

Qualitative Analysis of Siddha Formulation Nilavagai Chooranam by Using Modern Analytical Techniques

Janani A M

^{*1}Assistant professor, Department of Gunapadam- Marunthakaviyal, Nandha Siddha Medical college & Hospital, Chennai, India

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ABSTRACT

Medicines derived from herbs possess a unique advantage due to their higher standard of well-being and therapeutic properties. Simultaneously, herbal remedies are also cost-effective, making them accessible to a wider population. Medicinal plants have long played a significant role in the ancient Siddha system, offering natural solutions to various health concerns.

However, it is crucial to acknowledge that herbal resources are susceptible to contamination, particularly from bacterial or fungal infections during the stages of harvesting, processing, and storage of raw materials. When these contaminated parts are utilized in medicinal preparations, their bioactive properties may diminish, leading to a loss of potency and efficacy. Additionally, the use of pesticides to safeguard plants from infections and insects introduces the risk of toxic pesticide residues infiltrating the medicinal components.

In light of these concerns, a comprehensive analysis of the Siddha herbal preparation Nilavagai chooranam was conducted to assess pesticide residue, specific pathogens, and aflatoxins using modern techniques. The analytical reports conclusively demonstrate that the drug is free from contamination and exhibits the absence of aflatoxins B1, B2, G1, and G2. This substantiates the safety of the drug for use as medication.

This preliminary step in the herbal formulation process serves to uphold the quality and integrity of the herbal drug before it is introduced to the market. It underscores the commitment to ensuring the safety and efficacy of herbal medicines, thereby promoting confidence among consumers and healthcare practitioners.

In conclusion, the meticulous assessment of herbal preparations for potential contaminants is imperative in safeguarding public health and upholding the credibility of herbal medicine. By adhering to stringent quality control measures, we can continue to harness the benefits of herbal remedies while mitigating associated risks.

Keywords: Aflatoxins analysis, Medicinal plants, Pesticide residue, Quality of herbal drugs, Specific pathogen.

INTRODUCTION

Herbal drugs are widely avail of for health care in the world. They have primary importance due to their therapeutic values to various health issues. These drugs are important as traditional remedies and as trade commodities that satisfy the needs of far-flung markets [1]. The current practices of harvesting, production, transportation, and storage of herbal raw materials are significantly susceptible to contamination and the proliferation of microorganisms. Consequently, these factors compromise the quality and sustainability of herbal drugs. Moreover, the failure to control moisture levels during the production or storage process can lead to degradation of the products.

Pesticides, which are chemical substances with varying levels of toxicity and modes of action, are utilized to control target pests, often leaving behind residues in plant parts. This has raised concerns among consumers about the presence of toxic chemicals in herbal products. In response to these concerns, national authorities

rigorously evaluate the toxicity of pesticides before authorizing their use. The OECD guidelines for testing chemicals comprise a comprehensive collection of internationally agreed testing methods utilized by government, industry, and independent laboratories to ensure the safety of pesticides.

It is crucial to prioritize the protection of consumers and the environment by strictly adhering to these guidelines and regulations. By doing so, we can mitigate the potential risks associated with pesticide residues and uphold the quality and safety of herbal products (5). Each medicine should be testing the pesticide analysis. If that medicine free from pesticides, then only allowed to consume.

Aflatoxins B1, B2, G1, G2 are fungal secondary toxic metabolites produced by *Aspergillus flavus*, *Aspergillus parasiticus* and *Aspergillus nomius*. Aflatoxins are the strongest natural carcinogens and their main target organ is liver. The International Agency for Research on cancer (IARC) has classified Aflatoxin B1 into group 1 human carcinogen and B2, G1, G2 are the possible carcinogens to humans [2].

The contamination of microorganisms and their toxic chemicals that deteriorate the active principles of drugs and make them unsafe for consumption [1]. So, it is essential to identify the risks with their use as safety of herbal medicines as an important public health issue [2]. This present study aimed to assess the safety parameters including pesticide residue, Specific pathogen, Aflatoxins analysis through using modern analytical techniques under the standard Ayush guidelines.

MATERIALS AND METHODS

Preparation of Nilavagai chooranam

Raw drug collection:

The herbal raw materials are collected in reputed raw drug store in Chennai, Tamil Nadu.

Authentication:

Before making of medicine preparation, the ingredients should authenticate to prevent the usage of adulterant materials. The raw drugs are certified under Botanists of Gunapadam in Government Siddha Medical College, Chennai.

Method of preparation:

Preparation of chooranam is made under the procedure mentioned in Agathiyar Vaithiya Rathina Surukkam-360 [3]. Once chooranam is prepared, it will be purified by steam cooking [4].

