the regulatory framework for food and dietary supplements in India — FSSAI — and in USA — FDA/DSHEA 1994.
- LO-3: Explain FPO (Fruit Products Order), MPO (Meat Products Order), and AGMARK — their scope, standards, and legal authority.
- LO-4: Define HACCP; state and explain all 7 Principles and 12 Preliminary Steps of HACCP implementation in food safety.
- LO-5: Describe GMP (Good Manufacturing Practices) requirements for nutraceuticals and dietary supplements —elements, FSSAI GMP, and WHO GMP guidelines.
- LO-6: Define food adulteration; classify adulterants; name common adulterants in India; explain legal provisions (PFA Act/FSSAI) and Pharmacopeial specifications for dietary supplements (IP, USP, BP).

EFFECT OF PROCESSING ON NUTRACEUTICALS

Processing is defined as any **deliberate alteration of food** from its raw state to improve safety, palatability, shelf-life, or nutritional value. However, many processing operations **degrade or destroy nutraceuticals**, while some paradoxically **increase bioavailability**. Understanding which processing method helps or harms each nutraceutical is essential for product formulation.

Thermal Processing (Heat Treatment)

Heat is the most commonly applied processing treatment. **Temperature, time, and pH** determine whether a nutraceutical is preserved or destroyed.

Processing Method	Temperature / Condition	Nutraceutical LOST	Nutraceutical GAINED / ENHANCED
Blanching	70-100°C, 1-3 min (steam/water)	Vitamin C ↓ 30-60% (leaches into water); Thiamine ↓	Lycopene bioavailability ↑ (cell wall disruption); Inactivates oxidative enzymes (peroxidase, lipoxygenase) → protects carotenoids

Processing Method	Temperature / Condition	Nutraceutical LOST	Nutraceutical GAINED / ENHANCED
Pasteurisation	63°C/30 min (LTLT) or 72°C/15 sec (HTST)	Vitamin C ↓ 10-25%; some B vitamins ↓; lactoferrin partially denatured	Kills pathogens; minimal effect on minerals; whey protein mostly preserved
Sterilisation (UHT/Canning)	121°C/15 min (retort); 135-150°C/2-4 sec (UHT)	Vitamin C ↓↓ (up to 80%); Thiamine ↓↓; Lysine (Maillard) ↓; Folate ↓	UHT: minimal protein denaturation vs retort; lycopene ↑ (processed tomatoes)
Boiling / Cooking	100°C (variable time)	Vitamin C ↓ 30-80% (heat-labile + water-leaching); Folate ↓; Polyphenols ↓ (some)	Allicin release ↑ (garlic crushing before cooking); starch gelatinisation; protein digestibility ↑; lycopene ↑
Roasting / Baking	150-220°C (dry heat)	Lysine, Threonine (Maillard reaction ↓ protein quality); Thiamine ↓; Tocopherols ↓	Melanoidins (Maillard products) = antioxidants; Maillard = colour, flavour; Acrylamide (harmful — formed from asparagine + glucose)
Deep frying	160-190°C (oil)	Vitamin E (tocopherols oxidise); Omega-3 PUFA oxidised → LPO products; trans-fatty acids formed (partially hydrogenated oils)	Increases caloric density; fat-soluble vitamin absorption may ↑ if food is low in fat
Microwave	Non-ionising radiation → heat	Vitamin C ↓ less than boiling (shorter time + no leaching); minimal effect vs boiling	Better retention of Vit C and polyphenols than boiling — recommended cooking method for preservation

⚠ Exam Trick

LYCOPENE PARADOX: Raw tomato has MORE lycopene by weight, BUT processed tomato (paste, sauce, canned) has MORE BIOAVAILABLE lycopene. Reason: Heating + mechanical disruption breaks cell walls → lycopene released from chromoplasts → better absorption (also fat-soluble → consume with olive oil). This 'cooked > raw' reversal is the most commonly tested processing paradox!

Effect of Milling, Fermentation, and Drying

Process	Description	Nutraceutical Loss	Nutraceutical Gain
Milling / Refining	Removal of bran + germ from whole grain (wheat, rice, corn)	Massive loss: Vitamin E (tocopherols) ↓ 90%; B vitamins ↓ 60-80%; Dietary fibre ↓ 75%; Phytic acid ↓ (double-	Easier digestion of starch; improved palatability; FORTIFICATION compensates (B vitamins, iron added back)

Process	Description	Nutraceutical Loss	Nutraceutical Gain
		edged); Minerals ↓ 60-80%	
Fermentation	Microbial transformation (bacteria, yeast, moulds)	Phytic acid ↓↓ (beneficial — antinutrient removal → Fe, Zn, Ca absorption ↑); Lactose ↓ (in yogurt)	Probiotic organisms; short-chain fatty acids; Vitamin B12 (in some fermented foods); increased bioavailability of isoflavones (soy fermentation: daidzin → daidzein, genistin → genistein — MORE BIOAVAILABLE aglycone); GABA (in natto, tempeh)
Spray Drying	Hot air atomisation; inlet 150-220°C	Heat-sensitive compounds: Vitamin C ↓; some polyphenols ↓; probiotics — SIGNIFICANT LOSS (viability ↓)	Concentration of nutraceuticals; extended shelf-life; microencapsulation protects some compounds
Freeze Drying (Lyophilisation)	Ice sublimation under vacuum; -20 to -50°C	Minimal — best method for preserving heat-sensitive nutraceuticals (Vitamin C, probiotics, omega-3)	BEST RETENTION of bioactive compounds among all drying methods; preserves probiotic viability (>10^7 CFU/g achievable)
Sun/Hot-Air Drying	40-80°C, extended time	Vitamin C ↓↓ (heat + O_2 + light); Carotenoids ↓ (photo-oxidation); Polyphenols ↓ (enzymatic browning)	Concentrates sugars and some minerals (per gram basis ↑); solar drying better than hot-air for polyphenols
Germination / Sprouting	Seed soaking + germination (24-72h)	Starch ↓ (converted to sugars); Phytic acid ↓ (phytase activated) → net GAIN (antinutrient reduced)	Vitamin C ↑↑ (from near-zero in seeds); Folate ↑; GABA ↑; Sulforaphane precursors ↑ (broccoli sprouts have 20-50× more glucoraphanin than mature broccoli); Digestibility ↑; Enzyme activity ↑
Extrusion	High T, pressure, shear (100-180°C)	Vitamin B1, B6, folate ↓; Lysine ↓ (Maillard); Vitamin C ↓↓	Gelatinised starch (improved digestibility); Resistant starch RS5 (amylose-lipid complex) formed; Improved solubility of dietary fibre

★ Point

FERMENTATION INCREASES ISOFLAVONE BIOAVAILABILITY: In whole soybeans, genistein and daidzein exist as glucosides (genistin, daidzin) which are poorly absorbed. Fermentation (miso, tempeh, tofu to a lesser extent) → bacterial β-glucosidases → cleave the sugar → FREE aglycones (genistein, daidzein) → 2-3× more bioavailable. This explains why fermented soy products are pharmacologically more potent than whole soybeans.

Effect of Extraction Methods on Nutraceuticals

Extraction Method	Solvents / Conditions	Best For	Limitations
Aqueous extraction (water)	Water, 50-100°C	Polyphenols (tea catechins), mucilage, pectin, FOS, polysaccharides	Poor for lipid-soluble compounds (carotenoids, tocopherols, fat-soluble vitamins)
Ethanolic extraction	50-95% ethanol	Polyphenols, flavonoids, alkaloids, resveratrol, anthocyanins	Residual solvent concerns; some compounds degrade in high EtOH; food-grade limitations
Supercritical CO_2 (SC-CO_2)	CO_2 at >31.1°C, >73.8 bar	Carotenoids (lycopene, β-Carotene), tocopherols, essential oils, omega-3, caffeine	High capital cost; not suitable for polar compounds without modifier (methanol)
Cold press / Mechanical press	Physical pressure, no heat	Vegetable oils (EVOO), flaxseed oil (omega-3, SDG), wheat germ oil (Vit E)	Low yield; some polyphenols retained in press cake; heat can develop from friction
Enzymatic extraction	Cellulases, pectinases, proteases	Lycopene from tomato (pectinase → cell wall disruption → ↑ yield 40-50%); polyphenols from grape skins	Enzyme cost; potential for product modification; requires specific pH/T control
Microwave-Assisted Extraction (MAE)	Microwave energy + solvent	Polyphenols (faster, higher yield); carotenoids (with non-polar solvents)	Cannot use metallic equipment; selective heating; scale-up challenges
Ultrasound-Assisted Extraction (UAE)	Ultrasonic waves (20-100 kHz)	Polyphenols, essential oils — shorter time, lower T	Thermal effects at prolonged exposure; equipment cost

Regulatory

Supercritical CO_2 (SC-CO_2) extraction is the GOLD STANDARD for extracting heat-sensitive fat-soluble nutraceuticals (lycopene, β-Carotene, omega-3, tocopherols, essential oils). Advantages: No residual solvent (CO_2 simply evaporates), tunable selectivity by adjusting pressure/temperature, preserves thermolabile compounds, GRAS solvent. Used commercially for decaffeination of coffee, hops extraction for beer, and lycopene extraction. High cost limits use to high-value nutraceuticals.

EFFECT OF STORAGE AND ENVIRONMENTAL FACTORS

Even optimally extracted nutraceuticals degrade during **storage**. The four primary stability-affecting factors are: **Temperature (T), Light (L), Oxygen (O_2), and Moisture/Water Activity (aW)** —

remembered as '**TLOM**'. Food packaging must be designed to minimise ALL four factors simultaneously.

