

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**LOK SABHA  
UNSTARRED QUESTION NO. 31  
TO BE ANSWERED ON 02<sup>nd</sup> February, 2024**

**“Indigenous Medicines”**

**31. SHRI SANJAY JADHAV:  
SHRI VINAYAK RAUT:**

- (a) the details of the indigenous medicines pending approval during the last five years and the current year along with the names of said medicines and the diseases for which the said medicines are effective;
- (b) whether the applications regarding several medicines are pending with the Government for a long time;
- (c) if so, the details thereof along with the reasons therefor;
- (d) the list of AYUSH medicines approved, disapproved and pending approval during the last five years and the current year;
- (e) the details of the researches/experiments conducted to invent new medicines; and
- (f) the details of the AYUSH drug testing centres in the country, State/UT-wise and location-wise?

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

(a) to (c) 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. 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 Homoeopathy 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.

As per the information received from State/UT government, the details of the indigenous medicines pending for approval during the last five years and the current year are at **Annexure I**.

(d) Central Council for Research in Homoeopathy (CCRH) under Ministry of Ayush has approved 03 new indigenous drugs i.e. *Coleus forskohlii*, *Catharanthus roseus* and *Adansonia digitata* during the last five years.

As per the information received from State/UT government, the details of medicines approved, disapproved and pending approval during the last five years and the current year are at **Annexure-II**.

(e) Central Council for Research in Ayurvedic Sciences (CCRAS) under Ministry of Ayush has undertaken research for development of Ayurvedic drugs through systematic process of Drug Development viz. standardization, quality control, safety/ toxicity studies and clinical studies adopting prevalent guidelines in vogue as per requirement. Details are at **Annexure III**.

Central Council for Research in Unani Medicines (CCRUM) under Ministry of Ayush has conducted various researches to invent new medicine/ technique. Based on the innovations, CCRUM has got 18 patents from the Indian Patent Office.

Central Council for Research in Homoeopathy (CCRH) under Ministry of Ayush has conducted homoeopathic pathogenetic trials/ Drug proving trials to determine the pathogenetic effects of 03 new drugs i.e. *Coleus forskohlii*, *Catharanthus roseus* and *Adansonia digitata*.

(f) Pharmacopoeia Commission of Indian Medicine & Homoeopathy (PCIM&H), Ghaziabad, a sub-ordinate office under Ministry of Ayush, acts as Central Drug Testing cum Appellate Laboratory for testing of Ayurveda, Siddha, Unania and Homoeopathy drugs.

Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani

drugs. As on date, 34 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 106 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials. Details of the State Drug Testing Laboratories and Private Drug testing laboratories licensed under the provisions of Drugs and Cosmetics Rules, 1945 are available at [https://ayush.gov.in/images/domains/quality\\_standards/StateDrugTestingLaboratoryASUHEng](https://ayush.gov.in/images/domains/quality_standards/StateDrugTestingLaboratoryASUHEng). and [https://ayush.gov.in/images/domains/quality\\_standards/ListofAyurvedaSiddhaUnani.pdf](https://ayush.gov.in/images/domains/quality_standards/ListofAyurvedaSiddhaUnani.pdf).

\*\*\*\*\*

## Annexure-I

Details of the indigenous medicines pending approval during the last five years and the current year are as follows -

