GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 1077
TO BE ANSWERED ON 24th JULY 2026

Standardisation of AYUSH Medicines

1077. Shri Kuldeep Indora:
Shri Rahul Kaswan:
Shri Sanjna Jatav:

Will the Minister of AYUSH be pleased to state:

(a) the details of the projects undertaken, expenditure incurred and key achievements of the standardisation, quality testing, clinical trials, pharmacovigilance and scientific validation of AYUSH medicines during the last five years;
(b) whether the Government has conducted any independent or third Party assessment of the quality, purity and standardisation of AYUSH medicines, as well as the quality of products available in the market, if so, the key findings thereof;
(c) the details of the action taken by the Government against AYUSH medicine manufacturers who violated quality standards, the licences cancelled and the products recalled during the last five years, State/UT-wise, particularly from the districts under Bharatpur Parliamentary Constituency; and
(d) whether the Government is implementing any new action plan to develop world-class quality standards for AYUSH medicines and enhance their acceptance in the international market and if so, the details thereof?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a) Following activities are being undertaken by the ministry for standardization, quality testing, clinical trials, pharmacovigilance and scientific validation of Ayush medicines-

- Under Central Sector Scheme Ayush Oushadhi Gunavatta Evam Uttpadan Samvardhan Yojana (AOGUSY), support is being provided to Ayush Pharmacies and Drug Testing Laboratories both Government and Private, including MSMEs to achieve higher standards like WHO-GMP & NABL respectively. During last five years a total no. of 18 Pharmacies i.e. 08 Govt. 10 Pvt. and 07 DTLs i.e. 06 Govt. 01 Pvt. have been supported with a total funding of Rs. 40.85 Cr.

- To strengthen Central and State regulatory frameworks, support is being rendered for hiring Technical Human Resource & Capacity Building programs for Ayush drugs for Ayush Directorate/State Licensing authorities under AOGUSY Scheme. Further, Ayush vertical under CDSCO is also being supported for conducting training and capacity building programs. Three capacity building training programmes have been conducted so far.
- The Pharmacovigilance Program for Ayush drugs under AOGUSY scheme functions through a nationwide three-tier network comprising 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvCs), and 97 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. These centres are mandated to monitor suspected adverse drug reactions and report the misleading advertisements to the respective State Regulatory Authorities for suitable action against the defaulter(s). The brief details are attached at Annexure-I. Further, through this program, various stakeholders across the country are sensitised towards the quality of medicines, posologies and other drug-related issues. Brief details are attached at Annexure-II. For Pharmacovigilance program, a total of Rs. 26.97 Cr. has been released under the AOGUSY scheme.
- Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a sub-ordinate organization under Ministry of Ayush, lays down the formulary specifications and pharmacopeial standards for Ayush drugs, which serves as official compendia for ascertaining the quality (identity, purity and strength) of the Ayush drugs. As per the Drugs & Cosmetics Act, 1940 and rules made thereunder, the compliance to this quality standards are mandatory for manufacturing of Ayush drugs. PCIM&H also acts as the Appellate Drugs testing Laboratory for testing or analysis of Ayush Drugs. In addition, it conducts capacity-building trainings at regular intervals for the standardization, quality control, and testing or analysis of Ayush drugs for Drug Regulatory Authorities, Drug Analysts, and other relevant stakeholders, with a focus on laboratory techniques and methodologies essential for ensuring the quality of Ayush drugs. Standards developed by PCIM&H during last five years is furnished at Annexure-III.
- Ministry of Ayush has set up Research Councils for undertaking, coordinating, formulating, developing, and promoting research on scientific lines in Ayush sciences. The research activities of the Councils include Clinical Research, Drug Standardization, Pharmacological Research, Medicinal Plant Research, Literary Research & Documentation programme, Fundamental research, pharmaceutical research and Public Health Research. Central Council for Research in Ayurvedic Sciences (CCRAS) has generated scientific evidence of clinical efficacy and safety of 192 classical Ayurveda formulations for 42 disease conditions through clinical trials.

(b) An independent third-party evaluation of the Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY), which aims to strengthen quality and standardisation of Ayush medicines has been conducted by Quality Council of India. The evaluation reported that it has strengthened quality assurance, standardisation, and regulatory compliance by supporting Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards like WHO-GMP and NABL respectively.