Temperature Effects on Nutraceutical Stability

Temperature Range	Effect	Most Sensitive Nutraceuticals	Protective Strategy
>100°C (cooking/sterilisation)	Rapid destruction of heat-labile compounds; Maillard reaction; Strecker degradation of amino acids	Vitamin C (destroyed >70°C rapidly), Thiamine (B1), Folate, Omega-3 (oxidation), Probiotics (killed >60°C)	Minimal processing; UHT over retort; microwave > boiling; freeze-drying
40-100°C (pasteurisation/blanching)	Moderate loss; enzyme inactivation (helpful for preserving carotenoids by destroying peroxidase)	Vitamin C ↓ 30-50%; B-group vitamins ↓ 10-30%; EGCG ↓ (epimerises at >80°C)	HTST pasteurisation preferred; short time at lower T
Room temp (20-25°C)	Slow oxidation; enzymatic browning; rancidity in fats; gradual vitamin degradation	Vitamin C ↓ slowly; Omega-3 (slow LPO); Probiotics viability ↓	Refrigeration, vacuum packaging, antioxidant addition (ascorbic acid, tocopherols)
Refrigeration (2-8°C)	Slow chemical reactions; crystallisation of some lipids; condensation risk	Minimal for most; enzymes still active (some polyphenol oxidase activity)	Recommended for fresh juices, dairy probiotics, omega-3 oils
Freezing (-18°C)	Best long-term preservation; freezer burn risk; ice crystal damage to cellular structures	Minimal chemical degradation but mechanical damage releases enzymes on thawing → polyphenol oxidation	Freeze-dry for powders; blast freezing for intact structure; vacuum seal

Light / Photo-oxidation Effects

Nutraceutical	Light Sensitivity	Degradation Pathway	Protective Packaging
Riboflavin (Vit B2)	EXTREMELY sensitive — photosensitiser itself	Riboflavin absorbs light → excited state → reacts with O_2 → generates $^1O_2$ → destroys itself + other nutrients (especially tryptophan, ascorbic acid, Vit A)	Amber/brown glass; multilayer opaque packaging; UV-protective labels
β-Carotene / Carotenoids	Sensitive to UV and visible light	Photo-oxidation: Light + O_2 → carotenoid → epoxides + cleavage products; loses	Dark glass; opaque multilayer film; microencapsulation with cyclodextrin

Nutraceutical	Light Sensitivity	Degradation Pathway	Protective Packaging
		antioxidant activity; colour fades	
Vitamin C (Ascorbic acid)	Moderate — accelerated by light + O_2	Photo-oxidation and metal-catalysed oxidation → dehydroascorbic acid (DHA) → 2,3-diketogulonic acid (irreversible) → loss	Dark packaging; addition of chelating agents (EDTA, citric acid); N_2 or CO_2 flush
EGCG (Green tea catechins)	Moderate — photo-degradation in solution	Epimerisation of EGCG (3S,3'S → 3R forms = gallocatechin gallate, GCG) under heat and light; loses bioactivity	Powder form preferred; nitrogen flush; amber packaging; dry storage
Omega-3 (EPA/DHA)	HIGH — rapidly photo-oxidised	PUFAs + $^1O_2$ (photo-generated) → rapid lipid peroxidation → rancid odour; loss of EPA/DHA; harmful LPO products	Opaque capsules; nitrogen blanket in headspace; antioxidants added (Vit E, rosemary extract)
Anthocyanins	Moderate-HIGH — pH and light sensitive	Photo-degradation + colour change with pH; bleaching to colourless chalcones in light + alkaline conditions	Dark packaging; acidic pH maintained (pH 3-4 optimal stability); CO_2 atmosphere
Lycopene	Moderate — isomerisation	All-trans lycopene isomerises to cis-lycopene (less antioxidant capacity) under light + heat	Dark storage; antioxidant protection (Vit E); processed tomato products more stable than fresh

⚠ Exam Trick

RIBOFLAVIN is both the MOST light-sensitive vitamin AND a PHOTOSENSITISER — meaning when exposed to light, riboflavin itself generates singlet oxygen ($^1O_2$) which then destroys VITAMIN C and TRYPTOPHAN in the same product. This is why milk in clear glass bottles rapidly loses Vitamin C and riboflavin when exposed to sunlight. Milk should ALWAYS be stored in opaque/dark containers. This riboflavin-photosensitisation mechanism is a FAVOURITE exam question!

Oxygen, Moisture, pH, and Interactions

Environmental Factor	Effect on Nutraceuticals	Most Affected Compounds	Control Strategy
Oxygen (O_2) Exposure	Oxidation of PUFAs (rancidity/LPO); Oxidation of Vit C → DHA; Oxidation of Vit E → tocopheroxyl quinone; Colour loss in anthocyanins; Loss of	Omega-3 EPA/DHA (MOST sensitive), Vitamin C, Vitamin E, Carotenoids, Anthocyanins, Probiotics	Vacuum packaging; N_2 or CO_2 gas flush (modified atmosphere packaging, MAP); oxygen scavengers (iron powder sachets); antioxidant addition

Environmental Factor	Effect on Nutraceuticals	Most Affected Compounds	Control Strategy
	probiotics viability (anaerobes)		
Water Activity (aW) / Moisture	High aW (>0.7) → microbial growth, enzymatic browning (polyphenol oxidase), hydrolysis of esters (anthocyanin, ester-linked phenolics); Low aW → Maillard (if T ↑) → Maillard products (some antioxidant, some toxic — acrylamide)	Probiotics (need aW <0.25 for viability in dry powder); Spray-dried products; Omega-3 emulsions (high aW → hydrolysis of EPA/DHA esters)	Desiccants (silica gel, molecular sieve); hermetic sealing; low moisture ingredients; aW ≤0.25 for probiotics
pH Effects	Acidic pH (pH 3-5): stabilises anthocyanins (flavylium cation, red colour), stabilises Vit C, promotes acid hydrolysis of glycosides (→ aglycone — more bioavailable). Alkaline pH (pH >7): destroys Vit C (rapidly), destroys thiamine, destabilises anthocyanins (blue → colourless chalcone)	Anthocyanins (pH-dependent colour); Vitamin C (alkaline = rapid destruction); Thiamine; Isoflavone glycosides (acid-hydrolysed → aglycones)	Maintain acidic pH in fruit juices; buffer systems in liquid supplements; avoid alkaline processing (baking soda)
Metal Ion Catalysis (Fe^{2+}, Cu^{2+})	Catalyse Fenton reaction → •OH → destroy vitamins; Fe^{2+}/Cu^{2+} catalyse ascorbic acid oxidation; Cu^{2+} activates polyphenol oxidase → enzymatic browning	Vitamin C (Fe-catalysed oxidation is the PRIMARY degradation mechanism); Carotenoids; Omega-3; Anthocyanins (Fe^{2+} complexes → colour change to purple/violet)	Chelating agents: EDTA, citric acid (chelate Fe/Cu → prevent catalysis); Stainless steel equipment; Avoid iron/copper vessels

Environmental Factor	Effect on Nutraceuticals	Most Affected Compounds	Control Strategy
Matrix Interactions	Fibre binding (pectin binds lycopene → reduced bioavailability); Protein binding (casein micelles bind polyphenols → reduced absorption); Fat-soluble vitamins need dietary fat for absorption; Polyphenol-protein complexes (tannin-protein)	Fat-soluble nutraceuticals (Vit A, D, E, K; Carotenoids; CoQ10): NEED dietary fat for absorption; Polyphenols: binding to proteins (tannin-protein complexes in tea + milk = reduced catechin absorption)	Co-formulate fat-solubles with lipid vehicle; consume carotenoids with EVOO; avoid milk with green tea (casein binds EGCG → reduces bioavailability)

Stability of Nutraceuticals —

Nutraceutical	Heat	Light	O_2	Moisture	Optimal Storage
Vitamin C	Very unstable (labile)	Sensitive	Very sensitive	Unstable in water solution	Dry powder; dark; N_2; 2-8°C; pH 5-6
Vitamin E (Tocopherols)	Moderate — frying destroys	Sensitive	Sensitive (especially in unsaturated oils)	Stable (dry)	Dark glass; N_2; refrigerated oil
Beta-Carotene	Moderate — isomerises	Sensitive	Sensitive (peroxidation)	Stable (dry)	Microencapsulated; opaque packaging; dry
Lycopene	INCREASES with heat (bioaccessibility)	Moderately sensitive	Sensitive (lipid-phase)	Stable (dry)	Dark; antioxidant; processed forms stable
EGCG (Catechins)	Unstable >80°C (epimerises)	Moderately sensitive	Sensitive in solution	Hydrolyses in alkaline water	Dry powder; pH 5-6; low T; dark
Omega-3 (EPA/DHA)	Unstable (polyene LPO)	Very sensitive	MOST SENSITIVE (rapid rancidity)	Unstable (hydrolysis of ethyl esters)	Opaque caps; N_2; refrigerated; Vit E added
Probiotics (L. rhamnosus)	Killed >60°C	Minimal effect	Anaerobes: O_2-sensitive	High aW kills → dry: aW<0.25 needed	Freeze-dried powder; ≤25°C; low humidity; dark

Nutraceutical	Heat	Light	O_2	Moisture	Optimal Storage
Anthocyanins	Moderate	Sensitive	Sensitive (bleaching)	Stable at low aW	pH 3-4; dark; dry; cold; CO_2 atmosphere
GSH (Glutathione)	Unstable (thiol oxidation)	Minimal	Very sensitive (thiol → GSSG)	Hydrolyses at high aW	Lyophilised; N_2; dark; refrigerated; liposomal
CoQ10	Stable to heat	Sensitive in solution	Moderately sensitive	Stable (dry)	Oil suspension preferred; dark; room temp OK in caps

REGULATORY ASPECTS — FSSAI, FDA, FPO, MPO, AGMARK

Food regulation ensures **safety, quality, authenticity, and efficacy** of food and nutraceutical products reaching consumers. India and USA have distinct but complementary regulatory frameworks for dietary supplements and functional foods.

FSSAI — Food Safety and Standards Authority of India

IN FSSAI — Food Safety and Standards Authority of India	
Full Form / Acronym	Food Safety and Standards Authority of India. Established under the Food Safety and Standards Act, 2006 (FSS Act). Operational from 2008.
Established / Year	Established: 2006 (FSS Act enacted); Operational: 2008. Replaced: PFA Act 1954 (Prevention of Food Adulteration Act), FPO 1955, MPO 1973, VPO 1976, Edible Oil (Packaging & Labelling) Order 1998, and several other food laws.
Governing Authority	Ministry of Health and Family Welfare, Government of India. Headquartered in New Delhi. Chairperson appointed by Central Government. 29 members (representing ministries, industry, consumer groups). CEO: Day-to-day operations. 8 Regional offices + 6 Referral laboratories.
Scope / Applicability	ALL food business operators (FBOs) in India: manufacturers, processors, distributors, retailers, importers, exporters. Includes: Conventional food, Functional foods, Dietary supplements, Nutraceuticals, Food for special dietary uses,

	Health supplements, Novel foods. Does NOT cover drugs (Drugs & Cosmetics Act jurisdiction).
Provisions / Acts	FSS Act, 2006 (parent legislation). Regulations: (1) FSS (Licensing & Registration) Regulations, 2011 — FBO licensing (Annual turnover >12 Lakh = License; ≤12 Lakh = Registration); (2) FSS (Food Products Standards & Food Additives) Regulations, 2011 — standards for all food categories; (3) FSS (Packaging and Labelling) Regulations, 2011 — mandatory label info; (4) FSS (Contaminants, Toxins & Residues) Regulations, 2011 — permissible limits; (5) FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2022 — SPECIFIC to nutraceuticals.
Products Covered	ALL food categories including nutraceuticals, health supplements, dietary supplements, functional foods, probiotics, prebiotics, novel foods, energy drinks, sports nutrition, infant formula, food additives, contaminants.

