

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)**

**LOK SABHA
UNSTARRED QUESTION NO.3988
TO BE ANSWERED ON 9TH DECEMBER, 2016**

QUALITY OF HERBAL MEDICINES

3988. SHRI ASHWINI KUMAR CHOUBEY:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) the details of research activities in Ayurveda which includes literary and conceptual study, clinical and therapeutic research, drug development including drug standardization during the last three years and the current year;
- (b) whether the use of ayurvedic HMPs (Herbal Medicinal Products), can cause lead toxicity and cause conditions like epilepticus, encephalopathy, sensory neural deafness etc., if so, the details thereof along with the preventive steps taken by the Government in this regard;
- (c) whether storage conditions can also affect the quality of herbal medicines, which may lead to loss of activity, fungal or bacterial contamination resulting into batch to batch variation;
- (d) if so, the steps taken by the Government to ensure the delivery of the same marketed formulation of ayurvedic HMPs; and
- (e) whether the Government has any mechanism to keep a check on adulteration of the ayurvedic products, if so, the details thereof?

**ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)**

- (a): The Ministry of AYUSH, Govt. of India has set up Central Council for Research in Ayurvedic Sciences (CCRAS) for undertaking coordinating, developing and promoting research on scientific lines in Ayurveda. The activities are carried out through 30 institute/Centres/Units located all over India. The Council also conduct research through collaborative studies with various universities, hospitals and institutes. The research activities of the council include medicinal plant research (Medico-ethno botanical survey, pharmacognosy and tissue culture), Drug Standardization Pharmacological Research, Clinical Research, Literary Research & Documentation, and other outreach activities.

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The details of activities by CCRAS related to the research during last three years and current year are at **Annexure.**

(b) to (d): There is a specific category of herbo-mineral or metallic Ayurvedic medicines called Rasaushadies or Rasa yoga. Many of such medicines make use of heavy metals like Mercury, Arsenic and Lead as ingredients after subjecting them to a series of processes called Shodana, Marana, Amritkaram etc. to render them safe and therapeutically effective. Heavy metals in Ayurvedic formulations are not present in free elemental forms but in complex compounds. It is the synergy of various ingredients and use of purification and detoxification techniques that makes the formulation compatible to the body system for therapeutic action with judicious consumption. Permissible limits of heavy metals are defined in the Ayurvedic Pharmacopoeia and are not applicable to Rasaushadhies.

No observations regarding storage conditions have been recorded by the CCRAS.

The Government has issued directions to the States and Central Government Health Scheme (CGHS) to accept supply of Ayurveda, Siddha, Unani And Homoeopathy (ASU&H) medicines with batch wise quality analysis from an approved laboratory/NABL accredited Laboratory.

Good Manufacturing Practices for Ayurveda, Siddha and Unani (ASU) drugs has been made mandatory for license of ASU drugs to ensure storage conditions should be free from fungal or bacterial contamination. In-house quality control section is also made mandatory for batch wise testing facility of ASU products.

(e): The Government of India has defined adulterated drugs under section 33 EE(Chapter IV-A) of the Drugs & Cosmetics Act, 1940.

Under Section 33-I, penalties have been prescribed, for manufacture, sale etc. of Ayurvedic, Siddha or Unani drug in contravention of the Act. State Drug Licensing Authorities are empowered to take action accordingly.

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Annexure

Details of activities of CCRAS during last three years

Collaborative Clinical Research

Under the Collaborative Clinical Research, one study on coded Ayurvedic drugs on Improvement in quality of life of Breast cancer patients has been concluded.

Drug Research Programme

Medicinal Plant Research

Medico-ethno-botanical survey conducted 58 tours in selected areas of 5 states. During the survey 83 museum samples, 1421.57 Kg raw drug collected and documented 677 folk claims. 41 new medicinal plants introduced in demonstrative gardens of Institutes. 3 Intra Mural Medicinal Plant Research projects have been completed

Drug Standardization

Under Drug Standardization, 92 singles drugs and 28 compound formulations have been carried out.

Pharmacological Research

Under this programme, 5 Intra Mural Pharmacological Research Projects have been completed.

Literary Research Programme

24 books have been published. Further 3 Intra Mural Literary Research projects have been completed.

AYUSH Research Portal - A web based portal for Research publication in AYUSH is successfully continued and the information being updated periodically. Till date 21839 scientific publications have been uploaded.

Outreach Activities

- **Tribal Health Care Research Programme**
Under tribal health care research programme, the Council has covered a population of 2,27,546. 450 folk claims/local health traditions (LHTs) have been documented.
- **Ayurvedic Mobile Health Care Research Programme under Scheduled Castes Sub Plan (SCSP)**
A total 51001 Scheduled Castes population surveyed, 105 villages/colonies covered.
- **Swasthya Rakshan Programme**
A total of 96 villages/colonies covered for providing medical aids to 24308 patients.
- Integration of AYUSH (Ayurveda) with National Programme for Prevention and control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) started in 3 districts Surendra Nagar (Gujarat), Bhilwara (Rajasthan) &Gaya (Bihar).

Patent and Commercialization

CCRAS has developed an anti-diabetic drug AYUSH-82 and the License has been granted through National Research Development Corporation (NRDC), New Delhi for its commercial production.