Sterility Testing of Powders and Liquids - Record Review

Experiment 9 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To evaluate supplied powder and liquid sterility-test records.

Principle

A sterility test examines defined test portions using a validated method and controls. A passing test does not prove absolute sterility of every unit in a batch.

Requirements

- Instructor-prepared fixed slides, labelled images, demonstration records or coded teaching data for this practical.
- Activity form, microscope for prepared slides where applicable and calculator.

Procedure

1. Identify the teaching material

Record the slide, image or data code, method name and the assigned comparison. Use prepared material and supplied results for this exercise.

2. Identify the test

Record product type, test method, sample basis and the supplied batch/test code.

3. Read control records

Identify method suitability and control results; note product interference or invalid controls.

4. Review the observations

Compare the coded powder and liquid test outcomes with their stated acceptance rules.

5. Conclude correctly

Distinguish a valid passing result, a failed test and an invalid test requiring investigation. Relate the result to the broader manufacturing control system.

6. Assess controls and limitations

Confirm the meaning of the positive, negative, blank or process controls supplied. State which conclusions the results support and which require additional evidence.

7. Complete the record

Enter observations separately from interpretations. Record units, method conditions given with the data and the instructor-reviewed conclusion.

Observations and Record

Record component	Entry
Product type / code	_____
Assigned method	_____
Suitability / control finding	_____
Reported test outcome	_____
Supported batch-test conclusion	_____

Result

Material / data code: ____. Observed result: ____. Control assessment: ____. Interpretation and limitation: ____.

Precautions

- This activity uses prepared material and data interpretation; it is not a live microbial culture or pathogen-handling procedure.
- Keep morphological, quantitative and clinical interpretations separate.
- Use the method-specific assigned quality controls and current interpretive criteria where relevant.

Viva Questions and Answers

1. Why is method suitability important?

The product can interfere with detection, making an apparent negative result misleading.

2. Does a passing test prove every unit sterile?

No. Assurance depends on validated manufacturing controls as well as the test.

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