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Emergence of Ecopharmacovigilance and its possible implementation in Ayurveda

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Review

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ABSTRACT

Newer formulations and more compound drugs in AYUSH being manufactured and used in an ever-growing scale with various medical and non-medical conditions. The demand for more pharmaceutical products leads to destroying countless species of animals and plants, placing public at risk and disappearance of rain forests around the globe. The loss of these rainforests contributes to changes in the global climate. With growing research in the field of ecology and environment, many adverse effects of drugs on environment have come to light. Pharmacovigilance activities done to monitor any obnoxious reactions of drugs in Human and Animals. However, a branch of pharmacovigilance focuses on the environmental impact of pharmaceutical products, which originally started as "PharmacoEnvironmentology", involves monitoring, assessing, and mitigating the risks associated with the release of pharmaceuticals and byproducts into the environment and now known as Ecopharmacovigilance. It also covers the safe disposal of unused or expired drugs, managing waste from pharmaceutical manufacturing and understanding how pharmaceuticals and byproducts may affect ecosystems and human health. So, the environment is polluted not only by heavy metals, pesticides, emissions from gasoline engines, but also through pharmaceutical chemicals, industrial chemicals, therapeutic and non-therapeutic medicines. The manufacturing plants producing the active substances might unintentionally release pharmaceuticals into the environment. It is said that drugs lead double lives! once APIs in administered medications have completed their intended purposes, they can take on renewed lives in environment. Few drugs synthesized and persist in environment even after its metabolism and excretion. These pharmaceuticals including TM enter into environment through various routes causing harmful effects.

Keywords: *AYUSH, Pharmacovigilance, Pharmacoenvionmentology, Ecopharmacovigilance.*

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INTRODUCTION

Global use of medicines grew by 14% over the past five years and a further 12% increase is expected through 2028, bringing annual use to 3.8 trillion defined daily doses. Due to number of reasons the usage medicines are growing day by day.[1] The AYUSH industry has witnessed remarkable growth, with its manufacturing sector surging at a Compound Annual Growth Rate (CAGR) of over 30% between 2014-2020, reaching $24 billion by 2024, while the combined AYUSH sector (manufacturing and services) valued at $50 billion by 2024.[2] This is due to rapid increase in worlds population and the enhanced disease burden. Consequently, the pharmaceutical pollution and wastage is being increased from pharmaceutical manufacturing plants, healthcare institutions and facilities, veterinary clinicals, etc. which is posing impact on the environment that can be evidenced by vultures' death after consuming carcass of animals treated with Diclofenac sodium[3], Ethinyl estradiol adversely affecting fish through its "feminization" of males.[4]

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According to Vagbhata, everything in the universe has the potential to be used as medicine, provided one possesses the knowledge and understanding of its properties and purpose.[5] "Years ago, herbal medicine was the primary treatment, but its perishability, limited shelf life, and slow action led Acharyas to develop a parallel science called Rasa Shastra. This branch incorporated the use of mercury, various metals, minerals, and animal products to create medicinal preparations with enhanced potency and longer shelf life. During the preparation of rasaushadies (Herbomineral/ mercurical preparations) different byproducts, pollutants are arising, this will certainly affect the environment. Thus, the concept of ecopharmacovigilance is in emergence. There is no sufficient data available that how the ayurveda pharmaceuticals can lead to environmental damage. However, there seems that it can be possible by the following factors:

1. Emissions / pollutants during different pharmaceutical procedures mainly bhasma (incineration of minerals metals, kupipakwa, potali preparations)
2. Following the administration, drugs are excreted from the body as either metabolites or unchanged compounds. Owing to their water-soluble properties, drugs commonly find their way into sewage systems
3. Improper disposal of leftover, unused, expired ayurvedic medicinal products.

The main problem with herbal medicinal industry is waste produced from its process. Most of the herbal medicine waste contain phenol and its derivatives that have a serious effect to the environment. An herbal medicine industry normally produces wastewater with COD content of 200-20000 ppm and 9.8 ppm phenol.[6] During the preparation of various bhasmas (incinerated metallic nanoparticles), various emissions and pollutants arise, and there are limited regulations.

