LOK SABHA UNSTARRED QUESTION NO. 1020 TO BE ANSWERED ON 08th December, 2023

"Quality Standards of Ayurveda Medicines"

1020. SHRI G.M. SIDDESHWAR:

Will the Minister of AYUSH be pleased to state:

- (a) the number of herbal drug companies that obtained the mandatory Good Manufacturing Practices (GMP) certification as laid down by World Health Organisation (WHO), State/UT-Wise and company-wise;
- (b) the details of steps taken/proposed to be taken to ensure high quality and maintain international standards of Ayurveda medicines amid concerns that the majority of Ayurveda drug makers in the country have quality issues;
- (c) whether the Government proposes to establish Government-owned state-of-the-art testing facilities for Ayurveda drugs in every State to ensure the prescribed quality standards;
- (d) if so, the details thereof;
- (e) whether the Government has planned to attract Foreign Direct Investment (FDI) in the Ayurveda drug industry, taking into account the massive potential for exponential growth; and
- (f) if so, the details thereof?

ANSWER

THE MINISTER OF AYUSH

(SHRI SARBANANDA SONOWAL)

(a) Under Rule 157 and 85 E(2) of Drugs and Cosmetics Rules 1945, 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. Further the scheme for Certification of Pharmaceutical Product (CoPP) as per World Health Organisation(WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU) medicines. This scheme is administered by Central Drugs Standard Control Organization (CDSCO) and the certificate is granted on the basis of joint inspection of the applicant manufacturing unit by the representatives of CDSCO, Ministry of Ayush and the concerned State Licensing Authority. The company-wise & State wise details of Ayurvedic Products whose certificate of Pharmaceutical product (COPP) granted as per WHO-GMP Certification Scheme by CDSCO is available at https://cdsco.gov.in/opencms/opencms/en/Aayush/.

(b) The Drugs and Cosmetics Act, 1940 and Drugs and 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 Ministry of Ayush encourages following certifications of AYUSH products:-

- 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 and Cosmetics Act, 1940 and Rules made there under.

(c) and (d) The Ministry of Ayush has set up Pharmacopoeia Commission for Indian Medicines and Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging into it, the two erstwhile central laboratories namely Pharmacopoeial Laboratory for Indian Medicine (PLIM) and Homoeopathic Pharmacopoeial Laboratory (HPL) has been given the status for appellate laboratory for testing of ASU&H drugs. Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi has 03 Drug Testing Laboratory (DTL) at (i) Captain Srinivasa Murthy Central Ayurveda Research Institute (CSMCAR), Chennai, (ii) Central Ayurveda Research Institute (CARI), Jhansi and (iii) Regional Ayurveda Research Institute (RARI), Gwalior. Further 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, 35 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 102 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.

(The rest of the details are available in the public domain at https://ayush.gov.in/images/domains/quality_standards/StateDrugTestingLaboratoryAS
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(e) and (f) Yes sir, the Ministry of Ayush is working towards increasing Foreign Direct Investment in the Ayush sector, to tap the massive potential for growth. As per the Research and Information System for Developing Countries (RIS) Report on Ayush Sector in India: Prospects & Challenges, 100% FDI is permitted through automatic route in Ayush sector. (Details of the report is available at (https://www.ris.org.in/sites/default/files/Publication/Ayush%20Study-

Public%20Policy%20and%20Economic-FINAL%20REPORT%2028%20OCT_0.pdf)

Annexure-I
List of Ayurveda, Siddha, &Unani Drug Testing Laboratories Approved Under Rule – 160
A to J of the Drugs Cosmetics Rule, 1945