▸ FSSAI Nutraceutical Regulations 2022 —Points

- Definition of 'Health Supplement': A product intended to supplement the diet containing dietary ingredients (vitamins, minerals, amino acids, fatty acids, herbs).
- 'Nutraceutical': A food or part of food having health, medicinal or therapeutic benefit including prevention and treatment of disease.
- 'Functional Food': Conventional food that, by virtue of certain physiologically active components, provides health benefits beyond basic nutrition.
- Prohibited claims: Claim to diagnose, cure, treat, mitigate, or prevent disease — these require Drug licence under D&C Act.
- Permitted claims: Structure/function claims (e.g., 'calcium builds strong bones'); Nutrient content claims ('good source of Vitamin C').
- Label requirements for health supplements: Name, ingredients list, net quantity, manufacturer details, directions for use, storage conditions, 'Not to be used as drug', date of manufacture/expiry, batch/lot number.
- FSSAI 3-tier licensing: Central licence (for manufacturers with annual turnover >20 crore or interstate business); State licence (turnover 12 lakh to 20 crore); Registration (petty/small food businesses, turnover ≤12 lakh).

FDA — U.S. Food and Drug Administration

US FDA — U.S. Food and Drug Administration	
Full Form / Acronym	Food and Drug Administration (USA). Federal agency under Department of Health and Human Services (HHS).
Established / Year	Established: 1906 (Pure Food and Drug Act); Modern FDA: Federal Food, Drug, and Cosmetic Act (FDCA), 1938. Center

	for Food Safety and Applied Nutrition (CFSAN) handles nutraceuticals.
Governing Authority	U.S. Department of Health and Human Services (HHS). Commissioner of Food and Drugs heads the agency. Centers: CFSAN (food/dietary supplements), CDER (drugs), CBER (biologics), CDRH (medical devices).
Scope / Applicability	All food sold in interstate commerce in USA: conventional foods, dietary supplements, infant formula, cosmetics, drugs, medical devices, veterinary products. Dietary supplements regulated under DSHEA 1994 — as a SEPARATE category from drugs and conventional foods.
Provisions / Acts	Acts for Nutraceuticals: (1) DSHEA 1994 — Dietary Supplement Health and Education Act: defines dietary supplements; manufacturers responsible for safety (not FDA pre-approval); only structure/function claims permitted; Supplement Facts panel required; NDI notification required for new dietary ingredients; (2) FDCA 1938 — overall food safety; (3) FSMA 2011 — Food Safety Modernization Act: preventive controls, mandatory recalls; (4) FDA cGMP (21 CFR Part 111) — for dietary supplements; (5) FDA New Dietary Ingredient (NDI) pre-market notification requirement.
Products Covered	Dietary supplements: vitamins, minerals, herbs, amino acids, enzymes, organ tissues, metabolites, concentrates, extracts. Conventional food, food additives (GRAS determination). Does NOT cover: Drugs (CDER jurisdiction), Medical claims.

▸ DSHEA 1994 —Provisions (Most Exam-Tested FDA Regulation)

DSHEA Provision	Detail
Definition of Dietary Supplement	Product taken by mouth; contains 'dietary ingredient' (vitamin, mineral, herb, amino acid, enzyme, organ tissue, metabolite, concentrate, extract); intended to supplement the diet
Pre-market approval	NOT REQUIRED — manufacturer responsible for safety BEFORE marketing (unlike drugs which need FDA approval)
FDA burden of proof	FDA must prove a supplement is UNSAFE to remove it from market (not the manufacturer proving safety — reverse burden vs drugs)
New Dietary Ingredient (NDI)	Supplement with ingredient not marketed in USA before October 15, 1994 → must submit NDI notification to FDA 75 days before marketing
Permitted claims	Structure/Function claims (e.g., 'Calcium builds strong bones'); Nutrient content claims; NOT permitted: Disease claims ('cures diabetes')
Disclaimer required	'This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.'
Labelling	Supplement Facts panel (vs Nutrition Facts for foods); serving size, amount per serving, % Daily Value
cGMP (21 CFR Part 111)	Current GMP for dietary supplements — identity, purity, strength, composition standards

DSHEA Provision	Detail
Adverse event reporting	Mandatory serious adverse event reporting to FDA (since DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT 2006)

⚠ Exam Trick	EXAM COMPARISON: Under DSHEA (USA), dietary supplement manufacturers do NOT need pre-market FDA approval — FDA must PROVE the product is UNSAFE to ban it (reverse burden of proof). Under Indian law (FSS Act/D&C Act), the burden is on the manufacturer to demonstrate safety. This fundamental difference in regulatory philosophy is frequently tested in MCQs and comparison questions.

FPO — Fruit Products Order 1955

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Full Form / Acronym	Fruit Products Order 1955. A statutory order under the Essential Commodities Act, 1955.
Established / Year	Enacted: 1955. Now subsumed under FSSAI Regulations, 2011. Historical legal framework — reference in academic syllabus.
Governing Authority	Previously: Ministry of Food Processing Industries (MoFPI). Now: FSSAI has absorbed FPO functions under FSS Act 2006.
Scope / Applicability	Manufacturers and traders of fruit-based processed products in India. Required any person/factory processing fruits into commercial products to obtain FPO licence. Factory inspection, minimum standards, hygiene norms.
Provisions / Acts	Governed processing, manufacturing, packaging, and sale of fruit-based products. provisions: (1) FPO licence mandatory for commercial fruit processing; (2) Minimum standards for fruit content, sugar, preservatives, acidity; (3) Permitted preservatives: benzoic acid (max 70-600 mg/kg depending on product), SO_2; (4) Labelling: FPO mark on label; (5) Products must meet minimum TSS (Total Soluble Solids) by Brix; e.g., Fruit jam: TSS ≥68.5°Brix, fruit content ≥45%; Tomato ketchup: TSS ≥12%, tomato pulp ≥25%; Squash: fruit juice ≥25%, TSS ≥40°Brix.
Products Covered	Fruit juices, squashes, cordials, jams, jellies, marmalades, pickles, tomato products (ketchup, puree, paste), dehydrated fruits, fruit-based beverages, canned fruits.

MPO — Meat Products Order 1973

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Full Form / Acronym	Meat Products Order 1973. Statutory order under the Essential Commodities Act, 1955.
Established / Year	Enacted: 1973. Now subsumed under FSSAI Regulations. Historical regulatory framework.
Governing Authority	Previously: Ministry of Agriculture / MoFPI. Now: FSSAI has absorbed MPO functions.
Scope / Applicability	Manufacturers and processors of meat-based products. Mandatory licensing for meat processing establishments. Inspection by government authorities (veterinary inspection). Minimum standards for meat content, hygiene, labelling.
Provisions / Acts	provisions: (1) MPO licence mandatory for commercial meat processing; (2) Standards for meat content in processed products (e.g., Sausage: minimum 50% meat; Ham: minimum 90% pork); (3) Preservatives permitted: nitrites (max 200 ppm as sodium/potassium nitrite), common salt, ascorbic acid, acetic acid; (4) Banned: colour additives not permitted in meat; (5) Temperature requirements: chilled meat storage (0-4°C), frozen (-18°C); (6) Slaughterhouse hygiene: ante-mortem and post-mortem veterinary inspection mandatory; (7) Labelling: species of animal, % meat content, date of manufacture, storage conditions.
Products Covered	Fresh and processed meat: sausages, ham, salami, meat paste, canned meat, pork products, chicken products, meat extracts, meat-based ready-to-eat foods.

AGMARK — Agricultural Marketing Standards

AGMARK — Agricultural Produce Grading and Marking

Full Form / Acronym	AGMARK = Agricultural Mark. Under the Agricultural Produce (Grading and Marking) Act, 1937 (APGMA).
Established / Year	Act enacted: 1937 (one of India's oldest food laws). AGMARK grading voluntary since original Act; amended 1986. Now works alongside FSSAI.
Governing Authority	Directorate of Marketing and Inspection (DMI) under the Ministry of Agriculture and Farmers' Welfare,

	Government of India. DMI has 6 Regional, 26 Sub-regional, and field offices across India.
Scope / Applicability	VOLUNTARY grading scheme for agricultural produce intended for export or domestic sale. Any producer or trader may apply for AGMARK certification. Products must meet grade specifications before AGMARK label is affixed. DMI inspectors certify compliance.
Provisions / Acts	provisions: (1) Grade designations: 'Special Grade', 'Grade A', 'Grade B', 'Grade C' for different quality levels; (2) Product-specific standards covering: colour, size, moisture, purity, fat content, adulteration limits; (3) Quality seal: AGMARK logo (triangle with initials) guarantees minimum quality; (4) Important graded products: Butter (% fat: Special ≥82%, Grade A ≥82%); Honey (moisture ≤20%, glucose+fructose ≥65%); Edible oils (free fatty acids, peroxide value, moisture); Wheat flour (moisture ≤14%, ash ≤0.7% for Atta); Pulses; Spices; Rice; Ghee (fat ≥99.5%, moisture ≤0.5%); (5) Mandatory for export of many agricultural commodities.
Products Covered	Agricultural produce: Edible oils (groundnut, mustard, coconut, sunflower); Ghee and butter; Honey; Wheat, rice, pulses; Spices (turmeric, chilli, pepper); Cotton; Jute; Tobacco; Essential oils; Fruits and vegetables (optional grading).

Regulatory Body	Country	Year	Act/Order	Scope	Unique Feature
FSSAI	India	2006/2008	FSS Act 2006	All food incl. nutraceuticals	Single umbrella authority; replaced 8+ laws; 3-tier licensing
FDA / DSHEA	USA	1906/1994	FDCA 1938 + DSHEA 1994	Food + Dietary supplements + Drugs	No pre-market approval for supplements (DSHEA); manufacturer's responsibility
FPO	India	1955 (now FSSAI)	Essential Commodities Act 1955	Fruit-based processed products	Now subsumed under FSSAI; TSS (Brix) standards for fruit products
MPO	India	1973 (now FSSAI)	Essential Commodities Act 1955	Meat products	Veterinary inspection mandatory; nitrite preservatives regulated
AGMARK	India	1937	APGMA 1937	Agricultural produce (voluntary)	Voluntary grading; Grade designations (Special, A, B, C); DMI certification

HACCP — HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

HACCP	Hazard Analysis and Critical Control Points — A systematic, preventive science-based food safety management system that identifies, evaluates, and controls hazards that are significant for food safety. (Codex Alimentarius Commission, WHO/FAO definition). First developed by Pillsbury Company for NASA in 1960s.

HACCP has **7 Principles** (core framework) implemented through **12 Preliminary Steps**. The system focuses on **PREVENTION rather than end-product testing** — it controls hazards throughout the production process, not just at the end.

The 7 Principles of HACCP

HACCP — 7 PRINCIPLES (Core Framework)

PRINCIPLE 1 — HAZARD ANALYSIS:
Conduct a hazard analysis: Identify all potential hazards (Biological: bacteria, viruses, parasites;
Chemical: pesticides, heavy metals, allergens, mycotoxins, cleaning agents;
Physical: glass, metal, stones, bone fragments) at each step of the process.
Assess significance: likelihood × severity = Risk. Only SIGNIFICANT hazards proceed to Principle 2.

PRINCIPLE 2 — CRITICAL CONTROL POINTS (CCPs):
Identify Critical Control Points — steps in the process where control can be APPLIED and is ESSENTIAL to prevent or eliminate a food safety hazard.
'CCP Decision Tree' (Codex): A set of 4 questions to determine if a step is a CCP.
Examples: Pasteurisation (thermal kill of pathogens = CCP); Metal detector (physical hazard = CCP);
pH adjustment (prevents pathogen growth = CCP); Refrigeration (CCP for temperature-sensitive products).

