



Heavy Metal and Aflatoxin Analysis of Siddha formulation Pramega Prayogam- An analytical study

¹Sasikala L, ²Janani A M, ³M D Saravana Devi

^{*1}PG Scholar, ²PG Scholar, ³Head of the Department, Department of Gunapadam, Government of Siddha Medical college, Chennai – 106, Tamilnadu, India.

Abstract:

Siddha system is one of the traditional medicine systems in the world, which treats all chronic diseases through herbal drugs also. Most of the Siddha medicines needs standardization. AYUSH has given preliminary guidelines for standardization of the conventionally used formulations. Pramega prayogam is one of the Siddha medicines indicated for Kalladaippu, Sathaiyadaippu, Neeradaippu. This study reports the safety profile of the drug by Heavy metal and Aflatoxin analysis. The aim of the study is to evaluate the heavy metal and aflatoxin analysis of Siddha polyherbal formulation Pramega prayogam. The drug was prepared as per the Siddha literature Agathiyar pallu, page no: 165. The drug reveals the presence of lead (Pb), Mercury (Hg) at 4.517 and 0.024 ppm level in 217.0 and 253.7nm. The other heavy metals like cadmium (Cd) and Arsenic (As) are below detectable limit. The aflatoxin assay of the Siddha medicine Pramega prayogam is free from Aflatoxins B1, B2, G1, G2. The reported results will be supportive for further research works.

Keywords:

Siddha formulation, Pramega prayogam, Heavy metal analysis, Aflatoxin analysis.

Introduction:

The Siddha system (A traditional tamil system of medicine) is the foremost of all the other medical systems in the world. The term Siddha refers to achievements and Siddhars were the divine persons who achieved excellence in medicine. Siddha formulations formulated and hypothesized by ancient Siddha practitioners are still used for clinical management of several dreadful metabolic disorders. Starting from raw material to finished product the quality and genuinity of the product as to be ascertained. Standardization is necessary to make sure the availability of a uniform product in all parts of the world. Standardization assures a consistently stronger product with guaranteed constituents (1). Therefore, it is extremely desirable that these drugs should be characterized with modern instruments, based on which the specifications of such drugs can be well standardized on a scientific basis (2). The selected drug Pramega prayogam is a classical siddha formulation, simple and cost effective, has diverse medicinal properties and used in the treatment of various diseases like Kalladaippu, Sathaiyadaippu, Neeradaippu (3).

Heavy metal analysis is important to monitor due to their various concentrations of dangerous levels of metals such as lead, cadmium, arsenic, mercury and it can be accumulated in the body (4). Accumulation of metals will produce toxic effects like Nausea, Vomiting, head ache, gastro enteritis in acute stage while in chronic it may cause encephalopathy, seizures, nephrotic syndrome.

Aflatoxins are a class of mycotoxin compounds produced by *Aspergillus flavus* and *Aspergillus parasticus* that have structural similarities. The presence of aflatoxins in herbal drugs might negatively impact consumers health status. Thus, heavy metal and aflatoxin analysis is essential to ensure that herbal products are safe to consume.

Materials and methods:

1. Heavy metal analysis:

- Sample Digestion:**

Test sample (Pramega prayogam) was digested with 1mol/L HCl for determination of arsenic and mercury. Similarly, for the determination of lead and cadmium the sample were digested with 1mol/L of HNO₃.

- Standard preparation:**

As & Hg- 100 ppm sample in 1mol/L HCl

Cd & Pb- 100 ppm sample in 1mol/L HNO₃.

- Methodology:**

The total heavy metal content of the sample is performed by Atomic Absorption Spectrometry (AAS) model AA240 series. In order to determination the heavy metal such as mercury, arsenic, cadmium, lead concentration in the test item.

2. Aflatoxin assay:

- Methodology:**

Thin layer chromatography (TLC) has been the only technique capable of detecting and quantitating Aflatoxins at low levels. The level of Aflatoxins in the extract is determined by visually matching the intensity of fluorescene of the of the sample spots with those standard spots. Locate the spots by examination under UV light at 365 nm.

Result and Discussion:

The drug reveals the presence of lead (Pb), Mercury (Hg) at 4.517 and 0.024 ppm level in 217.0 and 253.7nm. The other heavy metals like cadmium (Cd) and Arsenic (As) are below detectable limit. The results were compared in Indian country maximum limit range (Table no. 1). Thus, the present investigation clearly shows that the sample has no traces of heavy metals.

Table.no.1: Reports of Heavy metal analysis

S.no	Heavy metals	Absorbance a Max	Result Of test sample	Limit for Heavy metals in medicinal products in India
1.	Lead	217.0 nm	4.517	10 ppm
2.	Mercury	253.7 nm	0.02	1 ppm
3.	Arsenic	193.7 nm	BDL	3 ppm
4.	Cadmium	228.8 nm	BDL	0.3 ppm

The results of Pramega prayogam shown that there were no spots were being identified in the test sample loaded on TLC plates when compare to the standard which indicates that the sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1 and Aflatoxin G2 (Table no. 2).

Table no.2: Aflatoxin Analysis report

S.no	Aflatoxin	Sample	AYUSH specification limit
1.	B1	Absent	0.5 ppm
2.	B2	Absent	0.1 ppm
3.	G1	Absent	0.5 ppm
4.	G2	Absent	0.1 ppm

Conclusion:

This study presents the status of heavy metals and aflatoxins in Pramega prayogam chooranam. Also, provides a simple and convenient AAS method and TLC method which can effectively be adopted at Industrial level for the Quality control and Standardizations of herbal medicines. Hence, this drug can be applied for further clinical studies.

Acknowledgement:

I would like to express my profound gratitude to Guide Dr.K.Nalina Saraswathi and staff of Gunapadam department and Dr.K.Kanakavalli, Principal, Government Siddha Medical college, Chennai and my friends, colleagues and The Tamilnadu Dr.M.G.R. Medical University for their Support and contributions to complete this research study.

Reference:

- 1.Nisha J, Anbu N, Parthibhan P, Kanakavalli K. Systematic standardization and physiochemical evaluation of novel siddha formulation pungampoo chooranam as per ayush guidelines by modern analytical techniques. International Journal of Medical Research and Pharmaceutical Sciences. 2017;4(10):55-64.
2. Vinodini R, Amala M, Hazel AA, Sundaram MM, Banumathi V. Standardization of the drug Parangipattai chooranam–A Siddha herbal formulation. Int. J. Curr. Res. Chem. Pharm. Sci. 2018;5(8):10-9.
3. *Agathiyar pallu:Agathiyar : 165,B.Hakkim,pa. Muhamad sayabu, Muslim abhimani Achiyandira salai, Chennai-79: 1907.*
4. Shanthini R, Anbu N. Analysis of Heavy metal, Aflatoxin, Pesticide Residue and Microbial Contamination of Siddha Herbal Formulation Muppirandai Chooranam. World Journal of Current Medical and Pharmaceutical Research. 2023 Sep 13:163-7.
5. <https://www.slideshare.net/akshaykakde1/heavy-metal-analysis-in-herbal-formulation-by-akshay-kakde>.
6. Luciana de CASTRO. Determining Aflatoxins B1, B2, G1 and G2 in Maize Using Florisil Clean Up with Thin Layer Chromatography and Visual and Densitometric Quantification. Ciênc. Tecnol. Aliment. vol.21 no.1 Campinas. 2001.