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

LOK SABHA
UNSTARRED QUESTION No. 2326
TO BE ANSWERED ON THE 2nd January, 2018

## Drug Impurities

†2326. SHRI ASHOK MAHADEORAO NETE:

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

(a) whether the Government has made available the information regarding toxic and non-toxic impurities to the drug manufacturers who need to ensure purity and standardisation of medicines;
(b) if not, the reasons therefor;
(c) whether the Government has taken steps to make detailed impurities profile available at economical cost to small pharmaceutical units from the National Institute of Pharmaceutical Education and Research; and
(d) if so, the deatils 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): Toxic and non-toxic impurities are regulated in pharmaceutical substances and products through related substances test in pharmacopoeias. Indian pharmacopoeia, which is published by Indian Pharmacopoeia Commission (IPC), under the aegis of Ministry of Health, specifies the impurities to be controlled in pharmacopoeial monographs. IPC publishes new edition of Indian pharmacopoeia every four years. The latest standards regarding impurity control to be followed by industry have been included in 2018 edition of Indian Pharmacopoeia.

(c) & (d): The impurity profiles are very specific to the synthetic process used by the manufacturer of Active Pharmaceutical Ingredient (API) or the formulation developed by the product manufacturer. So there are no standard impurity profiles that can be developed by National Institute of Pharmaceutical Education and Research (NIPER) or any agency. However, NIPER at SAS Nagar has been helping industry in their specific jobs for characterization of impurities, as and when approached. Furthermore, NIPER has been in forefront in proposing degradation chemistry, which is an intrinsic study for any drug and is very useful for the pharmaceutical industry. NIPER SAS Nagar has published more than 50 research reports on drug degradation behavior, a basic requirement for characterization and qualification of degradation products formed in drug formulations during their storage till shelf life.

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