iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 14 **Issue:** V **Month of publication:** May 2026

DOI: https://doi.org/10.22214/ijraset.2026.82978

www.ijraset.com

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 14 Issue V May 2026- Available at www.ijraset.com

Survey and Case Study of Traditional Herbs of Jalgaon District and Regulatory Aspects of Herbal Formulations as Per D and C Act

Sanjana Tandekar, Mubeen Ahmad Mohammad Aarif, Ishak Khan Saudagar, Jayash Choudhary
Aditya Institute of Pharmacy, India

Abstract: ***The present study focuses on a survey and case study of traditional medicinal herbs used in Jalgaon District, Maharashtra, and examines the regulatory aspects of herbal formulations under the Drugs and Cosmetics Act, 1940. Jalgaon district is rich in biodiversity and traditional knowledge, where local communities extensively use herbal plants for primary healthcare. Common medicinal plants such as Azadirachta indica (Neem), Ocimum sanctum (Tulsi), Withania somnifera (Ashwagandha), and Aloe vera are traditionally used for treating infections, inflammation, stress, and skin disorders, reflecting the deep-rooted ethnomedicinal practices of the region. The study also highlights the regulatory framework governing herbal formulations in India. Herbal medicines are regulated under the Ayurveda, Unani, and Siddha (ASU) systems by the Ministry of AYUSH. The Drugs and Cosmetics Act, 1940 and Rules, 1945 provide guidelines for licensing, manufacturing, labelling, quality control, and marketing of herbal drugs. As per Schedule T of the Act, manufacturers must comply with Good Manufacturing Practices (GMP) to ensure quality and safety. Herbal formulations are categorized into classical formulations based on authoritative Ayurvedic texts, and patent or proprietary medicines, which require scientific validation and regulatory approval. Furthermore, the Act enforces standards for raw materials, mandates proper labelling, and ensures safety and efficacy through regulatory monitoring. This study emphasizes the importance of integrating traditional herbal knowledge with modern scientific validation and regulatory compliance to promote safe, effective, and standardized herbal medicines. It also highlights the need for documentation and conservation of medicinal plants in Jalgaon district.***

I. AIM

To perform survey and case study of traditional herbs of Jalgaon district and regulatory aspects of herbal formulations as per d and c act

II. LITERATURE REVIEW

Traditional herbs are widely used in Jalgaon District by tribal and rural communities for the treatment of common diseases such as fever, cough, skin infections, digestive disorders, and liver problems. Ethnobotanical studies conducted by Fawar and Patil reported several medicinal plants including neem (*Azadirachta indica*), tulsi (*Ocimum sanctum*), aloe vera, shatavari, and adulsa used in folk medicine. These herbal remedies are generally prepared as powders, decoctions, juices, and pastes.

The increasing use of herbal medicines has highlighted the need for proper regulation and quality control. In India, herbal formulations are regulated under the Drugs and Cosmetics Act, 1940 and Rules, 1945. The Act provides guidelines for manufacturing, labeling, safety, and quality standards of Ayurvedic, Siddha, and Unani medicines. Schedule T specifies Good Manufacturing Practices (GMP) for herbal drug manufacturing. Proper scientific validation and regulatory compliance are important to ensure the safety and effectiveness of herbal formulations.

III. INTRODUCTION

Definition of herbal drug, Ayurveda, Siddha & Unani drugs.

A. Herbal drug

A herbal drug is medicinal product obtained from plants [whole plants or parts like leaves, roots, seeds, bark used for therapeutic purposes, either in raw form or processed form. [1]

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B. ASU Drugs [Ayurveda, Siddha, Unani]

ASU drugs refer to medicines used in Ayurveda, Siddha Unani system of medicines, regulated under traditional Indian medicines [1]

Definition: -

ASU drugs are formulations prepared using natural ingredients such as herbs, minerals, and animal products according to classical texts of Ayurveda, Siddha, Unani systems.[3]

C. Rising herbal medicine demand

Herbal medicines, used for centuries in systems like Ayurveda and Traditional Chinese Medicine, are now seeing a significant global rise in demand.[4]

This growth is driven by a shift toward natural, safe, and holistic treatments, as people avoid synthetic drugs due to side effects.[4]

