



Review Article

Review on Establishment of a Production and Export Unit for Cashew Based Nutraceutical Soft Gelatin Capsule

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Nutraceuticals are food-derived products that provide additional health benefits beyond basic nutrition. They include dietary supplements and functional foods containing beneficial bioactive compounds. Cashew kernels and oil are promising nutraceutical ingredients due to their nutritional and health-promoting properties. Cashew oil-based soft gelatin capsules can provide convenient, stable, and accurately dosed delivery of these beneficial compounds. The project focuses on establishing a production and export unit while ensuring proper formulation, quality control, regulatory compliance, packaging and export to united states. Cashew oil nutraceuticals have strong export potential in the USA due to growing consumer interest in natural, plant-based, and functional health products. The product can be marketed as a dietary supplement, provided it meets applicable U.S. FDA requirements for safety, labelling, manufacturing, and import compliance. With proper quality certification, attractive packaging, and effective marketing, cashew oil capsules can access health-conscious consumers and specialized nutraceutical markets in the USA.

Keywords: Nutraceutical , Cashew kernels, Soft gelatin capsule, US FDA.

INTRODUCTION

Nutraceuticals may be defined as ‘any substance that may belong to a plant, food or an essential component of food providing definitive medicinal usefulness and health promotion as well as physiological benefits and ultimately minimize the possible risk of the prevailing chronic disease significantly. Nutraceuticals is a term derived from “nutrition” and “pharmaceutics.” The term is applied to Products that are isolated from herbal products, dietary supplements (nutrients), specific diets, and processed foods such as cereals, soups, and beverages that other than nutrition are also used as medicine. Common examples are cashew nut, almonds, walnuts, pistachios, flaxseeds, chia seeds, sunflower seeds, oats, barley, quinoa, amla, salmon, sardines, olive oil, yogurt, honey, dark chocolate,

spirulina etc. and their chemical constituent’s relation to biological values has virtually succeeded in combating the human ailments and sufferings to an appreciable extent across the globe. There may be used to improve health, delay the aging process etc ^[1] Nutraceuticals have been used not only for nutrition but also as a support therapy for the prevention and treatment of various diseases, such as to reduce side effects of cancer chemotherapy and radiotherapy. Diverse novel ‘nano’ formulation approaches tend to overcome challenges involved in formulation development of nutraceuticals. Prior information on various interactions with drugs may help in preventing any deleterious effects of nutraceuticals products. Nanotechnology also leads to the generation

of micronized dietary products and other nutraceutical supplements with improved health benefits. The latest key findings (clinical studies) on nutraceuticals that show the therapeutic action of nutraceutical's bioactive molecules on various diseases have also been discussed. [2]

Market Interest of Nutraceuticals

The nutraceutical market is becoming more competitive with the entry of pharmaceutical and major food companies into the nutraceutical arena. Also, many food companies have established their nutraceutical divisions with a view toward a diversified product line. Recent years have marked the entry of major food and pharmaceutical companies into the nutraceutical marketplace, including Kellogg, Heinz, M&M, Quaker Oats, Unilever, Cargill, Hormel etc. The global nutraceutical retail market was estimated at approximately \$106 billion in 2004.

Relevance of Converting Cashew Kernel into Capsule Form

1. Dose Standardization

Converting cashew kernel (*Anacardium occidentale* L.) into capsule form ensures a precise and uniform dose of bioactive constituents such as monounsaturated fatty acids (oleic acid), phytosterols (β -sitosterol), flavonoids, phenolic compounds, tocopherols, magnesium, and zinc. This guarantees reproducible therapeutic benefits, especially for cardiovascular and metabolic support.

2. Controlled Therapeutic Intake

When consumed as whole nuts, the quantity of beneficial components varies depending on portion size and preparation. Capsule formulation provides a fixed daily dose, making it suitable for therapeutic use in conditions like hyperlipidemia, hypertension, and metabolic syndrome.

3. Improved Stability of Bioactive Compounds

Cashew kernels contain unsaturated fatty acids that are prone to oxidation and rancidity. Encapsulation protects these sensitive constituents from

environmental factors such as air, light, and moisture, thereby enhancing shelf life and maintaining antioxidant potency. [3]

4. Enhanced Patient Compliance

Capsules are convenient, portable, and easy to consume. They eliminate the need for measuring or consuming calorie-dense nuts daily. This improves adherence, particularly among elderly individuals and patients requiring long-term supplementation.

