

**GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA  
UNSTARRED QUESTION No. 1168  
TO BE ANSWERED ON THE 18<sup>th</sup> December, 2018

**Survey on Substandard Drugs**

1168. SHRI KUNDARIYA MOHAN BHAI KALYANJI BHAI:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether a recent survey has indicated a fall in substandard drugs being sold in the country;
- (b) if so, the details thereof indicating the major findings of the survey, Statewise;
- (c) whether the Government has taken steps to strengthen the monitoring mechanism to check substandard/fake drugs; and
- (d) if so, the details and the outcome thereof?

**ANSWER**

**MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS;  
MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS  
(SHRI MANSUKH L. MANDAVIYA)**

(a) & (b): In the year 2014-16 National Institute of Biologicals, Noida (NIB) with the concurrence of Ministry of Health conducted a National Drug Survey to assess the extent of Not of Standard Quality (NSQ)/Spurious drugs in the country.

As per the report of the said survey, details of no. of samples tested, No. of drugs samples declared not of standard quality/spurious/adulterated and percent thereof, are as under:

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/adulterated	% of drugs samples declared spurious/adulterated
2014-16	47012	1850	3.16	13	0.0245

Whereas, as per the information received from various State/U.Ts Drugs Controllers No. of drugs samples tested, No. of drugs samples declared sub-standard quality, spurious/adulterated drugs and percentage thereof during last three years are as under:

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% of drugs samples declared spurious/ adulterated
2015-16	74586	3703	4.96	234	0.31
2016-17	76721	2780	3.6	123	0.16
2017-18	82599	2783	3.36	236	0.28

Report of Drugs Survey & its findings are available on the website of NIB ([www.http://nib.gov.in](http://nib.gov.in)) & MoH&FW ([www.mohfw.gov.in](http://www.mohfw.gov.in)). Findings of the Drug Survey state-wise is attached as **Annexure-A**

(c) & (d): The Government of India have taken various regulatory measures to curb the menace of substandard/spurious drugs and to ensure the quality of drugs manufactured/sold in the country. Details are as under:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.
3. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.
4. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2018.
5. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.
6. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.
7. The Government has decided to strengthen both the Central and States drug regulatory system during the 12th Five Year Plan enabling them to keep more effective watch on unscrupulous elements indulging in unlawful activities relating to quality of drugs. The Cabinet Committee on Economic Affairs (CCEA) has approved the proposal for strengthening the drug regulatory system in the country, both under the Central and State Governments at a total expenditure of Rs. 1750 crores. Out of this, Rs. 850 crore is the Central Government's share. The share of the Centre and the States in case of state component will be in the ratio of 60:40 for all States except Jammu and Kashmir, Himachal Pradesh, Uttarakhand, Sikkim and North-Eastern States, for which the ratio will be 90:10.



## State wise Drug Survey Data

S. No.	Name of State/UT	Total Samples	NSQ Samples	Spurious Samples	Govt Sources			Retail Outlets			Oral Dosage Forms			Parenteral Dosage Forms		
					Number of samples	No. of NSQ Samples	% NSQ*	Number of samples	No. of NSQ Samples	% NSQ*	Number of samples	No. of NSQ Samples	% NSQ*	Number of samples	No. of NSQ Samples	% NSQ*
1	ANDAMAN AND NICOBAR ISLANDS	46	1	Nil	11	1	9.1	35	0	0.0	43	0	0.00	3	1	33.33
2	ANDHRA PRADESH	3531	142	Nil	94	10	10.6	3437	132	3.8	3238	111	3.43	282	31	10.99
3	ARUNACHAL PRADESH	232	17	Nil	104	14	13.5	128	3	2.3	172	10	5.81	58	7	12.07
4	ASSAM	630	36	Nil	282	26	9.2	348	10	2.9	590	31	5.25	32	5	15.63
5	BIHAR	1935	74	Nil	241	21	8.7	1694	53	3.1	1751	52	2.97	179	22	12.29
6	CHANDIGARH	46	1	Nil	6	0	0.0	40	1	2.5	42	1	2.38	3	0	0.00
7	CHHATTISGARH	828	39	Nil	279	23	8.2	549	16	2.9	731	25	3.42	93	14	15.05
8	DADRA AND NAGAR HAVELI	23	Nil	Nil	5	0	0.0	18	0	0.0	21	0	0.00	1	0	0.00
9	DAMAN AND DIU	48	1	Nil	12	0	0.0	36	1	2.8	41	1	2.44	7	0	0.00
10	DELHI	492	8	Nil	39	1	2.6	453	7	1.5	488	8	1.64	4	0	0.00
11	GOA	48	1	Nil	12	1	8.3	36	0	0.0	41	0	0.00	5	1	20
12	GUJARAT	1741	103	1	369	38	10.3	1372	65	4.7	1613	89	5.51	104	11	10.57
13	HARYANA	1042	52	1	200	19	9.5	842	33	3.9	987	45	4.55	51	7	13.72
14	HIMACHAL PRADESH	269	15	1	108	10	9.3	161	5	3.1	241	13	5.39	23	2	8.69