The global market was valued at about USD 70 billion in 2023 and is expected to exceed USD 328 billion by 2030.[5]

D. Importance of Safety, Quality, and Efficacy

1) Safety: Ensures medicines are safe, free from contaminants, properly labeled, and do not cause harmful effects when used correctly, protecting public health.[6]

2) Quality: Maintains purity, identity, and consistency of herbal products, preventing contamination and ensuring compliance with standards like the Indian Pharmacopoeia.[7]

3) Efficacy: Confirms that medicines provide the desired therapeutic effect through validation, preventing ineffective products and building trust among users and regulators.[6]

E. Role of WHO Guidelines in Traditional Medicines

WHO guidelines ensure the safety, quality, and efficacy of traditional medicines and address issues like adulteration and lack of standardization.[8]

They promote GACP and GMP practices, scientific validation, and regulatory frameworks for proper use and manufacturing.[9]

F. Legal Framework of Herbal Medicines in India

Herbal medicines in India are regulated under the Drugs and Cosmetics Act, 1940, covering Ayurvedic, Siddha, and Unani (ASU) drugs.[10]

The Drugs and Cosmetics Rules, 1945 define requirements for licensing, labelling, and GMP under Schedule T to ensure quality and safety.[11]

Regulation is overseen by the Ministry of AYUSH and CDSCO, responsible for policy, standardization, and enforcement.[12]

G. Overview of DNC ACT IN 1940

The Drugs and Cosmetics Act, 1940 regulates herbal medicines to ensure their safety, quality, and proper manufacture.[13]

It requires licensing, GMP compliance, and prevents sale of adulterated or misbranded products.[13][14]

H. Drug And Cosmatic Rule

The Drugs and Cosmetics Rules, 1945 provide detailed procedures for implementing the Act and regulate the manufacture, sale, import, and distribution of drugs, including ASU herbal medicines.[15]

Role of Regulatory Authorities

The regulation of herbal medicines in India is mainly governed by the Drugs and Cosmetics Act, 1940 and implemented through the Drugs and Cosmetics Rules, 1945, which ensure safety, quality, and standardization of Ayurvedic, Siddha, and Unani (ASU) herbal drugs [17].

1. Central Level Authority – CDSCO
2. Sub-Type of CDSCO (Zonal/Regional Offices)
3. State Licensing Authority (SLA)

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I. Chapter IVA of the Drugs and Cosmetics Act, 1940

Chapter IVA of the Drugs and Cosmetics Act, 1940 regulates ASU herbal medicines by ensuring they are prepared as per classical texts with proper licensing.[20]

It enforces quality standards and prohibits misbranded or adulterated drugs through strict inspection and control.[19]

J. Classification of Herbal Drugs

Type	Key Point	Examples
Classical Ayurvedic Drugs	Based on ancient texts, fixed formulation	Triphala, Chyawanprash
Phytochemical Drugs	Isolated active plant compounds	Morphine, Quinine
Nutraceuticals	Food-based, health promotion	Green tea extract, Omega-3
Herbal Drugs	Plant-based, used for treatment	Ashwagandha, Aloe vera
Patent/Proprietary	**Modern herbal formulations, new combinations**	**Herbal syrups, capsules**

K. Quality Control and Standardization in Herbal Drugs

In herbal drugs, quality control and standardization ensure safety, purity, and consistent therapeutic effectiveness.[21] It involves proper identification and authentication of medicinal plants, prevention of adulteration, and testing of raw materials and finished products for active constituents. These measures help maintain uniform quality in every batch and ensure compliance with GMP and pharmacopoeial standards

L. Labelling and Packaging Requirements as per Drugs and Cosmetics Act, 1940.

- Herbal (ASU) drugs must clearly mention the medicine name, manufacturer details, batch number, licence number, manufacturing and expiry date, and storage conditions.[32][33]
- Packaging should be hygienic, tamper-proof, and protect the product from contamination.[33]
- Misleading claims and incomplete labelling are strictly prohibited under GMP rules.[32][33]
- Herbal drugs can be imported only with a valid Import Registration Certificate and Import Licence under the Drugs and Cosmetics Act, 1940.[34]

M. Import of Herbal Drugs as per Drugs and Cosmetics Act, 1940 (India)

- They must meet safety, quality, and pharmacopoeial standards and should not be misbranded or adulterated.[35]
- Proper labelling and documents like batch number, expiry date, and manufacturer details are required.[34]
- Import is controlled by CDSCO and Customs, and quality responsibility lies with the importer.[36]

N. Export of Herbal Drugs as per Drugs and Cosmetics Act, 1940 (India)

Export of herbal drugs (Ayurvedic, Siddha, Unani and other herbal products) is regulated under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945, along with support from CDSCO and the Ministry of AYUSH. Export is allowed only when drugs are manufactured under valid licensing and GMP compliance and meet destination country requirements.

