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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment
To demonstrate the Leaker testingof sterile injections as per the monographs.

Aim:

To demonstrate the Leaker 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 176 – 179

Apparatus and Materials Required :

05-10% methylene blue,vacuum chamber with 27 inches Hg andsterile injections.

Theory :

The leak test can be carried out during the cycles of autoclaving by immersing the ampoules in a bath of dye. This method achieves two objectives, firstly it evaluates the presence of any leakage and secondly it sterilises the product. The leak test is not suitable for vials and bottles because they have rubber closures which are not rigid. Ampoules are scaled by tip sealing and pull sealing methods. Due to improper handling, there are chances that the ampoules are incompletely sealed and cracks may appear around the seal or at the base during the process of sealing Therefore, the leak test is used for identifying the improper filling and sealing of ampoules, and if found any they are rejected.

Procedure :

1) In this test, sample ampoules are immersed in a deeply coloured dye solution (0.5-1.0% methylene blue) and negative pressure is applied in a vacuum chamber with 27 inches Hg or more for 30 minutes.
2) After this period, vacuum is released and the dye under the influence of atmospheric pressure penetrates the ampoules through any opening present.
3) Then the ampoules are washed externally and visually observed to check any change in colour of the product due to the penetrated dye.

Result :

The Leaker testingof sterile injections as per the monographs was studied.

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