(c) As per the information received from States/UTs, the details of action taken by the State/UT Licensing Authorities including Samples collected/recalled, licences cancelled etc during the last five years including Bharatpur Parliamentary Constituency are furnished at Annexure-IV.

(d) Ministry of Ayush has launched Ayush Quality Mark (AQM) initiative through the Ayush Export Promotion Council (AYUSHEXCIL). Under this framework, the Ayush Quality Mark is being granted after scrutiny and verification of valid quality certifications and statutory approvals issued by the competent Government authorities, such as WHO-GMP, Ayush Premium Mark and other recognised certifications, as applicable. The initiative aims to strengthen quality assurance, enhance consumer confidence, and improve the credibility and Global competitiveness of Ayush products.

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Annexure-I

The brief details of misleading advertisements and suspected adverse drug reactions and reported by Pharmacovigilance Centres are as follows-

Year	Misleading Advertisements	Suspected ADR's
2018	411	-
2019	4395	298
2020	6032	279
2021	8187	360
2022	7371	324
2023	7771	420
2024	10161	521
2025	16129	728
2026 (Upto June 2026)	8194	409
Total	**68651**	**3339**

Annexure-II

The brief details of no. awareness Program conducted, and no. of Beneficiaries attended are as follows-

Year	Awareness Program	Beneficiaries
2018	1	50
2019	54	800
2020	60	4300
2021	118	14659
2022	292	23510
2023	586	43396
2024	1065	105148
2025	1483	134897
2026 (Upto June 2026)	506	44717
Total	**4165**	**371477**

Annexure-III

Standards developed by PCIM&H during last five years

AYURVEDA PHARMACOPOEIAL PUBLICATION

Publication	Part	Volume & Year	Number of Monographs
Ayurvedic Pharmacopoeia of India	Part 1 (Single Drugs)	Vol. X, 2022 (Minerals & Metals)	20
	Part II (Formulations)	Pharmacopocial Monograph of Ayush Kvatha Curna (Stand-alone) 2021	01
		Vol. V, 2025	21
Supporting Pharmacopoeial Publications	Thin Layer Chromatography (TCL) Atlas	API Drugs Pt. I, Vol. II, 2024	42

Publication	Part & Year	Number of Formulations
Ayurvedic Formulary of India	Formulary specification of Ayush Kvatha Churna (Stand-alone) 2021	01
	Part IV, 2022 (Veterinary)	50

SIDDHA PHARMACOPOEIAL PUBLICATIONS

Publication	Part	Volume & Year	Number of Monographs
Siddha Pharmacopoeia of India	Part II (Formulations)	Pharmacopocial Monograph of Ayush Curanam (Stand-alone) 2021	01

Publication	Part & Year	Number of Formulations
Siddha Formulary of India	Part I Revised (Tamil), 2025	248
	Part III (Tamil), 2024	133
	Formulary specification of Ayush Curanam (Stand-alone) 2021	01

UNANI PHARMACOPOEIAL PUBLICATIONS

Publication	Part	Volume & Year	Number of Monographs
The Unani Pharmacopoeia of India	Part-I(Single Drug)	Vol. VII, 2022	40

Publication	Part	Volume & Year	Number of Monographs
The Unani Pharmacopoeia of India	Part-II(Formulations)	Pharmacopocial Monograph of Ayush Safuf-i-Joshanda (Stand- alone), 2021	01

Publication	Part & Year	Number of Formulations
National Formulary of Unani Medicine	Part-I (Revised), 2025	441
	Part-II (Revised), 2026	202
	Part-IV (Revised), 2022	166
	Formulary specification of Ayush Safuf-i-Joshanda (Stand-alone), 2021	01

HOMOEOPATHY PHARMACOPOEIAL PUBLICATION

Publication	Part & Year	Number of Formulations
Homoeopathic Pharmacopoeia of India	Vol. IX, 2025	68

Annexure-IV

As per the information received from States/UTs, the details action taken by State/UT Licensing Authorities including Samples collected/recalled, licences cancelled etc during the last five years including Bharatpur Parliamentary Constituency are as follows:

<table>
<tr><th>States</th><th>No of Samples collected/recalled</th></tr>
<tr><td>Goa</td><td>
<table>
<tr><td>Year</td><td>No. of Ayurvedic samples tested</td></tr>
<tr><td>2022-23</td><td>227</td></tr>
<tr><td>2023-24</td><td>114</td></tr>
<tr><td>2024-25</td><td>89</td></tr>
<tr><td>2025-26</td><td>191</td></tr>
<tr><td>2026 till June 2026</td><td>169</td></tr>
</table>
</td></tr>
<tr><td>Delhi</td><td>
<table>
<tr><td>Year</td><td>No. of samples lifted/tested</td></tr>
<tr><td>2021-22</td><td>433</td></tr>
<tr><td>2022-23</td><td>335</td></tr>
<tr><td>2023-24</td><td>577</td></tr>
<tr><td>2024-25</td><td>694</td></tr>
<tr><td>2025-26</td><td>1312</td></tr>
<tr><td>Total</td><td>3351</td></tr>
</table>
</td></tr>
<tr><td>Arunachal Pradesh</td><td>
<table>
<tr><td>Year</td><td>No. of samples tested</td></tr>
<tr><td>2021-22</td><td>96</td></tr>
<tr><td>2022-23</td><td>274</td></tr>
<tr><td>2023-24</td><td>125</td></tr>
<tr><td>2024-25</td><td>209</td></tr>
<tr><td>2025-26</td><td>205</td></tr>
</table>
</td></tr>
<tr><td>Himachal Pradesh</td><td>In Himachal Pradesh, regulatory action against defaulting manufacturers is taken in accordance with the provisions of the Drugs and Cosmetics Act, 194 0 and the Rules made thereunder. Such action includes issuance of show-cause notices, and recall of products, wherever warranted based on the laborat ory reports and the nature of the violation. The details of which are as under:-
<table>
<tr><th>Year</th><th>Number of samples which do not comply with the Pharmacopeial Standards/D&C Act, 1945</th><th>Total Nos.</th></tr>
<tr><td>2021-22</td><td>31</td><td rowspan="4">272</td></tr>
<tr><td>2022-23</td><td>53</td></tr>
<tr><td>2023-24</td><td>38</td></tr>
<tr><td>2024-25</td><td>108</td></tr>
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<tr><td></td><td>
<table>
<tr><td>2025-
26 (Up to 09.7.2026)</td><td>42</td><td></td></tr>
<tr><td colspan="2">TOTAL</td><td>272</td><td></td></tr>
</table>
</td></tr>
<tr><td>Chennai</td><td>
<table>
<tr><th>S. no.</th><th>Year</th><th>Not of Standard Quality/Misbranded</th><th>Warning</th><th>Suspension</th><th>Recalled</th></tr>
<tr><td>1.</td><td>2021</td><td>10</td><td>10</td><td>00</td><td>10</td></tr>
<tr><td>2.</td><td>2022</td><td>20</td><td>17</td><td>03</td><td>20</td></tr>
<tr><td>3.</td><td>2023</td><td>33</td><td>32</td><td>00</td><td>33</td></tr>
<tr><td>4.</td><td>2024</td><td>08</td><td>06</td><td>02</td><td>06</td></tr>
<tr><td>5.</td><td>2025</td><td>34</td><td>07</td><td>21</td><td>28</td></tr>
<tr><td></td><td>TOTAL</td><td>105</td><td>72</td><td>26</td><td>97</td></tr>
</table>
</td></tr>
<tr><td>Madhya Pradesh</td><td>2023= 698 NSQ = 89
2024=391 NSQ = 80
2025=501 NSQ = 132
Total=l590 Total NSQ = 301</td></tr>
<tr><td>Rajasthan</td><td>In the past five years, drug inspectors collected a total of 1,551 legal samples and sent them to the State Ayurvedic Drug Testing Laboratory in Ajmer. Of these, 196 were found to be sub-standard. Of the samples found to be sub-standard, manufacturing approvals for 22 drugs from 10 pharmaceutical factories were suspended and revoked as per rules. No samples were collected from the Bharatpur parliamentary constituency.</td></tr>
<tr><td>Kerala</td><td>92 samples recalled</td></tr>
<tr><td>Sikkim</td><td>NIL</td></tr>
<tr><td>Mizoram</td><td>There is no manufacturing unit in the state of Mizoram</td></tr>
<tr><td>Odisha</td><td>NIL.</td></tr>
<tr><td>Puducherry</td><td>NIL</td></tr>
<tr><td>Tripura</td><td>There is no manufacturing unit for ASU medicine in Tripura Till date.</td></tr>
<tr><td>Uttar Pradesh</td><td>Nil</td></tr>
<tr><td>Manipur</td><td>There are no manufacturers in the State</td></tr>
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