PRINCIPLE 3 — CRITICAL LIMITS:
Establish CRITICAL LIMITS for each CCP — measurable values that must be met.
Examples: Pasteurisation ≥72°C for ≥15 seconds (HTST); pH ≤4.6 (prevents C. botulinum growth);
Refrigeration ≤5°C; Water activity ≤0.85; Metal detector sensitivity ≥2mm Fe / 2.5mm SS.

PRINCIPLE 4 — MONITORING SYSTEM:
Establish a monitoring system to ensure each CCP is under control.
Continuous vs. periodic monitoring. Documented records. Responsible person assigned.

Examples: Temperature probes at pasteuriser (continuous); pH meters (batch); metal detector (every unit).

PRINCIPLE 5 — CORRECTIVE ACTIONS:

Establish corrective actions when monitoring indicates a CCP is NOT under control (critical limit breached).

Two steps: (a) Correct the deviation (fix the process); (b) Determine disposition of affected product.

Examples: If pasteuriser temperature falls below 72°C → STOP; reprocess or discard; fix equipment.

PRINCIPLE 6 — VERIFICATION PROCEDURES:

Establish verification activities to confirm the HACCP plan is working effectively.

Methods: Microbiological testing (end-product), Audits, Review of monitoring records, Calibration.

Verification ≠ Monitoring. Monitoring = routine real-time; Verification = periodic confirmation HACCP works.

PRINCIPLE 7 — RECORD-KEEPING AND DOCUMENTATION:

Establish documentation and record-keeping systems.

Records: HACCP plan, Hazard analysis records, CCP monitoring records, Corrective action records,

Verification records, Employee training records. Legal requirement: records available for regulatory inspection.

⚠ Exam Trick	Memorise the 7 HACCP Principles in ORDER: 'Hazard CCPs Critical-Limits Monitor Correct Verify Record-Keep'. Mnemonic: 'H-C-C-M-C-V-R' = 'Healthy Cows Can Make Cheese Very Reliably'. The order matters — you CANNOT establish a monitoring system (P4) before identifying CCPs (P2) and Critical Limits (P3). In 10-mark questions: explain ALL 7 principles with examples for full marks.

12 Preliminary Steps of HACCP Implementation

Step	Action	Detail
Step 1	Assemble the HACCP Team	Multidisciplinary team: food microbiologist, production engineer, quality assurance, management representative. Document team composition.
Step 2	Describe the product	Complete product description: composition, physical/chemical properties, processing method, packaging, shelf-life, conditions of use, target consumer.

Step	Action	Detail
Step 3	Identify intended use	Define intended use and consumers — including vulnerable groups (infants, elderly, immunocompromised, pregnant women). Misuse scenarios.
Step 4	Construct Flow Diagram	Visual flowchart of all steps from raw material receipt to distribution. Include all inputs (ingredients, packaging, water, energy) at each step.
Step 5	On-site Confirmation of Flow Diagram	Verify the flow diagram by physical inspection of the production facility during all operating hours. Amend if discrepancies found.
Step 6	Conduct Hazard Analysis (Principle 1)	List all potential hazards at each step; assess severity and likelihood; identify control measures. Prerequisite Programs (PRPs) — GHPs, GMP — control general hazards.
Step 7	Determine CCPs (Principle 2)	Apply CCP Decision Tree at each step with significant hazard. Q1: Is control essential? Q2: Is step specifically designed to eliminate? Q3: Could contamination occur? Q4: Will subsequent step eliminate hazard?
Step 8	Establish Critical Limits (Principle 3)	Scientifically validated limits for each CCP (temperature, time, pH, aW, Brix). Must be measurable. Documented with scientific justification.
Step 9	Establish Monitoring System (Principle 4)	Define: WHAT to monitor, HOW to monitor, FREQUENCY, WHO monitors, DOCUMENTATION.
Step 10	Establish Corrective Actions (Principle 5)	For each CCP: predetermined corrective action when limit breached. Responsibility, product disposition procedure.
Step 11	Establish Verification Procedures (Principle 6)	Validation (before implementation), Verification (during operation), Reassessment (periodic — annually minimum or when changes occur).
Step 12	Establish Documentation (Principle 7)	HACCP Plan document; Hazard analysis worksheets; CCP monitoring records; Corrective action logs; Verification reports; Training certificates.

Hazard Type	Examples in Food Industry	CCP Control Measure
Biological	Salmonella (poultry), Listeria (dairy), E. coli O157 (beef), Hepatitis A (shellfish), Aflatoxin (peanuts, corn), Cryptosporidium (water)	Pasteurisation (thermal kill); chlorination of water; pH ≤4.6; aW ≤0.85; refrigeration ≤5°C
Chemical	Pesticide residues (produce); heavy metals (Pb, Cd, Hg — fish, shellfish); mycotoxins (aflatoxin B1 ≤2 ppb — peanuts); allergens (milk, nuts, wheat, soy, shellfish); veterinary drug residues; cleaning chemical residues	Raw material certification; supplier audits; allergen segregation; validated cleaning procedures; residue testing
Physical	Metal fragments (broken machinery), Glass (broken equipment/packaging), Bone (meat/fish), Stones/extraneous matter (grain, pulses), Plastic pieces (packaging)	Metal detectors (CCP — ≥2mm ferrous, ≥2.5mm stainless steel, ≥3mm non-ferrous); X-ray inspection; sieving/screening; visual inspection

5. GOOD MANUFACTURING PRACTICES (GMP) FOR FOOD SAFETY

GMP (Good Manufacturing Practices)	A system of quality assurance that ensures products are consistently produced and controlled according to quality standards appropriate to their intended use. GMP minimises risks of production that cannot be eliminated through testing the final product. (WHO Definition)

GMP is the **FOUNDATION of all food safety and pharmaceutical quality systems**. It is a PREREQUISITE PROGRAMME (PRP) for HACCP. Without GMP, HACCP cannot function effectively. **GMP addresses environmental conditions of manufacturing**, while HACCP addresses process-specific hazards.

Elements of GMP for Nutraceuticals / Dietary Supplements

GMP Element	Requirements / Standards	Specific Nutraceutical Considerations
Premises & Facilities	Appropriate design, construction, size, location; adequate lighting (≥540 lux in examination areas); ventilation; pest control; Separate areas: raw material, production, packaging, QC laboratory, reject material	Botanical ingredient processing: dedicated rooms for dusty herbs; stainless steel contact surfaces; positive pressure in sterile areas; humidity control for hygroscopic supplements (Fe, Vit C)
Equipment	Appropriate design, construction, material (food-grade: SS316L, HDPE, PTFE); cleaned and maintained; validated performance; calibrated instruments; equipment logs maintained	Granulators, tablet presses, encapsulators, coating pans — all must be cleaned and validated; no open lubrication systems over product; dedicated equipment for penicillin and hormones to prevent cross-contamination
Personnel	Qualified, trained staff; health requirements (no infectious disease); personal protective equipment (PPE); hygiene (handwashing, no jewellery, hair nets, gloves); no eating/drinking/smoking in production	Personnel: Qualified Person (QP) for batch release; Head of Production (degree in pharmacy/food tech); Head of QC; all staff trained on GMP principles annually; Training records maintained
Raw Materials	Approved suppliers; incoming inspection (CoA verification, identity test); sampling according to statistical plan (SQRT(n)+1 or n-plan); quarantine → testing → release	Botanicals: microscopic identity; thin-layer chromatography (TLC); HPLC marker quantification; microbiological limits; heavy metals testing; pesticide residue testing; aflatoxin screening (spices, herbs)

GMP Element	Requirements / Standards	Specific Nutraceutical Considerations
	or reject; storage conditions met; FIFO/FEFO	
Production / Process Control	SOPs for each process step; in-process controls (tablet weight variation, disintegration, hardness, pH, temperature, time); batch records; line clearance before each batch; deviation procedure	Microencapsulation critical parameters; lyophilisation: temperature profiles, vacuum levels; blending homogeneity (stratified sampling, RSD ≤5%); dissolution testing for bioavailability
Quality Control (QC)	Independence from production; analytical testing: identity, purity, potency, dissolution, microbial limits; QC laboratory equipped and validated; reference standards maintained; stability testing program	Identity testing: DNA barcoding, HPLC, NMR; Potency: HPLC (marker compounds); Microbial: TAMC ≤10^3 CFU/g (tablets), TYMC ≤10^2 CFU/g, E. coli absent, Salmonella absent in 25g; Pathogen-free certified
Labelling & Packaging	Accurate, legible labels; batch coding; expiry dating; correct Supplement Facts panel; storage instructions; tamper-evident seals; child-resistant packaging where required	FSSAI mandated label elements for nutraceuticals; FDA Supplement Facts panel format; 'Not a drug' disclaimer (India); net quantity by weight/volume/count; Allergen declarations
Storage & Distribution	Correct temperature, humidity, light conditions; FEFO (First Expired, First Out); segregation of rejected/quarantined goods; cold chain maintenance for temperature-sensitive products	Cold-chain for probiotics (2-8°C), omega-3 oils (refrigerated); temperature mapping of warehouses; data loggers for temperature-sensitive shipments; GDP (Good Distribution Practice) requirements
Cleaning & Sanitation	Validated cleaning procedures (cleaning validation for shared equipment); CIP (Clean-in-Place); COP (Clean-out-of-Place); swab testing (visual/ATP/microbiological); cleaning records	Cleaning of botanical processing equipment — critical for allergen removal (peanut, tree nut); validated cleaning limits — usually NOEL/1000 × batch size × minimum daily dose formula
Documentation	Master Manufacturing Record (MMR); Batch Manufacturing Record (BMR); QC test records; SOPs; Deviation/CAPA records; Validation documents; Change control records; All records traceable and secure for minimum 2 years beyond expiry	21 CFR Part 111 (USA cGMP): identity specifications for each ingredient; component, in-process, and finished product testing; batch record review before release; material review committee for deviations

FSSAI GMP Regulations for Nutraceuticals

- FSS (Food Products Standards and Food Additives) Regulations, 2011 — Schedule 4: Specifies GMP requirements for food business operators.

- Food Safety Management Systems (FSMS): FSSAI mandates FSMS certification (FSSC 22000, ISO 22000, or BRC) for large food manufacturers.
- FSSAI Basic GMP for Dietary Supplements: Premises (clean, pest-free, adequate space); Equipment (food grade, cleaned, calibrated); Staff hygiene; Quality system (testing, batch records); Labelling compliance.
- Schedule 3 of FSS Act: Mandatory quality standards for specific products including vitamin premixes, mineral supplements, protein supplements.
- NABL-accredited laboratories: Testing must be done at NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited labs for regulatory acceptance.