C	Ctoto/LIT	Nos	Name and Address of Dava Testing Laboratories
S.	State/UT	Nos.	Name and Address of Drug Testing Laboratories
No.	Cuionat	1	Accurace Descript Labo Dut Ltd. One Zuduc Dhomas
1	Gujarat	1.	Accupred Research Labs Pvt. Ltd, Opp. ZydusPharmaz,
			Changodar-Bavla Highway, Nr. MatodaPatia, Po: Matoda,
		2	Ahmedabad - 382213
		2.	Altra Analytical Laboratories, 3rd Floor, Silver Spring
			Complex, B/H. St. Xavier's Ladies Hostel, Nr. Swastik
		3.	Crossroad, Navarangpura, Ahmedabad - 380009 Aum Research Labs Pvt Ltd, Plot No. 555/1, 5a, Opp. Fresh
		3.	& Fresh Bakery, Behind Gulab Oil, Rakanpur - 382721
		4.	RMD Research And Development Center Governed By Shree
			Prabhav Hem KamdhenuGirivihar Trust, Shree RMD
			Ayurved College & Hospital, KesarsuriGyanviharSankul, NH
			48, Waghaldhara, Dist. Valsad, PIN - 396375
		5.	Ribosome Research Centre Pvt. Ltd, Sr. No. 261/1, Block No.
			271, Nr. Dhanvantary Pharmacy College, Kudsad, Ta.Olpad,
			Surat - 394110
		6.	Vasu Research Centre Pvt Ltd, A.2/624-625/2, G.I.D.C.,
			Makarpura, Vadodara - 390010
2	Himachal	7.	M/s Charak Pharmaceuticals (P) Ltd. Village – Katha, P.O. –
	Pradesh		Baddi, Tehsil- Nalagarh, Solan – 173205, H.P.
		8.	M/s Ayurvet Ltd. Village - Katha, P.O. – Baddi – 173205,
			Tehsil- Nalagarh, Distt. Solan (HP)
		9.	M/s Baijnath Research & Development Laboratory, Paprola,
			Tehsil - Baijnath, Dist. – Kangra – 176115 (HP)
3	Karnataka	10.	Karnataka Antibiotics & Pharmaceuticals Limited, No. 14,
		1.1	2nd phase, Industrial Area, Bangalore-560058
		11.	Radiant Research Services Private Limited #99/A, 8th Main,
		10	III Phase, Peenya Industrial Area, Bangalore- 58
		12.	K.L.E. Society's Shri B.M.
		12	Kankanawadi Ayurved Mahavidyalaya Shahapur, Belgum
		13.	,
		1 /	Veerasandra Industrial Area, Hosur Road, Bangalore-560100
		14.	Auriga Research Limited, No. 136, 6th Cross, 2nd Stage,
		1.5	Yeshwanthpur, Industrial Suburb, Bangalore- 560 022
		15.	M/s Bangalore Analytical Research Centre (P) Ltd
			Sy.No.57/1, Sri Vijayaraja Estate, Chokkanahalli, Jakkur Post,
			Bangalore-560064.
		16.	M/s Rajiv Gandhi Education Society's Ayurvedic Medical
			College, Hospital and Research Centre, Rona, Gadag-582 209

		17	M/a Amaidh I aha Ni Day 1,12fd El 37.1
		17.	M/s Amrith Labs Nisargam Pvt. Ltd.3 rd Floor Valyou Products Building, Raminakoppa, Shimoga-577202.
		18.	M/s Ramaiah Advanced Testing Laboratory No. 50, 80 Feet Road, BBMP Ward No. 19, Survey No.34/1, Devasandra, Near M.S. Ramaiah Memorial Hospital, Bangalore-560094.
4	Kerala	19.	M/s Nagarjuna Herbal Concentrates Ltd., Kalayanthani, Thodupuzha, Idukki, Kerala – 685588
		20.	M/s SreedhareeyamAyurvedic Medicines (P) Ltd, Door No. KGP V/485F, V/485 G, Nellikkattumana, Koothattukulam, Ernakulum – 686662, Kerala
		21.	The Pharmaceutical Corporation (IM) Kerala Ltd. (Oushadhi) Kuttanellur, P.O. Thrissur, Kerala
		22.	M/s. Confederation for Ayurvedic Renaissance Keralam Limited (CARE Kerala Limited), Door No. III/670, Kinfra Small Industries Park Kinfra Park, P.O. Koratty, Thrissur, Kerala
		23.	M/s New Udaya Pharmacy and Ayurvedic Laboratories (NUPAL), Raveendran road, Kadavanthra, Kochhi – 680020
		24.	M/s Vaidyaratnam P. S. Varrier's AryaVaidyasala, Door No. 1, K.PIII/1052, K.P.XIV/139, Kottakkal, Malappuram – 676503, Kerala
		25.	M/s VaidyarathnamOushadhasala Pvt. Ltd. Door no 14/474, Thaikkattussery, P.O. Ollur, Thrissur-680306
		26.	M/s Sitaram Ayurveda Pvt. Ltd., Door no-III/475 (old), New No. 43/1094. A-H, Gnadhi Nagar Road, Nedupuzha P.O., Thrissur- 680 007.
		27.	Haridev Formulations, Door no. VI/478 & 482, Nellad.P.O., Muvatupuzha, Ernakulam-686 669.
5	Odisha	28.	M/s BioLab, C/o Bio Sourcing, Com Pvt. Ltd A-41, Ashok Nagar, Janpath, Bhubaneswar - 751009
		29. 30.	M/s Bioatechayur Pvt. Ltd, Sergarh, NH-16, Balasore M/s Kalyani Laboratories Pvt. Ltd., Plot No 841-A,
		31.	Rasulgarh, Bhubaneswar – 10, Khurda M/s Sai Bio Care Pvt Ltd, Plot No 3103 (Neelaban), Near
6	Maharashtra	32.	MahavirChhak Lewis Road, Samantarapur, Bhubaneswar Precise Analytics, B-22, Road No. 16-Z, Wagle Estate
	Wanarasitra	32.	Opposite BradmaEngg
		33.	Jubilant Pharma And Chemical Lab (OPC) Pvt. Ltd., Surya Gayatri Plot No. D14/15, Shop no. 10 to 15, Sector no 6, Vijay Marg, New Panvel
		34.	Chemo Test Laboratory, Pusalkar House, JakeriaBunder Road Near Sewri Railway Stn. West Mumbai - 15
		35.	Charak Testing Laboratory, Gala no. 32 & 67, Evergreen Industrial Estate, Shakti Mills Lane, Mahalaxmi
			Near Sewri Railway Stn. West Mumbai - 15 Charak Testing Laboratory, Gala no. 32 & 67, Evergreen