B. Analytical methods:

Pesticide residue:

The chooranam were extracted with acetone, it is followed by homogenization. Further filtration was allowed. Then, subsequent addition of acetone to the test mixture. Heating of sample was performed at a temperature below 40°C until the solvent has almost completely evaporated. To the residue add a few ml of toluene. Heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered.

Test for Specific Pathogen:

Test sample was directly inoculated in to the specific pathogen medium by pour plate method. Colour characteristic in different media denotes the presence of specific pathogen. Table no. 1. expresses the different medium for specific pathogen.

Table no. 1: Specific Medium for pathogens

Organism	Medium
E-coli	EMB Agar
Salmonella	Deoxycholate agar
Staphylococcus Aureus	Mannitol salt agar
Pseudomonas Aeruginosa	Cetrimide Agar

Test for Aflatoxins

The assay done by TLC method under UV light at 365 nm. Identify the spots when compared to the standard.

RESULT AND DISCUSSION

Above analytical test was made under the AYUSH guidelines. From the pesticide residue report, the samples showed low levels of organochlorines, organophosphorus, organo carbamates and pyrethroids and compared with the limit of measurement of AYUSH. Thus, there is no traces of pesticides in the sample chooranam (Table no.2, Table no.3, Table no.4). Hence, the ingredients of the drug were pesticides free and the drug safe for consumption

Table no. 2: Organochlorine pesticides

S.no	Organo Chlorine Pesticides	Sample	AYUSH Limit (mg/kg)
1.	Alpha BHC	BQL	0.1mg/kg
2.	Beta BHC	BQL	0.1mg/kg
3.	Gamma BHC	BQL	0.1mg/kg
4.	Delta BHC	BQL	0.1mg/kg
5.	DDT	BQL	1mg/kg
6.	Endosulphan	BQL	3 mg/kg

Table no. 3: Organo phosphorus pesticides

S.no	Organo phosphorus Pesticides	Sample	AYUSH Limit (mg/kg)
1.	Malathion	BQL	1mg/kg
2	Chlorpyrifos	BQL	0.2 mg/kg
3.	Ichlorovos	BQL	1mg/kg

Table no. 4: Organo carbamates and Pyrethroids

S.no	Pesticides residue	Sample	AYUSH Limit (mg/kg)
1.	Organo-carbamates: Carbofuran	BQL	0.1 mg/kg
2.	Pyrethroid: Pyrethroid	BQL	1 mg/kg

BQL- Below Quantification Limit

Specific pathogen analysis reveals there is no colonies or growth observed in incubation period from the plates inoculated with the test sample. Thus, there is absence of pathogens in chooranam (Table no.5). It ensures sterile pharmaceuticals and substances are safe for use as medication.

Table no. 5: Specific Pathogen Test

S.no	Organism	Result	Method
1.	E-coli	Absent	As per AYUSH specification
2.	Salmonella	Absent	
3.	Staphylococcus Aureus	Absent	
4.	Pseudomonas Aeruginosa	Absent	

Aflatoxins test reveals there is no spots in test sample when compared with standard. Accordingly, the chooranam free from Aflatoxin B1, B2, G1, G2 (Table no. 6). Aflatoxins are highly toxic, carcinogenic and severe contamination to plant sources, leading to serious health consequences. In that way, the sample Nilavagai chooranam is safe for use as medication.

Table no. 6: Aflatoxins Test

Aflatoxins	Sample	AYUSH Specification Limit
B1	Not Detected – Absent	0.5 ppm (0.5mg/kg)
B2	Not Detected - Absent	0.1 ppm (0.1mg/kg)
G1	Not Detected - Absent	0.5 ppm (0.5mg/kg)
G2	Not Detected - Absent	0.1 ppm (0.1mg/kg)

CONCLUSION

The internal medicines are important role in human health. So, the drug should responsible for protecting public health by ensuring the safety and efficacy. The good manufacturing process only will ensure the safety of the drug; thus, it is free from contaminations, pesticides and aflatoxins. Through this, the ingredients are well processed, prepared, stored and safe. This preliminary study ensures the safety of Nilavagai chooranam. Further analytical research should be conducted to assess its efficacy. It is important to thoroughly evaluate the

potential benefits of Nilavagai chooranam through rigorous research. This will help to determine its effectiveness in addressing specific health concerns. It is imperative to prioritize the safety and efficacy of any medicinal product to ensure the well-being of consumers. Therefore, comprehensive research is essential in order to make informed decisions about the use of Nilavagai chooranam.

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