GMP vs HACCP —Differences

Parameter	GMP	HACCP
Focus	General manufacturing and environmental conditions	Specific hazard control at critical process steps
Scope	All aspects of production (premises, equipment, personnel, processes)	Process-specific; hazard-specific
Approach	Prescriptive (rules and standards)	Risk-based and preventive (systematic analysis)
Application	Applied to entire manufacturing operation	Applied to specific product/process
Flexibility	Less flexible — sets minimum standards	More flexible — product/process specific
Relationship	GMP is a Prerequisite Program (PRP) for HACCP	HACCP builds ON TOP of GMP
Documentation	SOPs, BMRs, QC records	HACCP Plan, Hazard analysis worksheets, CCP records
Regulatory basis	21 CFR Part 111 (USA); FSS Regulations Schedule 4 (India)	Codex Alimentarius, FSMA (USA), EU Food Law
Example	Clean room design, sanitisation procedure, staff training	Pasteurisation temperature/time CCP for Listeria control

ADULTERATION OF FOODS

Food Adulteration	The act of adding, substituting, removing, or abstracting any substance to or from food, or processing food in a manner that renders it injurious to health, inferior in quality, or not conforming to the declared standards. (FSS Act 2006 / PFA Act 1954 definition)

Classification / Types of Adulteration

Type	Definition	Example	Intent
Intentional (Fraudulent)	Deliberately adding inferior/cheaper substance to increase weight/volume or enhance appearance	Chalk powder in flour; brick dust in chilli powder; metanil yellow dye in turmeric; formalin in fish to extend shelf-life	Economic gain; fraud; criminal intent
Incidental (Unintentional)	Contamination due to ignorance, poor storage, handling, or processing without deliberate intent	Pesticide residues in produce; aflatoxin from moulds in stored grains; metal contamination from processing equipment; rodent droppings in grain	Negligence; ignorance; inadequate storage/processing
Metallic contamination	Heavy metal contamination from soil, water, packaging	Lead (Pb) from contaminated soil/water in vegetables; Cadmium in rice grown in contaminated soil; Mercury in fish (methylmercury)	Environmental contamination — not intentional adulteration per se
Natural decomposition	Spoilage due to microbial action — food rendered unfit	Aflatoxin B1 in peanuts, maize; ergot in rye; rancidity in fats; solanine in green potatoes; patulin in mouldy apples	Biological process — poor storage/handling
Synthetic adulteration	Use of synthetic chemicals, artificial colours, prohibited preservatives	Coal tar dyes in food (Metanil Yellow — not permitted); Sodium metabisulphite excess; Formalin in milk; Starch in spices	Economic gain; appearance enhancement

Common Food Adulterants in India — Commodity-wise

Food Item	Common Adulterant	Detection Method	Health Risk
Milk	Urea (increases SNF/protein reading); Detergent; Starch; Water; Melamine (in powdered milk)	Urea: Dimethyl aminobenzaldehyde test (yellow→orange); Detergent: Rosalic acid test (pink); Starch: Iodine test (blue-black)	Urea → kidney damage; Melamine → kidney stones/failure; Detergent → GI disorders
Turmeric powder	Lead chromate (gives bright yellow colour); Metanil Yellow (synthetic coal tar dye)	Lead chromate: HCl → purple colour with KI; Metanil Yellow: HCl → pink/magenta colour	Lead chromate → lead poisoning; Metanil Yellow → neurotoxicity; not permitted in India

Food Item	Common Adulterant	Detection Method	Health Risk
Red Chilli powder	Brick dust, Rhodamine B, Sudan Red dye; chalk powder; artificially coloured sawdust	Rhodamine B: add petroleum ether → filtrate is pink; Water extraction → dye bleeds (synthetic)	Sudan Red = carcinogen (IARC Group 3); Rhodamine B = potentially carcinogenic
Mustard seeds / Argemone seeds	Argemone mexicana seeds (contaminate mustard)	Press seeds between filter paper → argemone oil = yellow/orange stain; Nitric acid → red (argemone alkaloids)	EPIDEMIC DROPSY — argemone oil contains sanguinarine → pulmonary oedema, glaucoma, cardiovascular damage
Honey	Commercial glucose syrup (high fructose corn syrup), sugar syrup	NMR spectroscopy (C-4 sugar ratio — honey from C-3 plants vs adulterant corn syrup from C-4 plants); F/G ratio; HMF content	Economic fraud; loss of therapeutic properties; potential digestive disturbance
Edible oils	Mineral oil (paraffin); castor oil; karanja oil (Pongamia); argemone oil in mustard oil	Baudouin test (castor oil: refractive index); Belfour test (karanja: Rouche reagent); Mineral oil: UV fluorescence	Mineral oil → laxative effect, lipid granuloma; Argemone oil → epidemic dropsy
Black pepper	Papaya seeds; light berries; starch; mineral substances	Papaya seeds float in alcohol + water mixture (black pepper sinks); Microscopy	Papaya seeds → not harmful but economic fraud; Mineral adulterants → kidney damage
Coffee powder	Chicory root, tamarind seed powder, date seeds, caramel	Coffee: Chlorogenic acid (UV spectroscopy); Chicory: no chlorogenic acid; Flotation test in water — chicory sinks faster	Chicory: not harmful (prebiotic), but economic fraud; Caramel: sugar — not harmful at low levels
Asafoetida (Hing)	Soap stone (talc), chalk, other gum resins	Dissolve in water — chalk/talc settles; Acid test — effervescence with HCl (chalk = $CaCO_3$)	Talc/chalk → GI irritation, carcinogenic potential (talc — asbestos-contaminated forms)
Basmati rice	Non-basmati rice (cheaper varieties); artificially polished/flavoured ordinary rice	DNA fingerprinting (most accurate); Aroma: Basmati has 2-acetyl-1-pyrroline (popcorn aroma compound)	Economic fraud; allergic reactions in some; no direct health risk

Caution

ARGEMONE OIL ADULTERANT in MUSTARD OIL is the MOST DANGEROUS food adulterant in India. It causes EPIDEMIC DROPSY — outbreaks of massive oedema, glaucoma, cardiac failure, and death. Sanguinarine (alkaloid in argemone oil) inhibits cytochrome oxidase + Na-K ATPase → cardiovascular toxicity. MAJOR OUTBREAKS: Delhi 1998 (3000+ cases, 65 deaths); Rajasthan 1991. Legal status: Criminal offence under FSS Act. Detection: Nitric acid test or paper chromatography.

Legal Provisions Against Food Adulteration in India

Legal Framework	Provisions	Penalties
FSS Act 2006 (Primary law)	Defines sub-standard food, unsafe food, misbranded food, adulterated food; FSSAI enforcement; Food Safety Officers (FSOs); Adjudicating Officers; Food Safety Appellate Tribunal (FSAT)	Sub-standard food: Fine up to ₹5 lakh; Unsafe food: Imprisonment up to 6 months + fine up to ₹5 lakh; Grievous injury: 6 years imprisonment + fine up to ₹5 lakh; Death: Life imprisonment + fine up to ₹10 lakh
PFA Act 1954 (Replaced by FSS Act 2006, but still referenced)	Prevention of Food Adulteration — foundational Indian food law; defined food standards; Public Analyst system established	Criminal penalties; imprisonment 6 months to life depending on offense severity; fine up to ₹10,000 (old; now replaced by FSS Act amounts)
IPC (Indian Penal Code) Sections	Section 272 (Adulterating food/drink with intent to sell, knowing it to be noxious), 273 (Sale of noxious food/drink), 274 (Adulteration of drugs), 275 (Sale of adulterated drugs)	Section 272/273: Imprisonment up to 6 months + fine up to ₹1000 (augmented by FSS Act penalties now)
Essential Commodities Act 1955	Regulates production, supply, distribution of essential commodities including foodgrains, edible oils	Orders under ECA (FPO, MPO) have criminal penalties for violations

PHARMACOPEIAL SPECIFICATIONS FOR DIETARY SUPPLEMENTS & NUTRACEUTICALS

Pharmacopoeia	An official publication containing a list of medicinal drugs with their effects and directions for their use, as well as quality standards (tests, procedures, acceptance criteria). Pharmacopoeial monographs establish identity, purity, potency, and quality standards.

Dietary supplements and nutraceuticals must meet quality standards set by **pharmacopoeias and regulatory standards**. While not all nutraceuticals are 'drugs', the trend is toward pharmacopoeial-level quality assurance (identity, purity, potency, safety) to ensure product integrity and consumer protection.

Major Pharmacopoeias Relevant to Nutraceuticals

Pharmacopoeia	Country / Region	Abbreviation	Relevance to Nutraceuticals
Indian Pharmacopoeia	India	IP	Official pharmaceutical standards of India. Published by Indian Pharmacopoeia Commission (IPC), Ghaziabad. Contains monographs for vitamins (Ascorbic Acid, Vitamin D, Vitamin E), minerals (Ferrous Sulphate, Calcium Carbonate), amino acids, and botanical drugs (Senna, Ginger, Garlic). IP supplements standards align with FSSAI requirements.
United States Pharmacopoeia — National Formulary	USA	USP-NF	USP has dedicated Dietary Supplement compendium. Contains HUNDREDS of dietary supplement monographs. USP Verification Program = voluntary 3rd party certification for supplements. USP <2750> Dietary Supplements — general chapters. USP Botanical Dietary Supplement chapters: authenticity testing, adulterant screening.
British Pharmacopoeia	United Kingdom	BP	Published by Medicines and Healthcare products Regulatory Agency (MHRA). Contains monographs for vitamins, minerals. Used as reference in many Commonwealth countries including India (alongside IP). BP Herbal Medicines section — herbal drug monographs.
European Pharmacopoeia	European Union	Ph. Eur. / EP	Published by European Directorate for the Quality of Medicines (EDQM), Strasbourg. Applied in 39 European countries. Extensive herbal drug monographs (Echinacea, Ginkgo, Ginseng, Garlic, Milk Thistle). Ph. Eur. 2.8.x chapters — contaminant testing; 2.6.x — microbiological quality.
Japanese Pharmacopoeia	Japan	JP	Official Japanese standard. Contains functional food standards (FOSHU regulation — Foods for Specified Health Use). Important for Asian nutraceutical markets.
Ayurvedic Pharmacopoeia of India	India	API	Published by Dept of AYUSH. Standards for Ayurvedic medicinal herbs and formulations. Many nutraceuticals overlap (Ashwagandha, Ginger, Turmeric standards in API). WHO Monographs on Selected Medicinal Plants also relevant.