1. Regulatory Framework for Export
3. Role of Ministry of AYUSH
3. Country-Specific Regulations (Important for Export**)**

O. Regulatory Challenges

Herbal drugs face issues like lack of standardization, quality variation, adulteration, and contamination, affecting safety and consistency.[38][39]

Weak scientific validation, poor pharmacovigilance, complex regulations, and labelling errors also reduce global acceptance.[38][39]

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P. Recent Updates

Recent amendments focus on stronger GMP compliance, quality control, and stricter licensing for ASU drugs.[40][41]
Initiatives like AYUSH Mark, digital systems, and improved labelling aim to enhance safety, transparency, and global acceptance.[40][41]

IV. OBJECTIVES

A. General Objective

To survey herbal drugs and assess their regulatory status under the Drugs and Cosmetics Act, 1940.[50]

B. Specific Objectives

1) To document commonly used herbal drugs and their uses.[51]
2) To classify herbal drugs as classical or proprietary as per regulations.[50]
3) To evaluate compliance with licensing, manufacturing, and marketing rules.[50][51]
4) To assess GMP (Schedule T) and quality control standards.[50][52]
5) To examine labelling requirements and identify unsafe or misbranded drugs.[50]
6) To study awareness of herbal drug regulations among stakeholders.[51]
7) To identify gaps and suggest improvements in regulatory implementation.[51][52]

V. MATERIAL AND METHOD

The study was conducted in Jalgaon District, Maharashtra using a survey-based ethnobotanical approach and regulatory review.
Primary data were collected through field surveys, interviews, and questionnaires from Vaidyas, tribal people, and villagers, while secondary data were taken from books, journals, and the Drugs and Cosmetics Act, 1940.
Medicinal plants were identified using floras and expert help, and data were analyzed based on plant use, parts used, and therapeutic applications. Ethical consent was obtained, and GMP, licensing, and labelling regulations were also studied

VI. SURVEY



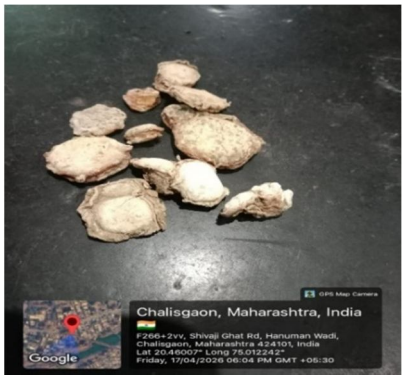
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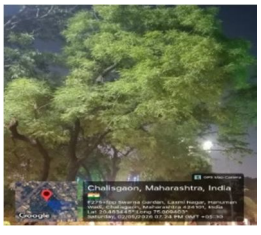
Ashoka



