3. Chronic Toxicity Studies:

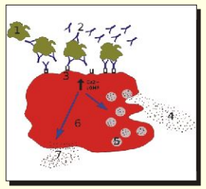
Chronic toxicity studies aims to characterize the effect of test compounds following repeated exposure for the long period of time in animals. The routes of exposure are most likely the one to which human are most likely to be exposed to that particular compound.

4. Irritational Study:

This is the surface effect of a compound on the body surface (skin and mucous membrane) is important because accidental contamination is always a possibility hence to check any such effects the following studies are performed

- **Primary Skin Irritation**
- **Mucous Membrane Irritation.**

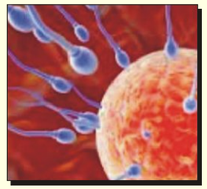
MUCOUS MEMBRANE IRRITATION



5) Allergic Sensitization:

Repeated exposure of a test substance can activate the immunological system that can be activated by prior exposure and the response may be characterized by various external factors like erythema, edema, nasal discharge, tearing etc. This study gives information regarding the sensitization of the immune system towards a particular compound.

- **Guinea Pig Maximisation Test (GPMT)**
- **Mouse ear swelling test (MEST)**
- **Local lymph node assay (LLNA)**



6) Reproductive Toxicity:

This study aim to find out effect of test compound on fertility and reproduction. The many compounds can affect the fertility and reproduction, often in an insidious manner without any overt signs of toxicity. Fertility of males & females can be affected or adverse effects on the developing embryo or fetus may result due to the exposure of chemicals.

7) Carcinogenicity:

A carcinogen is any substance, radionuclide, or radiation that is an agent directly involved in causing cancer. This may be due to the ability to damage the genome or to the disruption of cellular metabolic processes.
Carcinogenicity is the potentiality of a chemical/radiation to induced cancer. The main objective of this study is to find out carcinogenicity effect of test compound when exposed for a prolonged period.

8) Mutagenicity:

Adverse effects caused by any chemical / compound on the genetic material of the cells i.e. DNA or by altering its structure or function can be checked out by:

- **In- vitro Method: Ames test**
- **In vivo Method: Micronucleus Test**

9) Biocompatibility Study:

To determine the toxic effects of the medical devices (if any) as well the effects by leachable, the following studies are performed:

- **Cytotoxicity**
- **Irritation (skin, eyes, mucous membranes)**
- **Sensitising**
- **Toxicity (systemic, acute, sub acute, sub chronic)**
- **Intracutaneous reactivity**
- **Genotoxicity (in vitro and in vivo)**
- **Implant in different tissues (muscle, bone, subcutaneous)**
- **Haemocompatibility**

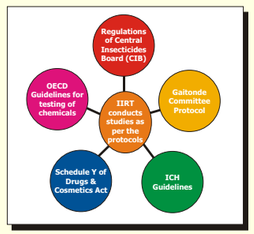
10) Supplementary toxicity Studies:

- **Neurotoxicity studies on Egg laying hens**
- **Synergism & Potentiating Studies (Combined effects of various chemicals)**

PHARMACOLOGICAL STUDY

- **Screening of drugs for Analgesics, Anti-Inflammatory and Antipyretic activity**
- **Hypoglycemic and hypocholestrimic effect of drug**
- **Hepatoprotective, hepatogenic and hepatoxic effect of drug**
- **Dermal permeability study of drug in rats**
- **Immunomodulatory activity of compound**
- **Hypersensitivity and anti hypersensitivity activity study**
- **In vitro haemolysis test**
- **Oxidative stress study**

IIRT conducts the studies as per the National & International Guidelines

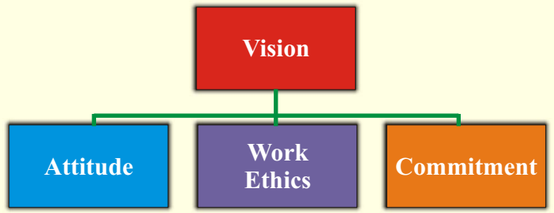


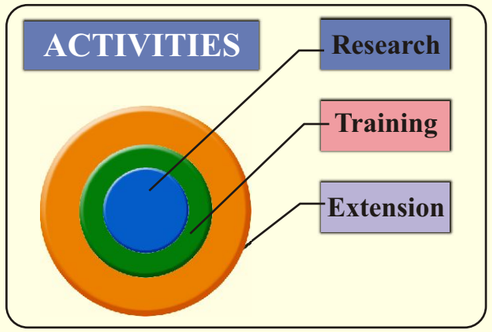
IIRT

Institute for Industrial Research & Toxicology
औद्योगिक अनुसंधान एवं विष विज्ञान संस्थान

Registration No. 1303/C/09/CPCSEA

Institute at a glance





PERFECTION IN COMMITMENT PCMS
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INTRODUCTION:

Institute for Industrial Research & Toxicology is an emerging contract Research Organization (CRO). Here we perform various toxicological studies of Organic and Inorganic chemicals, pesticides, insecticides and Pharmacological testing of Indigenous and synthetic drug molecules. We have performed the research studies of compounds coming from leading Industries of India and overseas. Institute for Industrial Research & Toxicology (IIRT) core value is "Integrity of Service through Honesty, Responsibility and Uncompromising Devotional Qualities in Generating Unbiased Preclinical Toxicological and Biosafety Data." All the Pharmacological & Toxicological Research conducted were done as per the National & International guidelines. We are constantly review our research quality for better than the best performance in testing compounds. Customer satisfaction through Nobel Research is our aim in conducting the studies.

