



Bioburden Testing: Application of Most Probable Number Method

Bioburden testing can be achieved using a number of techniques based on the medium to be tested. However, most of the commonly used methods may not be the best fit for sensitive products such as powders, gels or adhesives like wound dressings. Typically, this is because of the physical nature of these medical products that traditional extraction or filtration techniques are difficult to perform to achieve the desired results. To ensure quality control over such products, another suitable method known as Most Probable Number (MPN) is performed. This technique is helpful in achieving a more sensitive level of bioburden detection because the bioburden can be trapped in areas where it is difficult to remove by extraction.



How MPN Method Works?

To remove bioburden from medical products using MPN method, the product is placed into a liquid growth medium in 10-fold dilutions based on the principle of extinction dilution. The assumptions of the MPN method are that the liquid growth medium will support the growth of microorganisms and will turn the medium turbid. The level of medium's turbidity can give information about the presence of viable organisms in the sample. All the tube samples are

analyzed for turbidity and the trend is measured against a table of values (US Food and Drug Administration's Bacterial Analytical Manual). A typically used MPN design compares three replicates with a three-log unit. The pattern is then examined through the table to give the most probable number.

Where is it Used?

The MPN method can be used in various scenarios where other methods of bioburden testing cannot perform efficiently. MPN is applied in medical devices, delicate adhesives such as bandages or gauzes, tissue-based products, pharmaceuticals, powders and gels. As stated in ANSI/AAMI/ISO 11737-1:2006®2011, "The MPN method may have value for the determination of bioburden for liquid medical devices, viscous fluids, powders or in situations where the bioburden is being estimated in a liquid used as an eluent for a single product".

Implementation and Acceptance

The MPN method is a highly effective technique used in bioburden testing by microbiologists. However, it is vitally important to see if the method is performed correctly to achieve the results from a certain sample. If the MPN method is not carried out correctly, it can not only affect the quality check measures of the product, but can also lead to problems for a medical device manufacturer based on the standards of respective regulatory bodies.

There are many other products manufactured by pharmaceutical companies that require MPN method to check the bioburden levels because these products cannot be tested appropriately applying other bioburden testing techniques. At the same time, it is valuable to ensure the presence of knowledgeable microbiologists to carefully observe the test process starting from initial sampling to achievement of desired results.

By now, we have established the importance of bioburden testing and its various methods that are used for quality check over a variety of medical devices and products. To get the best lab testing results for your medical devices, you can get the services from experienced professionals having appropriate knowledge and all the modern equipment to give you the best results.