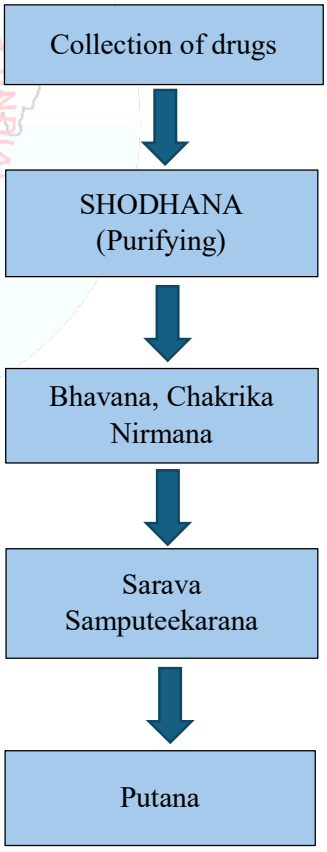
Historical background

In the past, people generally had stronger immune systems, but over time, immunity has decreased, leading to more dependency on medicines ultimately more pharmaceutical pollution. According to kashyapa Ahara is mahabhaishajya, just by administration of proper food/diet, it is possible to cure the majority of diseases.[7] Thus, by limiting the medicinal prescriptions, pharmaceutical wastage can be prevented up to some extent.

Author of Rasa tarangini had mentioned particular selected area for bhesajagara / Rasasala (Pharmaceutical/ drug manufacturing unit), विमलोपवनप्रदेशगां रमणीयां जलयन्त्रशोभिताम् । कमनीयगवाक्षसंयुतां जनबाधारहितामसंकुलाम् ॥[8] According to him it should be constructed in a clean, hygienic and plain area. The area should be free from danger of insects, creepers, birds and other wild animals. From this we can assume that other animal species, plants etc can be protected from the pollution/ emissions coming from the rasashala. Specific Direction for Agni karma procedures are also mentioned to prevent contamination of in-process drugs.

Depending on various conditions, the branch of Rasa Shastra has evolved over time. During this timeline, different techniques and methods were developed. As we move from the open method to kupipakwa, parpati, and to potali method, not only does the drug potency increases, but the emissions from them also decreases. Every drug has its own M.P, B.P, so different drugs need different degree of heat during pharmaceutical procedures. By selecting the appropriate puta (quantity of heat required for drug preparations) will help in controlled combustion, minimize particulate matter, reduces toxic gases, etc. For instance, Bhudhara Puta involves digging a small pit in the ground, placing the enclosed medicinal drug inside, and covering it with a 2-inch layer of sand on all sides. Then, heat is applied from above using dry cow dung cakes. This method effectively limits emissions within the ground, minimizing air pollution.

Traditional method for incineration of rasashadas (Herbo mineral metallic preparations) is as follows:



The Sarva Samputa technique (sealed container) in Rasa Shastra can significantly reduce or prevent emissions of Rasa Aushadhas during their preparation. By using a sealed container, we can precisely control the temperature, ensure a complete reaction between ingredients, thus minimizing the release of volatile substances and harmful byproducts. The resulting homogeneous mixture ensures uniform heating, reduces emissions, and minimizes oxidation, thereby mitigating harmful emissions.

Overall, Sarva Samputa makes the preparation process safer and more environmentally friendly. Now a days, Electronic Muffle Furnances are being used for different purposes and for various benefits. A 100 percent pollution free environment is a myth with operating factories and industries. Adequate and effective pollution control measures are required so that adverse effects on the environment are minimised. The three main laws relating to pollution are: The Water (Prevention and Control of Pollution) Act 1974, The Air (Prevention and Control of Pollution) Act 1981 and The Environment (Protection) Act 1986.[9] There are numerous rules under these acts relating to different matters prohibiting industries from spread of pollution.

The aim of this study is to explore the concept of eco-pharmacovigilance and its possible integration into Ayurveda, ensuring environmentally sustainable practices in the development, manufacturing, and disposal of Ayurvedic medicines. This paper helps to investigate the environmental impact of Ayurvedic medicine production, including raw material sourcing, manufacturing processes, and waste management.

AYUSH Medicine: Overview and Environmental Impact

The soaring demand for herbal medicine has led to unsustainable harvesting of plants, trees, and herbs, threatening their depletion and disrupting the ecosystem's delicate balance. To ensure a sustainable supply, cultivating herbal medicine is crucial. However, large-scale herb cultivation may divert resources and land from food crops, potentially reducing food production. Therefore, striking a balance between herbal medicine cultivation and food production is essential.

AYUSH medicine production often results in byproducts such as herbal residues, plant extracts, mineral waste, and organic solvents. AYUSH medicine preparations may generate byproducts from minerals such as sulfur and mercury. The use of solvents: ethanol, methanol, and acetone in the extraction of active compounds can result in chemical runoff if not handled correctly. The left over leaves, roots, and barks, after extraction process can decompose, leading to release of volatile organic compounds (VOCs) and other substances that may impact local ecosystems.

