

STERILE LUBRICANTS FOR PHARMACEUTICAL APPLICATIONS

WHAT IS STERILITY TEST ???

The test is applied to Lubricants which, according to pharmacopeia, are required to be sterile. However, a satisfactory result indicates that no contaminants like micro-organisms have been found in the sample examined in the conditions of the test.



NECESSITY

The instruments or machinery used in surgical operations often come in direct contact with the Human body. Few of the equipment from surgical machinery like endoscopes, etc. Which needs lubrication, here the lubricants used are needed to be completely sterile and should inhibit the growth of micro-organisms in it.



When a Lubricant passes the sterility test, it is declared that the Lubricating material can be used in the specific applications in the surgical and pharmaceutical equipment. Here the equipment comes in direct contact with Humans or the medicines prepared in the pharmaceutical facilities are consumed by the patients. Hence, it is at most important for the lubricant to be sterile.

GUIDELINES

- Sterilize all required accessories for sterility test in an autoclave at 121 deg C for 30 mins as per SOP.
- Enter the sterility of testing room with the proper gowning procedure as per SOP.
- Disinfect the outer surface of the container of the sample prior to testing and allow it to dry.
- Operate the UV lights and the other lights as per standard SOP.



TEST

- i. Take a 2 x 50 ml of sample Lubricant in a sterile container.
- ii. Arrange the filtration assembly and connect it with the vacuum pump.
- iii. Filter the collected solution aseptically through 0.45 microns membrane with the help of a vacuum.
- iv. If the testing sample has any antimicrobial properties/preservatives, filter with 3 x 100 ml of freshly prepared sterile 0.1 % peptone as a rinsing solution.
- v. Open the assembly and cut the membrane filter in 2 equal parts with a sterile cutter.
- vi. Inoculate aseptically one-half membrane to Thioglycollate medium and another half in a Soyabean casein digest medium, both for 14 days as per pharmacopeia.

Thioglycollate - For aerobic and anaerobic bacteria.
Soyabean Casein digest - For other microbes and fungus.
- vii. Daily observe the incubated media for presence (turbidity) or absence (clear) of microbial growth and note the results.



RESULTS OF MOSIL SAM - 9140

- MOSIL SAM - 9140 was observed to have stable consistency after testing it for sterility.
- This PTFE based synthetic grease is concluded with no microbial or fungal growth after observation.
- MOSIL SAM - 9140 is declared to be sterile lubricant and can be used in respective applications in pharmaceutical and surgical equipments.



MOSIL LUBRICANTS is a Manufacturer of Specialty lubricants and has a good basket of Food grade lubricants for pharmaceutical facilities with required NSF certifications and proven case studies for various customers in India.