



Microbiological Testing Capabilities in Kyoto Japan Site

➤ Microbiological testing under pharmacopoeia

For microbiological testing of pharmaceuticals, the test method defined in general test method of Pharmacopoeia is used. The three test methods shown in the table below are mainly used, and these are globally harmonized with three regulations (Japanese Pharmacopoeia, US Pharmacopoeia, and European Pharmacopoeia).

Japan Pharmacopoeia General Tests	
4.01 Endotoxins test	Aerobic viable count Test for specified microorganisms
4.05 Microbial limits test	
4.06 Sterility test	

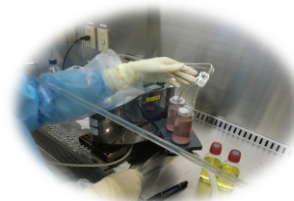
➤ Samples applied by microbiological testing

In addition to the microbiological quality assurance by testing on the final products (preparations), pharmaceuticals need to be monitored based on a risk basis throughout the processes as well. The table below shows the samples types applied to microbiological tests and the test items.

	Non-sterile products	Sterile products
Drug substance solutions	–	aerobic viable count
API/Intermediates /Raw materials	aerobic viable count	aerobic viable count endotoxins
Process solutions	–	aerobic viable count
Preparations	aerobic viable count specified microorganisms	sterile endotoxins

➤ Method development experience

We conduct method development and method validation under cGMP. We have developed a wide range of testing methods not only for pharmaceuticals, but also for drug substances, raw materials, process solutions, etc. For the purpose of monitoring raw materials, drug substances and processes, the number of test methods set for microbial limits testing (aerobic viable count) is increasing.



➤ Release test and technology transfer

We conduct release test / stability test using the test method we developed. In addition, if you want to conduct testing at a pharmaceutical manufacturing plant or another testing organization, we will transfer the technology of the test method.



➤ Other microbiological testing

We also conduct the following tests:

- Preservatives effectiveness tests
- Biological indicator (BI) evaluation by BIER

Contact us: Eurofins BPT Kyoto
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Comprehensive GMP Testing Services

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