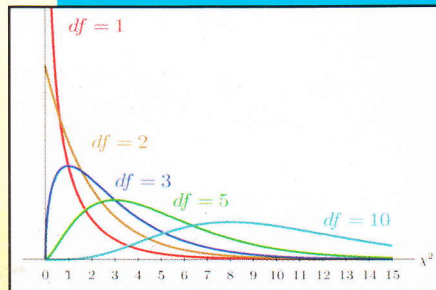
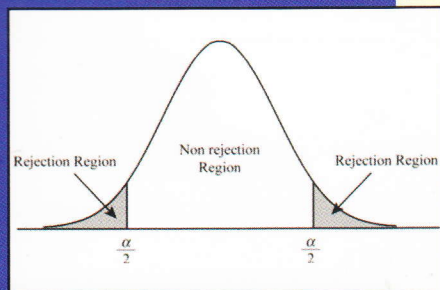
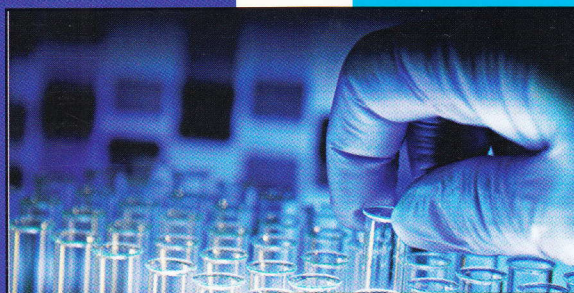


AS PER PCI REGULATIONS
THIRD YEAR B. PHARM.
SEMESTER-VI

EXPERIMENTAL PHARMACOLOGY-III

Dr. GHANSHYAM PANIGRAHI

Dr. ARJUN PATRA



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Experiment No. 9

TEST FOR PYROGENS (RABBIT METHOD)

(Chapter Contributed by Dr. Swaha Satpathy and Dr. Arjun Patra)

Purpose:

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

1. Know the detail about pyrogen test.
2. Know about the samples which should be subjected to pyrogen test.
3. Know the *in vitro* and *in vivo* methods of pyrogen testing.

Terminology:

Pyrogen: These are the agents that cause rise in temperature which can be polysaccharide or protein in nature.

Endotoxin: It is a type of pyrogen and is a component of outer cell wall of Gram negative bacteria. Chemically it is a lipopolysaccharide.

Description:

Pyrogens are by-products of bacterial metabolism and increases body temperature when administered parenterally. These are produced from all types of bacteria and closely related to bacterial antigens. Chemically they are lipids comprise of complex polysaccharide or polypeptide molecules containing phosphorous and nitrogen. They may enter into any parenteral preparations and make it pyrogenic. Pharmaceuticals such as; sodium citrate solution, dextran and many antibiotics prepared by fermentation process are especially liable to pyrogenicity. Hyperthermia, body aches, chills, rise in arterial blood pressure are the symptoms of pyrogenic reactions. Intravenous preparations before use should be carefully checked for pyrogenicity otherwise it would cause serious adverse effects in the patient. Pyrogenic solutions are either discarded or made pyrogen free (if possible by adsorption on charcoal, heating or distillation).

Objective: To determine the pyrogen free nature of given sample of the parenteral preparation in rabbit.

Principle: Human and rabbits are equally reactive to the threshold level of pyrogenic samples when administered intravenously. The assay is based on the increase in body temperature of rabbit after intravenous injection of the test compound as a sterile solution. As per I.P., B.P. and U.S.P. a sample is considered pyrogenic and rejected if the increase in body temperature in rabbits within 3 hours after i.v. administration of the sample exceeds 2.4°C. This test is important because presence of pyrogenic substances (exogenous or