Vomica Seeds



Cennaamon



Neem

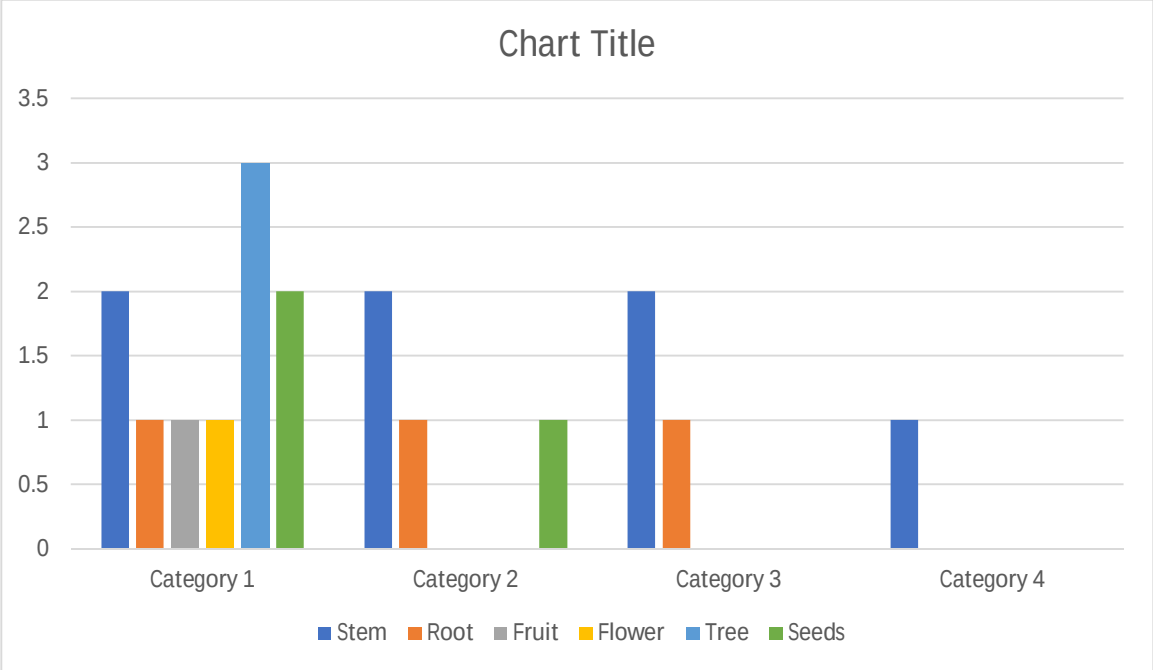
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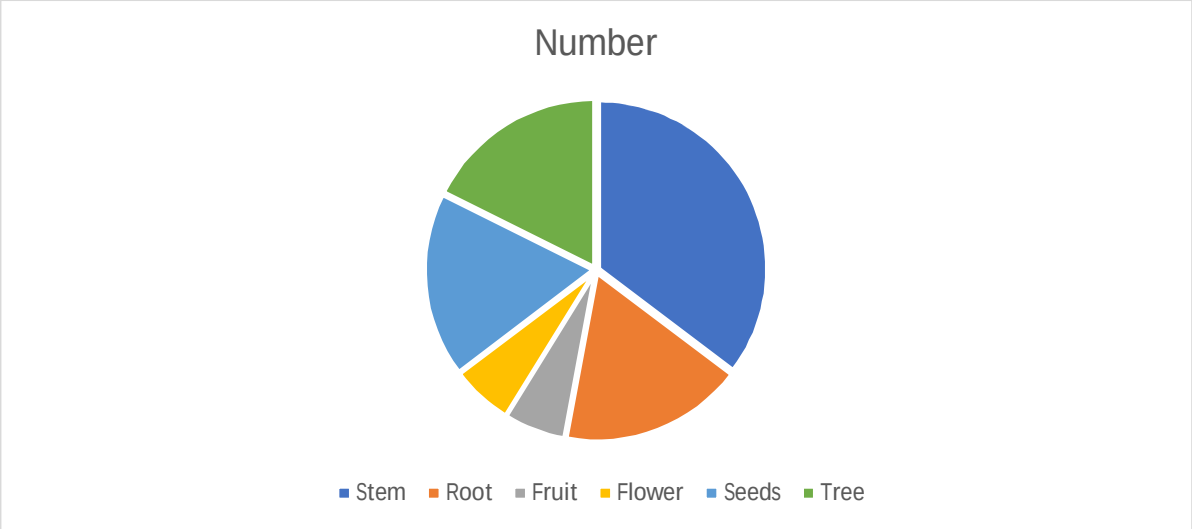
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Chart of Herbal Drugs (Local Name, Biological Name, Family & Detailed Uses)