USP Dietary Supplement Standards — Most Comprehensive

The USP is the most comprehensive pharmacopoeial resource for dietary supplements globally. general chapters:

USP Chapter	Title	Tests / Content
<1> Injections and Implanted Drug Products	General tests (referenced)	Sterility for injectable nutraceuticals (IV Vit C)
<61> Microbiological Examination	Microbial limit tests	TAMC, TYMC, specified organisms (Salmonella, E. coli, Staphylococcus) — for oral dietary supplements
<62> Microbiological Examination	Specified microorganisms	Absence of Salmonella in 10g; Absence of E. coli in 10g; for botanical supplements
<191> Identification tests — General	Chemical identification	Colour reactions, precipitation tests for minerals
<197> Spectrophotometric Identification	UV/Vis spectroscopy	Identification of vitamins (UV absorption maxima)
<232> Elemental Impurities — Limits	Heavy metals by ICP-MS/OES	Pb: Oral supplement ≤5 µg/day; As: ≤15 µg/day; Cd: ≤5 µg/day; Hg: ≤15 µg/day
<233> Elemental Impurities — Procedures	ICP-MS, ICP-OES methods	Validated methods for elemental impurities
<467> Residual Solvents	GC headspace methods	Class 1, 2, 3 solvent limits in botanical extracts
<561> Botanical Extracts	Identification, purity, potency	DNA-based identification; HPLC for marker compounds; specific gravity; moisture; ash; extractable matter
<565> Botanicals — Adulterant Screening	HPTLC, DNA barcoding	Authentication of botanical identity; screening for common adulterants
<2250> Detection of Irradiation in Dietary Supplements	Electron Paramagnetic Resonance	Detection of gamma irradiation treatment
<2750> Manufacturing Practices for Dietary Supplements	Quality systems	GMP principles for dietary supplement manufacturing; equivalent to 21 CFR Part 111

Indian Pharmacopoeia — Specifications for Dietary Supplements

Supplement	IP Monograph / Standard
Ascorbic Acid (Vitamin C)	IP Chapter + FSS Act Schedule
Vitamin E (Alpha-Tocopherol)	IP Tocopherol acetate monograph
Calcium Carbonate (Calcium supplement)	IP Calcium Carbonate monograph
Ferrous Sulphate (Iron supplement)	IP Ferrous Sulphate monograph
Fish Oil (Omega-3 Fatty Acids)	IP Fish Oil monograph (based on Ph. Eur.)
Ginger (Zingiber officinale)	API + WHO monograph
Garlic Powder (Allium sativum)	FSSAI standard + USP

Quality Parameters for Dietary Supplements — General Specifications

Quality Parameter	Test Method	Acceptance Criterion (General)
Identity / Authenticity	UV-Vis spectroscopy; HPLC retention time; IR spectroscopy; TLC; NMR; DNA barcoding (botanicals)	Matches reference standard spectrum/chromatogram; DNA sequence matches declared species
Purity / Assay	HPLC (primary method for most nutraceuticals); Titration; Atomic absorption spectrometry (minerals)	Label claim ±10% (USP); ≥90-110% of label claim (IP); Specific purity limits per monograph
Heavy Metals (Elemental Impurities)	ICP-MS (inductively coupled plasma mass spectrometry); ICP-OES; AAS	Pb ≤5 µg/day (USP <232>); As ≤15 µg/day; Cd ≤5 µg/day; Hg ≤15 µg/day; limit per class (oral non-systemic)

Quality Parameter	Test Method	Acceptance Criterion (General)
Microbial Limits	Pour plate (TAMC, TYMC); MPN (Staphylococcus); Selective media (Salmonella, E. coli)	Oral supplements (IP/USP): TAMC ≤10^3 CFU/g; TYMC ≤10^2 CFU/g; Salmonella absent/25g; E. coli absent/10g; S. aureus absent/g
Moisture / Loss on Drying	Karl Fischer titration (accurate); gravimetric LOD at 105°C/2h	Varies: vitamins ≤0.1-2%; herbal powders ≤12%; probiotics ≤5% (powder); minerals ≤2%
Particle Size (powder)	Sieve analysis; laser diffraction (Malvern)	Per product specification (affects dissolution and bioavailability — critical for CoQ10, curcumin — insoluble compounds)
Dissolution / Disintegration	USP Dissolution Apparatus 1 (basket) or 2 (paddle) for tablets/capsules	USP: ≥75% in 45 min (for most immediate-release tablets); Disintegration ≤30 min (uncoated tablets, IP)
Pesticide Residues	GC-MS/MS; LC-MS/MS (multi-residue methods)	Per EU MRL, FSSAI limits, or Codex MRL. e.g., Chlorpyrifos ≤0.01 mg/kg (botanicals); Organochlorines per product
Peroxide Value (PV) — oils/omega-3	Iodometric titration (ISO 3960)	Fresh oil/capsule: PV ≤5 meq O_2/kg; Totox value ≤26 (fish oil); oxidative quality indicator
Allergen Declaration	ELISA (enzyme-linked immunosorbent assay); PCR; Western blot for protein allergens	Mandatory declaration of 8 major allergens (USA: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybean); 14 allergens in EU

USP Verification Program for Dietary Supplements

The **USP Verified Mark** (USP Dietary Supplement Verification Program — DSVP) is a **voluntary third-party certification program** that verifies dietary supplements meet USP quality standards. Verification includes:

- Identity: Contains the declared ingredients at label-claimed potency.
- Purity: Does NOT contain harmful levels of contaminants (heavy metals, pesticides, microbes).
- Dissolution: Will break down and release properly in the body.
- Manufacturing: Manufactured under sanitary conditions following cGMP.
- Products bearing USP Verified mark are tested ANNUALLY and facilities inspected.

★ Point	Other Third-Party Verification Programs for dietary supplements: NSF International (NSF Mark — widely recognised); ConsumerLab (independent testing, publishes results publicly); Informed Sport / Informed Choice (for sports supplements — tested for banned substances); Banned Substances Control Group (BSCG). These voluntary certifications provide consumers and healthcare professionals with confidence in supplement quality — important in clinical pharmacy practice.

DEFINITIONS GLOSSARY —

FSSAI	Food Safety and Standards Authority of India — established under FSS Act 2006; single umbrella regulatory authority for all food including nutraceuticals and dietary supplements in India.
DSHEA 1994	Dietary Supplement Health and Education Act 1994 (USA) — defines dietary supplements; does NOT require pre-market FDA approval; manufacturer responsible for safety; permits structure/function claims with disclaimer.
FPO 1955	Fruit Products Order 1955 — under Essential Commodities Act; regulates quality standards for fruit-based processed products (jams, juices, squashes, canned fruits); now subsumed under FSSAI.
MPO 1973	Meat Products Order 1973 — regulates quality, hygiene, and standards for processed meat products; mandates veterinary inspection; regulated nitrite levels; now under FSSAI jurisdiction.
AGMARK	Agricultural Mark under Agricultural Produce (Grading and Marking) Act, 1937. Voluntary grading certification for agricultural produce (ghee, honey, edible oils, grains). Grade designations: Special, Grade A, B, C. Administered by DMI.
HACCP	Hazard Analysis and Critical Control Points — systematic, preventive food safety management system with 7 principles: Hazard Analysis, CCP identification, Critical Limits, Monitoring, Corrective Actions, Verification, Documentation.
GMP	Good Manufacturing Practices — quality assurance system ensuring products are consistently manufactured to meet quality standards; covers premises, equipment, personnel, materials, production, QC, documentation. Foundation/prerequisite of HACCP.
Critical Control Point (CCP)	A step in the food production process where control can be applied to prevent, eliminate, or reduce a food safety hazard to acceptable levels. Examples: pasteurisation, metal detector, pH adjustment, refrigeration.
Critical Limit	The maximum/minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce food safety hazard. Must be measurable and validated.

Food Adulteration	Adding, substituting, removing, or processing food in any manner that renders it injurious to health, inferior in quality, or not conforming to declared standards (FSS Act 2006). Criminal offence with penalties up to life imprisonment.
Epidemic Dropsy	Condition caused by argemone oil (sanguinarine) contaminating mustard oil; causes massive oedema, cardiac failure, glaucoma; several outbreaks in India. Most dangerous food adulteration in India.
Water Activity (aW)	Ratio of vapour pressure of water in food to that of pure water at same temperature. Range: 0-1. High aW (>0.85) supports microbial growth; aW <0.25 required for stable probiotic powders; aW <0.6 prevents moulds.
New Dietary Ingredient (NDI)	Under DSHEA 1994: any dietary supplement ingredient not marketed in USA before October 15, 1994. Requires 75-day pre-market notification to FDA before marketing. Manufacturer must demonstrate reasonable safety.
Supercritical CO_2 Extraction	Extraction using CO_2 above critical temperature (31.1°C) and pressure (73.8 bar). Gold standard for extracting heat-sensitive lipophilic nutraceuticals. No residual solvent. Tunable selectivity. Used for lycopene, omega-3, tocopherols, essential oils.
Pharmacopoeia	Official compendium of standards for drugs and pharmaceutical preparations including dietary supplements — specifying identity, purity, potency. Major: Indian (IP), US (USP), British (BP), European (Ph.Eur), Japanese (JP).
Peroxide Value (PV)	Measure of primary oxidation of lipids/oils — reflects hydroperoxide content. Fresh oil: PV ≤5 meq O_2/kg; fish oil: PV ≤5; Totox = 2PV + Anisidine value ≤26 (fish oil). Quality marker for omega-3 supplements.
USP Verified Mark	Voluntary third-party certification program (USP Dietary Supplement Verification Program) confirming that a dietary supplement meets USP standards for identity, purity, potency, and GMP manufacturing.
GRAS	Generally Recognised As Safe — FDA designation for substances considered safe at intended use levels based on established scientific consensus. Examples: BHA, BHT at regulated levels; most common food ingredients. No pre-market FDA approval needed for GRAS substances.

NABL	National Accreditation Board for Testing and Calibration Laboratories (India). FSSAI mandates testing at NABL-accredited laboratories for regulatory compliance testing of food and dietary supplements.

TOTOX Value	Total oxidation value = 2 × Peroxide Value + Anisidine Value. Composite measure of both primary (hydroperoxides) and secondary (aldehydes) lipid oxidation. Used for fish oil quality: TOTOX ≤26 (acceptable). Higher TOTOX = more rancid, less potent omega-3.

QUESTION BANK — 2 MARK QUESTIONS

Q. Q1. What is HACCP? Name its 7 Principles in order.

Ans: HACCP (Hazard Analysis and Critical Control Points) is a systematic, preventive, science-based food safety management system that identifies, evaluates, and controls food safety hazards throughout the food production process. Originally developed by Pillsbury/NASA in the 1960s. The 7 Principles in order are: (1) Conduct a HAZARD ANALYSIS; (2) Identify CRITICAL CONTROL POINTS (CCPs); (3) Establish CRITICAL LIMITS for each CCP; (4) Establish a MONITORING SYSTEM; (5) Establish CORRECTIVE ACTIONS when CCP fails; (6) Establish VERIFICATION PROCEDURES; (7) Establish RECORD-KEEPING AND DOCUMENTATION. Mnemonic: 'Hungry Cats Can Meow Constantly, Very Regularly.'