During the production of herbo-mineral and metallic preparations, depending on the Rasaushada used various emissions are generated, including mercury vapours, lead, copper, and tin fumes, etc, as well as gases such as CO_2, CO, SO_2, NO_2 etc. If released excessively and without proper regulatory adherence, these emissions can harm the environment.

A research paper on environmental risk and management of herbal-extraction residues induced by the composition and metal binding properties of DOM shows that China's rapidly growing traditional herbal medicine industry generates increasing amounts of extraction residues, rich in nutrients but prone to corruption and environmental harm. Conventional disposal methods (landfill, incineration, stacking) waste resources and harm the environment. Dissolved Organic Matter (DOM) in these residues can bind heavy metals, affecting their migration and eco-behaviour.[10] Understanding DOM's binding characteristics with heavy metals is crucial for environmental management and sustainable utilization of herbal extraction residues. Appropriate measures are needed for such issues.

Existing regulations and guidelines related to environmental sustainability in Ayurvedic manufacturing:

In the Drugs and Cosmetic Act (DCA) 1940 and rules 1945, schedule- T Part 2 section D, mentions that the manufacturing area should be designed with special attention to process the products that generate toxic fumes like SO_2, arsenic and mercury vapour, etc. When heating and boiling of the materials is necessary, suitable ventilation and air exhaust flow mechanism should be provided to prevent accumulation of unintended fumes and vapours. Such areas may be provided with properly designed chimneys or ducts fitted with exhaust system and suitable scrubbing system to remove fumes and smoke, so that safety of personnel and environment is taken care of.[11]

There are no specific regulations regarding the emission from incineration of rasaushadies. DCA 1940 and Rules 1945 have regulations for the manufacture of Ayurvedic drugs for sale or distribution. In addition to DCA, it is mandatory to comply all relevant laws such as Factory Act, Pollution Acts, GST registration, etc. while manufacturing Ayurvedic drug for sale or distribution.[12]

Sufficient data is not available that how much concentration of emissions are emitted during incineration of rasaushadas in the database searches, whereas guidelines for management of healthcare waste and emissions from the incineration of biomedical waste are available. The standard emission parameters of central or state pollution boards, should be followed.

“Emission” means any solid or liquid or gaseous substance coming out of any chimney, duct or flue or any other outlet.[13] Emission Standards as per Central Pollution Control Board, Ministry of Environment and Forests July 2000 are as follows[14]:

Parameters	Concentration mg/Nm3 at (12% CO_2 correction)
(1) Particulate matter	150
(2) Nitrogen Oxides	450
(3) HCI	50
(4) Minimum stack height shall be 30 meters above ground	
(5) Volatile organic compounds in ash shall not be more than 0.01%.	

Standards for Treatment and Disposal as per Biomedical Waste Management Rules, 2016 are Standards for Incineration.[15] All incinerators shall meet the following operating and emission standards:

A. Operating Standards

1. Combustion efficiency (CE) shall be at least 99.00%.

2. The Combustion efficiency is computed as follows: $\%CO_2$

$$C.E. = \frac{\%CO_2}{\%CO_2 + \%\ CO} \times 100$$

3. The temperature of the primary chamber shall be a minimum of 800^0C and the secondary chamber shall be minimum of 1050^0C + or - 500C.

4. The secondary chamber gas residence time shall be at least two seconds.

B. Emission Standards

S. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm3 unless stated	Sampling Duration in minutes, unless stated
1.	Particulate matter	50	30 or 1Nm^3 of sample volume, whichever is more.
2.	Nitrogen Oxides NO and NO_2 expressed as NO_2	400	30 for online sampling or grab sample
3.	HCl	50	30 or 1Nm^3 of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1ng TEQ/Nm3 (at 11% O2)	8 hours or 5Nm^3 of sample volume, whichever is more
5.	Hg and its compounds	0.05	2 hours or 1Nm^3 of sample volume, whichever is more

In addition, ayurveda pharmaceuticals or manufacturing units should follow Factory Acts, and all factories follows Air Pollution Act.