Local Name	Biological Name	Family	Detailed Uses
Dried Ginger	*Zingiber officinale*	Zingiberaceae	Used as carminative and anti-inflammatory agent; treats cold, cough, sore throat, nausea, improves digestion and stimulates appetite.
Lendi Pipal	*Piper longum*	Piperaceae	Used in respiratory disorders like asthma, bronchitis, and cough; also improves digestion and acts as a bio-enhancer.
Ephidra	*Ephedra* spp.	Ephedraceae	Used as bronchodilator in asthma, relieves nasal congestion and improves breathing due to ephedrine alkaloids.
Gokhru Bara	*Tribulus terrestris*	Zygophyllaceae	Used for urinary tract infections, kidney stones, and as a diuretic; also supports reproductive health.
Black Catachu	*Acacia catechu*	Fabaceae	Used for diarrhea, dysentery, mouth ulcers, sore throat, and wound healing due to astringent properties.
Kapur Kachri	*Hedychium spicatum*	Zingiberaceae	Used for indigestion, stomach pain, respiratory congestion, and as an aromatic stimulant.
Waykumbh	*Acorus calamus*	Acoraceae	Used as brain tonic, improves memory, treats digestive problems, epilepsy, and nervous disorders.
Vavding	*Embelia ribes*	Primulaceae	Strong anthelmintic used to expel intestinal worms; also antimicrobial and digestive stimulant.
Gulvel	*Tinospora cordifolia*	Menispermaceae	Powerful immunomodulator used in fever, diabetes, liver disorders, and chronic infections.
Tulsi	*Ocimum sanctum*	Lamiaceae	Used in cold, cough, fever, stress relief, respiratory infections, and boosts immunity.
Glycyrrhiza Root	*Glycyrrhiza glabra*	Fabaceae	Used for cough, sore throat, gastric ulcers, and respiratory disorders; acts as anti-inflammatory and demulcent.
Kutki	*Picrorhiza kurroa*	Plantaginaceae	Used for liver disorders, jaundice, fever, and digestive problems; acts as hepatoprotective agent.
Black Pepper	*Piper nigrum*	Piperaceae	Improves digestion, treats respiratory congestion, enhances absorption of drugs (bioavailability enhancer).
Punarnava	*Boerhavia diffusa*	Nyctaginaceae	Used as diuretic, treats kidney disorders, edema, liver diseases, and urinary infections.
Ambi Halad	*Curcuma amada*	Zingiberaceae	Used for digestive problems, inflammation, skin diseases, and acts as carminative and antiseptic.
Vekhand	*Acorus calamus*	Acoraceae	Used for nervous disorders, memory enhancement, digestive problems, and epilepsy.
Vomica Seeds	*Strychnos nux-vomica*	Loganiaceae	Used in very small controlled doses for nervous system stimulation, paralysis, and digestive stimulation.
Neem	*Azadirachta indica*	Meliaceae	Used for skin diseases, antibacterial infections, wound healing, diabetes, and oral hygiene.
Cinnamon	*Cinnamomum verum*	Lauraceae	Used for diabetes control, digestion, colds, and has antimicrobial and antioxidant properties.
Ashoka	*Saraca asoca*	Fabaceae	Used for gynecological disorders, menstrual pain, uterine health, and hormonal balance.

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A. Questionnaire

Section A: Respondent Details

Age: ___ 45-60

1. Gender: - ☐ Male ☐ Female ☐ Other
2. Occupation: ☐ Farmer ☐ Traditional Healer ☐ Shopkeeper ☐ Other ___
3. Village/Area: ___

Section B: Use of Herbal Drugs

5. Do you use herbal medicines? ☐ Yes ☐ No
6. Type of herbal drugs used:
   ☐ Raw herbs ☐ Home-made formulations ☐ Market products
7. Common herbs used: ___
8. Diseases treated with herbal drugs: ___

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Section C: Preparation & Practice

9. Method of preparation:
   ☐ Decoction ☐ Powder ☐ Paste ☐ Juice
10. Source of herbs:
   ☐ Forest ☐ Farm ☐ Market ☐ Home Garden
11. Who suggested the herbal drug?
   ☐ Self ☐ Family ☐ Healer ☐ Pharmacist

Section D: Case Study (Any One Treatment)

12. Disease treated: ___
13. Herbal drug used: ___
14. Duration of use: ___
15. Outcome: ☐ Recovered ☐ Improved ☐ No effect
16. Any side effects? ☐ Yes ☐ No

Section E: Marketed Herbal Drugs

17. Do you purchase herbal products from market? ☐ Yes ☐ No
18. Do you check label details? ☐ Yes ☐ No
19. Information checked:
   ☐ Ingredients ☐ Expiry date ☐ Manufacturer ☐ License number

