EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 11
Issue: 7
74-78
Year: 2024

REGULATORY PROVISONS OF MEDICINAL HERBS

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Article Received on 09/05/2024 **Article Revised on 30/05/2024** **Article Accepted on 19/06/2024**

ABSTRACT
India is a major exporter of herbs and medicinal plants, with a significant preference for plant-based medicines due to their minimal side effects and widespread use. The regulation of herbal remedies in India is governed by the Drugs and Cosmetics Act of 1940 and 1945, along with amendments, and overseen by bodies such as AYUSH and the Central Drugs Standard Control Organisation (CDSCO). AYUSH institutions in India have classified approximately 8,000 herbal remedies. This chapter examines the regulatory framework for herbal products in India, including comparisons with international standards set by regulatory bodies such as the FDA (U.S. Food and Drug Administration) and other global authorities.

KEYWORDS: AYUSH institutions in India have classified approximately 8,000 herbal remedies.

INTRODUCTION

International Regulatory Overview

India

Herbal drugs in India are regulated under the Drugs and Cosmetics Act (D and C) 1940 and Rules 1945. Regulatory provisions for Ayurveda, Unani, and Siddha medicines are clearly outlined, with the Department of AYUSH as the regulatory authority. Manufacturing or marketing herbal drugs requires a license. The Act extends control over licensing, formulation, manufacture, labeling, packing, quality, and export. Good Manufacturing Practice (GMP) requirements are specified in Schedule T of the Act, and official pharmacopoeias and formularies set quality standards. Herbal products are licensed under two categories: ASU drugs and patent or proprietary medicines.

Malaysia

In Malaysia, herbal products are classified as either traditional products or health supplements. Marketers must register with the Malaysia Registrar of Business. Traditional products must be labeled "traditionally used for" for any claim, while supplements can only make functional claims listed by the authority.

Philippines

Herbal medicines in the Philippines are regulated as traditionally used herbal products. The Bureau of Food and Drugs (BFAD) requires at least five decades of traditional use, documented in literature. Registration of these products is mandatory before manufacture, import, or marketing. Quality control standards must align with pharmacopoeial standards, and product indications must not require physician supervision.

Nigeria

The National Agency for Food and Drug Administration and Control (NAFDAC) regulates herbal products as "Herbal Medicines and Related Products." Premarketing registration and preclearance for advertisements are mandatory. No advertisement can claim to cure diseases listed in Schedule 1 of the Food and Drug Act 1990.

Saudi Arabia

Herbal products in Saudi Arabia are classified as traditional products, allowed if used traditionally for at least 50 years. Evidence can be pharmacopoeial or nonpharmacopoeial, with requirements for dose, preparation, and supporting references.

Australia

The Therapeutic Goods Administration (TGA) regulates herbal products as complementary medicines, including Ayurvedic, traditional Chinese, and Australian indigenous medicines. Low-risk medicines must be listed, while higher-risk products require registration on the Australian Register for Therapeutic Goods (ARTG).

United States

The FDA classifies botanical products as drugs, foods, or dietary supplements based on their intended use. Drugs must be marketed under an approved New Drug

Application (NDA). Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994, requiring safety and labeling compliance but not premarket approval.

Canada

Since January 1, 2004, Health Canada has regulated herbal remedies under the Natural Health Products Regulations. Manufacturers, packers, labelers, or importers must register and comply with GMP norms. Product composition, safety, and efficacy data must be submitted to the Natural Health Product Directorate (NHPD).

European Union

The European Medicines Agency provides two registration pathways: a full marketing authorization requiring comprehensive data on quality, safety, and efficacy, and a simplified procedure for traditional herbal medicinal products with long-standing use. Evidence of traditional use is accepted for efficacy, with additional safety evidence required.

DISEASE: Medicinal herbs and it's regulatory provisons
1. CVD's (cardiovascular diseases)

Ginger

REGULATORY PROVISONS

The regulatory provisions regarding the use of GINGER (Zingiber officinale) for the Treatment of CVD's can vary Significantly depending on the country and the specific Regulatory bodies involved.