S.no.	Name of the State/ UT	Details of the indigenous medicines pending approval during the last five years and the current year	Reasons																																							
1.	Karnataka	<p>Following 12 applications for product approval are pending since 02 years –</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Sl. No.</th> <th>Name of the Medicine</th> <th>Name of the Disease</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Charma Kleshari taila</td> <td>Tvakroga</td> </tr> <tr> <td>2</td> <td>Kesha samruddini taila</td> <td>keshiya</td> </tr> <tr> <td>3</td> <td>Madhu nivaran choorna</td> <td>madhumeha</td> </tr> <tr> <td>4</td> <td>Tridosaha nivarana choorna</td> <td>Tridosha prakopa</td> </tr> <tr> <td>5</td> <td>Vedana kleshari taila</td> <td>Vedanahara</td> </tr> <tr> <td>6</td> <td>Swastharakshak lep</td> <td>Tvaksnehi</td> </tr> <tr> <td>7</td> <td>Varam Herbals Hand Sanitizer liquid</td> <td>Krimihara</td> </tr> <tr> <td>8</td> <td>Varam Herbals disinfectant spray</td> <td>Krimihara</td> </tr> <tr> <td>9</td> <td>Rise and Shine</td> <td>Madathyaa</td> </tr> <tr> <td>10</td> <td>Medohar tablet</td> <td>Medoroga</td> </tr> <tr> <td>11</td> <td>Immune Prime tablet</td> <td>Rasayana</td> </tr> <tr> <td>12</td> <td>Tulasi bathing powder</td> <td>Snana Churna</td> </tr> </tbody> </table>	Sl. No.	Name of the Medicine	Name of the Disease	1	Charma Kleshari taila	Tvakroga	2	Kesha samruddini taila	keshiya	3	Madhu nivaran choorna	madhumeha	4	Tridosaha nivarana choorna	Tridosha prakopa	5	Vedana kleshari taila	Vedanahara	6	Swastharakshak lep	Tvaksnehi	7	Varam Herbals Hand Sanitizer liquid	Krimihara	8	Varam Herbals disinfectant spray	Krimihara	9	Rise and Shine	Madathyaa	10	Medohar tablet	Medoroga	11	Immune Prime tablet	Rasayana	12	Tulasi bathing powder	Snana Churna	12 applications are pending due to non-submission of documents as per Rule 158B, 161B & 169.
Sl. No.	Name of the Medicine	Name of the Disease																																								
1	Charma Kleshari taila	Tvakroga																																								
2	Kesha samruddini taila	keshiya																																								
3	Madhu nivaran choorna	madhumeha																																								
4	Tridosaha nivarana choorna	Tridosha prakopa																																								
5	Vedana kleshari taila	Vedanahara																																								
6	Swastharakshak lep	Tvaksnehi																																								
7	Varam Herbals Hand Sanitizer liquid	Krimihara																																								
8	Varam Herbals disinfectant spray	Krimihara																																								
9	Rise and Shine	Madathyaa																																								
10	Medohar tablet	Medoroga																																								
11	Immune Prime tablet	Rasayana																																								
12	Tulasi bathing powder	Snana Churna																																								
2.	Maharashtra	35 applications are pending for more than one year. (as per information from fdamfg.maharashtra.gov. in software)																																								
3.	Odisha	NIL																																								
4.	Mizoram	NIL																																								
5.	Delhi	NIL																																								
6.	Tripura	NIL																																								
7.	Arunachal Pradesh	NIL																																								
8.	Uttarakhand	NIL																																								

9.	Jammu & Kashmir	NIL
10.	Puducherry	NIL
11.	Gujarat	NIL
12.	Goa	NIL
13.	Ladakh	NIL
14.	Meghalaya	NIL
15.	Uttar Pradesh	NIL
16.	Himachal Pradesh	NIL
17.	Andaman & Nicobar	NIL

**Annexure-II**

State/UT-wise details of medicines approved, disapproved and pending for approval -

S.no.	Name of the State/UT	Details of medicines approved, disapproved and pending for approval			
1.	Karnataka	4650 medicines has been approved, 88 medicines disapproved and 12 applications are pending.			
2.	Odisha	<b>Year</b>	<b>Ayurvedic medicines approved</b>	<b>AYUSH medicines rejected/ disapproved</b>	<b>AYUSH medicines pending for approval</b>
		2020	152	10	NIL
		2021	231	8	NIL
		2022	381	1	NIL
		2023	189	NIL	NIL
2024	NIL	NIL	NIL		
3.	Uttarakhand	<ul style="list-style-type: none"> <li>In year 2018-19, approximately 2000 Ayurvedic Patent &amp; Proprietary Products approved, no medicine is disapproved and pending.</li> <li>In year 2019-20, approximately 2700 Ayurvedic Patent &amp; Proprietary Products approved, no medicine is disapproved and pending.</li> <li>In year 2020-21, approximately 3000 Ayurvedic Patent &amp; Proprietary Products approved, no medicine is disapproved and pending.</li> <li>In year 2021-22, approximately 2500 Ayurvedic Patent &amp; Proprietary Products approved, no medicine is disapproved and pending.</li> <li>In the year 2022-23 approximately 2700 Ayurvedic Patent &amp; Proprietary Products approved, no medicine is disapproved and pending.</li> <li>In current year 2023-24 approximately 1500 Ayurvedic Patent &amp; Proprietary Products approved, 10 medicines are disapproved and no medicine is pending for approval.</li> </ul>			
4.	Uttar Pradesh	No medicine is disapproved and pending for approval during the last five year and current year.			
5.	Maharashtra	From 2018 to till date, 36425 Ayush medicines approved, 4025 Ayush medicines disapproved/ rejected and 502 are pending. (as per information from fdamfg.maharashtra.gov.in software)			
6.	Goa	<b>Year</b>	<b>Approved</b>	<b>Disapproved</b>	<b>Pending</b>
		2018-19	9	NIL	NIL
		2019-20	57	NIL	NIL
		2020-21	45	NIL	NIL
		2021-2022	36	NIL	NIL
		2022-2023	16	NIL	NIL
		2023-24 (till July)	06	NIL	NIL
7.	Ladakh	NIL			
8.	Jammu &	NIL			

