



Formularies containing monographs of quality standards of AYUSH drugs are being published by the Government: Shri Shripad Naik

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Ayurvedic, Siddha, Unani and Homoeopathic drugs are regulated in accordance with the exclusive provisions for them in the Drugs & Cosmetics Act, 1940 and Rules there under. These drugs have to adhere to such standards and quality control parameters as given in the authoritative books, pharmacopoeias and formularies of Ayurvedic, Siddha, Unani and Homoeopathic systems, which are different from that prescribed for allopathic medicines. Till date, monographs of quality standards of 645 single drugs & 202 compound formulations of Ayurveda, 298 single drugs & 150 compound formulations of Unani system, 139 single drugs of Siddha and 1117 monographs of Homoeopathic drugs have been published in the respective pharmacopoeias. Similarly, Ayurvedic Formulary contains 985 standardized formulations, Unani Formulary 1229 formulations and Siddha Formulary has 399 standardised formulations.

Under the provisions of Drugs & Cosmetics Rules, 1945, Good Manufacturing Practices and Quality standards prescribed in the respective pharmacopoeias are mandatory for the manufacturing of licensed Ayurvedic, Siddha, Unani and Homoeopathic medicines. In addition, two voluntary certification schemes for Ayurvedic, Siddha and Unani medicines are implemented respectively by the Quality Council of India for grant of AYUSH Standard & AYUSH Premium marks and quality certification of products as per WHO-GMP and COPP guidelines by the Central Drugs Standard Control Organization (CDSCO).

Appellate Laboratories for Indian Medicine and Homoeopathy under the provisions of Drugs & Cosmetics Rules, 1945 have reported testing of referred samples of Ayurvedic, Siddha, Unani and Homoeopathy drugs during last three years as under-

Year	Pharmacopoeial Laboratory of Indian Medicine		Homoeopathic Pharmacopoeial Laboratory	
	Samples tested	Samples failed	Samples tested	Samples failed
2014-15	11	04	401	142
2015-16	25	01	351	150
2016-17	37	01	387	49

The Appellate Laboratories after testing of the referred samples send the analysis reports to the concerned authority for necessary action. Regulation and Quality control of Ayurvedic, Siddha, Unani and Homoeopathic medicines is carried out by the State Licensing Authorities / Drug Controllers. As per the information made available from the States, 11889 samples of AYUSH medicines have been tested in 24 States during the period 2013-14 to 2015-16 out of which 254 samples failed in quality testing. State Licensing Authorities reported to have initiated appropriate actions against the samples not complying with the standards including issue of show cause notice, suspension /cancellation of license, recall of the concerned batch of medicines from the market and prosecution.

This information was given by the Minister of State (Independent Charge) for AYUSH, Shri Shripad Yesso Naik in written reply to a question in Lok Sabha today.

NB/SK/UD