1. USFDA

Ginger is classified as "generally recognized as safe" (GRAS) by the U.S. Food and Drug Administration (FDA). Additionally, the British Herbal Compendium reports no adverse Effect" associated with the use of ginger. When it comes to dosage, for most purposes, a Typical dose ranges from 1 to 4 grams daily, administered in divided doses throughout the Day. To prevent motion sickness, recommended to start taking ginger 1 to 2 days prior to the Planned trip and to continue taking it throughout the duration of the travel. For alleviating Nausea and vomiting during pregnancy, ginger tea can be made by boiling fresh ginger root And diluting it accordingly. This preparation is both effective and safe for managing such Symptoms.

And specially for patients suffering from CVD's the dosage approved by USFDA is from 500 Mg – 6gm as per prescriber concern.

2. FDA

Title 21—Food and Drugs
Chapter I—Food and Drug Administration
Department of Health and Human Services
Subchapter B – Food for Human Consumption (Continued)
Part 182 – Substances Generally Recognized as Safe
Subpart A – General Provisions
Sec. 182.20 Essential Oils, Oleoresins (Solvent-Free), and Natural Extractives (Including Distillates).
Ginger, with the botanical name Zingiber officinale Rosc., is listed among the essential oils,
Oleoresins (solvent-free), and natural extractives (including distillates) that are generally Recognized as safe for their intended use, as per section 409 of the Act.
(2)https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.22&SearchTerm=ginger

3. INDIAN REGULATORY BODIES

FSSAI

FSSAI Standards for Ginger
Whole Ginger (Sonth, Adrak)
Whole ginger refers to the dried rhizome of Zingiber officinale Roscoe, characterized by Pieces of irregular shape and size, pale brown in color, with peel not entirely removed and Washed and sun-dried. It may be bleached with lime. The product should have a Characteristic taste and flavor, free from musty odor, rancid, or bitter taste, and should be Free from mold, living and dead insects, insect fragments, and rodent contamination. The Product must not contain added coloring matter.

Standards

Extraneous matter: Not more than 1.0 percent by weight
Moisture: Not more than 12.0 percent by weight

Total ash (dry basis)

Unbleached: Not more than 8.0 percent by weight
Bleached: Not more than 12.0 percent by weight
Calcium (as Calcium oxide on dry basis):
Unbleached: Not more than 1.1 percent by weight
Bleached: Not more than 2.5 percent by weight
Volatile oil content (dry basis): Not less than 1.5 percent by volume/weight
insect damaged matter: Not more than 1.0 percent by
(3)weighthttps://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.22&SearchTerm=ginger

4. AYUSH

The regulatory framework for ginger, as part of Ayurvedic medicines, falls under the Guidelines of the Drugs and Cosmetics Act, 1940 and its amendments. The Ministry of AYUSH, along with the Central Drugs Standard Control Organization (CDSCO), oversees The

quality standards and good manufacturing practices (GMP) for Ayurvedic products, Including ginger. Manufacturers must adhere to standards set by the Ayurvedic Pharmacopoeia Committee. The regulatory bodies ensure the safety, efficacy, and quality Control of Ayurvedic drugs, with regular monitoring and inspections 4.
(4)https://ayushnext.ayush.gov.in/detail/writeUps/ministry-of-ayush-published-good-clinical-

5. European monograph
The European monograph guidelines for ginger, specifically the dried rhizome of *Zingiber.
Officinale*, outline its use in traditional herbal medicinal products. According to the European Medicines Agency (EMA), ginger is recognized for its traditional use in treating Digestive disorders and alleviating nausea, including motion sickness.

This medication with combination of synthetic beta blockers and calcium channel blockers Are used to treat hypertension and dyslipidemia which are the common factors to rise CVD For registration under the simplified procedure outlined by Directive 2004/24/EC, a product Must demonstrate at least 30 years of traditional medicinal use, including 15 years within The EU. This directive helps ensure consistent quality, safety, and efficacy standards across Herbal medicinal products. The Committee on Herbal Medicinal Products (HMPC) at the EMA is responsible for creating monographs and lists of approved herbal substances Based on their long-standing use and safety profiles. To comply with these guidelines, manufacturers must provide detailed documentation on The quality, non-clinical, and clinical aspects of the herbal product. This includes Demonstrating good agricultural and collection practices, ensuring proper manufacturing Processes, and conducting necessary safety and efficacy assessments (5)https://www.ema.europa.eu/en/human-regulatory-overview/research-and-

CANCER: GARLIC (6)
1. United States
Dietary Supplement Health and Education Act (DSHEA) of 1994:
Section 3: Defines dietary supplements and outlines their regulation.
Section 6: Manufacturers are responsible for ensuring the safety of their products before marketing.
Section 7: Requires proper labeling, including ingredient lists and supplement facts.

