GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
DEPARTMENT OF SCIENTIFIC AND INDUSTRIAL RESEARCH

RAJYA SABHA

UNSTARRED QUESTION No. 445
(TO BE ANSWERED ON. 06.02.2025)

DEVELOPMENT OF PARACETAMOL BY CSIR

445 Shri Pramod Tiwari:

Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:

(a) whether Council of Scientific and Industrial Research (CSIR) has developed Paracetamol', a widely used pain reliever and fever reducer drug;
(b) if so, the details thereof;
(c) whether any domestic pharmaceutical company has been roped in to utilize this breakthrough to produce the drug;
(d) if so, the details thereof;
(e) whether several areas of technology gap have been found to exist in the manufacturing of paracetamol by Indian Industry; and
(f) if so, the way in which this innovation will make its production cheaper, faster and more eco-friendly?

ANSWER

THE MINISTER OF STATE (INDEPENDENT CHARGE) OF
SCIENCE AND TECHNOLOGY AND EARTH SCIENCES
(DR. JITENDRA SINGH)

(a) & (b) Yes, Sir. Constituent laboratory of the Council of Scientific and Industrial Research (CSIR) namely, National Chemical Laboratory (CSIR-NCL), Pune has developed the technology for continuous process for the production of Paracetamol under Mission Mode Project entitled "Innovative Processes and Technologies for Indian Pharmaceuticals and Agrochemical Sector Industries (INPROTICS)".

The process involves synthesis of Paracetamol by reacting Para Amino Phenol (PAP) with Acetic Acid using multi-functional reactor. The laboratory scale process for this synthesis was developed by CSIR-NCL in 2018 involving optimization of operational parameters, reaction kinetics and purification methodology. Based on the laboratory scale process, CSIR-NCL has designed basic engineering package (BEP) for Paracetamol pilot plant. Using this design, M/s. Texol Engineering Pune erected and commissioned the Paracetamol pilot plant which was successfully operated at CSIR-NCL. The purpose of Paracetamol pilot plant was to generate the realistic experimental data that can be used for design & development of commercial pilot plant and produce the Paracetamol samples for requisite commercial testing.

(c) & (d) Yes, Sir. M/s. Satya Deeptha Pharmaceuticals Limited (SDPL), Hyderabad, Telangana, India has signed an agreement with CSIR-NCL for licensing the know-how for continuous synthesis/production of Paracetamol on February 5, 2020. As a

part of license agreement with SDPL, CSIR-NCL first successfully demonstrated the Paracetamol production process to SDPL. As a follow-up CSIR-NCL has had multiple interactions involving detailed brainstorming session, exchange of ideas and trial visits. Based on these discussions, M/s. Satya Deeptha Pharmaceuticals Limited (SDPL) have designed, developed & erected a commercial plant at Humnabad, Karnataka for the continuous production of Paracetamol at a scale of 2800 TPA which was inaugurated in 2024.

(e) & (f) The primary objective of the INPROTICS mission mode projects was to develop viable, sustainable processes and products for pharmaceuticals and agrochemicals industries. Another important aspect of proposed projects was to serve the country with its contributions to 'Make in India' program and also towards better health and food security for all Indians. Conventionally, the production of Paracetamol is carried out in batch mode which causes inconsistency in product quality, larger plant footprint, larger raw material consumption per kilogram of product, generation of aqueous effluents leading to downstream processing of product. Further, the conventional process uses raw materials like acetic anhydride which are very expensive and are prohibited to be used.

All of the above-mentioned drawbacks get overcome in the continuous process for manufacturing Paracetamol thereby resulting in a cost-effective and cleaner process that is free of excess solvents and effluents, and having a smaller plant footprint.

The continuous processing plant for Paracetamol is the first of its kind ever created and established for the Pharmaceutical industries and lies very much within the domain of "Innovate in India", "Make in India" and "Import Substitution"

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