

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 2620
TO BE ANSWERED ON 06TH MARCH, 2020**

QUALITY TESTS FOR MEDICINES

**2620. SHRI SHANMUGA SUNDARAM K.:
SHRI RAVNEET SINGH BITTU:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the details of the number of medicines being supplied by pharmaceutical companies failing the standard quality test, State/UT-wise during the last three years, year-wise;
- (b) whether the Central Drugs Standard Control Organisation (CDSCO) has found five batches of medicine manufactured by three Government controlled drug manufacturers failing the quality tests, if so, the details thereof;
- (c) whether the Government has received any report in this regard, if so, the details thereof and the name of the companies along with the drugs found sub-standard or spurious;
- (d) the steps taken by the Government against the erring employees; and
- (e) whether these drug companies conducted dissolution test before marketing the paracetamol tablets, if so, the details thereof and the action taken to prevent any damages to the public who bought these medicines in good faith along with measures to ensure maintenance of quality standards by pharmaceutical companies?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)**

(a): As per information received from various State/UT Drugs Controllers, number of drugs samples tested, number of drugs samples declared sub-standard and spurious/ adulterated and action taken thereon during the last three years and current year is enclosed as **Annexure-I**.

(b) to (e): Details of drugs declared as spurious/substandard/adulterated/misbranded by Central Drug Testing Laboratories are regularly uploaded on Central Drugs Standard Control Organisation (CDSCO) website (www.cdsc.nic.in) under the heading “Drug Alert”.

Details with regard to five batches of medicines manufactured by three Government controlled drug manufacturers failing the quality tests have also been uploaded on the website of CDSCO (www.cdsc.gov.in) in the month of January 2020 and a copy of the same is enclosed as **Annexure-II**.

Licence for manufacturing, sale & distribution of drugs are granted by the State Licensing Authorities appointed by respective State Governments. State Governments are empowered to take action on violations of any of the provisions of Drugs & Cosmetics Act, 1940 and Rules made thereunder. In all the above cases, the State Drugs Controllers of the concerned State where the drugs were manufactured have been informed accordingly.

Out of above five cases, four had failed in the test for dissolution for Albendazole tablets and one failed in the test for disintegration for Diclofenac Sodium tablets I.P.

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Annexure-I

**Number of samples tested and enforcement actions taken by State Drugs Controller during
1st April 2016 to 31st March, 2017**

S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx. value of drug seized	No. of Raids Conducted	Action taken w.r.t no. of raids conducted
1	Andhra Pradesh	2979	22	Nil	Nil	Nil	Nil	13567403	Nil	Nil
2	Arunachal Pradesh	47	1	Nil	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	745	43	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar*	397	11	Nil	Nil	6	16	26311817	78	47
5	Goa	534	17	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	11071	535	22	2	Nil	Nil	Nil	3	under Investigation
7	Haryana	1901	12	1	5	1	Nil	Nil	6890	-
8	Himachal Pradesh	1001	36	5	Nil	Nil	Nil	Nil	Nil	Nil
9	Jammu & Kashmir	2958	60	Nil	Nil	Nil	Nil	13983937	Nil	Nil
10	Karnataka	8217	468	Nil	2	Nil	Nil	21 Lakhs NSQ Drugs	-	Nil
11	Kerala	8934	140	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	1624	15	3	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	4592	335	33	In all cases, prosecution orders are issued & In 4 cases prosecution are filed in the Court.	Nil	1	392235	10	7
14	Manipur*	19	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya*	97	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	79	8	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	22	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	4036	113	Nil	Nil	Nil	Nil	Nil	851	Nil
19	Punjab	2750	58	16	12 (Action under process in rest of cases)	1	3	1,771,725	1389	1 court case has been launched rest of the cases are under investigation

20	Rajasthan	2545	147	30	3	2	15	1615137.47	13	1- process in court for withdraw retesting request by manufacturers 12- under investigation
21	Sikkim	102	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	9510	392	4	6 #	Nil	Nil	Nil	447	370 #
23	Tripura	1151	10	Nil	Nil	Nil	Nil	Nil	Nil	Nil
24	Uttar Pradesh	7357	222	3	106	2	54	14,235,568	1119	FIR-57, persons arrested-54, Total seizure-Rs. 14235568
25	West Bengal	683	36	4	6	Nil	4	Nil	4	Nil
26	Pondicherry	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar *	Nil	Nil	Nil	Nil	Nil	Nil	Nil	10	Nil
28	Chandigarh	86	2	Nil	Nil	Nil	Nil	Nil	Nil	Nil
29	Delhi	278	18	2	5	5	Nil	15000	35	Total 289 firms were inspected out of which 82 firms were found contravening various provisions of Drugs and Cosmetics Rules, 1945. Action has been initiated/ taken against erring firms as per Rules.
30	Dadra & Nagar Haveli	4	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	15	2	Nil	Nil	Nil	Nil	468895	1	Case is under investigation
34	Jharkhand	148	13	Nil	6	Nil	13	2807000	66	Suspension-34 Procecutation - 35 Cancellation - 05 FIR -28
35	Uttarakhand	217	22	Nil	Nil	Nil	Nil	Nil	5	Nil
36	Telangana	2619	39	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Total		76,721	2,780	123	186	17	106	7,72,68,717.5	10,921	-

(*)= data as on 1st April 2016 to 30th Sept. 2016)