		36.	, , , , <u>1</u>
			Alumium, Western Express Highway, Gorgaon (E), Mumbai 400063
		37.	GEO- Chem Laboratories (Rajkot) Pvt. Ltd., Pragati Building Near Crompton Greaves, Survey No 1014(PT) Village KanjurMarg E
		38.	Ana Laboratories, 15-16-17, M K Bros, Industrial Estate, Jarimari, KurlaAndheri Road
		39.	Qualichem Laboratories, Swami Samarth Commercial Comples, 501-505, 407-408, 601-609, 506-508, 4th, 5th & 6th Floor, 4 North Bazaar Road, Dharampeth Extension
		40.	M.J. Labs Pvt. Ltd., Plot No. 16, Village Khaniwali, Taluka Wada, Palghar District
		41.	Bee Pharmo Labs Pvt. Ltd., C-2, HatkeshUdyog Nagar, Mira Bhayander Road, Mira Road (E)
		42.	Manisha Analytical Laboratories Pvt. Ltd., 135-A, Govt. Ind. Estate, Charkop, Kandivali(W), Mumbai-67
		43.	Poona College of Pharmacy, Public Testing Laboratory, Erandwane
		44.	Invochem Laboratory, 220 to 226, Gala No. A3, 3rd Floor, GauriAmbica Commercial Complex, Station Road Vasai Road, Vasai(E)
7	Rajasthan	45.	M/s Amol Pharmaceuticals Pvt. Ltd.(Analytical Division) E.1-362, Sitapura Industrial Area, Jaipur
		46.	M/s Ayushraj Enterprises Pvt Ltd, Mansinghpura, Dehmibegus Road, Jaipur
		47.	M/s S.R. Labs, 230/23, HaldighatiMarg, Sector No. 23, Pratapnagar, Jaipur
		48.	M/s Team Test House G.1-584, RIICO Industrial Area, Sitapura, Jaipur
		49.	M/s Ananta Medicare Ltd, G.1-265, Second Phase, RIICO Industrial Area, UdhyogVihar, ShriGanganagar
		50.	M/s KarnaniPharma Pvt. Ltd. F.67, Industrial Area, Bhiwadi, Alwar
		51.	M/s Jagdamba Laboratories, Plot No. 119, Solitaire Industrial Park, First Phase, Damikallan, Bagru, Jaipur
		52.	M/s Ayurved and Herbal VikasSansthan Opp. Power House, JhamarKotra, Eklingpura, Udaipur
		53.	M/s Cultivator Phyto Lab Pvt Ltd 1st Floor, Plot No. 24 to 31 & 25 to 30, Khasra No. 135/1, sonamukhi Nagar, Sangaria
			Fanta, Jodhpur - 342013(Raj.)
		54.	
		54.	Quality care laboratories & research centre, 2 nd floor, H-415(A), Sarnadungar Industrial area, Jhotwara extension,
8	Uttar	54. 55.	Quality care laboratories & research centre, 2 nd floor, H-