Sources

• Emissions from rasaushada preparations • Volatile organic compounds from some herbal preparations • Incineration processes	Air pollution
• Diverting the byproducts wastes etc into canals etc • Consumed pharmaceuticals are excreted as metabolites or unchanged compounds, entering the environment through sewage systems • While industrial pharmaceutical waste also contributes to environmental contamination • Despite treatment processes, outdated sewage treatment technologies often fail to completely remove residual pharmaceuticals, allowing traces to persist in waterways	Water pollution
• Improper disposal of medicinal waste. • Contaminated water effluents from manufacturing processes	Soil pollution

Key pollutants

Some Common types of emissions during the incineration of rasaaushada preparations includes the following

1. Mercury-based preparations (e.g., Makaradhwaja, Kajjali)
   - Mercury vapour (Hg)
   - Carbon monoxide (CO)
   - Carbon dioxide (CO_2)

2. Sulfur-containing preparations (e.g., Gandhaka Rasayana, Rasa sindura)
   - Sulfur dioxide (SO_2)
   - Hydrogen sulfide (H_2S)
   - Carbon disulfide (CS_2)

3. Arsenic-containing preparations (e.g., Preparations from Haratala, Manashila, Gouripashana)
   - Arsenic trioxide fumes
   - Carbon monoxide (CO)
   - Carbon dioxide (CO_2)

4. Lead, Tin containing preparations (e.g., Lead oxide/ Preparations of Naga):
   - Lead fume, Tin fumes, CO, CO_2

5. Copper-containing preparations (e.g., Copper oxide/ Preparations of Tamra etc):
   - Copper fumes CO, CO2

6. Zinc-containing preparations (e.g., Zinc oxide):
   - Zinc fumes, CO, CO_2

7. Herbal preparations (e.g., Ashwagandha, Turmeric):
   - Volatile organic compounds (VOCs), CO, CO_2

Exhaust gas analyser, emission gas analyser, spectrometers, etc should be used/ employed in ayurveda pharmaceuticals to detect what type and how much concentration of emissions are produced during the incineration of rasashadies. Incineration of rasaushadies should be done at a specific area, and the emissions from it are directed towards a chimney which in turn attached to a emission gas analysers and then specific Air Pollution controlling Control Devices are attached.

To prevent environmental pollution from these emissions, following points need to be considered.

1. Use high-temperature incinerators (>1000°C) to ensure complete combustion.
2. Install scrubbers to remove particulate matter and gases.
3. Employ fabric filters or electrostatic precipitators to capture fine particles.
4. Use activated carbon or zeolites to adsorb VOCs and toxic gases.
5. Implement wet scrubbing or spray towers to remove acidic gases such as SOx, NOx, etc
6. Monitor emissions regularly and maintain proper incinerator operation.
7. Using different bioremediation techniques.[16]

The pharmaceutical industry can employ various carbon dioxide (CO_2) pollution control devices to minimize environmental impact such as Carbon Capture Technology, Scrubbers, Adsorption Systems, Membrane Separation, Cryogenic Distillation, Bioreactors, Venturi Scrubbers, Biofilters. Regenerative Thermal Oxidizers (RTOs). Implementing CO_2 pollution control devices can help the pharmaceutical industry reduce its carbon footprint, meet regulatory requirements, and contribute to a more sustainable future.

Some of the Air pollution control devices include: Scrubbers, Electrostatic precipitators, Air filters, Catalytic oxidizers, Cyclone separators, Dust collectors, Oxidizers, Pollution control equipment, Mist collectors, Bag filters, etc. More tree plantation programmes to reduce CO_2 etc, using different microbes to reduce SO_2, NO_2 etc

Further research, education, and policy initiatives to address the Ecopharmacovigilance in ayurveda, is in dire need. One can do research to investigate and characterize the type and quantity of emissions/pollutants generated during the production of different Ayurvedic medicinal preparations. Secondly, one can explore Advanced Technologies and Machines for Real-Time Detection of Emissions, Wastes, and Byproducts in Ayurvedic Manufacturing Processes and Integrating Artificial Intelligence (AI) into Ayurveda can enhance eco-pharmacovigilance by predicting environmental risks, optimizing sustainability, and streamlining waste management including toxicity and health impact assessments.

In the education sector, one can give training for manufacturers and workers on emission management, wearing protection kits, etc during preparations. Awareness programs for communities near incineration site can be given. The deliberation from the workshops and conferences for knowledge sharing and collaboration would help policy initiatives and developing regulations and standards in tune with ancient and traditional principles and parameters. Strictly Enforcement of existing environmental laws and regulations and public engagement and participation in policy-making processes should be adhered. Inter-agency coordination and collaboration for effective emission management is another step that needs to be educated to the masses.