(#)= Figure indicates the number of cases detected before 01.04.2016

20	Odisha	3949	121	nil	nil	nil	nil	nil	994	Show cause notice issued
21	Punjab	3720	66	19	11	2	nil	71484	1787	cases are under investigation
22	Rajasthan	2346	218	123	3	nil	nil	26535506	11	nil
23	Sikkim	25	nil	nil	nil	nil	nil	nil	nil	nil
24	Tamilnadu	11601	172	5	6*	nil	nil	nil	177	under investigation for taking legal action
25	Telangana	2530	39	nil	nil	nil	nil	nil	nil	NA
26	Tripura	1303	19	nil	nil	nil	nil	28 lakhs	2	proseution launched
27	Uttarakhand	180	10	2	3	3	8	20 lakhs	20	16
28	Uttar Pradesh	9421	282	23	56	nil	101	60314082	592	105 FIR were lodged and 101 person were arrested
29	West Bengal	515	40	3	2	nil	3	3 lakhs	2	prosecution started
30	Pondicherry	nil	nil	nil	nil	nil	nil	nil	nil	nil
31	Andaman & Nicobar	nil	nil	nil	nil	nil	nil	nil	nil	nil
32	Chandigarh	64	1	nil	nil	nil	nil	nil	1	under investigation
33	Delhi	464	22	3	2	11	FIR-15	167 lakhs approx	82	269 firms were found contravening various provisio of D & C Act and Rules . Action against erring firm has been initiated as per said rules
34	Dadra & Nagar Haveli	12	1	nil	nil	nil	nil	nil	nil	nil
35	Daman & Diu	48	nil	nil	nil	nil	nil	nil	nil	nil
36	Lakshadweep #	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
TOTAL		82,599	2783	236	131	16	163	178,608,008	7067	

(*) including the cases of previous year

(#) data 1st Apr, 2017 to 30th Sept, 2017

17	Meghalaya	46	11	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Mizoram	440	6	Nil	Nil	Nil	Nil	Nil	Nil	Nil
19	Nagaland	88	4	Nil	Nil	Nil	Nil		Nil	Nil
20	Odisha	2358	71	Nil	Nil	Nil	Nil	Nil	1020	SCN issued
21	Punjab	2956	122	23	14	2	Nil	2169170	783	1 Court case launched, 2 cases manufacturer challenged the test reports, Rest under process
22	Rajasthan	2671	150	24	9	0	3	846875	9	03 FIR launched
23	Sikkim	68	nil	nil	nil	nil	nil	nil	nil	nil
24	Tamilnadu	10750	304	9	6 (no. of cases detected before 01.04.2018)	NIL	NIL	NIL	304 raids have been conducted during the said period against the sales premises	96 (the number of cases detected before 01.04.2018)
25	Telangana*	2530	39	Nil	Nil	Nil	Nil	Nil	Nil	NA
26	Tripura	2306	48	Nil	Nil	NA	Nil	15000	2	Under process
27	Uttarakhand	203	25	10	3	3	5	Approx. 2.25 Cr	18	15
28	Uttar Pradesh	7404	231	84	341	6	111	34645846	1085	132 FIR were lodged and 111 persons were arrested
29	West Bengal	348	12	1	3	Nil	2	Not Calculated	4	Sub-judice
30	Pondicherry	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
31	Andaman & Nicobar	73	NIL	NIL	NIL	NIL	NIL	NIL	12	NIL
32	Chandigarh	117	1	Nil	Nil	Nil	Nil	Nil	39	Under process/investigation

33	Delhi	725	13	9	3	7	Total no. of FIR registered = NIL	60 lacs (Approx.)	109	330 Firms were found contraventions of various provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. Action against erring firm has been initiated/taken as per Rules.
34	Dadra & Nagar Haveli	19	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
35	Daman & Diu*	48	nil	nil	nil	nil	nil	nil	nil	nil
36	Lakshadweep**	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
TOTAL		76,101	2,549	205	484	77	153	80389057 (Approx.)	33,492	

* Upto 31st March 2018

** Upto 30th Sept 2017

Annexure-II

S. N.	Name of Drugs/medical device/cosmetics	Batch No./Date of Manufacture/Date of Expiry/Manufactured By	Reason for failure
1.	Diclofenac Sodium Tablets I.P.	B. No.: DF-R008, Mfg dt: 02/2019, Exp dt: 01/2021, Mfd by: M/s. Bengal Chemicals & Pharmaceuticals Ltd., 115-C, Industrial Estate, Pologround, Indore – 452 015.	Disintegration
2.	Albendazole Tablets IP 400MG	B. No.: 8600219, Mfg dt: 01/2019, Exp dt: 12/2021, Mfd by: M/s. Karnataka Antibiotics & Pharmaceuticals Limited Plot no.14, II Phase, Peenya, Bangalore560058.	Dissolution
3.	Albendazole Tablets IP 400MG	B. No.: 8600119, Mfg dt: 01/2019, Exp dt: 12/2021, Mfd by: M/s. Karnataka Antibiotics & Pharmaceuticals Limited Plot No.14, II Phase, Peenya, Bangalore560058.	Dissolution
4.	Albendazole Tablets I.P. 400 mg	B. No.: 8491015, Mfg dt: 03/2019, Exp dt: 02/2021, Mfd by: M/s. Bengal Chemicals & Pharmaceuticlas Ltd. 164, Maniktala Main Road, Kolkata-700054.	Dissolution
5.	Albendazole Tablets I.P. 400 mg	B. No.: 9622, Mfg dt: 02/2019, Exp dt: 01/2022, Mfd by: M/s. Orissa Drugs & Chemicals Ltd. 1, Mancheswar Industrial Estate, Bhubaneswar Odisha.	Dissolution