

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 3794
TO BE ANSWERED ON 11 AUGUST, 2023**

“PROMOTION OF QUALITY AYUSH DRUGS/PRODUCTS”

**3794 SHRI UPENDRA SINGH RAWAT:
MS. DEBASREE CHAUDHURI:**

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

- (a) whether there is any law to check and control the quality of the AYUSH drugs and products, if so, the details thereof and if not, the reasons therefor;
- (b) whether the Government proposes to promote quality AYUSH drugs and products on a larger scale in the country, particularly in Uttar Pradesh;
- (c) if so, the challenges faced by the Government this regard, particularly in Uttar Pradesh;
- (d) the details of the number of samples of AYUSH drugs and products received, tested and failed during the last five years and the current year, State/UT-wise, year-wise and stream-wise;
- (e) whether any malpractices have been detected in manufacturing of AYUSH drugs and products and if so, the details thereof along with the steps taken to improve their quality; and
- (f) the funds allocated for testing of AYUSH drugs and products?

**ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)**

- (a) The Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs and Cosmetics Rules, 1945. Further Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs and Cosmetics Rules, 1945 pertain to Homoeopathic drugs. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing

units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

(b) and (c) Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) throughout the Country including for Uttar Pradesh. The total financial allocation to this scheme is Rs. 122.00 crores for five years. The components of Scheme are as follows:

- A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
- B. Pharmacovigilance of ASU &H drugs including surveillance of misleading advertisements.
- C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.
- D. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

Detailed guideline is available at <https://main.ayush.gov.in/schemes-2/central-sector-scheme/aogusy-scheme/>

Further Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH Premium mark to Ayurvedic, Siddha and Unani products on the basis of third party evaluation of quality in accordance with the status of compliance to international standards.

Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) is mandated to lay down the Pharmacopoeial Standards and Formulary specifications for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included herein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder.

(d) The details of the number of samples of AYUSH drugs and products received, tested and failed during the last five years and the current year, State/UT-wise, year-wise and stream-wise are attached at Annexure-I.

(e) 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 Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Further As per the information received from State/UT's Licensing Authorities, the details of malpractices detected in manufacturing of AYUSH Drugs and products are attached at Annexure- II.

(f) No funds have been allocated specifically for testing of AYUSH drugs and products. However Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) and the total financial allocation to this scheme is Rs. 122.00 crores for five years. One of the components of the Scheme is to Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards, under which Recurring expenditure covers:

1. Upto 10 Contractual Technical manpower.
2. Chemicals and Reagents.
3. AMC of equipments which are funded under the scheme.

Annexure- I

1. PCIM & H

Year	System	Samples Collected	Not tested due to less qty., Broken etc.	Samples Tested	Samples Failed
2019-2020	Homoeopathy	618	19	599	11
	Ayurveda	37	01	36	09
	Siddha	00	00	00	00
	Unani	07	00	07	00
2020-21	Homoeopathy	310	07	303	01
	Ayurveda	25	00	25	03
	Siddha	00	00	00	00
	Unani	00	00	00	00
2021-22	Homoeopathy	1027	21	1006	46
	Ayurveda	02	00	02	00
	Siddha	00	00	00	00
	Unani	00	00	00	00
2022-23	Homoeopathy	249	06	243	06
	Ayurveda	28	03	25	21
	Siddha	00	00	00	00
	Unani	03	00	03	00
2023-till date	Homoeopathy	00	00	00	00
	Ayurveda	01	00	01	01
	Siddha	00	00	00	00
	Unani	00	00	00	00

Sr. No.	States/UTs	Information			
		Year	Samples Collected	Samples Tested	Samples Failed
1.	Delhi	2017-18	2372	2372	15

		2018-19	449	449	09
		2019-20	1005	1005	15
		2020-21	540	540	14
		2021-22	433	433	14
		2022-23 (till date)	335	335	03
2.	Karnataka	Year	Samples Received	Samples Tested	Samples Failed
		2019-20	976	959	57
		2020-21	779	742	59
		2021-22	852	460	00
		2022-23	720	348	08
		2023-till date	335	97	00
3.	Kerala	Year	Samples Collected	Samples Tested	Samples Failed
		2018	938	938	55
		2019	719	719	28
		2020	308	308	15
		2021	391	391	13
		2022	531	531	36
		2023 (data till the month of June)	230	230	15
4.	Odisha	Year	Samples Received (A & H)	Samples Tested (A & H)	Samples Failed (A & H)
		2018-19	542	542	102
		2019-20	753	753	58
		2020-21	2176	2176	844
		2021-22	2073	2073	329
		2022-23	1635	1635	304
5.	Assam	Year	Samples	Samples	Samples Failed

