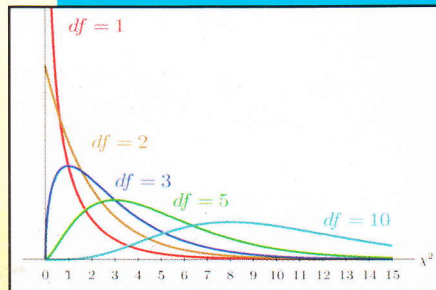
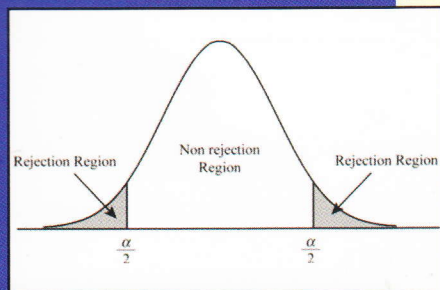
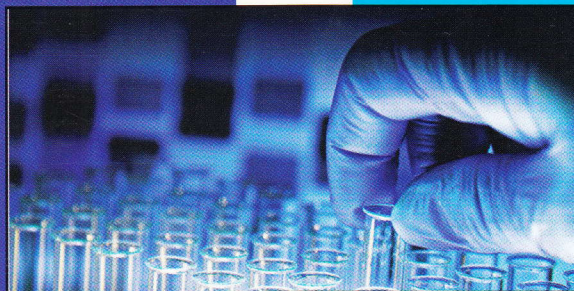


AS PER PCI REGULATIONS
THIRD YEAR B. PHARM.
SEMESTER-VI

EXPERIMENTAL PHARMACOLOGY-III

Dr. GHANSHYAM PANIGRAHI

Dr. ARJUN PATRA



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Experiment No. 12

DETERMINATION OF ACUTE EYE IRRITATION/CORROSION OF A TEST SUBSTANCE

(Chapter contributed by Dr. Ghanshyam Panigrahi and Dr. Arjun Patra)

Purpose:

At the end of practical class, the students shall be able to:

1. Know about eye irritation and eye corrosion.
2. Know about the OECD Test Guideline 405 for eye irritation/corrosion.
3. Know about testing and evaluation strategy for eye irritation/corrosion.

Terminology:

Eye Irritation: It is defined as "the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application" (UNECE, Part 3.3, 2015).

Eye Corrosion (Serious Eye Damage): It is defined as "the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application" (UNECE, Part 3.3, 2015).

Description:

The Organisation for Economic Co-operation and Development Test Guideline 405 (OECD TG 405) and the Globally Harmonized System (GHS) for Classification and Labelling of Chemicals, Part 3.3 (UNECE, 2015) describe internationally accepted guidelines using animal methods for eye irritation/corrosion studies. OECD TG 405 (adopted in 1981 and updated in 1987, 2002, 2012 and 2017) to reflect new efforts to refine and reduce animal use; and routinely use of topical anesthetics, systemic analgesics, and humane endpoints during *in vivo* ocular irritation safety testing. OECD guidelines, validation authority documents, and other regulatory acceptance for non-animal approaches for assessing serious eye damage/eye irritation are described. For certain substances, such an analysis may indicate the need for *in vivo* studies of the ocular corrosion/irritation potential of the substance. In all such cases, before considering the use of the *in vivo* eye test, preferably a study of the *in vitro* and/or *in vivo* skin corrosion effects of the substance should be conducted first and evaluated in accordance with the sequential testing strategy in OECD Test Guideline 404.