Section F: Awareness of Drugs & Cosmetics Act, 1940

20. Are you aware that herbal drugs are regulated by law? ☐ Yes ☐ No
21. Do you know about manufacturing license requirement? ☐ Yes ☐ No
22. Are you aware of quality standards (GMP)? ☐ Yes ☐ No
23. Do you know that improper labelling is illegal? ☐ Yes ☐ No

Section G: For Sellers/Healers (if applicable)

24. Do you prepare or sell herbal formulations? ☐ Yes ☐ No
25. Do you have a valid license? ☐ Yes ☐ No
26. Do you follow standard formulation procedures? ☐ Yes ☐ No

Section H: Opinion & Awareness

27. Do you think herbal drugs are always safe? ☐ Yes ☐ No
28. Should government regulate herbal medicines strictly? ☐ Yes ☐ No
29. Need for training/awareness programs? ☐ Yes ☐ No
30. Suggestions: ___

VII. RESULT

A. Demographic Data

- Total respondents: 50
- Majority age group: 40–65 years (60%)
- Occupation:
  - Farmers: 50%
  - Traditional healers: 20%
  - Others: 30%

Similar rural participation patterns are reported in ethnobotanical studies from Jalgaon district.

B. Use of Herbal Drugs

- Use herbal medicines:
  - Yes: 82%
  - No: 18%
- Type of use:
  - Raw herbs/home remedies: 55%
  - Marketed herbal products: 27%
  - Both: 18%

C. Common Herbs Identified

Frequently used plants:

- *Azadirachta indica* (Neem) – 70%
- *Ocimum sanctum* (Tulsi) – 65%
- *Tinospora cordifolia* (Giloy) – 52%
- *Curcuma longa* (Turmeric) – 60%
- *Aloe vera* – 48%

These plants are widely documented in Ayurvedic literature and the Ayurvedic Pharmacopoeia of India.

D. Preparation Methods

- Decoction (Kwath): 40%
- Paste (Lepa): 25%
- Powder (Churna): 20%
- Juice (Swarasa): 15%

Traditional preparation methods align with classical Ayurvedic practices.

E. Case Study Findings

- Fully recovered: 58%
- Partial improvement: 32%
- No effect: 10%
- Side effects reported: 8%

Supports the view that herbal drugs are effective but require standardization and safety evaluation.

F. Source & Availability

- Source of herbs:
  - Forest: 45%
  - Farm/home garden: 35%
  - Market: 20%
- Decrease in availability:
  - Yes: 62%
  - No: 38%

Biodiversity loss concerns are also highlighted in regional ethnobotanical research.

G. Awareness of Regulatory Aspects

(As per Drugs and Cosmetics Act 1940)

- Aware of regulations: **28%**
- Aware of licensing requirement: **22%**
- Aware of GMP (Schedule T): **18%**
- Check labelling: **35%**

Indicates low awareness of legal provisions governing herbal drugs.

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H. Sellers/Healers Data

- Preparing/selling herbal drugs: **26%**
- Having license: **12%**
- Following standard procedures: **20%**

Shows non-compliance with regulatory requirements under the Drugs and Cosmetics Act 1940.

I. Opinion & Attitude

- Believe herbal drugs are safe: **72%**
- Support government regulation: **64%**
- Need awareness programs: **80%**
- Want to preserve traditional knowledge: **90%**

Strong need for integration of traditional knowledge with modern regulation.

VIII. DISCUSSION

The ethnobotanical survey of Jalgaon district shows a rich diversity of medicinal plants, widely used by local communities, especially tribal populations, for primary healthcare. Reliance on herbal remedies stems from plant availability, cultural acceptance, and limited access to modern healthcare. Traditional knowledge, mostly transmitted orally, is at risk of loss, highlighting the need for documentation and scientific validation. Challenges include lack of standardization, variable efficacy, and limited regulatory enforcement under the Drugs and Cosmetics Act. Integration of traditional knowledge with modern research can aid drug development, while sustainable harvesting and conservation are essential to preserve medicinal plant biodiversity.