5. Calorie Control and Fat Regulation

Whole cashew nuts are energy-dense. Capsule form allows administration of beneficial lipid fractions and micronutrients without excessive caloric intake, making it appropriate for individuals managing weight or metabolic disorders.

6 Targeted Nutritional Therapy

Cashew kernel capsules can be positioned specifically for cardiovascular health (cholesterol regulation, endothelial protection), antioxidant support (free radical scavenging), bone health (magnesium and phosphorus supply), and immune enhancement (zinc and selenium support).

7 Scientific Validation and Market Positioning

Capsule formulation enables standardization, quality control, and clinical evaluation. This strengthens its credibility as a plant-based nutraceutical rather than merely a functional food.

8. Preventive Healthcare Application

With the growing focus on preventive medicine, cashew-based nutraceutical capsules provide a natural strategy to reduce cardiovascular risk, oxidative stress, and micronutrient deficiencies.

Departments Involved in the Formulation Process in Industry and Their Interrelations

1 Research and Development Department

The Research and Development (R&D) department is the starting point of the formulation process and is responsible for converting a product idea into a

workable formulation. It studies the nutritional and functional properties of cashew kernels and cashew oil, selects suitable active ingredients and excipients, and develops the capsule dosage form. For cashew nutraceutical capsules, R&D identifies the best extraction method for obtaining cashew oil and optimizes the formulation for stability, bioavailability, and ease of administration. The department also conducts laboratory-scale trials, stability studies, and scale-up studies before transferring the finalized formulation to production. In addition, R&D provides analytical methods to QC and works with QA to ensure the formulation meets regulatory and quality requirements.

2 Production or Manufacturing Department

The Production or Manufacturing department is responsible for converting the laboratory developed formulation into a marketable product on a large scale. Its work includes raw material processing, oil extraction, mixing and blending, capsule filling, drying, polishing, and packaging. In cashew capsule production, this department carries out practical operations such as cleaning and grinding cashew kernels, extracting and purifying cashew oil, blending it with excipients and filling it into soft gelatin capsules.

3 Quality Control Department

The Quality Control (QC) department ensures that materials, in-process products, and finished capsules meet the required specifications. It performs testing of raw materials, in-process samples, and final products, along with stability testing and other analytical evaluations. For cashew nutraceutical capsules, QC may test cashew oil purity, perform identification tests, check microbial limits, assess capsule weight variation, determine oil content, and conduct stability studies. These tests help confirm that the product is safe, effective, and uniform before it is released for sale. QC also communicates results to QA and collaborates with R&D for analytical method validation.

4 Quality Assurance Department

The Quality Assurance (QA) department is responsible for ensuring that the entire manufacturing

system follows Good Manufacturing Practices (GMP) and other regulatory standards. Unlike QC, which mainly tests products, QA focuses on systems, documentation, validation, audits, and compliance. In the cashew capsule case study, QA approves raw materials, reviews the Batch Manufacturing Record (BMR), validates the extraction and encapsulation process, and authorizes final product release.^[4]

Extraction Process with Equipment

This initial phase transforms raw cashew kernels into high-purity oil suitable for nutraceutical capsules. The cold-press method maximizes retention of bioactive compounds like oleic acid (up to 60%), omega-6 fatty acids, and natural tocopherols (Vitamin E), yielding 35-45% oil by weight from kernels.

Step 1: Cleaning of Cashew Kernels

Equipment: Vibratory cleaning machine or seed cleaner with air aspiration and sieves (capacity: 500-1000 kg/hr).

Process Details: Raw cashew kernels (post-shelling, whole or split) are fed into the machine. High-velocity air blows away dust and lightweight debris, while vibrating sieves (mesh sizes 4-8 mm) separate stones, shell fragments, and immature nuts. **Output:** Clean kernels with <0.5% impurities.

Step 2: Drying

Equipment: Tray dryer or hot air oven (stainless steel, 50-100 trays, temperature control $\pm 2^{\circ}\text{C}$).

Process Details: Spread cleaned kernels in thin layers (2-3 cm) on perforated trays. Dry at 50-60°C for 4-6 hours with forced hot air circulation (velocity 1-2 m/s), reducing moisture from 10-12% to 5-8%. Monitor with infrared thermometer.

Step 3: Size Reduction

Equipment: Hammer mill, grinder, or pulveriser (SS 304, 5-10 HP motor, adjustable screen 1-2 mm).