	Kashmir							
9.	Arunachal Pradesh	NIL						
10.	Puducherry	NIL						
11.	Tripura	NIL						
12.	Delhi	System of medicine	No. of classical medicine			No. of Proprietary Medicine		
			Approved	Disapproved	Pending	Approved	Disapproved	Pending
		Ayurveda	1695	NIL	NIL	1862	NIL	NIL
		Unani	2053	NIL	NIL	615	NIL	NIL
13.	Himachal Pradesh		<b>Year</b>	<b>Approved</b>	<b>Disapproved/Rejected</b>	<b>Pending</b>		
			2021	755	80	NIL		
			2022	451	80	NIL		
			2023	886	108	NIL		
14.	Mizoram	NIL						
15.	Meghalaya	No manufacturing unit in the state of Meghalaya						
16.	Gujarat	No. of Ayurveda medicine applications approved from 1 <sup>st</sup> jan 2022 to till date are 7113, no. applications disapproved are 141 and no. of applications pending is 38.						
17.	Andaman & Nicobar	NIL						

**Annexure-III**

**Details the researchers / experiments conducted by CCRAS to invent new medicines are as follows -**

A. List of some important drugs developed by CCRAS since inception:

<b>S. No.</b>	<b>Name of the Drug</b>	<b>Indication</b>
1.	AYUSH -64	(i) Malaria (ii) Mild to moderate Covid-19
2.	AYUSH-56	Epilepsy
3.	AYUSH-82	Diabetes Mellitus
4.	NIMBATIKTAM	Psoriasis and Duodenal ulcer
5.	AYUSH POSHAK YOGA AND PEYA	Immunomodulatory, Antistress and General Health Promotion
6.	SHUNTHI GUGGULU	Rheumatoid Arthritis (Amavata)
7.	KSHARASUTRA	Ano Rectal Disorders
8.	AYUSH BALARASAYANA	Promotion of Health in Children
9.	AYUSH GHUTTI	Prevention of Diarrhoea and Fever in Children
10.	AYURVEDIC FORMULATIONS	Antenatal Care

B. Drugs under development by CCRAS

<b>Name of the Drugs under Drug Standardization</b>	<b>Name of the drugs in under pre-clinical safety toxicity study</b>	<b>Name of the drugs in under clinical study</b>	<b>Name of the drug with completed Clinical study</b>
1. Ayush–Manas AYUSH–AG AYUSH – PG	1. Ayush-HR	1. Ayush – M3 – Migraine and Hypertension	1. AyushPJ-7 - Dengue
2. AYUSH – 56	2. Ayush-SDM tablet	2. Ayush – A – Asthma	2. AyushQOL-2C – Quality of life in Cancer patients
3. AYUSH-HR	3. Ayush-PK Avaleha	3. Ayush – SR – Occupational	3. Ayush Rasayan A&B – Geriatric Health



		Stress	
4. AYUSH-64		4. Ayush – PTK – ATT induced Hepatotoxicity	4. Ayush – PE Eye Drops – Conjunctivitis
5. AYUSH-SG	4. Ayush-SS granules	5. Ayush – GMH – Non alcoholic fatty liver diseases	5. C-1 oil for Wound healing
6. AYUSH Ghutti	5. Ayush-LND	6. Ayush – HR – Pre Hypertension	6. Ayush – D – Pre Diabetes and Diabetes
7. AYUSH KVM Syrup	6. AYUSH-64	7. Ayush BR Leham in moderate malnutrition	7. Ayush – SL – Filariasis
8. AYUSH – M3	7. AYUSH SG-5	8. Ayush RP-Sickle Cell Anemia	8. Ayush – 64 (Repurposing) –(i) Malaria (ii)Mild to Moderate Covid – 19
9. AYUSH–SS Granules	8. AYUSH-V13	9. Carctol S – Serologically relapsed Ovarian Cancer	9. Ayush – AGT – Dandruff
10. AYUSH-SC3	9. AYUSH V-24	10. Ayush Manas- Cognitive Deficit	10. Ayush – AGT – Wound healing
11. AYUSH-SR	10. Padmakanta Yoga		11.Ayush CCT – postoperative cardiac care
12. AYUSH-PTK	11. Ayush-PTK		12. AyushSS granules - Lacatation insufficiency
13. AYUSH-GMH			13.Ayush LND - Abnormal Uterine Bleeding (AUB)
14. AYUSH-PVK Gel			14.Ayush PVK gel –Shweta Pradara (Leucorrhoea)
15. AYUSH– NT Capsule			15.Ayush NT Capsule- Psoriasis
16. AYUSH – LK Gel			
17. AYUSH - SL			
18. AYUSH-D			
19. AYUSH- Carctols			
20. AYUSH-CCT			
21. AYUSH-82			
22. AYUSH-AGT			