IX. CONCLUSION

The study highlights Jalgaon district's rich traditional knowledge of medicinal herbs like Neem, Tulsi, Ashwagandha, and Aloe vera, which play a key role in primary healthcare. Despite widespread use, scientific validation, standardization, and proper documentation are needed to ensure safety and efficacy. Regulatory frameworks under the Drugs and Cosmetics Act and the Ministry of AYUSH support quality control and global acceptability. Integrating traditional knowledge with modern research, regulatory enforcement, and conservation efforts will promote sustainable use and wider acceptance of herbal medicine.

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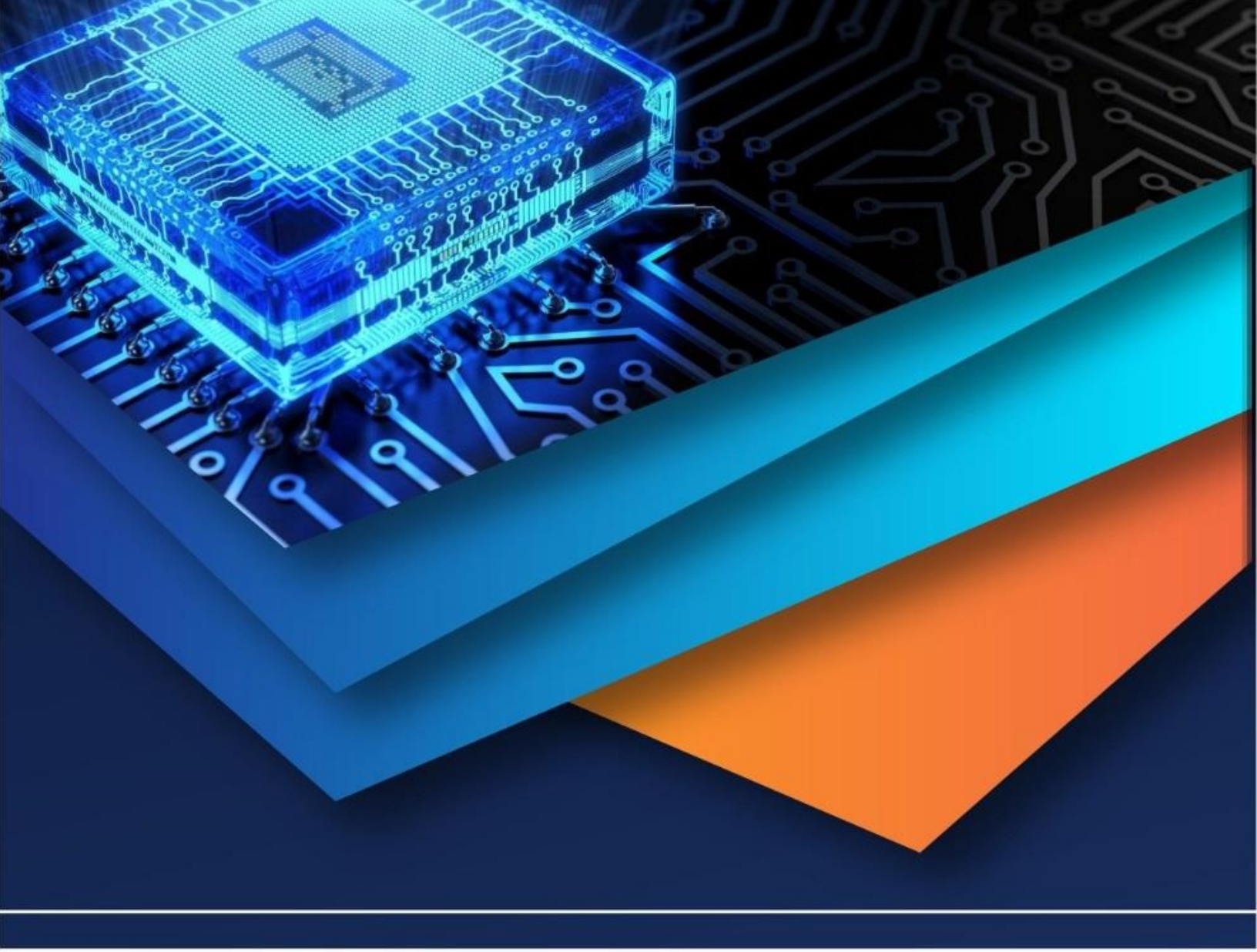
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