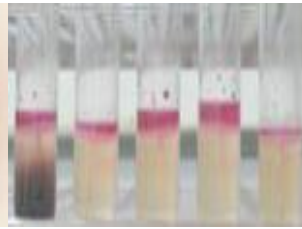
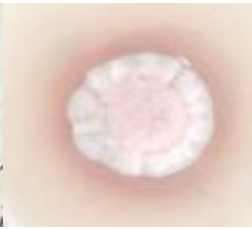
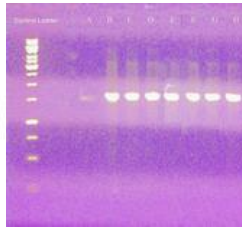


The role of Microorganisms in Quality Assurance

Presented by: Farzneh Azizmohseni

Director of Persian Type Culture Collection (PTCC)

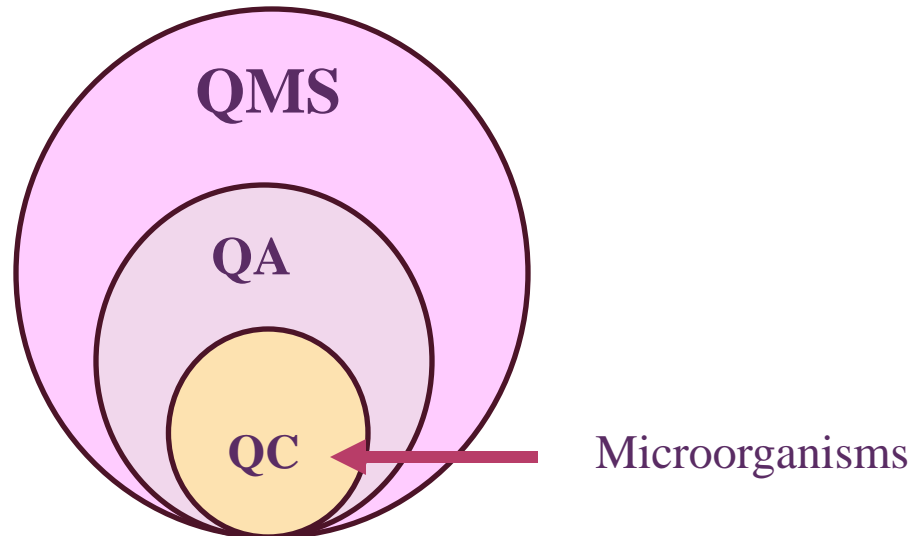
Iranian Research Organization of Science and Technology (IROST)

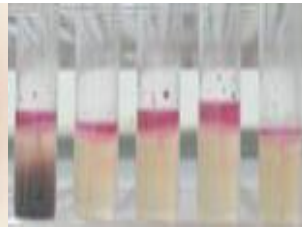
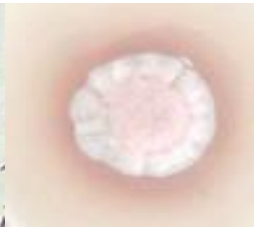
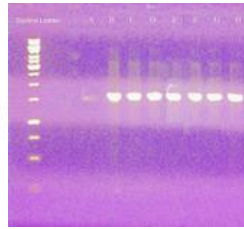


Quality Assurance vs. Quality Control

QA: part of quality management focused on providing confidence that quality requirements will be fulfilled

QC: that part of QA, which primarily concerns the control of errors in the performance of tests and verification of test results.