CORE AREAS OF RESEARCH

- Drugs, Pharmaceuticals & Cosmetics
- Food, Farm & Herbal Products
- Chemicals, Pesticides & Agro chemicals
- Inorganic Chemicals & Fertilizers
- Metals & Alloys
- Minerals & Ores
- Petroleum products & Fuel

ANIMAL HOUSE FACILITY AT IIRT

RAT | MICE | RABBIT | CHICKEN | QUAIL | GUINEA PIG

LABORATORY FACILITIES

HAEMATO-BIOCHEMICAL LAB	HISTOPATHOLOGY LAB	MICOBIOLOGY LAB	ANALYTICAL LAB
Complete hematology kit	Distillation Unit	All the basic requirements for the microbial study	High Performance Liquid Chromatography (HPLC)
UV Spectrophotometer	Microtome, Staining kit	Laminar flow	Thin Layer Chromatography (TLC)
Biochemical auto analyzer ERBA 5X	Homogenizer	Biological Incubator	Gas Liquid Chromatography
Deep freezer	Hot Plate	Hot Air Oven	IR Infrared spectrometer
Binocular microscope with attached camera	Tissue processor	Autoclave	Water Bath
Centrifuge machine	Cryostat Microtome	ELISA	Refrigerated Centrifuge
Digital pH Meter	Trinocular Research Microscope	Gel Electrophoresis	Magnetic Stirrer with hot plate
Hematology auto analyzer	Slide staining Machine	Colony Counter	Atomic Absorption spectrophotometer

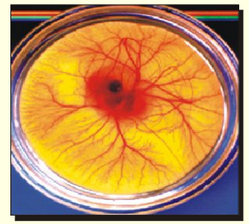
TOXICOLOGICAL STUDY

A) INVITRO TOXCITY STUDY:

1. OCCULAR IRRITATION ASSAY

❖ **Chorioallantoic membrane vascular assay**

- Non-animal alternative to Draize eye test
- Uses the vascularized chorioallantoic membrane
- High concordance to in vivo data
- Used to investigate the vascular effects such as neovascularization, angiogenesis, and anti-angiogenesis, which are of particular interest to pharmaceutical and cosmetic product research and development.



❖ **MatTek epiocular model**

MatTek's **EpiDerm™** is a in vitro 3-D human skin tissue model and **EpiOcular™** in vitro 3-D human corneal tissue model have become increasingly important as replacements for traditional animal-based toxicology testing in the **pesticide cosmetics, cleaning products and pharmaceutical industries.**

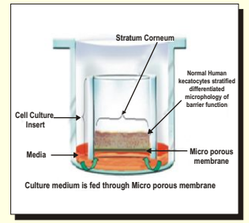
2. DERMAL IRRITATION ASSAY

- **3D human skin equivalent system**

3. DERMAL CORRISION ASSAY

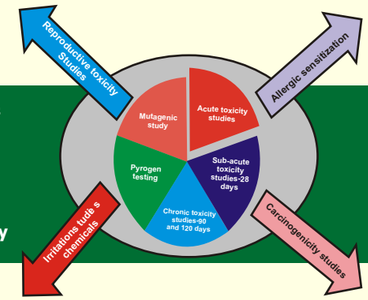
- **Corrositex test**

It is an in vitro method used to determine the dermal corrosive potential of chemicals and chemical mixtures.



4. PHOTO TOXICITY ASSAY

B) INVIVO TOXICITY STUDY

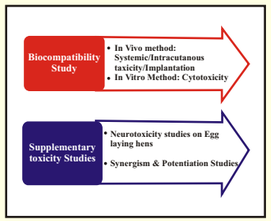


1. Acute toxicity studies
2. Sub-acute toxicity studies- 28 days
3. Chronic toxicity studies 90 & 120 days
4. Irritation studies chemicals
5. Allergic sensitization
6. Reproductive toxicity studies
7. Carcinogenicity studies
8. Mutagenicity studies
9. Biocompatibility Study
10. Supplementary Toxicity Study

1. Acute Toxicity Study:

Acute toxicity study aim to determine toxic manifestation of the test substances that occurs when animal exposed to one or more dose of test substance with in 24 hrs. This study provides information regarding the possible health hazards which are likely to occur, if human are exposed to a single dose of a substance. This way, can help determine the level of usage of that substance. The following routes of exposure for acute toxicity study were followed according to respective guidelines.

- **Oral**
- **Dermal**
- **Inhalation**
- **Intravenous**
- **Intraperitoneal**
- **Other protocol specified route**



2. Sub Acute Toxicity Study:

Sub-acute toxicity study aim find out toxic effect of drug on repeated exposure and also provide the valuable information i.e. delayed effect which may result due to the cumulative effect of the chemicals on the tissues or other biochemical mechanisms. This study also helps in establishing the level of the safe usage of compound. The following routes are commonly used:

- **Oral**
- **Dermal**
- **Inhalation**
- **Intravenous**
- **Intraperitoneal**
- **Other Intraperitoneal Route**
- **The period of exposure may vary from 14 days to 90 days.**