contd.---

S. No.	Name of State/UT	Total Samples	NSQ Samples	Spurious Samples	Govt Sources		Retail Outlets		Oral Dosage Forms			Parenteral Dosage Forms				
					Number of samples	% NSQ*	Number of samples	% NSQ*	Number of samples	% NSQ	Number of samples	% NSQ	Number of samples	% NSQ		
15	JAMMU & KASHMIR	644	32	Nil	203	17	8.4	441	15	3.4	559	27	4.83	81	5	6.17
16	JHARKHAND	2502	62	Nil	208	22	10.6	2294	40	1.7	2378	51	2.14	121	11	9.09
17	KARNATAKA	2039	77	1	406	35	8.6	1633	42	2.6	1874	60	3.20	145	17	11.72
18	KERALA	2469	124	Nil	946	94	9.9	1523	30	2	2358	119	5.04	66	3	4.54
19	LAKSHADWEEP	12	1	Nil	6	0	0.0	6	1	16.7	9	1	11.11	3	0	0.00
20	MADHYA PRADESH	1423	79	1	570	60	10.5	853	19	2.2	1269	60	4.72	135	18	13.33
21	MAHARASHTRA	4246	161	Nil	443	40	9.0	3803	121	3.2	3831	123	3.21	376	38	10.10
22	MANIPUR	214	18	Nil	138	14	10.1	76	4	5.3	168	12	7.14	36	6	16.66
23	MEGHALAYA	153	17	Nil	69	12	17.4	84	5	6	129	13	10.08	23	4	17.39
24	MIZORAM	182	20	1	80	11	13.8	102	9	8.8	171	18	10.52	10	2	20
25	NAGALAND	223	22	Nil	106	14	13.2	117	8	6.8	205	17	8.29	17	5	29.41
26	ODISHA	1217	55	1	263	20	7.6	954	35	3.7	1149	45	3.91	64	9	14.06
27	PUDUCHERRY	120	8	Nil	42	4	9.5	78	4	5.1	114	7	6.14	5	1	20
28	PUNJAB	1051	70	2	360	41	11.4	691	29	4.2	934	51	5.46	110	17	15.45
29	RAJASTHAN	1946	90	1	463	46	9.9	1483	44	3	1798	72	4	125	18	14.4
30	SIKKIM	53	9	Nil	24	8	33.3	29	1	3.4	44	4	9.09	9	5	55.55

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S. No.	Name of State/UT	Total Samples	NSQ Samples	Spurious Samples	Govt Sources			Retail Outlets			Oral Dosage forms			Inj. and Dosage forms		
					Number of samples	No of NSQ Samples	% NSQ*	Number of samples	No of NSQ* samples	% NSQ*	Number of samples	No. of NSQ Samples	% NSQ	Number of samples	No. of NSQ Samples	% NSQ
3.1	TAMILNADU	2596	122	1	583	45	7.7	2013	77	2.8	2285	100	41.9	191	21	10.9
3.2	TELANGANA	2304	85	Nil	167	21	12.6	2137	62	2.9	2187	73	33.3	106	10	9.4
3.3	TRIPURA	191	14	Nil	95	9	9.5	96	5	5.2	156	10	6.41	34	4	11.76
3.4	UTTAR PRADESH	3955	214	2	1084	129	11.9	2871	85	3	3543	15.8	44.5	397	56	14.18
3.5	UTTARAKHAND	355	22	Nil	124	15	12.1	231	7	3	306	1.4	43.7	48	6	17.28
3.6	WEST BENGAL	3219	66	Nil	227	16	7.9	2992	42	1.4	3179	5.5	1.73	35	5	14.28

\* Figures rounded off

National Survey NSQ percentage is 3.16%

National Survey Spurious percentage is 0.0245%