

Microbiology Glossary

- **Aerobic Plate Count (APC/TAMC):** A test that measures the total number of aerobic bacteria in a product. It is used to evaluate overall microbial cleanliness.
- **Bioburden:** The total number of microorganisms present in a raw material, in-process sample, or finished product before preservation or sterilization.
- **Burkholderia cepacia Complex (BCC):** A group of waterborne bacteria associated with serious infections and product recalls in non-sterile products.
- **CFU (Colony Forming Unit):** A unit used to estimate the number of viable microorganisms in a sample based on colony growth on agar.
- **Challenge Test (Preservative Efficacy Test):** A study that evaluates how well a product's preservative system controls microbial growth over time after intentional contamination. Also referred to as USP <51>.
- **Contamination:** The unintended presence of microorganisms in a product, raw material, or manufacturing environment.
- **Environmental Monitoring:** Testing of air, surfaces, and equipment to assess microbial control within a manufacturing or laboratory space.
- **Objectionable Organisms:** They are specific bacteria that must not be present in certain products due to safety risk, such as *Salmonella*, *Candida albicans*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. coli*, and *Burkholderia cepacia* complex.
- **ISO 17516:** An international standard that defines acceptable microbiological limits for cosmetic products.
- **Microbial Limits Test:** A regulatory test that determines whether microbial levels in a product meet established acceptance criteria.
- **USP <51> (Antimicrobial Effectiveness Test):** A standardized challenge test used to evaluate how effectively a product's preservative system controls microbial growth throughout its shelf life.
- **USP <60> (Burkholderia cepacia Complex):** A USP chapter focused on detection of *Burkholderia cepacia* complex, an objectionable organism of concern in non-sterile pharmaceutical, cosmetic, and personal care products.
- **USP <61>:** United States Pharmacopeia method for microbial enumeration testing.
- **USP <62>:** United States Pharmacopeia method for testing specified objectionable organisms.
- **Water Activity (Aw):** A measurement that indicates how much free water is available to support microbial growth.
- **Pathogen:** A microorganism capable of causing disease in humans.
- **Preservative System:** Ingredients added to a formulation to prevent microbial growth throughout shelf life.
- **Sterility Test:** A test that confirms complete absence of viable microorganisms in products required to be sterile. Also known as USP <71>.
- **Total Yeast and Mold Count; Fungal Count (TYMC):** A test that measures combined yeast and mold populations in a product.



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