2. European Union
Regulation (EC) No 1924/2006 on nutrition and health claims.
Article 5: Claims must be based on scientific evidence and well understood by the average consumer.
Article 10: Specifies conditions under which health claims can be made
Annex: Lists permitted health claims for food products, including dietary supplements.

3. Canada
Natural Health Products Regulations (NHPR) under the Food and Drugs Act:
Section 5: Requires pre-market review and licensing of natural health products.
Section 8: Outlines good manufacturing practices.
Section 12: Specifies labeling requirements, including medicinal and non-medicinal ingredients.

4. Australia
Therapeutic Goods Administration (TGA): Therapeutic Goods Act 1989.
Section 3: Defines therapeutic goods, including supplements.
Section 15: Registration and listing of products.

Therapeutic Goods (Listed Goods) Order No.1 of 2014:
Part 4: Requirements for evidence supporting health claims.
5.India
Food Safety and Standards Authority of India (FSSAI):
The Food Safety and Standards Authority of India (FSSAI) regulates garlic, along with other food products, under the Food Safety and Standards Act, 2006, and it associated regulations. Garlic is considered a food item and falls under the category of vegetables. Here are some key regulatory provisions regarding garlic by FSSAI:

1. Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

These regulations specify the standards for various food products, including vegetables like garlic. This includes parameters such as quality, purity, and safety standards that garlic must meet. products, under the Food Safety and Standards Act, 2006, and its associated regulations. Garlic is considered a food item and falls under the category of vegetables.

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1. Maximum Residue Limits (MRLs)
FSSAI sets Maximum Residue Limits pesticides and other contaminants in garlic to ensure food Safety. These limits specify the maximum permissible levels of residues that can be present in garlic Without posing a risk to human health.

2. Labelling Requirements
FSSAI mandates specific labelling requirements for garlic products sold in the Indian market. This Includes

accurate labelling of ingredients, nutritional information, and other relevant details to ensure Consumer awareness and safety.

3.Good Manufacturing Practices (GMP).
FSSAI provides guidelines for Good Manufacturing Practices to ensure the quality and safety of garlic Products during manufacturing, processing, and packaging.

4.Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2016:
This amendment includes specific standards for dehydrated garlic products, which must comply with the Prescribed quality and safety parameters.

5.Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.
These regulations specify limits for various contaminants and toxins, including heavy metals and Aflatoxins, in garlic and other food products to safeguard public health.

6. Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

FSSAI mandates specific requirements for the packaging and labelling of garlic and garlic products to Prevent adulteration, misbranding, and ensure consumer safety.

(6)https://www.nccih.nih.gov/health/garlic
https://www.sciencedirect.com/science/article/pii/S20490 8012201706X

ARTHRITIS: EUCALYPTUS[7]

REGULATORY PROVISONS
FDA
Guidelines for the Use of Eucalyptus Oil in Food
TITLE 21—FOOD AND DRUGS
CHAPTER I—FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B – FOOD FOR HUMAN CONSUMPTION
PART 172 – FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION
- SEC 172.510: Natural flavoring substances and natural substances used in Conjunction with flavors.

Natural flavoring substances and natural adjuvants, including eucalyptus oil, may be safely Used in food under the following conditions.

Minimum Quantity Use: Eucalyptus oil must be used in the minimum quantity Required to produce its intended physical or technical effect. This ensures that only The necessary amount is added to food products, preventing excessive use.

Good Manufacturing Practice: The use of eucalyptus oil must comply with all Principles of good manufacturing practice (GMP). This involves ensuring the safety, Consistency, and quality of the product through controlled processes.

