

MICROBIOLOGICAL TESTING

Microbiology testing is critical to ensuring sterility of your product and to determine Antimicrobial Effectiveness Test (AET), Microbial limit test, as well as identifying microorganisms and potential contamination. Our dedicated microbiology laboratory is on standby to provide qualitative and quantitative assessments of non-sterile products using USP, FDA/BAM, and in-house methods. With over 40 years of experience in this space, we help our clients determine the tests that best fit their needs and support their products' compliance with relevant regulatory requirements or support on research product by microbiologically.

Microbiological Examination of Nonsterile Products

METHOD QUALIFICATION

Testing will determine if the method can neutralize any inherent antimicrobial properties of drug products and ingredients (tested according to USP chapters <51>, <61> and <62>) when sample preparations are challenged with specific, viable test microorganisms.

Microbial Enumeration Tests - USP <61> Suitability of the Counting Method
Suitability of the Counting Method (Total Aerobic & Total Combined Yeast/Mold Counts)

Tests for Specified Microorganisms - USP <62> Suitability of the Test
Bile Tolerant Gram-Negative Bacteria, Presence/Absence (Qualitative)
Bile Tolerant Gram-Negative Bacteria, Most Probable Number (Quantitative)

*B.cepacia USP<60>	Presence/Absence Qualification
E.coli	Presence/Absence Qualification
Pseudomonasaeruginosa	Presence/Absence Qualification
Salmonellaspecies	Presence/Absence Qualification
Staphylococcus aureus	Presence/Absence Qualification
Candidaalbicans	Presence/Absence Qualification
Clostridiumspecies	Presence/Absence Qualification

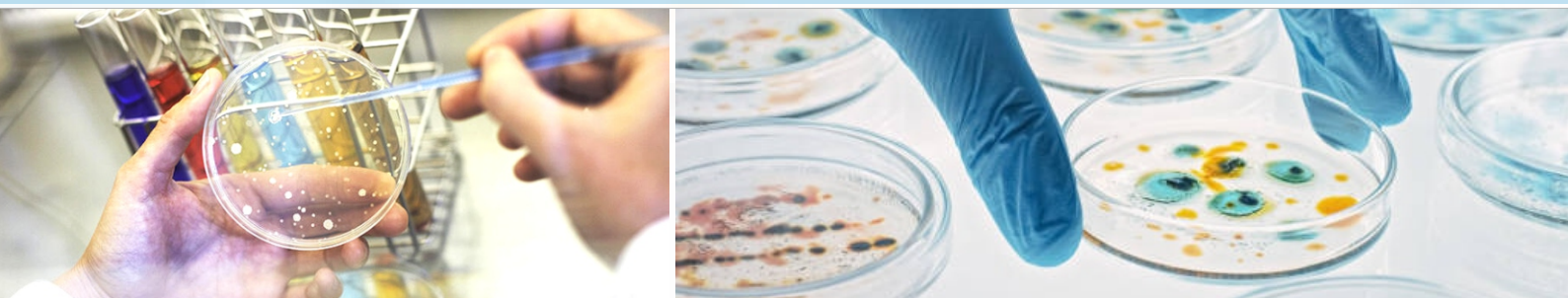
RELEASE TESTING

Microbial Enumeration Tests - USP <61>
Total Aerobic Microbial Count and Total Combined Yeasts/Molds Count
Total Aerobic Microbial Count only

Tests for Specified Microorganisms - USP <62>
Bile Tolerant GramNegative Bacteria, Presence/Absence (Qualitative)
Bile Tolerant Gram-Negative Bacteria, Most Probable Number (Quantitative)

* B.cepacia	USP<60> Presence/Absence Release
Test E.coli	Presence/Absence ReleaseTest
Pseudomonasaeruginosa	Presence/Absence ReleaseTest
Salmonellaspecies	Presence/Absence ReleaseTest
Staphylococcus aureus	Presence/Absence ReleaseTest
Candida albicans	Presence/Absence ReleaseTest
Clostridiumspecies	Presence/Absence ReleaseTest

USP <60>, <61>, <62>test requirements are not the same for all materials. Refer to current USP official monographs and to Chapter <1111>in the current USP for guidance.Please contact Laboratories for assistance.



Process Water Testing (EP/USP/JP/BP)

On-Site Sample Collection
Coliform Bacteria (presence/absence)-Qualitative
Coliform Bacteria Count (quantitative)
Total Aerobic Microbial Count (membrane filtration or pour plate)
Endotoxin Testing (By Gelclot Method)
Conductivity, USP <645>
Total Organic Carbon (TOC), USP<643>
Heterotrophic Plate Count
Heavy Metals Testing

Environmental Monitoring

On-Site Sample Collection
Total Aerobic Plate Count, Viable Air Sampler or Settling Plates
Total Combined Yeast / Mold Count, Viable Air Sampler or Settling Plates
Total Aerobic Plate Count, Compressed Air Sample

Cleaning Validation

Total Aerobic Plate Count, Contact (RODAC)Plates
Total Aerobic Plate Count, Swab Samples
Total Combined Yeast/ Mold Count, Contact (RODAC) Plates
Total Combined Yeast/ Mold Count, Swab Samples
Total Organic Carbon (TOC), Swab Samples, USP <643>

Organism Identification of Isolates

Gram stain only
Coagulase Test
Oxidase Test
AccuPro-ID® (environmental monitoring & water samples)
AccuGENX-ID® (raw materials & product samples)

1.AccuPro-ID® and AccuGENX-ID® are performed by subcontract Laboratories

- Chromak Research offers a comprehensive range of microbiology and chemistry capabilities in support of your projects—all performed in strict adherence to cGMP requirements.
- We offer outstanding service and flexible options in sample collection with daily sample courier service in the U.S. and pickup and analysis of samples on weekends (with advance arrangements by the client).
- We can provide sample collection containers for your Process Water Testing and Environmental Monitoring.



CHROMAK RESEARCH INC

4 Leonard St, Metuchen, New Jersey 08840

Phone: (732) 560-1366 | Toll Free Number : 1-833-CHROMAK (1-833-247-6625)

info@chromakresearch.com | www.chromakresearch.com

Laboratories are fully equipped with standard laboratory equipment and state of the art analytical instrumentation including ICP-MS, LC-MS, GC-MS, HPLC, GC with Headspace, TLC, UV, IR, Polarimeter, Refractometer, muffle furnace, vacuum ovens, stability chambers and Amino Acid Analyzer.