	- /	M/s Dalam India Diseased /A 12' 1 D 1 D 1
	56.	M/s Dabur India Limited (Analytical Dabur Research
		Development Division Centre) Plot No. 22, Site –IV,
		Sahibabad, Ghaziabad – 201010(UP)
	57.	U.P. Standard Research & Testing Lab, C-10, Industrial
	5 0	Estate, 1 st Floor, Distt. – Muzaffarnagar – 251003 UP)
	58.	M/s Eko Pro Engineers Pvt. Ltd., 32/41, South Side of G.T. Road, UPSIDC Industrial Area, Ghaziabad – 201009(UP)
Uttarakhand	59.	M/s Multani Pharmaceuticals Ltd. (Analytical Division) situated at Khasra No. 37, Village MakkanpurMehmoodAlam, Pargana&Tehsil Bhagwanpur, Haridwar,Uttarakhand
	60	M/s Devansh Testing & Research Laboratory Pvt. Ltd, 94
	00.	Shiv Ganga Industrial Estate
		LakeshariBhagwanput,Roorkee,District,Haridwar,Uttarakhan
		d
	61	M/s Ayush Drug Testing Laboratory, Indian Medicines
	01.	Pharmaceutical Corporation Limited, Mohan
		Almora, Uttarakhand
	62.	M/s SanskarAyush Medicare Pvt. Ltd., Drug Testing
		Laboratory, ImlikheraBhagwanpur Bypass Road
		HaridwarUttarakhand
	63.	M/s Patanjali Food & Herbal Park Pvt. Ltd, Drug Testing
		Laboratory, Laksar Road, PadarthaHaridwar, Uttarakhand
Delhi	64.	M/s Arbro Pharmaceuticals Pvt. Ltd., 6/14, Kirti Nagar,
		Industrial Area New Delhi-110015
	65.	M/s Sophisticated Industrial Materials Analytical Labs Pvt.
		Ltd., A-3/7, Phase-2, Mayapuri Industrial Area, Delhi-110064
	66.	M/s Shree Sai Test House Pvt. Ltd, C-165 2nd Floor
		Mayapuri Industrial Area, Delhi-110064
	67.	M/s Standard Analytical Laboratory (ND) Pvt. Ltd., 69, F.I.E.
		Patparganj Industrial Area, Delhi-110092
	68.	M/s Catts Labs & Research Pvt. Ltd., S-78, 1st FloorOkhla
	60	Industrial Area, Phase-2, New Delhi-110020
	69.	M/s Green Lab Analysis & Research Center Pvt. Ltd., A-74,
	70	Naraina Industrial Area, Phase-1, New Delhi-110028
	70.	M/s Shree Krishna Analytical Services, A-5/4, Phase-2, Mayapuri Industrial Area, Delhi-110064
	71	M/s ITL Labs Pvt. Ltd, B-283,284, Phase-I, Industrial Area,
	/1.	Mangolpuri, Delhi-110083
		1114112VIVIII 12VIII 11VVV.
	72	
	72.	M/s Delhi Test House, A-62/3, G.T. Karnal Road, Opp Hans
		M/s Delhi Test House, A-62/3, G.T. Karnal Road, Opp Hans Cinema, Azadpur Industrial Area, New Delhi-110033
	72. 73.	M/s Delhi Test House, A-62/3, G.T. Karnal Road, Opp Hans Cinema, Azadpur Industrial Area, New Delhi-110033 M/s Avon Food Lab (Pvt.) Ltd, C-35/23, Lawrence Road
		M/s Delhi Test House, A-62/3, G.T. Karnal Road, Opp Hans Cinema, Azadpur Industrial Area, New Delhi-110033 M/s Avon Food Lab (Pvt.) Ltd, C-35/23, Lawrence Road Industrial Area, Delhi -110035
	73.	M/s Delhi Test House, A-62/3, G.T. Karnal Road, Opp Hans Cinema, Azadpur Industrial Area, New Delhi-110033 M/s Avon Food Lab (Pvt.) Ltd, C-35/23, Lawrence Road
		60. 61. 62. 63. Delhi 64.