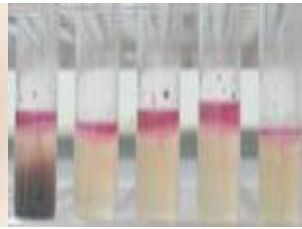
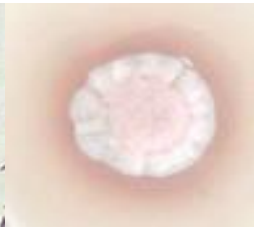
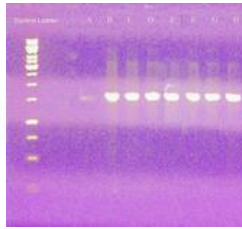


Type strain, Reference strain, Quality Control strain

Type Strains: The type strain is defined in the context of formal bacterial taxonomy

Reference Strains/ Quality Control Strains: The strain that is widely referred by a recognized organization such as CLSI, ASTM, Pharmacopeia, ISO, etc....

They play a pivotal role in meeting regulatory requirements for various tests such as Growth Promotion, Method Suitability, Antimicrobial Effectiveness, Sterility and many more.



Stages of Lab testing

- Pre-analytical stage:**

Begins before performing laboratory tests and the most vulnerable part of the total testing process



- Analytical phase:**

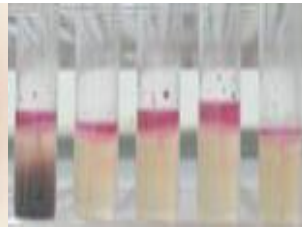
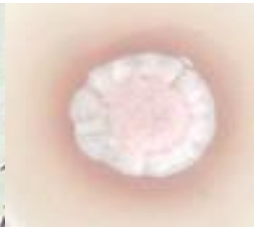
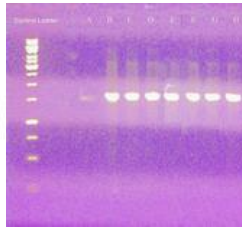
This phase is comprised of all the lab testing procedures.



Reference Microbial Strains

- Post-analytical phase:**

Involves reporting the final result. Results are sent to the required individual in a timely manner.



Reference strains in Pre-Analytical QC

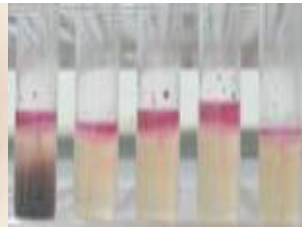
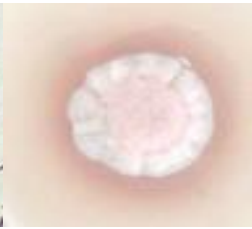
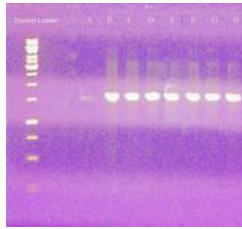
- ❑ **ISO 11133:2014 (=INSO 8663)** Used for QA of culture media intended for microbiological analysis of food, animal feed and water

- ❑ **Growth Promotion Test (GPT) in pharmacopeia (exp. USP<61>)**

GPT is performed by inoculating new batches of media with a small number of **Reference Microorganisms** and compare with prior tested or approved media batches.

- ❑ **CLSI M100 ED34: 2024**

Performance Standard for Antimicrobial Susceptibility Testing, 34th Edition (QC of Antibiotic discs with **Reference Microorganisms**)

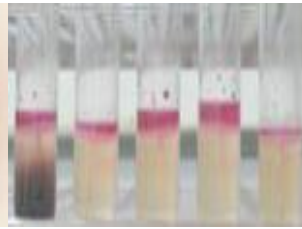
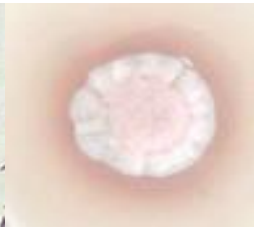
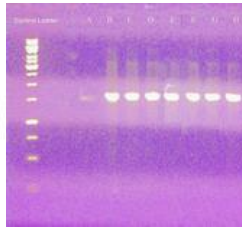


Reference strains in Pre-Analytical QC

❑ Biological Indicators (USP <55>)

Biological Indicators are typically spores of specific microorganisms in a growth medium or inoculated to a paper strip, which are put through the sterilization cycle.