Process Details: Feed dried kernels at 200-300 kg/hr; grind to coarse powder (particle size 0.5-1 mm) or paste-like slurry. Cool jackets prevent temperature rise $>40^{\circ}\text{C}$. **Yield:** 95-98% powder.

Step 4: Oil Extraction

Equipment: Cold-press screw expeller (capacity 50-200 kg/hr, SS barrel, variable speed 20-50 RPM).

Process Details: Feed crushed kernels into the hopper. Slowly rotating screw compresses material (pressure up to 300 bar), forcing oil through narrow slits (0.3-0.5 mm). Collect crude oil (yellow-orange, 35-45% yield); press cake (50-60% fiber-rich residue) exits separately for animal feed. No heat applied (temp <50°C).

Step 5: Primary Filtration

Equipment: Plate-and-frame filter press or centrifugal separator (10-20 bar pressure).

Process Details: Pump crude oil (viscosity 30-50 cP) through filter cloths (5-10 micropores) at 100-200 L/hr. Removes 80-90% solids (Fiber, fines). Backflush with hot water for cleaning.

Step 6: Oil Clarification

Equipment: Jacketed stainless-steel settling tank (1000-5000 L, conical bottom, agitator optional).

Process Details: Transfer filtered oil; hold at 40-50°C for 12-24 hours undisturbed. Heavier waxes/impurities (foots) settle (5-10% volume); decant clear supernatant via Overflow.

Step 7: Fine Filtration

Equipment: Cartridge filter (1-5 micron) or polishing filter with activated carbon bed.

Process Details: Pass clarified oil at 50-100 L/hr for final polish. Output: Golden, clear oil (peroxide value <5 meq/kg).

Soft Gelatin Capsule Preparation**Step 1: Preparation of Gelatin Mass**

Equipment: Gelatin melting tank (SS, steam-heated, vacuum mixer).

Process Details: Mix bovine/pork gelatin (35-45 Bloom), glycerine (20-30%), purified water (25-

35%), and opacifier (0.5-1%) at 70-80°C for 2-4 hours under vacuum. Viscosity: 2000-5000 cP; cool to 50°C. Yield: Translucent mass.

Step 2: Encapsulation

Equipment: Rotary soft gelatin encapsulation machine (e.g., 24-36 die stations, 20,000-100,000 capsules/hr).

Process Details: Extrude gelatin into two ribbons (0.4-0.6 mm thick). Inject 200-800 mg oil fill per capsule via rotary dies. Seal via heat/wedge pressure; trim excess.

4. Capsule Drying

Equipment: Dehumidified drying tunnel (temp 20-25°C, RH 20-30%, conveyor speed 0.5 m/min).

Process Details: Pass wet capsules (30-40% moisture) through tunnel for 12-48 hours until 6-10% moisture/hardness 10-15N.

5. Capsule Polishing

Equipment: Soft gel polishing machine (rotating drum with sawdust or starch). Process Details: Tumble capsules 10-20 min to remove surface oil.

6. Packaging

Equipment: Automatic blister packer or bottle filler (PVC/PVDC blisters or HDPE bottles with desiccants).

Process Details: Pack 10-30 capsules/unit under nitrogen flush; label with batch no., expiry (24 months).^[5]

Sequence of Steps Before Formulation

The pre-formulation phase involves a methodical process of material qualification, documentation, and facility preparation.

• Step 1: Literature Review and Pre-formulation Studies

Objective: To determine the appropriate cream base (O/W or W/O emulsion) and predict the physical stability of the final formulation.

• **Step 2: Procurement and Vendor Qualification**

Objective: Ensuring all starting materials are acquired only from reliable, pre-approved vendors to minimize contamination risks.

• **Step 3: Quarantine and Sampling**

Objective: To isolate untested materials and prevent their accidental use in the manufacturing process.

• **Step 4: Pharmacognostic & Analytical Evaluation (QC Testing)**

Objective: To authenticate the herbal material and verify it meets standard specifications (e.g., absence of heavy metals, microbial limits, correct refractive index).

• **Step 5: Preparation of the Master Formula Record (MFR)**

Objective: To create a standardized, approved blueprint that will be used to generate the Batch Manufacturing Record (BMR) for the specific batch.

• **Step 6: Facility and Equipment Readiness**

Objective: To ensure all measuring instruments are correctly calibrated and the environment is prepared to prevent cross-contamination.

Approvals to be Made Before Formulation

Transitioning from preparation to actual formulation requires formal, documented sign offs. In an academic Practice School or industrial setting, these represent critical quality milestones.

