



राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

**NATIONAL INSTITUTE OF PHARMACEUTICAL  
EDUCATION AND RESEARCH (NIPER)**

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### Press Release

#### 'Impurity profiling of Pharmaceutical products: A Regulatory Requirement'

Seminar held at NIPER's SMPIC (Small and Medium Pharmaceutical Industry Centre)

One day seminar on 'Impurity profiling of Pharmaceutical products: A Regulatory Requirement', held at NIPER's SMPIC on 7<sup>th</sup> July, 2018. The centre organizes seminars on issues related to GLP, GMP and other allied areas. In these series, SMPIC with Indian Pharmaceutical Association (IPA), New Delhi jointly organized a one day seminar on 'Impurity profiling of Pharmaceutical products: NIPER's SMPIC at S.A.S. Nagar is set up under the ministerial guidelines to support/to cater the needs of Indian Pharmaceutical Industry. The centre aims at creating commercial synergy between industry and academia.

The inaugural session was held with welcome address of Director, NIPER Prof. Raghuram Rao Akkinapally. Dr. Rao welcomed all the distinguished guests Dr Jens Boertz, Pharmaceutical Product Manager, LGC -Germany, Dr Naresh Sharma, Deputy Drugs Controller (India), CDSCO, DGHS, MoHFW, India , Dr Mymoona Akhtar, Associate Prof. SPER, Jamia Hamdard and Mr Sidharth Sahai Malhotra, DI,CDSCO, New Delhi. Incharge SMPIC Prof. Arvind Bansal was present in the seminar.

Pharmaceutical impurities are the unwanted chemicals which are introduced during the manufacturing process for drug substance, drug product, excipient or during their storage. These impurities should be controlled throughout the manufacturing process as these can affect safety of medicines. It is therefore, important to have an accurate detection of impurities.

Dr Jens Boertz, (Pharmaceutical Product Manager, LGC , Germany detailed about "The Global regulatory context for impurity testing and Characterisation of Impurity Reference Standards were delivered by LGC team Germany.

Dr. Mymoona Akhter, Associate Professor, SPER, Jamia Hamdard, delivered lecture on Impurities- Regulatory Requirements

The seminar provided an insight into the regulatory aspects of Impurity Profiling of Pharmaceutical Products, testing of the Pharmaceutical impurities, characterization of reference standards and regulatory requirements on usage of Impurity Standards. All the topics were discussed at length by the experts, eminent personalities from regulatory agencies of GOI and Germany.

At the end all invited delegates/speakers were honored. The seminar could not have been a success without the team of SMPIC-NIPER- Prof. Arvind Bansal, Ms. Nishi Sharda and Mr. Baljinder Singh .

The seminar was well attended by about 55 personnel from industry and students from various institutes.

#### **About Photographs:**

- 1 Dr. Jens Boertz ,Incharge SMPIC Dr. Arvind Bansal & Director, NIPER Prof. Raghuram Rao Akkinapally during seminar**
- 2. Dr. Jens Boertz delivering lecture**
- 3. Dr. Naresh Sharma Dy. Drug Controller GOI**
- 4. LGC executive honouring Dr. Naresh**
- 5. Team of LGC with participants**
- 6. Group Photograph**

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