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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment
To demonstrate the friability testof the tablets as per the monographs.

Aim:

To demonstrate the pyrogen testingof sterile injections as per the monographs.

Reference :

‘ Dr. Gupta G.D , Dr. Sharma Shailish , Dr. Sharma Neelam’ “Practical Manual of Pharmaceutics” Published by Nirali Prakashan, Page no 183 – 186

Apparatus and Materials Required :

test solution (sterile injections), rabbit, watchand Limulus polyphemus

Theory :

Pyrogens are endotoxin metabolites of microorganisms that increase the body emperature when parenteral preparations contaminated with them are administered.

Procedure

The pyrogen test is carried out as flows

1) **Rabbit Test:** For this test, healthy rabbits maintained under suitable environment and diet before the test, are used. Normal or control temperatures are selected for each animal and are used as the base for easily determining any increase in temperature when the test solution is injected. Three rabbits whose temperature differs from each other by not more than 1°C and whose body temperatures are also normal are selected.

The test solution (obtained from the product to be tested) is warmed up to 37°C +2°C and injected in the marginal ear vein of each rabbit, completing each injection within 10 minutes of the start of administration. The temperature should be monitored at intervals of 30 minutes for 1-3 hours after the injection.

The product is considered to fulfil the requirements for the absence of pyrogens if no rabbits show a rise in temperature of 0.5°C or more, on the other hand if any of the three rabbits show a rise in temperature of 0.5°C or more, the test is continued using five more rabbits. Now if not more than three out of the eight rabbits show a rise in temperature, the product is considered to meet the requirements for the absence of pyrogens.

2) **Limulus Amebocyte Lysate (LAL) Test:** This in vitro test method for detecting pyrogens in the product utilises the gelling property of the lysate of the amebocyte of Limulus polyphemus (the horseshoe crab). If the pyrogenic endotoxins from gram-negative bacteria are present in the product, a firm gel is formed within 60 minutes on incubating the product at 37°C. The LAL test is 5-10 times more sensitive than the rabbit test, and with the use of serial dilutions, it is assumed to be semi-quantitative

Result :

The pyrogen testing of sterile injections as per the monographs was studied.

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