• **Approval 1: Raw Material Release (QC Approval)**

Requirement: The Quality Control department must issue an "Approved" or "Passed" green label for the cashew kernel oil and all excipients based on testing results.

• **Approval 2: Master Formula Record (MFR) Sign-off**

Requirement: The drafted MFR must be reviewed, dated, and signed by the Head of Production and the Head of Quality Assurance (or the supervising Faculty Guide).

• **Approval 3: Line Clearance Approval**

Requirement: A formal physical inspection of the formulation workbench or manufacturing room by the QA officer prior to bringing in the new materials.

• **Approval 4: Regulatory / Ethical Approvals**

Requirement: For commercial manufacturing, prior formulation approval must be obtained from the State Licensing Authority (e.g., State AYUSH Directorate) or CDSCO. For academic projects, approval from the institutional guide or formulation committee is required.

Regulations of nutraceuticals

The term “foods for particular dietary needs” refers to nutraceuticals throughout India. “Foods for specialized dietary applications or functional food ingredients or nutraceuticals or health products,” according to the Food Safety and Standards Authority (FSSAI), are defined. The Food Safety and Standards Act of 2006 in India created the Food Safety and Standards Authority of India (FSSAI), that combines several statutes and rules and were in place to address food-related problems in several Ministries/Departments. In place to ensure that there is a supply of healthy” safe food for humans, the FSSAI was established to establish scientific food standards commodities and to control their production, preservation, delivery, sales, and purchase.

India: FSSAI’s comprehensive 2022 regulations

India has established a detailed regulatory framework through the Food Safety and Standards Authority of India’s 2022 regulations. These regulations, re-operationalized in October 2022, outline requirements for health supplements, nutraceuticals, foods for special dietary use, and related products.

FSSAI's key requirements

The regulations provide clear product categorization, and permit ingredient lists with specific usage ranges. Manufacturers must follow detailed labelling requirements, including mandatory warnings and recommended usage information. Products cannot make disease treatment claims and must clearly state they are not substitutes for a varied diet

Essential testing requirements for compliance

Regardless of the regulatory framework, nutraceuticals must undergo rigorous testing to ensure consumer safety and regulatory compliance. These tests verify product quality and substantiate health benefit claims.^[6]

Indian regulatory requirements

1. Product assessment: evaluation of every compound and active component. There are several steps in the product evaluation.
2. Licenses: About 4–5 licences necessary to register a product.
3. Health claims on food labels: A “health claim” is any statement, suggestion, or implication that there is a connection in between food or one of its ingredients and health.

GMP GUIDELINES

Good Manufacturing Practices, or GMP, are a set of regulations designed to ensure that products are consistently produced and controlled according to quality standards. In the context of pharmaceuticals and nutraceuticals, GMP guidelines are critical for safeguarding public health, ensuring the safety, quality, and efficacy of products intended for human consumption. For nutraceuticals, GMP compliance is governed by the U.S. Food and Drug Administration (FDA) under 21 CFR Part 111, also known as the Dietary Supplement Current Good Manufacturing Practices (CGMPs). The FDA's CGMP requirements specifically address the manufacturing, packaging, labelling, and storage of dietary supplements to prevent adulteration, contamination, and mislabelling.

- Quality Management Systems (QMS)
- Personnel & Training

- Facilities & Equipment
- Raw Material Control
- Production Controls
- Packaging & Labelling
- Documentation & Traceability

HACCP

HACCP (Hazard Analysis and Critical Control Points) for nutraceuticals is a systematic, preventive management system used to minimize biological, chemical and physical hazards. It ensures dietary supplements and health foods are safe for consumption, rigorously tracing and controlling risks from raw ingredients to final packaging.^[7]

Three Major Types of FSSAI License in India

There are three types of FSSAI/Food Licenses in India: Basic, State, and Central licenses. These are classified in the basis of turnover and described below:

- FSSAI Basic License/Registration: For businesses with an annual turnover under 12 lakhs, they must register with FSSAI through FSSAI Basic License.
- FSSAI State License: Businesses with an annual turnover between 12 to 20 crores should apply for the FSSAI State license using Form B.
- FSSAI Central License: If the annual turnover exceeds 20 crores, businesses should opt for the Central License using Form B.

