

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**RAJYA SABHA
UNSTARRED QUESTION NO. 1767
TO BE ANSWERED ON 02ND AUGUST, 2022**

QUALITY CONTROL OF AYUSH DRUGS

**1767 SHRI ABIR RANJAN BISWAS:
DR. SANTANU SEN:**

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

- (a) whether there is a specific law to control the quality of the AYUSH drugs and products;
- (b) if not, the reasons therefor;
- (c) the details of the number of AYUSH drug and product samples tested in the last five years, year-wise and State-wise;
- (d) the details of action taken against the manufacturers of failed samples, year-wise and State-wise; and
- (e) whether separate funds were allocated for AYUSH drugs and products testing?

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

(a) and (b) Sir, 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 and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathic medicines. 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.

Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate office under Ministry of Ayush lays down Pharmacopocial Standards and Formulary specifications for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs within the ambit of Drugs & Cosmetics Act, 1940, which serve as official compendia for ascertaining the quality of the drugs included therein. Further, PCIM&H as an appellate drug testing laboratory receives the samples from Government agencies as per Drugs & Cosmetics Act & Rules there under for ascertaining their quality.

(c) Details of the number of AYUSH drug and product samples tested by PCIM&H is as follows -

S. No.	Name of the State/UT	Year-wise no. of samples of ASU&H tested by PCIM&H					
		2017-2018	2018-19	2019-20	2020-21	2021-22	April 2022 to 13.07.2022
1.	Bihar	03	-	01	03	-	-
2.	Delhi	211	466	252	51	319	08
3.	Gujarat	02		-	-	-	-
4.	Karnataka	46	09	20	-	-	-
5.	Maharashtra	66	26	04	10	03	20
6.	Odisha	58	69	43	09	220	12
7.	Punjab (Chandigarh)	04	-	79	-	-	62
8.	Rajasthan	88	-		-	-	76
9.	Uttar Pradesh	05	05	02	-	01	-
10.	Uttrakhand	03	08	37	08	132	06
11.	West Bengal	39		02	01	18	05
12.	Arunachal Pradesh	-	04	-	03	-	-
13.	Goa	-	02	06	-	-	-
14.	Jharkhand	-	36	22	58	14	02
15.	Rajasthan	-	71	132	143	287	-
16.	Tripura	-	45	-	-	02	-
17.	Kerala	-	-	03	-	-	01
18.	Madhya Pradesh	-	-	01	-	-	-
19.	Manipur	-	-	39	39	-	-
20.	Andaman & Nicobar	-	-	-	-	05	-
Total		525	741	643	324	1008	192

As per the information received from State/ UT Governments, list of Ayush drug and product samples tested in the last five is as follows –

S.no.	Name of the State/UT	Information received from State/ UT Governments regarding Ayush drug samples tested in the last five					
		2017-18	2018-19	2019-20	2020-21	2021-22	2022-till date
1.	Manipur	NIL	NIL	38	16	33	-
2.	Chhattisgarh	333	693	511	376	566	-
3.	Goa	10	01	07	29	75	54
4.	Odisha	967	451	2506	1969	2672	-
5.	Himachal Pradesh	590	38	462	404	443	-
6.	Arunachal Pradesh	155	145	161	172	96	-
7.	Tamil Nadu	1754	1104	3448	1725	1746	-
8.	Kerala	483	938	719	308	244	-
9.	Andhra Pradesh	101	07	16	164	25	-
10.	Karnataka	1014	882	1706	1259	416	-
11.	Andaman & Nicobar	NIL	NIL	NIL	NIL	10	
12.	Gujarat	302	304	97	408	71	-
13.	Maharashtra	259	443	406	167	458	115 (from 01.04.20 22 to 30.06.20 22)
14.	Madhya Pradesh	290	265	05	521	353	482
15.	Uttar Pradesh	0	09	37	54	89	-
16.	Puducherry	NIL					

(d) As per the information received from State/ UT Governments, the details of action taken against the manufacturers of failed samples is at **Annexure-I**.

(e) Yes Sir, Under Centrally Sponsored Scheme of National Ayush Mission (NAM) as per the proposals received from State/UT Governments through their State Annual Action Plans, an amount of Rs. 10723.14 Lakhs has been approved under the component of quality control of Ayurveda, Siddha, Unani & Homeopathy drugs (ASU&H drugs) for different activities including quality testing of drugs from the year 2014-15 to 2019-20.

Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY). The objectives of the Scheme are as under;

- i. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.
- ii. To facilitate adequate infrastructural & technological upgradation and institutional activities in public and private sector for standardization, quality manufacturing and analytical testing of Ayush drugs & materials.
- iii. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
- iv. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

The components of the AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) Scheme are as under;

- 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.

AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) was approved by Standing Finance Committee (SFC) on 16.03.2021. The total financial allocation to this scheme is Rs 122.00 crores for five years.

Annexure-I

S.no.	Name of the State/UT	Information received from State/ UTs regarding details of action taken against the manufacturers of failed samples					Action Taken
		2017-18	2018-19	2019-20	2020-21	2021-22	
1.	Manipur	-	-	-	-	-	A testing report from PCIM&H was found that Calendula Q manufactured by Kerala State Homoeopathic Co-operative Pharmacy Ld. is "Not of Standard Quality" and a memorandum has been sent to Managing Director, Kerala State HOMCO Ltd. to take appropriate immediate necessary action.
2.	Chhattisgarh	06	07	04	01	03	From 2017 to 2022 regarding not of standard quality ASU&H drugs, 12 ASU&H drug license are under sub-judice, 03 manufactures license suspended, 03 warning issued to manufacturer and 03 samples are under process.
3.	Odisha	29	04	255	03	08	1. Show Cause have been issued. 2. Product recalls have been made. 3. Payment has been withheld for failed samples and specific batches have been replaced by the manufactures.
4.	Himachal Pradesh	61	23	50	27	31	Action against the defaulters has been taken as per the provisions of Drugs & Cosmetic Act 1940 and Rules thereunder.
5.	Tamil Nadu *	25	30	30	03	04	
6.	Kerala	26	55	28	15	06	Prosecution initiated for 17 manufactures and department action (drug recall, Product suspension/ cancellation) for 113 manufactures.
7.	Andhra Pradesh	05	NIL	NIL	NIL	04	Manufacturing license of manufacturing units were cancelled
8.	Karnataka	70	79	32	34	22	Stoppage of further sale and recall of batch of the drugs from the market, Manufacturer was asked to

							intimate stock and distribution details of the particular batch. Explanation sought from the manufacturer. Issue of show cause notices and initiated administrative action.
9.	Gujarat	13	17	0	70	12	In 2019-20, 10 licenses suspended and 09 warning issued. In 2020-21, 03 license suspended and 36 P.P W & license suspended. In 2021-22, 02 license suspended and 03 P.P W & license suspended.
10.	Maharashtra	16	17	13	20	16	From 2017 to 2022, till date - 63 prosecution order issued, 19 prosecution filed and 44 samples are pending .
11.	Madhya Pradesh	Show cause notices issued and withdraw such batch medicine from market.					
12.	Andaman & Nicobar	The action against one failed sample of Homeopathy medicine of M/s Goa Antibiotics Ltd. is under process as per the provisions of Drugs & Cosmetics Act 1940 and Rules thereunder.					
13.	Uttar Pradesh	NIL					
14.	Arunachal Pradesh	NIL					
15.	Puducherry	NIL					
16.	Goa	NIL					

*No. of suspension/ cancellation