

GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

**LOK SABHA**  
**UNSTARRED QUESTION No. 582**  
**TO BE ANSWERED ON THE 19<sup>th</sup> December, 2017**

**Quality Tests of Life Saving Drugs**

†582. SHRI AJAY MISRA TENI:

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

- (a) whether there are reports of sharp increase in the incidents of life saving drugs failing the quality tests/checks during the last few years;
- (b) if so, the details thereof;
- (c) whether the Government is contemplating to issue good manufacturing practices certificate to all pharmaceutical companies in the country after high quality test and if so, the details thereof; and
- (d) whether the Government proposes to take action against pharmaceutical companies for failing to conform to the quality standards and if so, the details 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): As per the information received from Central Drugs Standards Control Organization (CDSCO), no such report of sharp increase in the incidents of life saving drugs failing the quality tests has been reported to them. As per information received from States/U.Ts Drugs Controllers, Number of drugs samples tested, Number of drugs samples declared not of standard quality, percent of drugs samples declared not of standard quality and Number of drugs samples declared spurious/adulterated and percent of drugs samples declared spurious/adulterated during last three years i.e. 2014-15, 2015-16 and 2016-17 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
2014-15	74199	3702	4.98	83	0.11
2015-16	74586	3703	4.96	234	0.31
2016-17	76721	2780	3.62	123	0.16

Over the years, through the concerted efforts of Ministry of Health & Family Welfare, CDSCO and States, there has been increase in testing capacities of both Central and State Drug Testing Laboratories from 32264 samples per annum in 2006-07 to 76721

samples per annum in 2016-17. With continuous improvement in monitoring of quality of drugs by State Drug Control Authorities and CDSCO, % of Not Of Standard Quality (NSQ) Drugs reported in the country has been reduced from 6.20% in the year 2007 to 3.62 % in 2016-17.

(c) & (d): Manufacturing sale and distribution of Drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. Licensees are required to comply with all the condition of license and follow Good Manufacturing Practices (GMP) as per the Rule to ensure that the drugs manufactured by them are safe and of standard quality. The State Licensing Authorities (SLA) are empowered to take action in case of any violation of above requirements.

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