Environmental Control & Room Specifications for Cashew Based Nutraceutical Capsule Manufacturing:

1. Regulatory & Structural Foundation

The facility must adhere to a combination of Schedule M (India GMP), WHO GMP, and FSSAI Nutraceutical Guidelines (2018) to prevent contamination and ensure consistent quality.

Premises and Layout

- Location: The unit must be isolated from pollutants such as dust, smoke, sewage, and chemical/biological contamination sources.

- **Structural Integrity:** Walls, floors, and ceilings must be smooth, crack-free, no shedding, and resistant to moisture to facilitate easy disinfection.
- **Flow Design:** The layout must follow a logical sequence (Raw materials right arrow Processing right arrow Packaging right arrow Finished goods) with dedicated areas for storage, manufacturing, and quality control to prevent mix-ups.
- **Contamination Barriers:** Doors and windows must be tight-fitting, and airlocks are preferred for critical processing areas.

2 Environmental & Cleanroom Specifications

While capsule manufacturing is non-sterile, it requires a "controlled area" classification to protect the product while it is exposed to the environment.

Cleanroom Classification

- **Standard:** Typically, ISO Class 7-8 cleanrooms.
- **Critical Zones:** Specific environmental controls must be maintained in the weighing, mixing, encapsulation, and packaging rooms.

HVAC and Air Quality Air Handling Units (AHUs) are mandatory to manage the internal atmosphere through the following:

- **Filtration:** Use of HEPA filters to remove dust and microbes.
- **Pressure:** Maintenance of positive pressure differentials to prevent Cross-contamination from outside areas.
- **Ventilation:** Adequate filtered air supply and exhaust systems, particularly for drying or coating stages.^[8]

3 Specialized Atmospheric Controls

Cashew-based nutraceuticals are sensitive to environmental fluctuations, particularly due to the fatty acid content in cashew oil.

Temperature: $\leq 25^{\circ}\text{C}$

Relative Humidity: $\leq 60\% \pm 5\%$

4 Operational Controls & Monitoring

Maintaining the cleanroom environment requires strict personnel protocols and continuous surveillance.

2.4 Labelling Requirements of Finished Product: Cashew Based Nutraceutical Capsules

1. Basic Product Identification Information.
2. List of Ingredients
3. Nutritional Information Nutritional information must be declared per serving or per capsule.
4. Net Quantity and Dosage Instructions.
5. Manufacturer Details The label must include the name and complete address of the manufacturer, packer, or marketer. In addition, the FSSAI license number must be clearly displayed
6. Batch Number, Manufacturing Date, and Expiry Date.
7. Storage Conditions
8. Warning and Safety Information
9. Other Mandatory Label Information

FDA Registration - FDA Certificate – FDA Agent

FDA Registration

FDA registration is the basic requirement for domestic and foreign establishments that manufacture or market food, drug, API, medical devices, or cosmetic products in the USA. Companies that manufacture, process, pack, or store these products in the United States may be required to register with the FDA. Here are some examples of the types of companies that require FDA registration:

- Food manufacturers, processors, and packers
- Drug manufacturers, packers, and repackers.
- Medical device manufacturers and importers
- Cosmetics manufacturers and processors

It's important to note that the FDA has specific registration requirements for each type of product,

and the registration requirements for all kinds of companies are not the same.

US FDA Agent

All foreign Establishments must identify a US FDA Agent while in the registration process. This is a mandatory requirement, and without US FDA Agent, the registration cannot be completed.

FDA Registration Renewal

All Drug, API, and Medical Device establishments registered with FDA must renew their registration annually between October 1st and December 31st. Food facilities must renew their FDA registration between October 1st and December 31st of every even-numbered year (once every 2 years).^[9]

FDA Certification

FDA Registration or FDA registration number does not denote FDA certification or FDA approval of your facility or products. Any representation of the FDA registration number on the product label or labeling which implies FDA certification or FDA approval of a facility or product is misleading and may cause misbranding of the product.

1.General Steps for FDA Registration –

1. Identify the product category
2. Create the FDA Unified Registration and Listing System (FURLS) account /Centre for Drug Evaluation and Research (CDER) account
3. If you are a food facility, obtain a DUNS number. DUNS number is mandatory for food facility registration.
4. Appoint a US agent. US agent appointment is mandatory for all types of registrations.
5. Prepare and review the registration
6. Submit the registration to the FDA.

Regulatory framework of nutraceuticals in the USA

In the United States, there is a well-organized system for the taxation of nutraceuticals, which reflects the complex nature of these products and the increasing interest among consumers. Nutraceuticals are a broad category of products that include pharmaceutical-grade goods, functional foods, and dietary supplements.