Forms and Combinations: Eucalyptus oil can be used in various forms, including Plant parts, fluid and solid extracts, concentrates, absolutes, oils, gums, balsams, Resins, oleoresins, waxes, and distillates. It may be used alone or in combination With other flavoring substances and adjuvants that are generally recognized as safe (GRAS) in food, previously sanctioned for such use, or regulated in any section of This part.

2. EFSA (EUROPEAN FOOD SAFETY AUTHORITY)
Regulation (EC) No 1334/2008 on Flavorings and Certain Food Ingredients with Flavoring Properties for Use in and on Foods: Eucalyptus oil is included in the Union list of authorized flavoring substances .Its use is subject to the condition that it must not present a safety concern to Consumers when used at levels necessary to achieve the desired flavor effect.

3. Australian Therapeutic Goods Administration (TGA)
Therapeutic Goods (Permissible Ingredients) Determination: Eucalyptus oil is listed as a permissible ingredient in therapeutic goods, provided it Meets specified purity and quality standards. Products containing eucalyptus oil must include specific labeling information and Usage warnings to ensure safe consumption and application.

4. Health Canada
Natural and Non-prescription Health Products Directorate (NNHPD)
Eucalyptus oil is classified under natural health products and is subject to pre-Market assessment and approval. Its use in natural health products must comply with established safety and efficacy Standards, and products must include detailed labeling information regarding safe Usage.

(7)https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.510&SearchTerm=eucalyptus

DIABETIS: OCIMUM SANCTUM (HOLY BASIL)[8]

REGULATORY PROVISIONS

United States

FDA Regulation

In the United States, the Food and Drug Administration (FDA)

Does not approve holy basil as a treatment for diabetes. Holy basil May be sold as a dietary supplement, but it cannot be marketed With claims that it can diagnose, treat, cure, or prevent any Disease, including diabetes, without FDA approval.[8] https://www.webmd.com/vitamins/ai/ingredientmono-1101/holy-basil

Dietary Supplement Regulations

Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, dietary supplements like holy basil can be Marketed with more general health claims, provided they include A disclaimer that the FDA has not evaluated these statements.

European Union

EFSA Regulation

In the European Union, the European Food Safety Authority (EFSA) oversees the safety of food supplements. Like the FDA, EFSA does not allow holy basil to be marketed with medicinal Claims unless it is authorized through the proper medicinal Product channels.

Herbal Medicines

Holy basil could potentially be registered as a traditional herbal Medicinal product under the Traditional Herbal Medicinal Products Directive (THMPD), provided sufficient evidence of its Traditional use and safety is submitted.

India

AYUSH Regulation

In India, the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy (AYUSH) regulates the use of holy Basil in traditional medicine. Holy basil is widely recognized and Used in Ayurveda, and products containing it are regulated under The Drugs and Cosmetics Act, 1940.

Traditional Use

Ayurvedic practitioners commonly prescribe holy basil for Various ailments, including diabetes, under traditional use Provisions. These products are subject to standards for safety, Quality, and efficacy as outlined by AYUSH.

Canada

Health Canada Regulation

In Canada, Health Canada regulates natural health products, Including holy basil, under the Natural Health Products Regulations. Holy basil can be marketed with approved health Claims if sufficient scientific evidence is provided.

Licensing Requirements

Products must obtain a Natural Product Number (NPN) and meet Standards for safety, efficacy, and quality.

Australia

TGA Regulation

The Therapeutic Goods Administration (TGA) regulates holy Basil under the Therapeutic Goods Act 1989. Holy basil products Can be listed as complementary medicines if they meet the TGA's Requirements for safety and quality. However, claims regarding.

General Considerations Scientific Evidence

Regardless of the jurisdiction, substantial scientific evidence is Required to support any health claims related to the treatment of Diabetes. This includes clinical trials demonstrating efficacy and Safety.

Labeling and Marketing

Products containing holy basil must comply with labeling and Marketing regulations, which generally prohibit making unapproved medical claims.

It is important for consumers and healthcare providers to refer to the specific regulatory guidelines of their country to ensure compliance and safety when considering the use of holy basil for diabetes treatment medical claims. It is important for consumers and healthcare providers to refer to The specific regulatory guidelines of their country to ensure Compliance and safety when considering the use of holy basil for Diabetes treatment (https://www.webmd.com/vitamins/ai/ingredientmono-1101/holy-basil).