Q. Q2. What is FSSAI? When was it established and what act governs it?

Ans: FSSAI (Food Safety and Standards Authority of India) is the apex food regulatory authority in India. Established under the Food Safety and Standards Act, 2006 (FSS Act) and became operational in 2008. It is under the Ministry of Health and Family Welfare, Government of India. FSSAI replaced multiple earlier laws including PFA Act 1954, FPO 1955, MPO 1973, and 5 other food orders — becoming the single umbrella regulatory authority for all food in India including conventional foods, dietary supplements, nutraceuticals, functional foods, novel foods, and food for special dietary uses. regulations: FSS (Packaging and Labelling) Regulations 2011; FSS (Health Supplements, Nutraceuticals, Functional Food) Regulations 2022.

Q. Q3. What is AGMARK? Who administers it and what grade designations exist?

Ans: AGMARK (Agricultural Mark) is a quality certification mark for agricultural produce under the Agricultural Produce (Grading and Marking) Act, 1937 (APGMA). It is administered by the Directorate of Marketing and Inspection (DMI) under the Ministry of Agriculture and Farmers' Welfare, Government of India. Certification is VOLUNTARY (not compulsory). Grade designations: SPECIAL GRADE (highest quality), GRADE A, GRADE B, GRADE C. Products covered: Edible oils (groundnut, mustard, coconut), Ghee (fat ≥99.5%), Honey (moisture ≤20%, F+G ≥65%), Butter, Wheat flour (atta), Pulses, Spices, Rice, Essential oils, and Cotton. AGMARK logo = triangle with the letters printed — guarantees minimum quality standard is met.

Q. Q4. What is the difference between HACCP and GMP?

Ans: GMP (Good Manufacturing Practices) and HACCP are complementary but distinct: GMP = general environmental and manufacturing conditions (premises, equipment, personnel hygiene, documentation) applied to ALL aspects of production; HACCP = systematic risk-based approach to identify and control SPECIFIC food safety hazards at CRITICAL CONTROL POINTS in the process. GMP is a PREREQUISITE PROGRAM (PRP) for HACCP — HACCP cannot function

without GMP in place. GMP is PRESCRIPTIVE (sets minimum standards); HACCP is FLEXIBLE and product-process specific. Regulatory basis: GMP = 21 CFR Part 111 (USA), FSSAI Schedule 4 (India); HACCP = Codex Alimentarius, FSMA (USA). Together: GMP provides the foundation; HACCP controls process-specific critical hazards ON TOP of GMP.

Q. Q5. What is Epidemic Dropsy? Name the causative adulterant and its detection method.

Ans: Epidemic Dropsy is a severe poisoning condition caused by ARGEMONE OIL contaminating MUSTARD OIL. Argemone oil (from Argemone mexicana seeds — Mexican poppy — which resemble mustard seeds) contains the toxic alkaloid SANGUINARINE and DIHYDROSANGUINARINE. Mechanism: Sanguinarine inhibits cytochrome oxidase + Na-K ATPase → cardiovascular toxicity, massive oedema (dropsy), glaucoma, cardiac failure, death. Major outbreaks in India: Delhi 1998 (>3000 cases, 65 deaths); Rajasthan 1991. Detection: (1) NITRIC ACID TEST: Argemone oil + conc. HNO_3 → RED colour (positive); (2) Paper chromatography; (3) Baudouin test for contamination. Prevention: Source traceability, AGMARK certification for mustard oil; FSSAI testing.

Q. Q6. What is the Lycopene Processing Paradox? Explain with example.

Ans: The Lycopene Processing Paradox refers to the fact that PROCESSED tomatoes have HIGHER BIOAVAILABLE LYCOPENE than RAW tomatoes, despite raw tomatoes having more total lycopene by weight. Explanation: In raw tomatoes, lycopene is tightly bound within chromoplasts (cellular compartments) in the all-trans configuration (poorly bioaccessible). Processing effects: (1) HEAT + MECHANICAL disruption breaks cell walls and chromoplasts → lycopene released; (2) Heat also converts all-trans lycopene to cis-isomers (which are MORE bioavailable — absorbed 2.5× better than all-trans); (3) Homogenisation further disrupts cell structures. Examples: Tomato paste > tomato juice > raw tomato for lycopene bioavailability. Cooking with oil further enhances absorption (lycopene is fat-soluble → co-consumption with EVOO ↑ absorption by 2-3×). Practical implication: Tomato ketchup, paste, and cooked tomato sauce are BETTER lycopene sources than raw tomatoes!

Q. Q7. What are the specifications under DSHEA 1994 for dietary supplements in the USA?

Ans: DSHEA 1994 (Dietary Supplement Health and Education Act) specifications: (1) DEFINITION: Product taken by mouth containing dietary ingredient (vitamin, mineral, herb, amino acid, enzyme, metabolite, concentrate, extract); intended to supplement the diet — NOT a conventional food or drug. (2) NO PRE-MARKET FDA APPROVAL REQUIRED — unlike drugs; manufacturer is responsible for safety. (3) NEW DIETARY INGREDIENT (NDI): ingredients new to market after Oct 15, 1994 require 75-day pre-market notification to FDA. (4) PERMITTED CLAIMS: Structure/function claims ('helps maintain joint health') + Nutrient content claims. NOT permitted: Disease claims ('cures arthritis'). (5) MANDATORY DISCLAIMER: 'This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.' (6) LABELLING: Supplement Facts panel (not Nutrition Facts) with serving size, amounts per serving, % DV. (7) cGMP compliance: 21 CFR Part 111. (8) Serious Adverse Event Reporting mandatory (since 2006 Amendment).

Q. Q8. Name three common food adulterants and their detection tests.

Ans: (1) LEAD CHROMATE in TURMERIC POWDER: Detection: Add HCl (dilute) to turmeric solution → add KI → PURPLE colour indicates chromate; OR dilute HCl alone → silver nitrate → yellow precipitate of silver chromate. Health risk: Lead poisoning (neurotoxic, nephrotoxic). (2) METANIL YELLOW (coal tar dye) in TURMERIC/SPICES: Detection: Add HCl (dilute) to water suspension → PINK/MAGENTA colour indicates metanil yellow (approved test in PFA/FSSAI). Health risk: Neurotoxin, not permitted in India. (3) ARGEMONE OIL in MUSTARD OIL: Detection: Nitric acid test — add conc. HNO_3 to oil → RED colour indicates argemone oil

(sanguinarine). Alternatively: paper chromatography of oil extract. Health risk: Epidemic dropsy — sanguinarine → CV toxicity, massive oedema, death.

QUESTION BANK — 5 MARK QUESTIONS

- Q1. Describe the effect of thermal processing and storage conditions on the stability of nutraceuticals. Give specific examples. (5 marks)
- Q2. Write a detailed note on FSSAI — its establishment, structure, and regulations for nutraceuticals. (5 marks)
- Q3. Write a note on Food Adulteration — classification, common adulterants in India, and legal provisions. (5 marks)
- Q4. Write a note on FPO, MPO, and AGMARK — their scope, administration, and standards. (5 marks)
- Q5. Describe the Pharmacopeial specifications for dietary supplements with reference to IP, USP, and BP. (5 marks)

QUESTION BANK — 10 MARK QUESTIONS

- Q1. Write a detailed account of HACCP — definition, 7 principles, 12 steps, and types of food hazards with examples. (10 marks)
- Q2. Write a comprehensive note on: (a) Effect of processing on nutraceuticals; (b) Effect of storage and environmental factors on nutraceutical stability. (10 marks)
- Q3. Write a comprehensive note on food adulteration — definition, classification, common adulterants in India, detection methods, and legal provisions under FSS Act 2006. (10 marks)

PREVIOUS-YEAR STYLE QUESTIONS

#	Question	Marks
1	Write a note on FSSAI — establishment, structure, and regulations for nutraceuticals and dietary supplements in India.	5
2	Explain the 7 Principles and 12 Steps of HACCP. What are the three types of food hazards?	10
3	Differentiate GMP and HACCP. Describe elements of GMP for nutraceuticals.	5
4	Write a detailed note on food adulteration — classification, common adulterants in India, detection, and legal provisions.	10
5	Compare FPO, MPO, and AGMARK — their scope, standards, and administration.	5
6	Describe the effect of thermal processing and storage conditions on nutraceutical stability with examples.	5/10
7	Write a note on Pharmacopeial specifications for dietary supplements — IP, USP, BP quality tests and acceptance criteria.	5

TOP 15 MCQs — WITH ANSWERS & EXPLANATIONS

Q1. FSSAI was established under which Act of the Indian Parliament?

(A) Prevention of Food Adulteration Act, 1954
(B) Food Safety and Standards Act, 2006
(C) Essential Commodities Act, 1955
(D) Drugs and Cosmetics Act, 1940

✓ Correct: (B) Food Safety and Standards Act, 2006

Explanation: FSSAI (Food Safety and Standards Authority of India) was established under the Food Safety and Standards Act, 2006 (FSS Act). It became operational in 2008. The FSS Act 2006 replaced 8 earlier food laws including PFA Act 1954, FPO 1955, MPO 1973, and others, making FSSAI the single umbrella food regulatory authority in India.

Q2. Which is the CORRECT order of HACCP Principles?

(A) CCP → Hazard Analysis → Critical Limits → Monitoring → Corrective Action → Verification → Records
(B) Hazard Analysis → CCP → Critical Limits → Monitoring → Corrective Action → Verification → Records
(C) Monitoring → CCP → Hazard Analysis → Critical Limits → Verification → Corrective Action → Records
(D) Verification → Hazard Analysis → CCP → Critical Limits → Monitoring → Corrective Action → Records

✓ Correct: (B) Hazard Analysis → CCP → Critical Limits → Monitoring → Corrective Action → Verification → Records

Explanation: The CORRECT order of the 7 HACCP Principles is: P1-Hazard Analysis → P2-Identify CCPs → P3-Establish Critical Limits → P4-Monitoring System → P5-Corrective Actions → P6-Verification → P7-Records/Documentation. Mnemonic: 'Hungry Cats Can Meow Constantly, Very Regularly'. The ORDER matters — you cannot establish monitoring (P4) before defining what the critical limits are (P3) and what the CCPs are (P2).

Q3. Under DSHEA 1994 (USA), dietary supplement manufacturers require:

(A) Pre-market FDA approval before selling the supplement
(B) Post-market FDA notification within 30 days of first marketing
(C) 75-day pre-market notification to FDA only for NEW dietary ingredients (NDI)
(D) No notification or approval — completely unregulated

✓ Correct: (C) 75-day pre-market notification to FDA only for NEW dietary ingredients (NDI)

Explanation: Under DSHEA 1994, standard dietary supplements do NOT require pre-market FDA approval. HOWEVER, for NEW DIETARY INGREDIENTS (NDI = ingredients not marketed in USA before October 15, 1994), manufacturers must submit a 75-DAY PRE-MARKET NOTIFICATION to FDA before marketing. FDA then has 75 days to object. For existing dietary ingredients (pre-1994), no notification is required. This is the fundamental difference from drugs which require full pre-market approval.

