

FSSAI Compliance Checklist for Nutraceutical Product Formulation (2025)

1. Product Category & Ingredient Approval

1. Identify your product type: Health Supplement, Nutraceutical, FSU, or FSMP.
2. Use only ingredients listed in Schedules I–VIII of FSSAI's Nutra Regulations.
3. Ensure all nutrients (vitamins, minerals) are within ICMR RDA limits.
4. Avoid banned/restricted herbs (e.g., Ephedra, Yohimbe).
5. For new/novel ingredients, prepare extra safety and efficacy documentation.

2. Smart & Safe Formulation

1. Use standardized herbal extracts for consistent potency.
2. Choose natural sweeteners (stevia, jaggery) over artificial ones.
3. Check ingredient compatibility for taste, stability, and safety.
4. Formulate for daily safety—no ingredient should exceed safe limits.
5. Maintain scientific backing for all functional claims.

3. Lab Testing & Quality Assurance

1. Test your prototype in a NABL-accredited lab for:
2. Nutritional profile (matches your label)
3. Stability (shelf life, separation, potency)
4. Heavy metals, toxins, and microbial safety
5. Caffeine (if included): ≤ 145 mg/300 ml
6. Keep all lab reports and certificates ready for FSSAI submission.

4. Documentation & Application

Prepare a full product dossier:

1. Formula sheet (all ingredients, % composition)
2. Lab reports and scientific studies
3. Manufacturing facility details and GMP compliance
4. Label draft (as per FSSAI 2025 rules)
5. Register your business and product on the FSSAI FoSCoS portal.
6. Pay the required application fee (₹50,000 for nutraceutical registration).

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5. Label Compliance

1. Mention "Nutraceutical" or "Health Supplement" on the front.
2. List all ingredients (common + botanical names for herbs).
3. Show nutritional table (per serving).
4. Add FSSAI License Number, batch/lot number, and shelf life.
5. Include daily serving size, usage instructions, and warnings (e.g., "Not for children/pregnant women" if applicable).
6. No false or disease-curing claims—stick to FSSAI-approved health claims only.
7. Declare allergens and caffeine content if present.

6. Marketing & Advertising

1. Self-certify all broadcast/video ads via the Ministry of Information & Broadcasting's Broadcast Seva portal.
2. Ensure influencer and digital marketing claims are FSSAI-compliant.
3. Prepare scientific support for all claims made in ads or on social media.

7. Facility & Ongoing Compliance

1. Maintain GMP and hygiene standards in your manufacturing unit.
2. Be ready for FSSAI inspections and audits at any time.
3. Update FSSAI if you change your formula, claims, or packaging.
4. Renew your license annually and keep all compliance documents updated.

8. Stay Updated

1. Follow the latest FSSAI advisories and interim orders (2025 Nutra Regulations are still under review).
2. Use the Indian Nutraceutical Regulatory Portal (INRP) for new product approvals.
3. For products with "grey area" herbs or medicinal claims, get AYUSH clearance if needed.

Pro Tip:

Keep this checklist handy from concept to launch. FSSAI compliance isn't just a legal step—it's your brand's foundation for trust, safety, and long-term success in India's booming nutraceutical market.