			Road, near Hansraj College, Delhi-110007
		76.	M/s AGSS Analytical & Research Lab Pvt. Ltd, C-37/2,
		70.	Lawrence Road, Industrial Area, Delhi-110035
11	Madhya	77.	M/s. Choksi Laboratories, 6/3 ManoramaGanj,, Indore (M.P.)
11	Pradesh	77.	M/s JRD Tata foundation for Research in Ayurveda and Yoga
	Tradesii	76.	Science, (Deendayal Research Institute), Chitrakoot, Satna –
			485331 (M.P.)
		79.	M/s. Anusandhan Anal. & Bio. Res. Laboratory Pvt. Ltd. 68-
		,,,,	Industrial Area, Rangwasa, Rau, Distt-Indore (M.P.)
		80.	M/s. Quality Control Laboratory A-35, Vidhya Nagar, In front
			of GyanVigyanBhawan, B.U. Gate No. 3, Hoshangabad Road,
			Bhopal (M.P.)
		81.	M/s. Shilpachem Laboratory 47-D Industrial Estate Forte,
			Indore (M.P.)
12	Telangana	82.	M/s Varun Herbals, D.No. 5-8-293/A, Mahesh Nagar, Chirag-
10	***	0.2	Ali-Lane, Hyderabad – 500001
13	West	83.	M/s Quality Testing Laboratory, IRDM faculty Centre,
	Bengal		Ramakrishna Mission, Vivekanand Educational & Research
			Institute, Ramakrishna Mission Ashram, Narendrapur,
14	Haryana	84.	Kolkata- 700103, West Bengal M/s. Ozone Pharmaceuticals Ltd. (Analytical), Plot No. 639-
14	Tiai yana	04.	640, MIE, Bahadurgarh, Jhajjar
		85.	M/s. International Testing Centre, Plot No. 86, Industrial
		05.	Area, Phase -1, Panchkula
		86.	M/s. Alcatech Research Lab, Plot No. 1652, MIE, Part B,
			Jhajjar
		87.	M/s. Satiate Research & Anatech Pvt. Ltd., Plot No. 264, 1st &
			2nd Floor, HSIIDC, Barwala, Panchkula
		88.	M/s DN Laboratory Plot No. 263, Industrial Area, Phase-1,
			Panchkula (Haryana)
		89.	M/s VardanEnviro Lab, Plot no. 82A, Sector-05, IMT
		2.0	Manesar, Distt. Gurugram
		90.	M/s Fare Labs Pvt. Ltd. L-17/3, DLF, Phase-II, IFFCO
		0.1	Chowk, M.G. Road, Gurugram
		91.	M/s Idma Laboratories Ltd, Plot no. 391, Industrial Area, Phase-I, Panchkula
		02	,
		92.	M/s Charak Testing Laboratory, Jaurasi Road, Pauti Village, G.T. Road, SamalkhaDistt. Panipat(Haryana)
			G.1. Road, SamaikhaDistt. 1 ampat(11aryana)
		93.	Herbal Health Research Consortium Pvt. Ltd. village & P.O.
			KhyalaKhurd, Ram Tirath Road, Distt Amritsar.
15	Dunioh	94.	CCP - Herbal & Ayurvedic Product Testing &
15	Punjab		Standardization Lab (HAPTSL) Chitkara College of
			Pharmacy, Chitkara University, Rajpura, District - Patiala,
			Punjab.
16	Tamil Nadu	95.	Cholayil Pvt. Ltd. 31-A/24 SIDCO Industrial Estate,

	Ambattur, Chennai – 600098
96.	Centre for Advanced Research in Indian System of Medicine
	(CARISM), SASTRA Deemed university, Thanjavur -
	613401
97.	Asthagiri Herbal Research Foundation, 162-A, II Floor,
	Perungudi Industrial Estate, Perungudi, Chennai – 600096
98.	Interdisciplinary Institute of Indian System of Medicine, SRM
	University, SRM Nagar, Kattankulathur, Kancheepuram
	District - 603203
99.	SMS Labs Services Private Limited, 39/6, Thiruvallur High
	Road, Puduchatram Post, Thirumazhisai Via,
	PoonamalleeTaluk, Chennai – 600124
100	Sanjeev Biomedical Research Centre, 1/15, Kumaran Nagar,
	Keelkatalai, Chennai – 600117
101	Bioscience Research Foundation, Sengadu Village & Post,
	Via Manavalanagar, Kandamangalam, Kancheepuram -
	602002
102	Chennai Mettex Lab Private Limited, Jothi Complex, 83,
	M.K.N. Road, Guindy, Chennai – 600032.