Q4. AGMARK certification in India is administered by:

(A) FSSAI (Food Safety and Standards Authority of India)
(B) Bureau of Indian Standards (BIS)
(C) Directorate of Marketing and Inspection (DMI), Ministry of Agriculture
(D) Ministry of Health and Family Welfare

✓ Correct: (C) Directorate of Marketing and Inspection (DMI), Ministry of Agriculture

Explanation: AGMARK (Agricultural Mark) is administered by the Directorate of Marketing and Inspection (DMI) under the Ministry of Agriculture and Farmers' Welfare, Government of India. DMI has 6 Regional Offices, 26 Sub-regional offices, and field offices across India. AGMARK certification is VOLUNTARY — it is NOT mandatory for sale but provides quality assurance to consumers. BIS administers the ISI mark (Industrial Standards). FSSAI administers FSS Act compliance.

Q5. Which processing method BEST PRESERVES heat-sensitive nutraceuticals like Vitamin C and probiotics?

(A) Spray drying at inlet temperature 180°C
(B) Sun drying for 48 hours
(C) Freeze drying (Lyophilisation)
(D) Extrusion at 150°C

✓ Correct: (C) Freeze drying (Lyophilisation)

Explanation: FREEZE DRYING (Lyophilisation) is the BEST method for preserving heat-sensitive nutraceuticals. The process involves freezing followed by sublimation of ice under vacuum — the product never reaches high temperature. This preserves: Vitamin C (minimal loss vs >50% in heat drying); Probiotic viability (>10^7 CFU/g achievable — much better than spray drying); Omega-3; Polyphenols; Enzymes. Disadvantage: High cost. Spray drying involves hot air at 150-220°C — significant loss. Sun drying involves prolonged UV exposure → Vitamin C ↓↓ (photodegradation + heat).

Q6. The MOST dangerous food adulterant in India, causing Epidemic Dropsy, is:

(A) Metanil Yellow in turmeric
(B) Argemone oil in mustard oil
(C) Lead Chromate in chilli powder
(D) Melamine in milk powder

✓ Correct: (B) Argemone oil in mustard oil

Explanation: ARGEMONE OIL contaminating MUSTARD OIL is the MOST DANGEROUS food adulterant in India, causing EPIDEMIC DROPSY — a condition characterised by massive oedema, glaucoma, cardiac failure, and death. The toxic alkaloid SANGUINARINE in argemone oil inhibits cytochrome oxidase and Na-K ATPase. Major outbreaks: Delhi 1998 (>3000 cases, 65+ deaths); Rajasthan 1991. Detection: Nitric acid test → RED colour (positive for argemone oil). While Metanil Yellow and Lead Chromate are also dangerous, argemone oil in mustard oil causes the most acute, life-threatening mass poisoning.

Q7. Which vitamin is MOST sensitive to light and acts as a photosensitiser destroying other nutrients?

(A) Vitamin C (Ascorbic Acid)
(B) Vitamin A (Retinol)
(C) Riboflavin (Vitamin B2)
(D) Vitamin E (Tocopherol)

✓ Correct: (C) Riboflavin (Vitamin B2)

Explanation: RIBOFLAVIN (Vitamin B2) is the MOST LIGHT-SENSITIVE vitamin AND acts as a PHOTOSENSITISER. When riboflavin absorbs light (especially UV and visible), it reaches an excited state and reacts with oxygen to generate SINGLET OXYGEN ($^1O_2$). This $^1O_2$ then destroys other nutrients in the same product — especially VITAMIN C and TRYPTOPHAN. This is why milk exposed to sunlight in clear bottles rapidly loses both riboflavin and Vitamin C. Protective measure: Amber/opaque packaging for milk and riboflavin-containing products.

Q8. The HACCP term 'Critical Limit' refers to:

(A) The maximum number of critical control points in a process
(B) A measurable value (temperature, pH, time) that separates acceptable from unacceptable conditions at a CCP
(C) The minimum frequency of monitoring at a CCP
(D) The threshold above which corrective action documentation is required

✓ Correct: (B) A measurable value (temperature, pH, time) that separates acceptable from unacceptable conditions at a CCP

Explanation: A CRITICAL LIMIT is a maximum or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce food safety hazard to acceptable levels. It must be MEASURABLE and VALIDATED. Examples: Pasteurisation ≥72°C for ≥15 seconds (kills Listeria, Salmonella); pH ≤4.6 (below which C. botulinum cannot grow); Refrigeration ≤5°C; Metal detector sensitivity ≥2mm ferrous. If the critical limit is BREACHED → CORRECTIVE ACTION must be taken (Principle 5).

Q9. Processed tomato products have HIGHER lycopene bioavailability than raw tomatoes because:

(A) Processing adds synthetic lycopene to increase content
(B) Heat and mechanical disruption break chromoplasts and convert all-trans to more absorbable cis-lycopene
(C) Cooking removes dietary fibre that inhibits lycopene absorption
(D) Pasteurisation activates enzymes that release lycopene from cell walls

✓ Correct: (B) Heat and mechanical disruption break chromoplasts and convert all-trans to more absorbable cis-lycopene

Explanation: Processed tomato products (paste, ketchup, sauce) have higher BIOAVAILABLE lycopene than raw tomatoes due to TWO mechanisms: (1) MECHANICAL DISRUPTION (homogenisation, chopping) + HEAT breaks chromoplasts (cellular compartments where lycopene is stored) → lycopene released from the protein matrix; (2) HEAT converts all-trans lycopene to CIS-ISOMERS (5-cis, 9-cis, 13-cis) which are absorbed 2-3× better than all-trans. Additionally, consuming lycopene WITH dietary fat (e.g., EVOO in tomato sauce) further enhances absorption 2-3× (lycopene is fat-soluble). This is the 'Lycopene Processing Paradox'.

Q10. Detection of Lead Chromate in turmeric powder is done by:

(A) Adding iodine solution → blue-black colour
(B) Adding dilute HCl then KI → purple colour
(C) Adding Rosalic acid → pink colour
(D) Adding Dimethylaminobenzaldehyde → orange colour

✓ Correct: (B) Adding dilute HCl then KI → purple colour

Explanation: Lead Chromate ($PbCrO_4$) in turmeric is detected by: Adding DILUTE HCl → dissolves $PbCrO_4$ to Pb^{2+} + CrO_4^{2-}; then adding POTASSIUM IODIDE (KI) → forms PURPLE/LEAD IODIDE (PbI_2) precipitate (yellow) + chromate stays. More specifically: HCl dissolves → acidified solution + KI → Lead(II) iodide (yellow) confirms Pb. Alternatively, silver nitrate test: chromate + $AgNO_3$ → yellow silver chromate precipitate. Rosalic acid test = detergent in milk. Iodine test = starch in milk/flour. DMAB test = urea in milk.

Q11. The GOLD STANDARD extraction method for heat-sensitive fat-soluble nutraceuticals (lycopene, tocopherols, omega-3) is:

(A) Steam distillation
(B) Hot water extraction at 100°C
(C) Supercritical CO_2 (SC-CO_2) extraction
(D) Soxhlet extraction with hexane

✓ Correct: (C) Supercritical CO_2 (SC-CO_2) extraction

Explanation: Supercritical CO_2 (SC-CO_2) extraction is the GOLD STANDARD for extracting heat-sensitive fat-soluble nutraceuticals. Advantages: CO_2 at >31.1°C and >73.8 bar acts as a solvent that is tunable (change pressure/temperature to select different compounds); NO RESIDUAL SOLVENT (CO_2 simply evaporates at atmospheric pressure → GRAS solvent); GENTLE TEMPERATURES (minimal heat damage); HIGH SELECTIVITY (lipophilic compounds extracted without polar impurities). Commercial applications: Lycopene extraction from tomato; omega-3 from fish; tocopherols from vegetable oils; decaffeination of coffee; hops extraction. Soxhlet uses hot organic solvents (hexane) at boiling point → thermal degradation of sensitive compounds + solvent residues.

Q12. The Water Activity (aW) required for stable probiotic powder (below which probiotics remain viable) is:

(A) aW ≤ 0.85
(B) aW ≤ 0.60
(C) aW ≤ 0.40
(D) aW ≤ 0.25

✓ Correct: (D) aW ≤ 0.25

Explanation: Probiotic powders require WATER ACTIVITY ≤ 0.25 (25% relative humidity) for good long-term stability and viability. At aW >0.25, moisture is absorbed → probiotics resume metabolic activity → rapidly die in the absence of nutrients and appropriate conditions. For comparison: aW >0.85 → bacterial growth (most pathogens); aW 0.6-0.85 → mould/yeast growth; aW 0.4-0.6 → non-enzymatic browning (Maillard). Probiotics need the LOWEST aW of all nutraceuticals. Packaging with desiccants (silica gel) is essential. Freeze-drying achieves aW <0.25 reliably.

Q13. Under FSSAI FSS Act 2006, an FBO with annual turnover of ₹8 lakh requires:

(A) Central FSSAI License
(B) State FSSAI License
(C) FSSAI Registration only
(D) No regulatory requirement

✓ Correct: (C) FSSAI Registration only

Explanation: FSSAI uses a 3-TIER licensing system based on turnover: (1) CENTRAL LICENCE: Annual turnover >₹20 crore OR interstate/export food business; (2) STATE LICENCE: Turnover between ₹12 lakh and ₹20 crore; (3) REGISTRATION: Small/petty food businesses with turnover ≤₹12 lakh. An FBO with ₹8 lakh turnover falls below ₹12 lakh → requires only FSSAI REGISTRATION (simplest compliance tier — no physical inspection required; just basic documentation). Registration is also required for hawkers, home-based food businesses, and petty retailers regardless of turnover.

Q14. The USP General Chapter <232> covers which quality parameter for dietary supplements?

(A) Microbial limits (TAMC, TYMC)
(B) Elemental Impurities (Heavy metals by ICP-MS)
(C) Dissolution testing
(D) Botanical identification by DNA barcoding

✓ Correct: (B) Elemental Impurities (Heavy metals by ICP-MS)

Explanation: USP General Chapter <232> covers ELEMENTAL IMPURITIES LIMITS — the maximum permissible daily intake of heavy metals (elemental impurities) in pharmaceutical products and dietary supplements, tested by ICP-MS (inductively coupled plasma mass spectrometry) or ICP-OES (optical emission spectrometry). limits per class 1 (oral): Pb ≤5 µg/day; As (inorganic) ≤15 µg/day; Cd ≤5 µg/day; Hg ≤15 µg/day. Chapter <233> covers the PROCEDURES for these tests. Chapter <61>/<62> = Microbial limits. Chapter <565> = Botanical adulterant screening (DNA barcoding).

Q15. Fermentation of soybean (to produce miso/tempeh) INCREASES the bioavailability of isoflavones because:

(A) Fermentation adds more genistein to the product
(B) Bacterial beta-glucosidases cleave sugar groups → free aglycones (genistein, daidzein) which are better absorbed than glycosides
(C) Heat from fermentation destroys anti-nutritional factors that inhibit isoflavone absorption
(D) Fermentation increases the fat content of soy, enhancing fat-soluble isoflavone absorption

✓ Correct: (B) Bacterial beta-glucosidases cleave sugar groups → free aglycones (genistein, daidzein) which are better absorbed than glycosides