			Received	Tested							
		2017-18	101	111	00						
		2018-19	174	161	00						
		2019-20	92	74	01						
		2020-21	230	115	27						
		2021-22	117	175	14						
		2022-23	64	137	02						
		2023-21/07/2023	152	64	17						
6.	Tamilnadu	Year	Samples Tested			Samples Failed					
			Ayurveda	Unani	Siddha	Ayurveda	Unani	Siddha			
		2018	388	31	685	23	00	27			
		2019	1264	152	2032	27	01	06			
		2020	675	41	1009	18	00	05			
		2021	533	37	1176	26	00	05			
		2022	1100	91	1539	15	01	05			
		2023 (Up to july)	495	41	845	01	00	01			
7.	Manipur	Year	Samples Collected			Samples Tested			Samples Failed		
			A.	U.	H.	A.	U.	H.	A.	U.	H.
		2019	07	01	35	07	01	35	00	00	01
		2020	00	00	16	00	00	16	00	00	01
		2021	07	03	00	07	03	00	00	00	00
		2022-23	00	00	00	00	00	00	00	00	00
8.	Rajasthan	Year	Samples Collected			Samples Tested			Samples Failed		
		2019-20	193			181			36		
		2020-21	736			537			99		
		2021-22	613			639			84		

		2022-23	581	549	39
		2023-till date	146	145	22
9.	Goa	Year	Samples Collected	Samples Tested	Samples Failed
		2018-19	01	01	NIL
		2019-20	29	07	NIL
		2020-21	58	29	NIL
		2021-22	70	75*	NIL
		2022-23	202	227*	01
		04/2023-07/2023	30	47*	01
		(* -Extra samples analysed are the samples carried forward from the previous years)			
10.	Gujarat	Year	Samples Tested	Samples Failed	
		2018-19	304	17	
		2019-20	97	00	
		2020-21	408	70	
		2021-22	71	12	
		2022-23	172	12	
11.	Haryana	Year	Samples Tested	Samples Failed	
		2018-19	240	11	
		2019-20	799	42	
		2020-21	1038	54	
		2021-22	600	43	
		2022-23	1133	59	
12.	Uttarakhand	Year	Samples Tested	Samples Failed	
		2018-19	199	06	
		2019-20	74	08	
		2020-21	114	09	
		2021-22	55	15	

		2022-23	116	16
		2023-till date	32	01
13.	Mizoram	Year	Samples Tested	Samples Failed
		2019-june 2023	1574	38
14.	Himachal Pradesh	Year	Samples Tested	Samples Failed
		2018-19	385	23
		2019-20	462	50
		2020-21	404	27
		2021-22	443	31
		2022-23	816	53
15.	Andhra Pradesh	Year	Products Received, tested	
		2018-19	108	
		2019-20	16	
		2020-21	176	
		2021-22	17	
		2022-23	07	
16.	West Bengal	Year	Products Received, tested	
		2017-22	NIL	
		2022-23	08	
17.	Chandigarh	Year	Sample Collected	
		2022	01	

Annexure- II

Sr. No.	States/UTs	Malpractices detected			
1.	Andhra Pradesh	NIL			
2.	Delhi	NIL			
3.	Gujarat	Year	Product	Reason	Action Taken
		2019	Without Licence Ayurvedic Product Manufactured-V inubhai Kantibhai Patel Gandhinagar	Without Licence Ayurvedic Medicine Manufactured	Court Case Launched
		2020	Krish Hand Sanitizer Gel	The Does Not Show Presence Of Isopropyl, Alcohol & The Sample Shows Presence Of Methanol	Product Permission Cancelled
			Collage G7 Hand Sanitizer	Nil	Product Permission Cancelled
		2021	NIL		
		2022	Relaxo Mood Support 500 Ml	Herbal Sample Contains 20.27% Ethyl Alcohol	Investigation is going on.
			Relaxo Mood Support 250 Ml	Herbal Sample Contains 22.34% Ethyl Alcohol	Investigation is going on.
			Tulsi Santra-Ashva Herbal Tonic	The Sample Contains 13.38 percent V/V Ethyl Alcohol.	Investigation is going on.
		2023	NIL		
4.	Kerala	The drugs that were tested Not of Standard Quality were subjected to departmental action and in serious offences such as			

		detection of allopathic drugs prosecution was initiated.
5.	Rajasthan	Action is taken as per rules against the producer firm, when the samples found Sub-standard.
6.	Goa	NIL
7.	Haryana	-
8.	Karnataka	NIL
9.	Mizoram	NIL
10.	Odisha	NIL
11.	Puducherry	NIL
12.	Tamilnadu	-
13.	Uttarakhand	NIL
14.	West Bengal	NIL
15.	Himachal Pradesh	NIL
16.	Chandigarh	NIL
