



National Institute of Pharmaceutical Education and Research (NIPER)

Sector 67, SAS Nagar, Mohali - 160062 (Punjab) INDIA



National Toxicology Centre*

Dedication

This facility is dedicated to small animals who sacrifice their lives for the betterment of mankind

*Partially funded by DPR Programme from DST, GOI, New Delhi

(First Govt. test facility approved by National GLP Compliance Monitoring Authority (NGCMA), DST, New Delhi

ABOUT NIPER

National Institute of Pharmaceutical Education and Research (NIPER), SAS Nagar is the first National Level Institute in pharmaceutical Sciences with a proclaimed objective of becoming a centre of excellence for advanced studies and research in pharmaceutical sciences. The institute is conceived to provide leadership in pharmaceutical sciences and related areas as well as toning up the level of pharmaceutical education and research.

NATIONAL TOXICOLOGY CENTRE

The National Toxicology Centre (NTC), a state-of-art test facility is constructed on an area of 700 sq. meters. established for toxicity studies of new chemical entities, food / feed additives / Pharmaceuticals / Chemicals / Pesticides from industries and other research organizations. The National GLP Compliance Monitoring Authority from Dept. of Science and Technology, Govt. of India New Delhi approved National Toxicology Centre (NTC) for conducting various toxicological studies under GLP certified environment. This centre was accredited first GLP certification in the year 2009. This has facilitated the testing of new chemical entities for regulatory submission in a quality environment, which is acceptable to different regulatory bodies. Till now we have successfully completed many studies sponsored by both of national and international sectors. We are routinely conducting acute and sub-chronic toxicity studies on small laboratory animals for various sponsors which are from both public and private sectors.

INFRASTRUCTURE

The National Toxicology Centre (NTC) is designed on a concept of clean and dirty corridor and has six state-of-art animal rooms including two quarantine rooms. The Centre is also equipped



with the individual ventilated caging system and metabolic cages. The centre is having an in vitro facility for screening of new chemical entities (NCEs) in the initial stage of drug development.

Quality Assurance Office

A full fledged Quality Assurance Unit (QAU) is in place to monitor all the GLP related activities of the Centre.

Archive Section

There are two Archive sections present in the test facility for proper storage of different kinds of study related dry and wet materials. There are two fire proof cabinets available in the Archives for the storage of important documents. The facility is also having well equipped necropsy room. There are three laboratories:

Biochemistry and hematology lab

It is equipped with modern instruments like hematoanalyser validated for veterinary use, Sophisticated Spectrophotometer (Flex station) with a facility to use ELISA plates, Shimadzu HPLC, Olympus microscope with attached computer and provision for taking high resolution photographs and Refrigerated Centrifuge.

The Centre is having 275 SOPs and 222 log books for different activities and instruments. The facility receives animals for different toxicity testing from the Central Animal Facility (CAF), NIPER.

Histopathology Laboratory

This laboratory is equipped with Automated tissue processor and stainer units, microtome and paraffin embedding unit for routine histopathology work.

Genotoxicity Laboratory

In vitro laboratory

The laboratory is fully equipped for conducting cytotoxic studies under cell culture conditions.





Test Item Control Office (TICO)

There is an independent TICO for the receipt, maintenance and further distribution of test item.

CAPABILITIES

The facility can undertake the following studies under the principles of Good Laboratory Practice (GLP) for testing of New Chemical Entities (NCEs) in small laboratory animals.

- Acute Toxicity Study
- Repeated dose toxicity Study

This facility can also take the following non-GLP studies:

- Toxicokinetic study
- *In vitro* cytotoxicity study
- Genotoxicity study

Genotoxicity Screening using Metasystem : The fast Msearch metaphase finding software, running with scanning hardware platform Metafer, helps to vastly increase the throughput in routine toxicological screening. Micronuclei in bi-nucleated cells and comet scan can be efficiently carried out on the same platform with specified software.

Toxicogenomic Screening: Major changes during the next decade is expected, as new technologies and knowledge become incorporated into regulatory and industrial practices. Evaluation of toxicological profile using DNA microarray are being used to predict the toxicity of NCEs early in the preclinical processes.

Toxicity Screening of nanoparticles: The rapidly developing field of nanotechnology is a potential source of toxicity through inhalation, ingestion, skin uptake and injection of engineered nanomaterials. Information about the safety and potential hazards is urgently needed. NIPER has been conducting projects on nanoparticles toxicity.

Inhalation toxicity Testing: The test facility is equipped with state-of-art inhalation exposure system (CH Technologies, California) for nose only exposure to both mice and rats.

ORGANIZATIONAL STRUCTURE

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| Head, Management | Director, NIPER |
| Management | Prof. K.B. Tikoo |
| Study Directors / Study Personnel | Dr. G.B. Jena Ms. Rupinder Pal Kaur Ms. Nidhi Mr. Sharath S Babu Ms. Vibha Ahuja Mr. Vinod Kumar |
| Quality Assurance Unit | Ms. Kanwaljit Kaur Dr. Malti Singh |
| Veterinarian | Dr. K. Srinivasan |
| Test Item Controller | Mr. Shantaram R. Bhade Mr. Vijay Mishra |
| Archivist and Archive Staff | Mr. Shantaram R. Bhade Mr. Sanjeev Bhardwaj Mr. Vijay Mishra |
| Statistician | Dr. Pooja Arora |
| Pathologist | Dr. B.N. Datta |

Inauguration of the first GLP Certified test facility in Govt. Sector