Challenges in Safe Disposal of AYUSH Medicine Byproducts

The lack of awareness and education in the AYUSH industry and limited understanding of modern waste management practices and their importance, leading to non-compliance. The inadequate disposal infrastructure such as facilities such as Effluent Treatment Plants (ETPs), hazardous waste treatment centers, and specialized composting units either lacking or insufficient or non-functional. Likewise, the cultural and traditional practices also impact disposal such as hazardous traditional methods such as burying herbal waste, burning residues, or releasing them into water bodies.

Best Practices for Disposal of AYUSH Medicine Byproducts

There should be AYUSH-specific guidelines for example the identify byproducts classification and segregate waste management. Clearly label all containers and store byproducts in designated areas. Following treatment methods for each byproduct could be followed:

i. Herbal Byproducts: Compost or use other eco-friendly methods such as bioremediation
ii. Mineral Byproducts: Follow specific protocols for disposing of mineral-based byproducts
iii. Chemical Byproducts: Use appropriate chemical waste treatment methods: neutralization or incineration

Types of Bioremediations

i. Aerobic Bioremediation: Utilizing oxygen-dependent microorganisms to degrade organic matter into carbon dioxide, water, and biomass
ii. Anaerobic Bioremediation: Employing microorganisms that thrive in oxygen-deprived environments to break down organic matter into methane, carbon dioxide, and biomass.
iii. Phytoremediation: Utilizing plants to absorb, accumulate, or transform contaminants in soil or water.

The main advantages of bioremediation are its specificity that it is environmentally friendly, cost-effective, *In-Situ* or *Ex-Situ* Treatment and Sustainable

Sustainable Solutions and Innovations in AYUSH Medicine Production and Disposal

Green chemistry approaches in AYUSH medicine production are one option. Green chemistry focuses on designing products and processes that minimize use and generation of hazardous substances.

- Use of Renewable Resources: Employing plant-based and renewable resources as raw materials. It reduces reliance on non-renewable resources
- Energy Efficiency: Implementing energy-efficient processes, such as using low-energy extraction methods
- Waste Minimization: Optimizing extraction methods to maximize yield and reduce byproducts
- Utilizing Non-Toxic Solvents: Ethanol, Ethyl Lactate , Glycerol, Vegetable Oils, Supercritical Carbon Dioxide (scCO2)
- Atom Economy: Developing chemical processes that maximize incorporation of all materials used in the process into the final product, reducing waste generation.

Innovative Technologies for Reducing Environmental Impact

Advanced Extraction Techniques such as supercritical fluid extraction and microwave-assisted extraction reduces waste and energy consumption. The biodegradable packaging may include reduction of plastic waste associated with AYUSH medicine packaging. The Waterless Processing includes implementing waterless or low-water technologies in manufacturing process. The On-site Waste Treatment included deploying technologies like small-scale bioreactors for on-site treatment of organic byproducts. The use nanotechnology can enhance efficacy of herbal medicines, allowing for lower doses and reduced raw material usage, leading to less waste.

Importance of Reporting Adverse Environmental Effects

The early detection and prevention enables rapid response and corrective measures. It would increase regulatory compliance as reporting ensures compliance and transparency in disposal process. Early reporting does continuous improvement through data-driven decisions and environmental stewardship. This would also improve public and environmental health. The reporting adverse effects helps protect local ecosystems from long-term damage and prevent contamination of natural resources (water, soil, air). Lastly, the role of ADR monitoring centres under the Pharmacovigilance Programme should be proactive as these centres may help in data collection and adverse event reporting, establishing centralized database for environmental impact reports, collaborating with Environmental Protecting Agencies (EPAs) to conduct joint monitoring of disposal site. Pharmacovigilance centers can conduct outreach programs to educate manufacturers, healthcare providers, and the public. They can also provide guidance and training to stakeholders.

Conclusion

Humanity's relentless pursuit of innovation and exploration in medicinal preparations has inadvertently led to various forms of environmental pollution, underscoring the need for sustainable and eco-friendly practices. As the world grapples with environmental degradation and climate change, it is imperative that traditional systems of medicine like Ayurveda adopt eco-friendly approaches. Eco-pharmacovigilance offers a comprehensive framework for monitoring and mitigating the environmental impact of Ayurvedic medicines. Implementation of eco-pharmacovigilance in Ayurveda requires a multi-stakeholder approach, involving education, research, policy support, and industry collaboration. By integrating eco-pharmacovigilance into Ayurvedic education, practice, and manufacturing, we can ensure a safer environment and promote sustainable healthcare.

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