

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

**LOK SABHA
STARRED QUESTION NO. 358
TO BE ANSWERED ON THE 24TH MARCH, 2023**

COSMETIC PRODUCTS

***358. SHRI RAJENDRA DHEDYA GAVIT:**

Will the Minister of AYUSH be pleased to state:

- (a) whether the Government is aware that authoritative Ayurvedic texts are replete with references on cosmetic combinations which are supposed to have no side effects in comparison to chemical based cosmetic products available in the market;
- (b) if so, whether scientific studies followed by clinical trials have been conducted in this regard by the Government controlled or aided scientific research institutions of the country; and
- (c) if so, the details thereof and if not, the reasons therefor?

**ANSWER
THE MINISTER OF AYURVEDA, YOGA & NATUROPATHY, UNANI,
SIDDHA AND HOMOEOPATHY (AYUSH)**

(SHRI SARBANANDA SONOWAL)

(a) to (c) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 358* FOR 24TH MARCH, 2023**

(a) to (c) Yes Sir. Authoritative books of Ayurvedic system of medicines prescribed under first schedule of Drugs & Cosmetics Act, 1940 are replete with references on cosmetic combinations which may be used for cosmetic purposes. Some references from Ayurvedic Formulary of India (AFI), having indications of cosmetic purpose are as follows –

S.no.	Name of the Ayurvedic formulation	Reference
1.	<i>Kunkumadi taila</i>	AFI, Part-I, Second edition, page no. 131
2.	<i>Nilikadya taila</i>	AFI, Part-I, Second edition, page no. 139
3.	<i>Nilibhrngadi taila</i>	AFI, Part-I, Second edition, page no. 139
4.	<i>Kimsukadi taila</i>	AFI, Part-III, First edition, page no. 184

Ayurveda drug is defined under section 3(a) and 3 (h) (i) of Drugs & Cosmetics Act, 1940. Classical ayurvedic drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic system of medicine, as specified in the First Schedule of Drugs & Cosmetics Act, 1940. As per section 3 (h) (i) of Drugs & Cosmetics Act, 1940, Patent or proprietary medicine means, in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine of all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or UnaniTibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified under section 3 (a). Schedule I A of the Drugs & Cosmetics Act, 1940 comprises of 59 authoritative text books of Ayurvedic system of medicine.

As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is

vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.

Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines with respect to *Saundarya Prasadak* i.e. cosmetics. The person who applied for license is required to:-

- (i) Submit photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of Ist schedule;
- (ii) Conduct safety studies, in case the formulation contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda, Siddha and Unani formulation;
- (iii) For textual indications the safety and effectiveness study is not required.
- (v) For issue of license with respect to medicine Aushadh Ghana extract of medicinal plant (dry or wet).

<i>Sl. no.</i>	<i>Category</i>	<i>Ingredient (S)</i>	<i>Indication (s)</i>	<i>Safety study</i>	<i>Experience/Evidence of Effectiveness</i>	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1	(A) Aqueous	As per text	As per text	Not Required	Not Required	Not Required
2	(A1). Aqueous	As per text	New Indication* *	Not Required	Not Required	Required
3	(B) HydroAlcohol	As per text	As per text	Not Required	If Required	Not Required
4	(B1) HydroAlcho	As specified	New Indication* *	Required	If Required	Required
5	Other than Hydro/ HydroAlcohol	As specified	As specified	Required Acute, Chronic, mutagenicity and teratogenicity	If Required	Required

** New indication means which is other than mentioned in Ist schedule books of Drugs & Cosmetics Act 1940.]

Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals. The identified centers under this program report instances of misleading advertisements to the respective state licensing authorities for suitable action against the defaulters.

Department of Saundarya Ayurveda in National Institute of Ayurveda (NIA), Jaipur under Ministry of Ayush is running M.Sc. and short term regular course for awareness concept in Cosmetology. Till date, 93 academic research works with respect to Cosmetology (skin, hair, nail etc.) has been done in various departments of NIA.