- ❖ *Geobacillus stearothermophilus*: used to verify steam sterilization cycles.
- ❖ *Bacillus atrophaeus*: used to verify Ethylene oxide and hot air sterilization
- ❖ *Bacillus pumilus*: used to verify gamma irradiation cycles



Reference strains in Analytical QC

- ❑ **Antimicrobial Effectiveness testing (USP <51> harmonized with European Pharmacopoeia 5.1.3 and Japanese Pharmacopoeia 19)**

which confirms the effectiveness of antimicrobial preservatives added to pharmaceutical products. This test ensures that these preservatives inhibit microbial growth effectively.

- ❑ **Antibiotic Potency Testing (USP <81>**

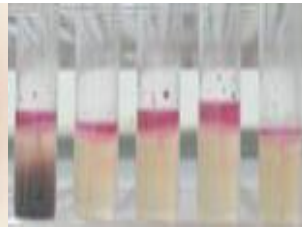
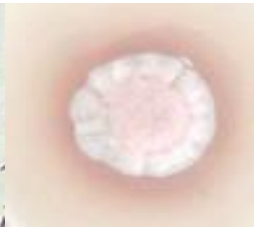
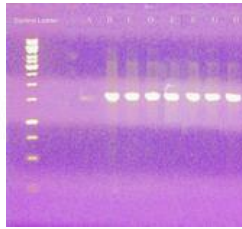
Microbial assays for determining antibiotic activity/potency

- ❑ **Evaluation of products for specified microorganisms (USP <62>)**

To ensure the quality and safety of many products such as cosmetics and foods, manufacturers evaluate the product for the absence of, or limited occurrence of, a specified list of microorganisms

- ❑ **Determination of antimicrobial efficacy of chemical disinfectants and antiseptics in accordance with the European standard (EN 1276)**

Several microorganisms are used to challenge the product



Supply of reference strains

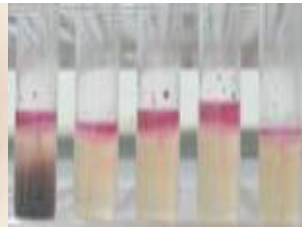
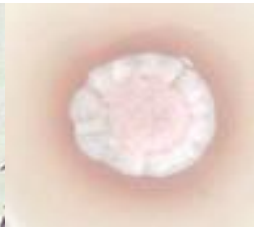
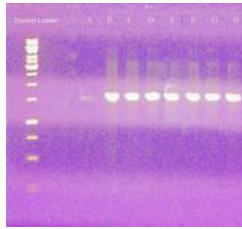
❑ Equivalence with bacterial reference strains

Historically, reference cultures were circulated between collections to make the strains as widely accessible as possible for the scientific community.

❑ A single strain can have multiple equivalents

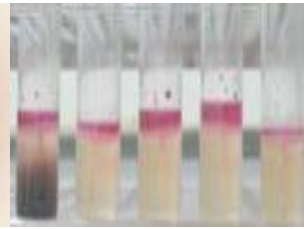
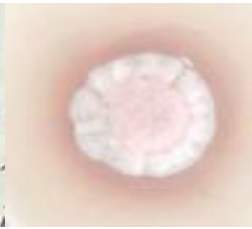
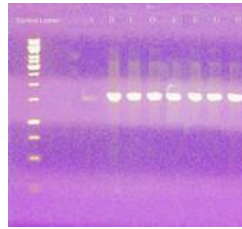
Staphylococcus aureus PTCC 1112

Other collection No.: ATCC 6538, FDA 209, CIP 4.83, DSM 799, IFO 13276, NCIB 9518, NCTC 10788, **WDCM 00032**



WDCM Reference Strain catalogue

- ❑ This catalogue was produced to enable broader and easier access to the reference strains in the ISO 111331.
- ❑ RSC provides a unique system of identifier for reference strains
- ❑ The 29th version of RSC was published online
- ❑ The last edition of RSC covers 205 reference strains related to 72 standards.



Thank you for Your Time and attention