

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**RAJYA SABHA
UNSTARRED QUESTION NO. 806
TO BE ANSWERED ON 30th July 2024**

“Heavy Metal Toxicity in Ayurvedic Medicines”

806. Dr. Fauzia Khan

Will the Minister of **Ayush** be pleased to state:

- (a) whether Government has conducted studies on heavy metal toxicity in Ayurvedic medicines to identify potential health risks associated with their consumption to assess the toxicity levels;
- (b) if so, the details thereof;
- (c) If not, the reason therefor;
- (d) whether Government has implemented mechanisms to flag instances of heavy metal toxicity in Ayurvedic medicine and to provide consumers with compensatory benefits regarding their safety and efficacy;
- (e) if so, the details thereof; and
- (f) if not, the reason therefor?

ANSWER

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAP RAO JADHAV)**

(a) to (c) Yes Sir. Details of the studies conducted on heavy metal toxicity in Ayurvedic medicines are as follows –

- (i) Central Council for Research in Ayurvedic Sciences (CCRAS), an autonomous body under the Ministry of Ayush has conducted preclinical studies on the safety of Ayurvedic formulations. Further, CCRAS has also conducted preclinical studies on some metal / mineral based Ayurvedic formulations (Rasaushadhis) to generate evidence on safety on scientific lines. The studies revealed safety of these formulations and outcomes of the studies are published. The details of Ayurvedic formulations for the safety and the research publications are at **Annexure I**.

(ii) Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar has conducted repeated dose Toxicity studies of more than 23 formulations and genotoxicity study of 08 formulations containing processed metals which in their raw form (not after recommended pharmaceutical processing and not in formulation) may have potential for toxicity. Institute has conducted repeated dose Toxicity studies of more than 08 formulations and its details are at **Annexure-II**.

(d) to (f) Yes Sir. Ministry of Ayush has implemented following mechanisms to flag instances of heavy metal toxicity in Ayurvedic medicine -

(i) Ministry of Ayush Government of India has established Pharmacopeia Commission for Indian Medicine and Homoeopathy (PCIM&H) as its subordinate office. PCIM&H on behalf of Ministry of Ayush lays down the formulary specification and Pharmacopeial standards for Ayurvedic medicine Drugs, which also include the prescribed limit of heavy metals as per the World Health Organisation (WHO) standards. These specifications and standards serve as official compendia for ascertaining the quality control (identity, purity and strength) of the Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, include herein, as per Drug and Cosmetic Act, 1940 and rules 1945, thereunder and compliance to these quality standards are mandatory for the production of ASU&H drugs being manufacturer in India. Implementation of these pharmacopeial standards insure that the medicines reaching to masses conform to optimum quality standards in terms of identity, purity and strength.

(ii) Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar runs Intermediate Pharmacovigilance Centre for Ayurveda medicine. Possible Adverse drug reactions, possible adverse drug events if any are monitored and recorded. Institute has National accreditation board of Hospitals (NABH) accredited hospital and complies with recommendations & guidelines for management of medication as per standards for Ayurveda Hospital by NABH.

(iii) Department of Rasa Shastra and Bhaishajya Kalpana, All India Institute of Ayurveda (AIIA), New Delhi is establishing safety, efficacy and toxicity of metallic and herbo-mineral preparations and has huge collection of such reports. Further a research activity on establishing safety of Swarna Makshika Bhasma is going on. Acute and chronic toxicity of Vata Gajankusha Rasa (containing Parada, Swarna Makshika, Loha, and Haratala),

Chandramruta Rasa (Parada, Abhraka), Hari Shankara Rasa (Abhraka, Rasa Sindhura) are being conducted.

(iv) Under pharmacovigilance program, there is a component for reporting adverse drug reaction where consumers if suffers from any such incidence of adverse drug reaction can report through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and 99 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. Each Centre (NPvCC, IPvCs&PPvCs) has provided with ADR reporting format and the healthcare professionals can lodge complaints either directly or through online portal: <https://www.ayushsuraksha.com>.