Current Good Manufacturing Practice (CGMP)

Regulations FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations.

2. Batch Record

A batch record documents everything that happens when you make a specific batch of drug product. It proves that you followed your master procedures and met all quality requirements. The FDA defines batch production records as documents that must include "complete information relating to the production and control of each batch.

Key GMP Requirements for Nutraceuticals

GMP regulations for nutraceuticals are extensive and cover various aspects of the production process. Below are some of the critical requirements:

1. Personnel Training and Qualifications
2. Facility and Equipment Standards
3. Raw Material Quality Control
4. Production and Process Controls
5. In-Process and Finished Product Testing
6. Documentation and Record Keeping
7. Packaging and Labelling
8. Warehouse and Storage Controls

3. Certificates of Analysis

CoA is a document which describes the necessary characteristics, such as appearance, purity, solubility, and water content, as well as the analytical standards,

such as name, (Chemical Abstract Service) CAS number, molecular formula, and molecular weight. In the context of the nutraceutical, nutrition, and functional food industry, CoA documents act as an identification document or serve as a basis for product comparison.^[10]

The FDA states the following statements on every nutraceutical labelling.

1. Name of the supplement
2. Amount of supplement
3. Nutrition labelling
4. Ingredient list
5. Name and place of business of the manufacturer or distributor

Additional labelling elements may include,

- Warnings or cautions: Any potential risks or side effects to the usage of the nutraceutical product.
- Suggested use: Recommended dosage and frequency of the nutraceutical supplements.
- Expiration date: The date by which your nutraceutical product is used.
- Storage instructions: Guidelines for proper storage, such as in a cool, dry place.
- Manufacturer/distributor information: Contact details for the company responsible for the product.

4 Essential Documentation for Exporting Goods to the USA

Exporting goods to the United States presents numerous opportunities for suppliers, supply chain professionals, exporters, and manufacturers. However, navigating the complex landscape of export documentation is crucial for ensuring a smooth and successful shipment process. This guide covers the essential documentation required for exporting goods to the USA, providing detailed insights and nuances that are vital for compliance and efficiency.^[11]

1. Commercial Invoice

The commercial invoice is a critical document in international trade.

2 Packing List

The packing list is a detailed document that accompanies the commercial invoice and provides information on the contents of the shipment. It helps in verifying the cargo during customs clearance and delivery.

3 Certificate of Origin

The certificate of origin certifies the country where the goods were manufactured. It is essential for determining the applicable tariffs and ensuring compliance with trade agreements.

4 Export License

An export license may be required for certain goods, especially those that are regulated or subject to export controls, such as military goods, technology, and dual use items.

5 Importer Security Filing (ISF)

The ISF, also known as the 10+2 rule, is a U.S. Customs and Border Protection (CBP) requirement that mandates importers to provide advance information about the shipment.^[12]

6 Letter of Credit

A letter of credit is a financial document issued by a bank guaranteeing the seller's payment will be received on time and for the correct amount, provided the seller meets all the terms specified in the letter.

7 Insurance Certificate

An insurance certificate provides proof of insurance coverage for the shipment, protecting against potential loss or damage during transit.

8 Importer of Record

The Importer of Record (IOR) is responsible for ensuring that the imported goods comply with local

laws and regulations, including payment of duties and taxes.

9 Nuances and Best Practices

Accuracy and Consistency: Ensure all records are correct and match supporting documents to avoid delays and penalties

10. The Customs Clearance Process

Entry Filing: Use a customs broker to file entry documents with CBP, who will then transmit information to the FDA

CONCLUSION

The establishment of a cashew-based nutraceutical soft gelatin capsule manufacturing and exporting unit is scientifically significant and commercially promising in the growing nutraceutical industry. The project demonstrates how cashew kernel oil can be effectively transformed into a standardized and value-added health supplement with potential benefits in cardiovascular health, antioxidant protection, and nutritional support. Successful implementation of the project requires validated manufacturing procedures, advanced extraction technologies, GMP compliant facilities, proper documentation, and strict quality assurance practices. Compliance with national and international regulatory standards such as FSSAI, WHO, GMP, and FDA requirement is essential to ensure product safety, legal acceptance, and consumer confidence. With increasing global demand for natural and preventive healthcare products, cashew - based nutraceutical capsules possess strong potential for industrial growth, export opportunities and contribution to public health.

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