Further to generate awareness among the facts about AYUSH formulations, concerns being raised on possibility of metal toxicity, myths & facts in this relation; Pharmacovigilance is regularly organizing awareness programs among various cohorts of healthcare professionals and general population. Awareness programs focus upon generating awareness on usage of Ayush drugs and to inculcate reporting of suspected adverse reactions. Till date a total 1505 awareness programs has been conducted with 115283 beneficiaries.

A. List of metal mineral based Ayurvedic formulations (Rasaushadhis) on which council have conducted preclinical studies:

S.no.	Formulations	Bhasmas
1.	Dhatrilauha	Tamra Bhasma
2.	Mahalaxmivilas Rasa	Trivanga Bhasma
3.	MahayogarajGuggulu	Naga Bhasma
4.	Arogyavardhinivati	Swarna Bhasma
5.	Kajjali yoga	Kasisa Bhasma
6.	Makardhwaja	
7.	PunarnavaMandura	
8.	Rasa Sinura,	
9.	Vasant Kusumakar Rasa	
10.	Rasamanikya	
11.	Hridayarnava Rasa	
12.	Navaratna Rasa	
13.	ShvetaParpati	

B. List of publications by CCRAS:

1. Evidence based safety of Ayurvedic Herbo - Mineral formulations.
2. Evidence based safety of Ayurvedic Medicines.
3. Quality and Safety of Select Rasakalpa - Technical report (Arogyavardhinivati, MahayogarajGuggulu, Vasant Kusumakar Rasa &Mahalaxmivilas Rasa) Volume -1
4. Quality and Safety of Select Rasakalpa -Technical report (Rasamanikya, Makardhwaja, Kajjali& Rasa Sinura) Volume -2
5. Quality and Safety of Select Rasakalpa - Technical report (Hridayarnava Rasa). Volume - 3
6. Quality and Safety of Select Rasakalpa - Technical report. (TamraBhasma). Volume -4
7. Quality and Safety of Select Rasakalpa - Technical report. (Naga Bhasma). Volume -5
8. Quality and Safety of Select Rasakalpa - Technical report. (TrivangaBhasma). Volume-6
9. Quality and Safety of Select Rasakalpa - Technical report. (SwarnaBhasma). Volume -7
10. Quality and Safety of Select Rasakalpa - Technical report. (Makaradhwaja). Volume -8

Details of Toxicity studies and Genotoxicity studies conducted by ITRA -

A. Toxicity studies-

Repeated dose Toxicity studies

Rasasindura, (Sublimed Mercuric Sulphide), Makaradhwaja (Sublimed Mercuric Sulphide with gold), TamraBhasma (Processed (Calcined) Copper), Rasamanikya (Processed Arsenic trisulphide), Naga Bhasma (7Putra), Naga Bhasma (10 Putra), Naga Bhasma (30 and 60 Putra), MallaSindura (Sublimed Mercurial and Arsenical with and without Manahshila; additional arsenical), Rasakarpuradrava, Rasakarpura gel (formulation of Mercuric chloride), Hridayarnava Rasa, Tribhuvankirti Rasa, SwarnamakshikaBhasma (Processed Calcined, Copper pyrite) samples from 3 mines, Khetri, Hatti, Malanjkhanda), TrivangaBhasma, Sutshekhara Rasa, Anandbhairava Rasa, AgnitundiVati, PanchamritParpati, *Garbhapala Rasa*

Except 2 formulations, all formulations are found to be safe in animal model at therapeutic recommended dose.

B. Genotoxicity studies-*Rasasindura, Makaradhwaja, TrivangaBhasma, Naga Bhasma, Rasamanikya, Garbhapala Rasa, Rasaparpati, Shwasakuthara Rasa*

All formulations are found to be safe (devoid of genotoxicity potential) in animal model at therapeutic recommended dose.